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RADIOACTIVITY IN CONSUMER PRODUCTS

United States
Nuclear Regulatory Commission

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RADIOACTIVITY IN CONSUMER PRODUCTS

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August 1978

U. S. Nuclear Regulatory Commission
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PREFACE

The idea of compiling the available information dealing with radioactivity in consumer products originated during a workshop on the same subject in the summer of 1975. Very quickly, a consensus was reached that a symposium was the most appropriate way to reach the scientific and technical community and obtain the necessary information. Various U.S. Government agencies were contacted, and the following agreed to cosponsor the symposium: Bureau of Radiological Health, Food and Drug Administration; Office of Radiation Programs, U.S. Environmental Protection Agency; and Office of Standards Development, U.S. Nuclear Regulatory Commission. The Symposium was organized by the Office of Interdisciplinary Programs, Georgia Institute of Technology, and was held on February 2-4, 1977 in Atlanta, Georgia.

This book is not the proceedings of the Symposium. It is not intended as a description of what happened during those three days. Although this book is based on papers presented at the Symposium, the review process substantially altered the character of various papers. However, the Editors decided to include the remarks of M. Mitchel-Smith and an edited version of the panel discussion. They contained information which, in the judgement of the Editors, enriches the book.

The preparation of this book and the Symposium that preceded it required the assistance of a large number of people. We are indebted to the following individuals: G.A. Arlotto, E.D. Baily, W.J. Bennice, M.A. Carter, G.W. Casarett, P.L. Cox, R.E. Cunningham, R.V. Dean, E.R. Freeburn, A.M. Freke, R.J. Guimond, J.H. Harley, D.P. Hensley, E.L. Hill, G. Kahn, P.A. McDonald, M.L. Meadows, B.D. Moghissi, H.L. Morgan, K.Z. Morgan, R.H. Neill, A.C. Richardson, A.D. Ross, B. Ruegger, F.G.D. Shuman, R.E. Simpson, A.C. Tapert, and D.L. Thompson.

We particularly appreciate the support of the sponsors of the symposium. We are indebted to William D. Rowe for his help, to John C. Villforth for his patience and assistance, and to Robert B. Minogue for his continuous interest and support.

INTRODUCTION

MURIEL MITCHELL-SMITH
DIRECTOR, OFFICE OF CONSUMER AFFAIRS

City of Atlanta
Atlanta, GA

On behalf of Mayor Jackson, I would like to extend a warm welcome to all of you to Atlanta. Our city is an international city. We think it is a great city, and we hope that you will share our feelings as you move around and enjoy the sights and the hospitality. The City and its staff, especially the Office of Consumer Affairs, will be happy to assist you during your stay. Please feel free to call on us.

I would like to take just a few moments to share with you my concerns on radioactivity and its relationship to consumers and consumer products. My general observation as it relates to this conference and to the various regulatory discussions and measures involving radioactivity is that the level of public involvement and awareness seems to be limited. Meetings such as this have been conducted with little or no public involvement and all too often without any public exposure. The issues discussed here will likely produce valuable results, but without consumer awareness and involvement, this value is diminished. We spend great sums of money annually regulating products for consumer use. Most, if not all, of that cost is passed on to consumers; but all too often, the benefit is lost due to consumer ignorance. Food labeling, warnings, and other such measures are meaningless to the majority of consumers at present because the educational process that is so vital to effective consumer protection has been missing. My obsession as a consumer advocate is cost (the bottom line, unfortunately, for most consumers). The cost of protection that is put to a meaningful use by consumers is worth every penny. In your endeavors to ensure public safety, take time to ensure that the public is involved and aware.

Another concern that seems to go unnoticed by many is that of the hazards of radiation that workers are exposed to in producing products for consumer use. In this country and far more importantly in smaller countries where less stringent controls are imposed, workers may be exposed to unacceptable hazards. Having grown up in Berkeley where your banquet speaker, Dr. John Lawrence, worked for many years, I am especially sensitive to the exposure problems that evolve around radiation sources. It is strongly believed by his doctors that my brother was exposed to radiation while working at the cyclotron at Berkeley and later died from leukemia as a result. This makes my concern for this subject even greater. Workers are many times overlooked, and adequate protection and disclosure for workers and consumers must be sought.

Finally, I am concerned with closing the gap that now exists among researchers, manufacturers, and government. Little can be accomplished efficiently and effectively without the cooperation of all groups. Joining with the consumers, we can face the issues and solve the problems. There is a valuable resource available to mankind if it is used carefully and cautiously. Working together, we can produce valuable results for all.

CHAPTER I

REGULATIONS AND STANDARDS

CHAPTER I

Regulations and Standards

Radioactivity in consumer products is subject to various laws, regulations, standards, and guides. Historically a distinction has been made between naturally occurring and man-made radioactive materials. Many countries have recognized the importance of including all radioactive materials in their regulations. This chapter contains many examples of these regulatory actions. Regulations and standards dealing with consumer products have not allocated population doses for these products. Instead, national authorities have attempted to minimize the population exposure from use of the product. Certain regulations and guides specify an upper radiation dose limit in case of accidental exposure to the radioactive materials contained in consumer products. As a matter of convenience, certain regulations and guides have been included in the following chapters in their entirety to facilitate the use of this book as a reference compendium.

THE NCRP STUDY OF RADIATION EXPOSURE FROM CONSUMER PRODUCTS

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The definition of a consumer product in the radiation industry is not clear. In the broadest sense it might be said that any product, device, or material that emits, or is involved in the emission of, ionizing radiation and used by a member of the public would be a consumer product. This could be drawn to include, let us say, all radiation devices used by the medical profession or the profession of industrial radiography. If it is that inclusive, it can be properly said that the National Council on Radiation Protection's (NCRP) first concern with consumer products began in the early 1930s because, beginning at that time, substantial attention was directed toward the improvement of apparatus and procedures to minimize or at least reduce the exposure of people to ionizing radiation.

If a more narrowly defined concept is used, it might be limited to devices or materials that are used by the general public free and independent of any technical supervision or control. In old days this might have included shoefitting fluoroscopes, automobile-tire inspectoscopes, electrostatic or radioactive dust precipitators, and luminous devices. One of the first specific actions of the NCRP in this more limited area resulted from a request from the Federal Trade Commission in February 1955 asking for a statement on the safety of over-the-counter items containing radioactive material such as radium or polonium. A few months later a similar inquiry was made by the Isotopes Division of the Atomic Energy Commission. Another example would be the NCRP's recommendations with regard to radiation from household television receivers in 1960.

The question then might reasonably be asked as to why the Council did not more actively follow up and continue its study of radiation exposure from consumer products. To a limited extent, it did. In 1968, the NCRP established a committee on consumer products that held several meetings, but failed to develop recommendations. Part of the reason for failure was the fact that the problem was so elusive and involved such small doses that there seemed to be no working material upon which safety recommendations could be based. It is now recognized that there were some unsuspected problems of a more substantial magnitude, but at that time the levels of radiation to which people were exposed were so small, and the numbers of people so small, that no basis could be found for defining protection limits. The problem is not really very different today.

In the meantime, the NCRP has established a group of committees to collect and evaluate the existing information on radiation exposure of the population from various sources. These include (1) medical practice, (2) industrial practice, (3) production of nuclear power, (4) consumer products, and (5) radiation from natural background. The reports of the committees are in various stages of preparation or are published.

The study by the committee on consumer products included an evaluation of the potential exposures from some 30 product sources used by the public. The outstanding feature of this study is the conclusion that, in most instances, exposures are so small and the numbers of people involved are so few that on the average, as far as the total population is concerned, the exposures must be regarded as unimportant at the present time.

At the same time there were extremely few instances where individual exposures could be regarded as having any significance. It may be that the problem is unimportant for the individual sources involved, but one might then properly ask if, in the aggregate, there might be a problem. However, even in the aggregate, the numbers are so small as to defy any rational statistical evaluation of the problem. Perhaps some kind of definition to signify the presence or absence of a problem could be based on a comparison with the exposure from natural background. For example, if the levels of exposure from consumer products are less than the normal variations that the average public experiences on a day-to-day basis from variations in the levels of natural background radiation, it might be said that the extra radiation exposure is unimportant and may be neglected.

Problems on a wider scale and involving more exposure of more people appear to be increasing—at least in localized regions—as a result of the use of building materials made from radioactive scrap, from building materials that are naturally more radioactive than others, from the use of byproducts (as from phosphate mining) for building materials, road pavings, etc. While radiation levels due to such uses are higher than natural background in the area, the majority of the instances are such that the extra exposure may readily fall into a category of insignificance.

Again, this is not to negate the problem, but to give some indication of its relative importance compared to the myriad of other risks with which the human population lives. Comparisons of normal risks to which the population is subjected may be interesting, and sometimes even amusing. In any such comparison the radiation industry and the use of its byproducts must be among the safest, best understood, and most controlled industries we have to deal with. This is not to suggest relaxation of protective efforts, but to urge that the problem be looked upon with care.

To illustrate the problem, some examples will be given of the average dose equivalents in millirems per year and the estimated number of individuals subjected to various types of exposure. The listing will include data from the better-evaluated sources of exposure. The risk of presenting this in simplified tabular form is recognized and it should be pointed out that with each source of exposure, there will be caveats, limitations, and estimations that can only be obtained from the textual material in the report of the Committee on Consumer Products when it is available.* Nevertheless, the particular numerical quantities should serve as a useful, if rough, guide to the relative importance of the different sources that may be subject to some degree of control. *Any of this material should be used with great caution and should not be referenced. The same numbers may or may not appear in the finished report itself.* Where some obvious items of exposure may have been omitted, it is because of lack of data or that the overall effects are too small.

It was suggested above that some kind of definition might be provided which would give a dividing line between radiation exposures that are psychologically worrisome and others that are not psychologically worrisome. To provide such a base, Table 1 lists some sources that the public seems to commonly accept or about

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*The report of the committee on consumer products, NCRP Report No. 56, "Radiation Exposure from Consumer Products and Miscellaneous Sources," was issued on November 1, 1977.

Table 1

SOURCE	TYPE OF EXPOSURE*	NUMBER EXPOSED	AVERAGE DOSE EQUIVALENT (mrem/year)	"DOSE INDEX" (Exposed Groups)						
				x10^8	x10^7	x10^6	x10^5	x10^4	x10^3	x1
Television Receivers	GD	10^8	1				1			
Nuclear Power	WB	2 x 10^8	1				2			
Medical	WB	10^8	100		1					
Medical, GSD	GSD	10^8	20			2				
Natural Background	WB	2 x 10^8	100		2					
(10 story building)**	WB	——	0.7				(0.7)			
(500 ft. altitude)**	WB	——	3.5				(3.5)			

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*Type of Exposure (dose equivalent)
WB – Whole Body
GD – Gonads
GSD – Genetically Significant Dose

**Increase in natural background radiation which little or nothing can be done by way of reduction or avoidance. Again, the numbers in these tables are roughly rounded out.

Columns 1 and 2 give, respectively, the sources of radiation and the type of exposure for which the data are given. The latter would include for example, the whole-body dose, dose to the gonads, dose to mucous membrane, etc. The columns at the right give the product of the average dose equivalent by the estimated number of individuals exposed. These will be referred to arbitrarily as "dose index" without any further definition. *It is deliberately an improper term.*

It might be noted that the same product is frequently called "man-rem" (Taylor and Wyckoff, 1976). The term man in this context would be used in the generic sense, meaning "man" as a "member of the human race" or "human being", unless the context showed that only the male was meant.

The avoidance of the use of the man-rem concept is because the dose index averages in column 4 could cover a fairly wide range in some instances, and there might well be cases of individual exposures being unacceptably large while the average appeared to be acceptable. Furthermore, the oversimplification of using the man-rem concept has led some individuals into a dangerous interpretation of radiation effects or radiation risks.

It will be noted that the dose index resulting from television receivers and nuclear power is of the order of 1 or 2 x 10^5. The dose index from overall medical exposures is of the order of 10^7 units, and the genetically significant dose from diagnostic medical procedures is about 2 x 10^6 units. These might be reduced some but probably by no more than a factor of 2 at this time. Natural background radiation would produce a "dose index" of 2 x 10^7 units.

Natural background radiation is something about which we can do very little, if anything, except to possibly change living and working habitats. For example, if an individual were to move from sea level to some point about 500 feet above sea level he would increase his annual dose equivalent by about 3.5 mrem. Even the difference between the first floor and tenth floor of an office building would involve a dose difference of 0.7 mrem/year. If half of the population of the United States were to move to a 500 foot or ten story higher altitude, the dose increases would be 3.5 x 10^5 and 0.7 x 10^5 units, respectively. These may be compared with the radiation from television receivers. Of the several exposures noted above, only those from medical procedures carry such enormous benefits that they can be justified with little question. For these sources the requirement of unreasonable reductions could easily result in increasing the cost of medical care and forcing unwarranted restrictions on medical diagnosis, the risks of which could easily outweigh whatever the risks from radiation might be.

Table 2 lists some of the items that will be covered by the forthcoming report of the Committee on Consumer Products, following the same general scheme as in Table 1. Again, it should be emphasized that the numbers in this table have been severely rounded and no caveats or limitations are included. Comparisons between the collective effects of the doses resulting from the different sources listed becomes even more tenuous for two principal reasons. First, the dose equivalents apply to a number of different individual organs or portions of the body and second, the range of dose equivalents covered in any average may be very great and hence exclude the proper application of the man-rem concept. Nevertheless, the table provides a rough picture of the relative importance of the various sources of exposure to which the general public may be subjected.

Table 2

SOURCE	TYPE OF EXPOSURE*	NUMBER EXPOSED	AVERAGE DOSE EQUIVALENT (mrem/year)	"DOSE INDEX" (Exposed Groups) x10^8	x10^7	x10^6	x10^5	x10^4	x10^3	x1
Uranium in dentures	A	9×10^7	7×10^4	65						
Dental Prosthetics	B	10^7	6.5×10^4	6.5						
Tobacco	C	5×10^7	8×10^3	4						
Natural Gas, Cooking	C	1.3×10^8	9			1				
Natural Gas, Unvented Heating	C	1.6×10^7	22				3			
Building Materials	WB	10^8	7				7			
Television Receivers	GD	10^8	1				1			
Wrist Watches (Ra-226)	GD	10^9	3				1			
Wrist Watches (H-3)	WB	1.6×10^7	0.6					1		
Pocket Watches	GD	2×10^4	6							120
Clocks	WB	10^7	3					3		
Highway Materials	WB	5×10^6	4					2		
Smoke Detectors	WB	4×10^6	1						4	
Electron Microscopes	WB	10^4	500						3	
High Voltage Switches	GD	4×10^4	30						1.2	
Air Transport, Passengers	WB	6×10^6	.5						3	
Air Transport, Crew	WB	2×10^4	5							100
Gas Discharge Tubes	WB	5×10^5	1							500
Airport Passenger Inspection	WB	10^7	2×10^{-3}							200
Thorium in Dosimeters	WB	1.5×10^5	10^{-3}							200
										0.1

*Type of exposure (dose equivalent)

A – Superficial Tissue	WB – Whole Body
B – Mucous Membrane	GD – Gonads
C – Bronchial Epithelium	

It is interesting to note that of all of the sources listed, only four would yield a "dose index" greater than 10^5 units. It will be further noted that all four of these involve exposures to limited portions of the body, as, for example, the superficial tissue or mucous membrane near the teeth or the bronchial epithelium resulting from tobacco use. The largest average dose equivalents occur for the use of radioactive material in connection with dentures or dental prosthetics. On the other hand, no evidence of injury has ever been found however high the dose may seem to be. The case for tobacco is much more complicated since there are other deleterious effects such as from tar or nicotine that may mask or add on to any radiation effects. It is not possible to singly identify the effects of these several agents.

Doses from natural gas vary widely, and because the main source of exposure is from radon, the dose may diminish with longer storage time or greater transmission distances of the gas between the well and the point of use. Both cooking and unvented heating are conditions of use such that the dose may be reduced by simple means, improved venting probably being the most readily available. It is probably not practical to entirely avoid some radiation exposure from almost any gas used.

In the case of normal building materials, there are again wide variations in radioactivity content that will be greatly influenced by the geographical location of the buildings and the types of building materials that are available in the area.

Wristwatches will supply a small increment to the dose and are estimated to yield a "dose index" of the order of 10^5 units. This is probably an exposure that can be substantially reduced as it is highly likely that there is only occasionally a real necessity for being able to read a watch in the darkness.

It will now be noted that the last three sources of group exposure all fall within the "dose index" range of 10^5 units, and in no cases is there any evidence that any such exposures have resulted in untoward injuries.

It will also be noted that all of the other exposures listed fall into lower categories of "dose index" units. Even of these, there is some possibility of further reduction, but the level of effort applied to such reductions should involve careful evaluation of the social and economic factors that would be involved.

Having listed a series of the products of the average dose equivalent by the number of individuals exposed, it is recognized that we are opening the door to temptation, i.e., the misuse of the figures for risk calculations. There will always be a few individuals who, by one process or another, will call these numbers man-rems and then convert them into some kind of "health effects".

The first step in this would be to adopt, without caveat, the linear dose-effect relationship from high doses down to zero dose in the form of a single straight line. This would mean that there is no recovery of biological effect, there is no threshold of effect, and all dose effects are totally additive no matter how and when the dose is received. Under most circumstances this has to be nonsense, but it will, nevertheless, be used to enter upon what is referred to as the body counting game.

During the last world war we counted so many enemy planes that we had "shot down" that, by the middle of the war, we had shot down twice as many as had ever been produced. We count bodies of the enemy and those of our own men when we are trying to explain a war, as in Viet Nam, or we count the bodies of the policemen and the bodies of the demonstrators when we try to prove who was right or wrong in some protest. By the simplistic use of the linear dose-effect relationship and the man-rem concept, it can be said that anyone exposed to 1000 rads will die, regardless of how the dose is delivered. There are other methods for calculating bodies that appear to be much more sophisticated but that are, in fact, no better. The problem is further complicated when attempts are made to establish a theoretical relationship between health effects and deaths.

As a forewarning about the misuse of the data in the report on consumer products, it should be emphasized that the three largest exposures in the report are partial body, and there is no way of equating them to whole-body doses, gonad doses, etc. In spite of the probable misuse of these data, it was nevertheless considered worthwhile to present them in the fashion given here. Limited comparisons will be valid, and the final results may be of some assistance in deciding to undertake specific studies in the field of regulation or control of radiation in consumer products.

In conclusion, the NCRP is stepping up its concern with radiation exposure resulting from consumer products, and at this time I would not venture to suggest what its ultimate position may be. The NCRP recognizes that, at some stage, the problem has to be treated in some pseudo-quantitative fashion. However, at the present time, the Council is not enthusiastic about the attempts to legislate or regulate levels of safety into many radiation uses when these levels are based on such shaky models and assumptions as to provide readily distortable conclusions. The Council is seriously examining the matters of radiation risk on a quantitative basis, but not with the over-simplified models that have been applied in recent years. It is fairly certain that, over the next few years, the NCRP will include such detailed studies as it considers rational in relationship to consumer products, even though the end result for many of these products may result in the expression of the opinion that they are unimportant.

The main benefit of this study has been in pointing out what may be a way to avoid future problems rather than indicating any serious problems at the present time.

REFERENCE

L.S. Taylor and H.O. Wyckoff (1976), "Implications of the Man-Rem Concept," *Proc. Int. Symp. Mgmt. Wastes LWR Fuel Cycle*, ERDA Conference 76-0701, p. 506.

NRC'S ROLE IN REGULATING CONSUMER PRODUCTS

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INTRODUCTION

The Nuclear Regulatory Commission was established as an independent agency by the Energy Reorganization Act of 1974. This Act placed the regulatory functions of the Atomic Energy Commission with the NRC and the developmental functions of the old Commission with the Energy Research and Development Administration. In separating out the regulatory functions, the Energy Reorganization Act recognized the need for strong effective regulation to keep pace with the increasing use of nuclear energy.

THE NRC ORGANIZATION

Organizationally, the NRC consists of five Commissioners, each appointed by the President with the advice and consent of the Senate. One member is designated by the President as Chairman and acts as executive agent and official spokesman. Each Commission member, including the Chairman, has equal responsibility and authority and exercises one vote in Commission decisions.

The Energy Reorganization Act of 1974 explicitly established three major program offices that report directly to the Commission. The Office of Nuclear Reactor Regulation is responsible for regulating nuclear reactors. The Office of Nuclear Material Safety and Safeguards is responsible for regulating the balance of the nuclear fuel cycle and the use of nuclear material. And the Office of Nuclear Regulatory Research is responsible for planning and carrying out confirmatory research necessary for the performance of the Commission's regulatory responsibilities. In addition, an Executive Director for Operations is charged with coordinating and directing the day-to-day operational and administrative activities of the agency.

Two other program components complete the NRC line organization. The Office of Standards Development develops criteria and standards pertaining to health and safety, environmental protection, and safeguards in all activities related to nuclear facilities and nuclear materials. And the Office of Inspection and Enforcement ensures that licensees are complying with license requirements and NRC regulations.

NRC'S AUTHORITY AND RESPONSIBILITY

The Energy Reorganization Act gave NRC the responsibility for carrying out the regulatory provisions of the Atomic Energy Act of 1954. This earlier Act established a national policy and a framework for regulating civilian nuclear energy activities to ensure that they are conducted in a manner that will protect the public health and safety, maintain national security, and comply with the antitrust laws.

Under the National Environmental Policy Act of 1969, the Commission also was assigned responsibility for evaluating the nonradiological, as well as the radiological, environmental impact of major nuclear facilities and activities, and for balancing the benefits of such facilities against their environmental and social costs.

In addition to regulating nuclear power plants and other nuclear facilities, NRC regulates the production and use of a wide variety of nuclear materials in industry, medicine, and research. With regard to consumer products, the NRC is authorized to exercise regulatory control over the manufacture, distribution, possession, use, and transfer of products containing byproduct, source, and special nuclear material. To accomplish its missions, NRC conducts broad programs of standards-setting and rulemaking, technical reviews, licensing actions, inspection and enforcement, and regulatory research.

WHAT ARE "CONSUMER PRODUCTS"

This subject is addressed in an Atomic Energy Commission Notice, published in the Federal Register in 1965, concerning criteria for the approval of products for general public use. Essentially, for the purposes of regulatory control, consumer products are considered to be those products, commodities, or materials containing byproduct, source, or special nuclear material that are available in the marketplace to the general public as "off-the-shelf" items and that are intended for widespread personal or household use.

The criteria published by the AEC in 1965 set forth the essential terms of policy currently used by the NRC with respect to approval of consumer products. The criteria state that approval of a proposed product will depend on two factors: the radiation exposures that will be associated with the product and the product's apparent usefulness. The criteria state that risks of exposure to radiation will generally be considered acceptable if it is unlikely that the individuals in the population will receive more than a few hundredths of the individual dose limits recommended by the International Commission on Radiological Protection, the National Council on Radiation Protection and Measurements, and the Federal Radiation Council. (The authority and functions of the Federal Radiation Council now rest with the Environmental Protection Agency.)

Radioactive material may appear in products for several reasons:

First, it could be deliberately added to a product because of its radioactive, chemical, or physical properties. Examples are the use of radioactive materials to produce ionization for static elimination, radiation-activated luminous compounds, uranium used as shielding material to reduce exposure of patients, or, as was once proposed but not approved, radioactivity in cufflinks simply for physical appearance.

Second, radioactive material could be added to products as a contaminant, either intentionally or unintentionally. For example, radioactive material could be used in process control for such purposes as tagging interfaces in pipelines or as a catalyst in petroleum cracking, resulting in some carryover into the products.

Third, radioactive materials could be naturally occurring in consumer products but could increase in concentration after processing. Examples are increased uranium or thorium concentrations after the processing of rare earth oxides.

At present, there are 192 NRC licenses held by 120 licensees to import, manufacture, or distribute exempt products. Although NRC received authority in August 1974 to amend its regulations to authorize the possession and use of consumer products containing special nuclear material, there have been no petitions for such amendments and no such authorizations have been issued.

Approximately 6 million timepieces containing tritium were distributed last year. In the same year, about 3 million smoke detectors containing americium-241 were distributed, along with about 100 million electron tubes containing krypton-85.

POINT OF CONTROL – CONSUMER PRODUCTS

The Commission is authorized to exempt from licensing and regulation certain quantities or classes of material or certain uses of material that are unimportant in the opinion of the Commission. The purpose of such exemptions is to avoid the imposition of regulatory controls on consumer uses of products that present little or no radiation risk.

Before a product is exempted for distribution, however, the NRC must exercise its regulatory responsibility to approve or deny the petition for uncontrolled distribution to ensure that the health and safety of the public is adequately protected.

In addition, specific licenses from NRC are required to manufacture or to import for sale or distribution consumer products containing byproduct or source materials. If a manufacturer is located in an Agreement State, he must have two licenses: one from the Agreement State authorizing manufacture of the product and one from the NRC authorizing transfer.

(The NRC is authorized to enter into an agreement with any state to discontinue the Commission's authority to license and regulate the possession, use, and transfer of certain materials and to transfer that authority to the state, where the state has an adequate program for carrying out such regulatory controls. Hence, the term "Agreement State." Thus far twenty-five states have agreements.)

SPECIFIC AREAS OF CONCERN TO NRC

There are three major areas of concern to the NRC in the regulation of consumer products: (1) the radiation safety of workers; (2) the radiation safety of the general public, including both users and non-users; and (3) long-term contamination of the environment.

The radiation exposure of workers in licensed facilities must be kept below the limits of 5 rems per year and further should be kept as far below those limits as is reasonably achievable. NRC's regulations in 10 CFR Parts 19 and 20 provide the regulations for control over the radiation safety of workers and the release of effluents from licensed facilities.

Radiation exposure of individuals in the general public as a result of the distribution, marketing, installation, repair, and use of consumer products must be kept at even lower levels. The calculated doses must include contributions from normal use and from misuse or accidents. In general, as indicated previously, risks of exposure to radiation will be considered acceptable when the individual dose is less than a small fraction of the recommended dose limits. Further, the probability of individual doses approaching any of the specified limits must be negligibly small. The potential cumulative dose from the use of multiple products and from other sources must also be taken into account.

In licensing consumer products, and consistent with EPA requirements, the NRC gives careful consideration to the associated release of radioactive material to the environment, with special attention devoted to the long-lived alpha emitters such as americium-241 and neptunium-237.

Another area of concern is avoiding the use of radioactive material in consumer products if the radioactive material does not serve a useful purpose or if the same results can be achieved with non-radioactive materials and without significant disadvantages.

In addition to looking at the risks associated with the use of a radionuclide in a consumer product, we examine the benefits. In general, the level of risk considered acceptable will vary according to the expected societal or individual benefits.

Where the benefits are significant and readily identifiable and quantifiable, and where no reasonable alternative product exists, the risk-benefit assessment is not so difficult. It is in the marginal cases that arriving at a sound balanced judgment becomes much harder. For example, it is difficult to evaluate the use of a radioactive timing reference source in wrist watches where both the risk and benefit are extremely small.

APPROVAL PROCEDURES AND PUBLIC PARTICIPATION

Procedures for authorizing the distribution of a consumer product are as follows: In most cases, a petition for rulemaking to exempt a new product from further regulatory control is submitted to the Commission by one or more interested companies. If the product is found acceptable after an independent assessment of its environmental and safety impact, the regulations will be amended to allow the exemption under appropriate standards. In a separate action, a company must demonstrate to NRC that its product is designed and will be manufactured to meet those specific standards before it can be licensed to manufacture the product for distribution.

Public participation and input is encouraged and deliberately sought at every stage of this regulatory process. Notice of receipt of the petition is published in the Federal Register, and public comments are invited. It is our practice to place all correspondence between the petitioner or others and the NRC staff on such a rulemaking action in our Public Document Room.

The five-man Commission must make the decision to grant or deny the petition. If the initial decision is favorable, a proposed rule and notice of availability of a draft Environmental Impact Statement are published in the Federal Register, and public comments from interested agencies, organizations, and individuals are invited.

After due consideration of the comments, and changes to the rule where appropriate, the final rule is published in the Federal Register, along with a notice of availability of the final Environmental Impact Statement.

STANDARDS

Part of NRC's responsibility is to set broad policy to protect the public health and safety. Methods of achieving this goal include establishing safety standards and requirements for the nuclear industry. The basic objective of the standards is to present a written set of rules or guidelines that define the levels of performance required to protect the public health and safety.

The basic safety standards are set forth in the Commission's regulations in Title 10 of the Code of Federal Regulations. In the area of consumer products, pertinent regulations are found in Parts 30, 32, and 40 of Title 10. For example, subpart C of Part 32 defines the standards regarding sampling procedures for the acceptance of a product.

In addition, the NRC staff issues regulatory guides to provide guidance and explanatory information to supplement the regulations. Regulatory guides are not intended to substitute for the regulations and compliance with them is not required; that is, methods and solutions different from those described in guides are acceptable if fully justified as complying with the basic requirements set forth in the regulations.

The guides are of three basic types: (1) guides that identify to petitioners or applicants the information that should be submitted to NRC in support of a petition or application, (2) guides that describe methods acceptable to the NRC staff for implementing specific parts of the regulation, and (3) guides that provide information on techniques used by the NRC staff in evaluating safety problems.

In the area of consumer products, we have two regulatory guides: Regulatory Guide 6.6 describes the acceptance sampling procedures for exempted and generally licensed items containing byproduct material. Regulatory Guide 6.7 provides information on the preparation of environmental reports in support of rulemaking petitions seeking exemptions for consumer products.

APPROVAL POLICY

The Commission's exemptions for consumer products include certain long-standing uses of source material, most of which predate the Atomic Energy Act of 1954. These include

1. The use of uranium to color glass and glazes for decorative purposes;
2. The use of thorium to provide desirable physical properties in alloys and products such as gas mantles, tungsten wire, and optical lenses; and
3. The use of uranium and thorium in photographic film and prints.

AEC policy for the approval of consumer products was set forth in the 1965 criteria mentioned earlier. The general considerations involved in evaluating products are (1) the potential radiation exposures of individuals in the population as a result of the manufacture, handling, use, and distribution of the product; (2) the effect on the environment; and (3) the benefits to be derived by the public from use of the product.

One way to understand how the Atomic Energy Commission applied its policy on consumer products is to look at some of its denials. Exemption of self-luminous fish lures was denied because of concern for accessibility to children. Exemption of self-luminous screws was denied for lack of demonstrable benefit. Exemption of cufflinks made of depleted uranium was denied because they are adornments, the use of which would result in a small increase of radiation exposure among the general public without commensurate benefit.

The 1965 criteria established by the Atomic Energy Commission to formulate its policies on proposed consumer products have also been used by the Nuclear Regulatory Commission. However, these criteria were developed some years ago, and during the intervening years we have seen a broadening of NRC's responsibilities under the National Environmental Policy Act, along with advances in the concept of minimizing radiation exposure to as low as practicable levels and improvements in understanding of the biological effects of low-level radiation.

The application of the 1965 criteria to NRC decisions is now under review as part of a general review by NRC of regulations and procedures established by the former AEC in areas now under the jurisdiction of NRC as an independent regulatory agency.

In its review of the overall policy on consumer products, views and suggestions from all sectors of the public are important to aid the Commission in deciding whether to retain or revise the existing policy or to formulate a new policy. This symposium is extremely important in that it provides a unique opportunity for the exchange of concerns, views, ideas, and technical and other information on consumer products among informed persons from industry, research organizations, universities, regulatory agencies, and members of the public. A vigorous exchange of views and in-depth discussion on the problems and technical issues can provide an improved data base for consideration by the Commission.

The major considerations in formulating a sound policy on regulating consumer products are the need for systematic balanced consideration of risks and benefits, the need for effective measures to reduce risk, and the need to inform the public fully of the basis of policy and to ensure effective public participation in the decision-making process.

How does one decide whether a product containing radioactive material can be distributed to consumers without further regulatory control? A simplistic answer is that one should show that the product does not impose any radiological risk whatsoever to the users and to society.

Unfortunately, the decision cannot be made so simply. Few societal actions in the modern world entail no risk. Based on current knowledge of radiation effects, there may be, and probably is, no threshold for induction of deleterious effects following exposure to radiation; the relationship between the probability of such effects and dose may be linear, and in fact is assumed to be so as a matter of prudent public health judgment. Thus no exposure to radiation can be considered to be without some level of risk, and no exposure should be permitted without some tangible benefit. But how does one evaluate that benefit and weigh the risk and benefit to the individual against the risk and benefit to society as a whole? That is the basic question for the regulator.

In the area of consumer products containing radioactivity, society as a whole may accept certain small radiological risks in exchange for unique benefits to individuals that can be otherwise obtained either not at all or at greater risk by some other method. Or conversely, individuals may accept risk where the benefit accrues to society. This sort of choice is by no means unique to products containing radioactivity. Such choices are a central feature of modern technological society.

The role of the regulatory agency in a sense is to act as the agent of the public in making that choice; hence we emphasize the need to take public views into account and the importance of an informed public.

Benefits can be very great – ranging from the possible saving of life to the prevention of injury – or may consist only of improving reliability or merely of providing social amenity. Exposure to radiation may lead to increased cancer incidence or genetic damage; the effect of low levels of exposure may involve only very small increases in incidence, possibly even zero, but such effects cannot be precluded.

Many things can be done to reduce risk, especially in the design stage. Such actions include using careful encapsulation and adequate shielding, selecting radionuclides with less radioactivity and with suitable chemical and physical forms, using smaller quantities of radioactive material, and making the part containing radioactive material less accessible to children and other persons during use. Other steps can also be taken to reduce risk, such as providing labels and clear and concise instructions and recovering material for controlled disposal.

In summary then, a difficult judgment must be exercised to determine the acceptability of a product in terms of its risk/benefit. It is essential that this regulatory judgment be based on the soundest data base possible, with full public participation.

FUTURE DIRECTIONS

Where are we going from here in terms of NRC's role in consumer products? Here are some possible directions:

First, as mentioned previously, NRC plans to review and update the 1965 criteria for approval of consumer products in light of current technology and safety philosophy.

Existing control over use of naturally occurring and accelerator-produced radioactive materials is being studied. At the request of the Agreement States, a task force has been established in NRC to look at the question of whether and to what extent NRC or other appropriate Federal agency should seek legislative authority to regulate such materials.

The Nuclear Energy Agency, in its guide on consumer products, proposes dose apportionment for consumer products based on risk-benefit considerations. NRC plans to evaluate the need to establish similar procedures in the United States.

We will also consider whether to structure our regulations to establish class treatment of groups of products containing extremely small quantities of radioactive materials, so that licensing actions, rather than rulemaking actions, will be required to approve a product within a class. This will reduce the amount of time and effort required to process the approval or disapproval of a product without compromising safety. Further, rulemaking actions for class exemptions will provide a focus for public comment and for participating in the resolution of the broad issues involved, rather than addressing these issues in the narrow context of an individual product.

CONCLUSION

In conclusion, NRC's principal concern in regulating consumer products is to protect the health and safety of the general public who use the products and of the workers who manufacture them. All interested persons and organizations are encouraged to participate and comment on NRC's regulatory process and help to establish a sound basis for decision making in the public interest.

U.S. NUCLEAR REGULATORY COMMISSION

Revision 1
June 1976

REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 6.7

PREPARATION OF AN ENVIRONMENTAL REPORT TO SUPPORT A RULE MAKING PETITION SEEKING AN EXEMPTION FOR A RADIONUCLIDE-CONTAINING PRODUCT

A. INTRODUCTION

1. Purpose of This Regulatory Guide

The National Environmental Policy Act of 1969 (83 Stat. 852), implemented by Executive Order 11514 and the Council on Environmental Quality's Guidelines of August 1, 1973 (38 FR 20550), requires that all agencies of the Federal Government prepare detailed environmental statements on proposals for legislation and other major federal actions significantly affecting the quality of the human environment. The principal objective of the National Environmental Policy Act of 1969 is to build into the agency decision-making process an appropriate and careful consideration of environmental aspects of proposed actions.

As part of its policy and procedures for achieving this objective, the U.S. Nuclear Regulatory Commission (NRC) requires (see 10 CFR § 51.40) that an environmental report be submitted by any person petitioning the NRC to establish an exemption from licensing for the use of radioactive material in a product. The purpose of this guide is to provide assistance to petitioners in their development of environmental reports.

This guide is intended to be quite comprehensive in scope. However, the petitioner may need additional clarification. Therefore, if a petitioner or a person considering submission of a petition has questions about the applicability of certain recommendations of this guide to his product, he is encouraged to contact the Office of Standards Development, U.S. Nuclear Regulatory Commission.

2. Preparation of Environmental Reports

Part 51 of 10 CFR provides regulatory requirements for the content of a petitioner's environmental report. Specific and detailed guidance is provided in Section B, "Standard Format and Content of an Environmental Report to Support a Rule Making Petition Seeking an Exemption for a Radionuclide-Containing Product," of this guide.

A number of the topics discussed in Section B may apply only in part, or not at all. The petitioner should apply the guidelines appropriate to the product for which the licensing exemption is sought; any topic that is not relevant to the particular product being discussed should be so identified.

Descriptive or narrative text as well as tables, charts, graphs, etc. should be used in the report. Each subject should be treated in sufficient depth and should provide sufficient documentation to permit the NRC to evaluate independently the extent of the environmental impact. Tables, line drawings, and photographs should be used wherever they contribute to the clarity of the report. Descriptive and narrative passages should be brief and concise. The number of significant figures stated in numerical data should reflect the accuracy of the data; wherever practical the degree of accuracy should be indicated by plus or minus values.

Pertinent published information relating to the product and to its distribution, use, and disposal should be referenced or included as appendices.

Some of the information to be included in the environmental report may have been prepared by the petitioner during consideration of the safety and marketing aspects of the product. Where appropriate, this information (in the form of text, tables, or figures) should be incorporated in, or appended to, the environmental report in order to provide a complete document.

USNRC REGULATORY GUIDES

Regulatory Guides are issued to describe and make available to the public methods acceptable to the NRC staff of implementing specific parts of the Commission's regulations, to delineate techniques used by the staff in evaluating specific problems or postulated accidents, or to provide guidance to applicants. Regulatory Guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the findings requisite to the issuance or continuance of a permit or license by the Commission.

Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience. This guide was revised as a result of substantive comments received from the public and additional staff review.

Comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Section.

The guides are issued in the following ten broad divisions:

1. Power Reactors
2. Research and Test Reactors
3. Fuels and Materials Facilities
4. Environmental and Siting
5. Materials and Plant Protection
6. Products
7. Transportation
8. Occupational Health
9. Antitrust Review
10. General

Copies of published guides may be obtained by written request indicating the divisions desired to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Office of Standards Development.

If the petitioner considers any information requested by this guide to be a trade secret or commercial or financial information submitted in confidence, the requested information should be submitted as a separate document with a written request that NRC withhold the information from public disclosure in accordance with 10 CFR § 2.790 on the grounds that it is proprietary data.

3. Commission Action on Environmental Reports

The environmental report submitted by the petitioner is placed in the Commission's Public Document Room at 1717 H Street NW., Washington, D.C. At the same time, NRC issues a public announcement and publishes a summary notice in the *Federal Register.*

The petitioner's environmental report, relevant published information, and any comments received from interested persons are considered by the staff in preparing a "Draft Environmental Statement" concerning the proposed rule making action. The staff's draft statement and the petitioner's environmental report are transmitted for information to the Council on Environmental Quality and for comment to appropriate federal agencies and state officials. The draft statement is also made available to the general public. Comments on both the environmental report and the draft statement are requested within a specified time interval.

As described in detail in § § 51.22 through 51.26 of 10 CFR Part 51, the staff considers the comments on the environmental report and on the draft statement and prepares a "Final Environmental Statement" (FES). This final statement is then transmitted to the Council on Environmental Quality and made available to appropriate state agencies. NRC issues a public announcement and publishes a notice of availability in the *Federal Register.*

Subsequent hearings, if required, on the environmental aspects involved in rule making on an exemption from licensing requirements are based on the petitioner's environmental report and NRC's *Final Environmental* Statement. The FES takes into account information from many sources, including the petitioner's environmental report and its supplements and the comments of the various governmental agencies, private organizations, and individuals.

The environmental statement prepared by the staff is intended to provide a generic treatment of the product. This treatment is appropriate for a rule making procedure involving a licensing exemption that permits distribution of products by any person who satisfies the conditions of the regulations. In this regard, in the absence of information to the contrary, the staff will view the petitioner's particular product as typical of all products likely to be distributed for use under the exemption. Accordingly, detailed and complete information on the petitioner's particular product and on the petitioner's planned distribution system is important to consideration of the petition.

The petitioner's environmental report is not expected to address the impact of manufacturing the product. Accordingly, the possible creation of manufacturing jobs at the petitioner's plant and the possible radiation exposures to individuals who may perform those jobs should not be treated in the petitioner's environmental report. In most instances the manufacturing impact will be negligible. In those few instances where it is not, NRC will assess the manufacturing impact when considering issuance of the materials license that authorizes manufacture of the product.

B. STANDARD FORMAT AND CONTENT OF AN ENVIRONMENTAL REPORT TO SUPPORT A RULE MAKING PETITION SEEKING AN EXEMPTION FOR A RADIONUCLIDE-CONTAINING PRODUCT

SUMMARY

The summary should support a conclusion that adoption of the requested rule change would be consistent with the national environmental goals. In preparing the summary and much of the remainder of the report, the petitioner should assume the requested rule change to be in effect and assess the impacts accordingly. Since the rule change would permit any person who satisfied the specific licensing requirements to distribute products for use under the exemption, the scope of the report should go beyond the petitioner's own particular product. For most types of products the report should show that the petitioner's particular product and means of distribution should be viewed as "typical examples" of models and distribution systems that can reasonably be expected to develop if the requested rule change is made.

The summary should include the following information:

1. A concise description of the specific product, including specific design features, intended use, and methods of use, operation, distribution, and disposal or recycle.

2. A brief comparison of alternative product designs (both radioactive and nonradioactive); of alternative methods of use, distribution, and disposal; and of alternative actions as extracted from the material prepared for Chapter 6 of this guide.

3. A brief listing of significant environmental impacts associated with the product as extracted from the benefit-cost analysis of Chapter 7 of this guide. The listing should include both adverse and beneficial environmental and socioeconomic impacts that would occur if the Commission takes the action proposed by the petitioner.

Chapter 1

INTRODUCTION

1.1 The Petition for Rule Making

The petitioner should give the substance or text of the proposed rule change in this section. He should elaborate on the purpose to be served by the rule change requested in the petition, provide pros and cons for the change, and indicate why he believes the change should be made.

1.2 The Petitioner

1.2.1 Description

The petitioner should identify himself by name and address and should describe his business and the types of products he manufactures. He should also estimate the number of persons (i.e., competitors) who can reasonably be expected to request regulatory approval to distribute products similar to the petitioner's if the rule change is accomplished.

1.2.2 Relationship to *(specific name of product)*

A clear statement of the petitioner's interest in the distribution of such a product should be provided. Also state whether the petitioner will manufacture, subcontract the manufacture, purchase, or import the product and whether the manufacturer or importer will distribute the product directly or through others.

Chapter 2

DESCRIPTION AND USE OF *(SPECIFIC NAME OF PRODUCT)* THAT CONTAINS *(NAMES OF RADIONUCLIDES)*

This section should describe the product; how it works; what it will be used for; how it will be used, distributed, installed, serviced, and repaired; and the method of its disposal. In the absence of information to the contrary, NRC may consider this information to be "typical" for all such products, whether distributed by the petitioner or by his competitors.

2.1 Description

2.1.1 General Construction

The petitioner should describe how the product is constructed, emphasizing particularly how the radioactive material is incorporated. The following information is needed:

1. Identity of all radioactive materials contained in the product.

2. Description and drawing of the product, including all designs. Indicate the maximum and average amount of radioactive material used and its chemical and physical form. Show how the radioactive material is incorporated into the product. Include drawings. The composition, dimensions, density, thickness, and location of any substrates, coatings, or sandwich material should be specified. The measured radiation dose rates at the surface and at specified distances from the product should be indicated. Also specify the measured radiation dose rates at the surface and at specified distances from separable components such as pieces that could be replaced or repaired or parts that could be disassembled. Give the results of any tests (wipe, leak-rate, leach-rate, combustion, vibration, abrasion, etc.) that show the degree of integrity of the containment and shielding of the radioactive material in the product under expected conditions of use. A description of the test procedures *| and radiation measuring instruments should also be provided.

2.1.2 The Radionuclides

The petitioner should describe in detail the radioactive material used, including all radionuclides (parents, daughters, and contaminants) present and their nuclear properties and abundances. Give pertinent chemical, biological, and physical data. The availability and cost of the material should also be indicated.

2.2 Operations

The petitioner should discuss how the product functions, giving particular emphasis to its unique features and the function of the radioactive material. Typical operating conditions and environments should be described, for example, temperature and gas or air flows. Describe typical labels and instructions as they relate to safety and operation of the product.

2.3 Uses

The use for which the product is designed should be discussed, along with possible uses unintended by the manufacturer but which the product may experience after distribution. Emphasize how the radioactive material facilitates such uses.

2.4 Methods of Use

The petitioner should describe how, where (geographic locations, facilities, homes, etc.), and by whom the product will be used. The expected useful life of the product under the various use conditions should be specified. Include descriptions and numbers of persons, other than actual users, who might be affected by use of the product.

2.5 Distribution

2.5.1 Packaging

For each package design that will contain the product, the petitioner should give the number and arrangement of:

- Units per package;
- Packages per box;
- Boxes per carton.

The petitioner should also discuss the geometry and composition of construction materials for boxes, packages, and cartons. Describe labeling, markings, and instructions–both outside and inside the container. The radiation dose rates at specified distances from packages, boxes, and cartons should also be indicated.

2.5.2 Distribution

The petitioner should characterize the sites (such as warehouses, freight terminals, or large or small retail stores) where the product will be temporarily located during distribution. Estimate the number of units, packages, boxes, cartons, or shipments that will pass

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*Lines indicate substantive changes from previous issue.

through each site; how long they will remain there; how they will be handled and stored at each site; and all important environmental factors, e.g., temperature ranges in freight terminals and probability and consequences of accidents or fires.

2.5.3 Transport

A list should be provided concerning the modes of transport (long-haul or local-delivery truck, rail, mail, etc.) that will be used to transfer the product from its place of manufacture to the sites described above and, ultimately, to the user. For each mode, give the size of a shipment (number of cartons), number and frequency of shipments, likely routes of shipments, and average distance and environment. The radiation dose rate at a specified distance from the shipping vehicle should also be provided for each mode.

2.6 Installation, Maintenance, and Repair

The petitioner should describe the intended methods of performing installation, maintenance, and repair activities relating to radiation safety features of the product. Also indicate methods precluded by design and methods that are possible and likely to be performed, but not specifically planned or recommended. Include the frequency of the installation, maintenance, and repair activities; the time required; and the general operations to be performed. Emphasize any operations during which persons will come into contact with the radioactive material or during which the shielding of the radioactive material might be significantly reduced or the radioactive material released.

2.7 Disposal

The petitioner should describe likely methods of disposal of the product and predicted percentages for each method. These methods may include disposal as domestic, commercial, or industrial solid or liquid waste. Identify any efforts made to encourage return of the product to the manufacturer for controlled disposal as radioactive waste.

Define any disposal procedures during which persons will come into contact with the product and any conditions under which the radioactive material may be released from the product.

Chapter 3

MARKET FOR *(NAME OF PRODUCT)* THAT CONTAINS *(NAMES OF RADIONUCLIDES)*

The petitioner should demonstrate that the product is needed, should describe the need, and should indicate how the need is presently being filled. He should also provide estimates of the demand for the product and should indicate how the demand will be met.

3.1 Need

This section should describe the need for the general and specific product.

3.1.1 For *(general name of product)*

Identify the need for the product to be provided by the petitioner and for similar products. Describe how the need is presently being met and how it would be met in the future without the product.

3.1.2 For *(name of specific product)*

The petitioner should describe how the specific product that he will provide will fill the need for products of this type. Identify and discuss those aspects of the product that will fill the need differently from existing or planned products (new, better, worse, etc.) of the same general type.

3.2 The *(name)* Industry

The petitioner should characterize the likely manufacturers and distributors of the product (e.g., timepiece manufacturers, medical device manufacturers, firearms manufacturers). Discuss their normal manufacturing business transactions, products manufactured, and inter- and intra-industry practices (for example, purchase components such as small sealed sources of radioactive material and assemble the components to make the final product).

3.3 Demand

This section should provide estimates of historical demand for the product – both the general type and the specific product. It should also project estimates of demand for the short term (1 to 10 years) and the long term (10, 20, 30, 40, and 50 years). Bases should be provided for the estimates.

3.3.1 For *(general name of product)*

Past, present, and future short- and long-term demands for the general type of product should be discussed.

3.3.2 For *(specific name of product)*

The petitioner should estimate the demand (present and future) for the specific product. Relate the demand for the specific product to the demand for the general type of product, as described in Section 3.3.1, and show how the demands will interact.

3.4 Supply

This section should show how the demands given in Section 3.3 have been, are being, and will be met.

3.4.1 Of *(general name of product)*

Identify and quantify past, present, and future sources and means of satisfying the demands for the general type of product.

Chapter 4

ENVIRONMENTAL EFFECTS OF NORMAL DISTRIBUTION, USE, AND DISPOSAL OF *(NAME OF PRODUCT)*

The distribution, use, and disposal of the product will inevitably affect the environment. Effects are considered adverse if the environmental change provides an added stress that lessens a desirable characteristic of an important biotic population or natural resource (e.g., safety, health, abundance, and productivity); if the change provides an added stress that tends to lower the quality of renewable resources or to impair the recycling of depletable resources; or if the change provides an added stress that reduces the diversity and variety of individual choice, the standard of living, or the extent of sharing life's amenities. Effects are considered beneficial if they enhance the characteristics just enumerated. Both adverse and beneficial effects should be discussed in this section.

The petitioner should use the information presented in Chapters 2 and 3 to describe the environments and populations that will be affected by the distribution, use, and disposal of the product. Include the effects of transportation and storage as they relate to wholesale and retail marketing.

Any impacts arising from interactions of the product with the environment and the populations should be quantified and systematically presented. In the discussion of each impact, the petitioner should make clear whether the supporting evidence is based on theoretical, laboratory, or field studies. The source of each impact and the population or resource affected should be made clear. Impacts on water, land, air, and biota should be distinguished, and any changes that may be brought about in the ecological system due to these impacts should be defined.

Radiological, economic, technological, social, ecological, aesthetic, and any other impacts should be identified and quantified. These impacts should address both a single product and multiple products. The numbers used for multiple products should be consistent with the demand estimated in Chapter 3.

4.1 Environments and Populations Affected

This section is intended to provide the scenarios from which the impacts discussed in Sections 4.2 to 4.4 are determined. For each stage in the life span of the product (as described in Sections 2.3 to 2.7) describe the following:

1. Geographic locations;

2. Site and environments;

3. Persons involved directly with the stage and their actions;

4. Bystanders or persons not involved directly with, but affected by, the stage and their actions.

The above should be discussed under the following topics:

4.1.1 During Distribution

4.1.2 During Use

4.1.3 During Installation, Maintenance, and Repair

4.1.4 Due to Disposal

4.2 Radiological Impacts

This section should contain detailed, quantified estimates of the radiation doses (both external doses and dose commitments) to individuals and to the population. Include any radiological consideration affecting the use of land, air, water, or other resources. These estimates are to be based on the scenarios given in Section 4.1.

The petitioner should consider the radiological effects of distribution, use, and disposal of the product on man and important biota. Provide estimates of the radiological impact on man, both to individuals and to population groups, via various exposure pathways. The various pathways for external and internal exposure should be identified and described in textual and flowchart format.

4.2.1 On Man

In each of the following sections estimate radiation doses to all exposed persons.

4.2.1.1 During Distribution

4.2.1.2 During Use

4.2.1.3 During Installation, Maintenance, and Repair

4.2.1.4 Due to Disposal

4.2.2 On Terrestrial and Aquatic Ecology

In each of the following sections estimate radiation doses to and contamination of terrestrial and aquatic flora and fauna.

4.2.2.1 During Distribution

4.2.2.2 During Use

4.2.2.3 During Installation, Maintenance, and Repair

4.2.2.4 Due to Disposal

4.2.3 On Land, Air, and Water Use

In each of the following sections estimate contamination of or restrictions placed on the use of land, air, water, and other resources.

4.2.3.1 During Distribution

4.2.3.2 During Use

4.2.3.3 During Installation, Maintenance, and Repair

4.2.3.4 Due to Disposal

4.3 Nonradiological Impacts

This section should contain detailed estimates of any nonradiological impacts on man, on terrestrial and aquatic ecology, and on the use of land, air, water and other resources for the stages in the life span and disposal of the product. It should include evaluations of any toxic substances and alterations of existing environments or resources.

The structure of this section should be the same as that of Section 4.2.

4.4 Impacts on the Community

The petitioner should describe and estimate the expected magnitude of impacts of the product, both beneficial and adverse.

4.4.1 Economic

In each of the sections indicated below, discuss:

1. Employment—new jobs, transfer of jobs from one location (or country) to another, job improvement, effects of product on job market, etc.;

2. Secondary effects—such as crime reduction, energy conservation, etc.;

3. Tax revenues—if applicable;

4. Service revenues—to transporters, users, repairers, nonusers (general economic benefit or cost);

5. Use of resources;

6. Improved service—costs that the product eliminates by providing a better service and costs that the product imposes.

The above should be discussed in the following sections:

4.4.1.1 During Distribution

4.4.1.2 During Use

4.4.1.3 During Installation, Maintenance, and Repair

4.4.1.4 Due to Disposal

4.4.2 Social

In each of the sections listed below, discuss:

1. Community services—the need for more or fewer services such as housing, schools, hospitals, police and fire protection, recreation areas, and other institutions;

2. National goals and security—energy conservation, new technologies, improved (or reduced) national security, balance of payments, more or less efficient use of resources;

3. Concern about introducing radionuclides into the environment.

The above should be discussed in the folloiwng sections:

4.4.2.1 During Distribution

4.4.2.2 During Use

4.4.2.3 During Installation, Maintenance, and Repair

4.4.2.4 Due to Disposal

4.5 Resources Committed

The petitioner should discuss any irreversible commitments of resources involved in manufacturing the product and in its distribution, use, repair, and disposal. The discussion should include both direct commitments and irreversible environmental losses and natural resource uses.

In this discussion, the petitioner should consider lost resources from the viewpoint of both relative impacts and long-term net effects. As an example of a relative impact assessment, the commitment of a given resource to the manufacture, distribution, use, and disposal of the product should be given as the percentage of the total available resource committed and should be discussed in terms of the resources that would be committed to provide an equivalent service by an alternative means.

Chapter 5

ENVIRONMENTAL EFFECTS OF POSTULATED ACCIDENTS OR MISUSE

The petitioner should postulate, describe, and indicate the probability of occurrence of all credible accidents or misuses of the product. Describe the effects of each, and assess the impacts associated therewith. Each accident or misuse should be described and assessed in the same manner as the normal events discussed in Chapter 4. Accidents may involve fire, explosion, submersion (flooding), mechanical failure, abrasion, wind, shredding, etc.

5.1 Radiological Impacts of Accidents

In each of the following sections, accidents or misuses in which exposure to or release of the radioactive material is a significant factor should be described and assessed. Exposure conditions and modes of release (to air from rupture or fire, to water, to land) and the quantity of radioactive material released should be stated.

5.1.1 During Distribution

5.1.2 During Use

5.1.3 During Installation, Maintenance, and Repair

5.1.4 During Disposal

5.2 Nonradiological Impacts of Accidents

Each of the following sections should describe and assess accidents or misuses in which exposure to or release of the radioactive material is not a significant factor, but in which significant personal injury or property loss may occur. Special attention should be given to potential chemical effects of such occurrences.

5.2.1 During Distribution

5.2.2 During Use

5.2.3 During Installation, Maintenance, and Repair

5.2.4 During Disposal

Chapter 6

ALTERNATIVES

This section should identify and discuss feasible alternatives related to (1) the design, distribution, use, and disposal of the product and (2) the licensing requirements for the product. Reasons for rejecting the alternatives should be clearly stated.

6.1 Alternatives Related to *(specific name of product)*

Alternatives to the specific product and to its design, distribution, use, and disposal should be described and compared with those proposed in Chapter 2. The discussion should show which alternative is best and the bases for the decision (environmental, technical, economic, etc.).

6.1.1 Alternative Radionuclides

The petitioner should discuss all feasible alternative radionuclides and indicate why they are not being used.

6.1.2 Other Products or Designs

In this section the petitioner should discuss feasible alternative designs of the specific product, the advantages and disadvantages of those designs, and the reasons why they are not used. Discuss all alternative products, both radioactive and nonradioactive, that could be used in place of the proposed product and compare them with the product. The petitioner should consider both his own products and those manufactured by other companies.

6.1.3 Other Means of Distribution, Use, and Disposal

Discuss feasible alternatives to the proposed methods of packaging, labeling, transport, routing, storage, sales, intended use, unintended use, return for disposal, disposal, installation, maintenance, and repair. Compare these alternatives with the proposed methods.

6.2 Alternatives Related to Licensing Requirements for *(name of product)*

The petitioner should indicate what the effects (administrative, economic, psychological, etc.) of a different licensing action would be if applied to the product (i.e., the effects of an action other than an exemption from licensing and regulatory requirements).

6.2.1 General License

This alternative to a license exemption normally would require issuance of a general license that would (1) authorize the receipt, possession, use, export, ownership, and acquisition of the radioactive material in the product and (2) control the use, transfer, and disposal of the radioactive material in the product. The petitioner should discuss the administrative and other effects of such a license. For example, detailed records of product purchases and transfers would probably be required to facilitate verification that the distributor and the purchaser have complied with the use, transfer, and disposal requirements of the general license.

6.2.2 Specific License

This alternative normally would require each purchaser or user of the product to obtain a specific license. An application would have to be filed and a specific license issued to a named person (user) prior to the receipt of the radioactive material contained in the product. Possession, use, transfer, and disposal of the radioactive material would be controlled under the terms and conditions of the specific licenses. The petitioner should provide a discussion of these and other implications of obtaining a specific license.

Chapter 7

SUMMARY OF POTENTIAL BENEFITS AND POSSIBLE COSTS

In this section the petitioner should provide a summary of the potential benefits and costs associated with the distribution, use, and disposal of the product. Significant benefits and costs identified in previous sections should be listed, summarized briefly, and quantified in the text.

A table (see example in Table 7.1) should summarize and quantify the impacts. Emphasis should be placed on environmental and societal benefits and costs, but private (producer-consumer) benefits and costs should be considered as well. Some benefits could become costs, and vice versa, depending on the particular way in which the impact is imposed. Such factors should be identified and the probability that they will be costs or will be benefits should be stated. If significant changes in the numbers of products distributed annually are expected, multiple entries (e.g., short-term, long-term) should be made for many of the impacts.

Table 7.1

SUMMARY OF POTENTIAL BENEFITS (AND COSTS) DUE TO THE INTRODUCTION OF THE (SPECIFIC NAME OF PRODUCT)

Impact	*Means of Describing Impact*
Radiological	
Potential radiation doses to individuals under:	
Normal conditions	millirems/year
Accident conditions	millirems/year
Potential radiation doses to population	person-rems/year
Introduction of radioactive materials into the environment	μCi/year
Potential contamination of the environment (disposal sites, etc.)	$\mu Ci/m^3$ or $\mu Ci/m^2$ and total volumes or areas
Socioeconomic	
Provision of new or better product	Summarize implications of product availability, e.g., improved safety
Savings from new or better product	Money, energy, etc. per year.
Uses of resources	Summarize; provide estimates of relative efficiency of resource use and magnitude of use.
Employment	Summarize and quantify jobs made available, lost, or upgraded.
Stimulation of competition within industry	Summarize effect of proposed product.

Table 7.1 (Continued)

Impact	*Means of Describing Impact*
Socioeconomic (continued)	
National security	Summarize potential contributions of product.
Balance of payments	Summarize potential effects of product; include import and export estimates.
Effects on existing products	Summarize effects on utilization of existing products.
Technological	
Introduction of new or improved product	Summarize implications.
Other	Identify and discuss any other important technological factors.
Ecological and other	Summarize any important effects or impacts on air, land, water, and biota.

June 1974

U.S. ATOMIC ENERGY COMMISSION

REGULATORY GUIDE

DIRECTORATE OF REGULATORY STANDARDS

REGULATORY GUIDE 6.6

ACCEPTANCE SAMPLING PROCEDURES FOR EXEMPTED AND GENERALLY LICENSED ITEMS CONTAINING BYPRODUCT MATERIAL

A. INTRODUCTION

Part 32, "Specific Licenses to Manufacture, Distribute, or Import Exempted and Generally Licensed Items Containing Byproduct Material," of Title 10 of the Code of Federal Regulations requires certain minimum quality assurance practices for exempted and generally licensed items containing byproduct material, including the use of acceptance sampling. Section 32.110, "Acceptance Sampling Procedures Under Certain Specific Licenses," specifies acceptance sampling procedures for use under certain specific licenses.

This guide describes certain information needed by the Regulatory staff in its review of applications for licenses and provides guidance concerning alternative mpling plans that are acceptable to the Regulatory aff.

B. DISCUSSION

The purpose of the acceptance sampling procedures specified in §32.110 is to limit the risk that inspection lots of devices of excessively poor conformance to specifications will reach the public. Of the various criteria for selecting plans for acceptance sampling by attributes, lot tolerance percent defective (LTPD) is the most appropriate for this purpose.

The following definitions* are relevant to this guide:

1. **Lot Tolerance Percent Defective** is defined by the American Society for Quality Control as ". . . expressed in percent defective, the poorest quality in an individual lot that should be accepted."

2. **Consumer's Risk** (or β), the risk of accepting a lot of quality equal to the LTPD, is defined by the American Society for Quality Control as "Risk, Consumer's—(β)—For a given sampling plan, the probability of accepting a lot, when the sampling plan is applied to a submitted lot or process of a given relatively poor quality, whichever is applicable."

3. **Acceptance Number** means the largest number of defectives (or defects) in the sample or samples under consideration that will permit the acceptance of the inspection lot.

4. **Acceptance Sampling** means sampling inspection in which decisions are made to accept or reject product; also, the science that deals with procedures by which decisions to accept or reject are based on the results of the inspection of samples.

Note 1: The alternative to acceptance is termed "rejection" for purpose of the definition, although in practice the alternative may take some form other than outright rejection.

Note 2: In lot-by-lot sampling, acceptance and rejection relate to individual lots. In continuous sampling, acceptance and rejection relate to individual units, or to blocks of consecutive units, depending on the stated procedure.

5. **Defect** means an instance of a failure to meet a requirement imposed on a unit with respect to a single quality characteristic.

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*ASQC STANDARD A2-1962, "Definitions and Symbols for Acceptance Sampling by Attributes," American Society for Quality Control. Copies may be obtained from the American Society for Quality Control, 161 W. Wisconsin Avenue, Milwaukee, Wisconsin 53203. This document is the source for standard definitions used in this guide.

6. **A Defective** means a defective unit; a unit of product that contains one or more defects with respect to the quality characteristic(s) under consideration.

7. **Inspection** means the process of measuring, examining, testing, gaging, or otherwise comparing the unit with the applicable requirements.

8. **Operating Characteristic Curve for an Acceptance Sampling Plan** (OC Curve) means a curve that shows for an acceptance sampling plan the relation between the probability of acceptance and the submitted lot or process quality, whichever is applicable. Expressed another way: A curve that shows for an acceptance sampling plan the percentage of lots that may be expected to be accepted for all possible submitted lot or process qualities, whichever is applicable.

9. **Sample** means, in acceptance sampling, one or more units of product (or a quantity of material) drawn from a lot for purposes of inspection to reach a decision regarding acceptance of the lot.

10. **Sampling, Single** means sampling inspection in which the decision to accept or to reject a lot is based on the inspection of a single sample.

11. **Sampling, Double** means sampling inspection in which the inspection of the first sample leads to a decision to accept a lot, to reject it, or to take a second sample; the inspection of a second sample, when required, leads to a decision to accept or to reject the lot.

12. **Sampling at Random**, as commonly used in acceptance sampling theory, means the process of selecting sample units in such a manner that all units under consideration have the same probability of being selected.

Note: Actually, equal probabilities are not necessary for random sampling–what is necessary is that the probability of selection be ascertainable. However, the stated properties of published sampling tables are based on the assumption of random sampling with equal probabilities. An acceptable method of random selection with equal probabilities is the use of a table of random numbers in a standard manner.

The sampling tables of §32.110(b) were adapted from the Dodge and Romig sampling inspection tables* which are the most commonly used tables indexed directly for LTPD (among other criteria). The consumer's risk, β, for the Dodge and Romig tables is set at 0.10, and also is set at 0.10 for the sampling plans given in §32.110(b). The tables of §32.110(b) are based on the simplest attribute sampling procedure that will give the required protection against acceptance of a lot of poor quality, in terms of LTPD, with a consumer's risk of 0.10.

There is no intention of optimizing efficiency of total inspection effort. To do this would require taking into account the process average quality level. A licensee may improve efficiency by selecting from the full set of Dodge and Romig sampling inspection tables a plan for the designated LTPD and for his process average. Double sampling available in the Dodge and Romig tables is more efficient than single sampling and gives essentially the same protection.

Typical operating characteristic curves for the sampling tables of §32.110(b) are given in Figures 1 through 8, identified by sample size *n* and acceptance number *c*. Each curve was computed for the largest lot size of the interval to which the sample applies, using the hypergeometric distribution. For any given LTPD, operating characteristic curves for sample sizes other than those plotted, computed on the same basis, would generally fall between the two typical curves shown.

Values of LTPD for which tables are given should be chosen when designating the LTPD for characteristics for which sampling risks are allowable.

It should be remembered that LTPD represents the poorest quality which should rarely be accepted. The manufacturing goal should be a process whose actual process average quality level is substantially better than the LTPD.

C. REGULATORY POSITION

The acceptance sampling procedures set out in §32.110 represent the minimum procedures to adequately ensure conformance to requirements.

Although the tables of §32.110(b) are based on attributes, variables measurements converted to attributes information would be a generally acceptable method for complying with the procedures.

It is not the intent, however, to preclude a licensee from taking advantage of the more efficient methods which may be applicable to his processes, provided they afford at least equivalent quality assurance. Under §§32.15(b), 32.55(c), and 32.62(d), an application for a license or for amendment of a license may include a description of procedures proposed as alternatives to the procedures prescribed in §§32.15(a)(2), 32.55(b), and 32.62(c). A variables sampling plan, or properly documented process control data, for example, might be applicable and more efficient. The licensee would be expected to show that the operating characteristic curve or confidence interval estimate for his procedure meets the required LTPD at the consumer's risk of 0.10.

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*H. F. Dodge and H. G. Romig, "Sampling Inspection Tables," 2nd ed., John Wiley & Sons, Inc., New York, 1959.

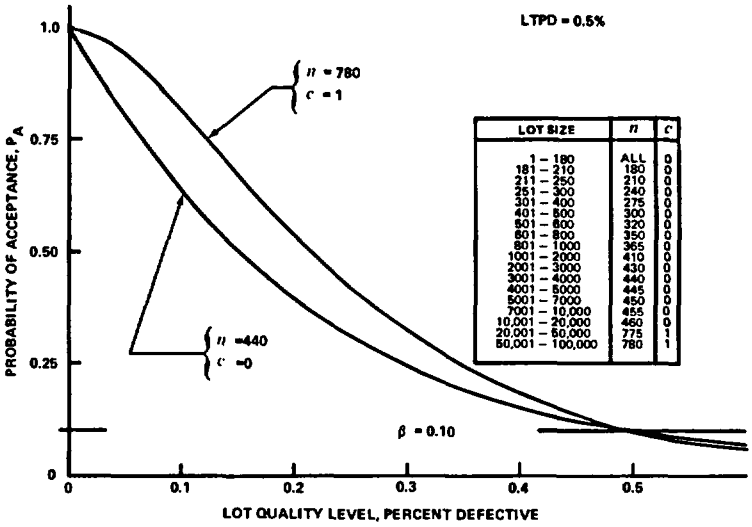
BIBLIOGRAPHY

1. A. J. Duncan, "Quality Control and Industrial Statistics," 3rd ed., Irwin, Homewood, Illinois, 1965. Duncan's book presents theory and principles for analyzing and comparing various standard plans for effectiveness, efficiency, and economy. In addition, he includes material useful for designing sampling plans for optimum operation for special conditions. Duncan also covers in a similar fashion related subjects in the field of quality control, such as control charts, tests of hypotheses, and analysis of variance.

2. E. L. Grant, "Statistical Quality Control," 3rd ed., McGraw-Hill Book Company, New York, 1964. Chapters on Probability Theory and Acceptance Sampling treat principles and theory of the most commonly used acceptance sampling plans including Dodge-Romig tables and MIL-STD-105D (the current revision of military sampling by attributes).

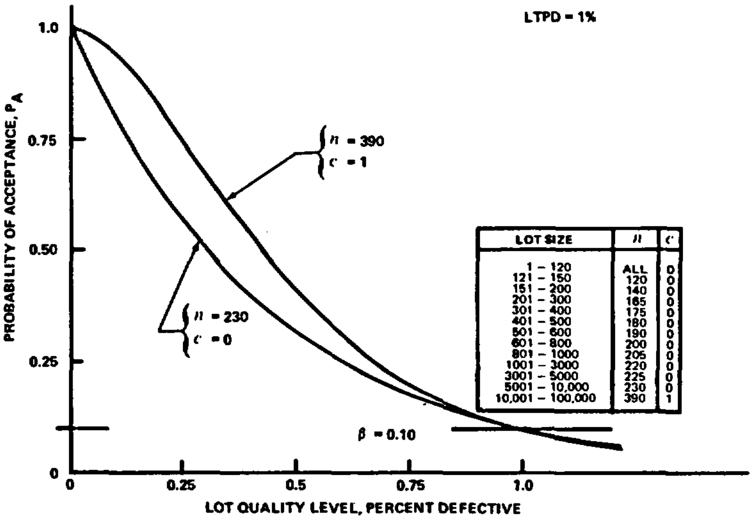
3. J. M. Juran and F. M. Gryna, "Quality Planning and Analysis," McGraw-Hill Book Company, New York, 1970. Chapter 17 entitled "Acceptance Sampling" is a concise treatment of the practical application of sampling plans. This chapter explains the concept of sampling in relatively nontechnical terms, discusses briefly the economics of sampling, sampling risks, and sampling criteria. There is given a very abbreviated section (17-5) on theory, with reference to another source, and examples of analyses of some common sampling plans. A comparison is made of Attributes and Variable plans. Concise descriptions of the following commonly used plans are given: Dodge-Romig sampling inspection tables, MIL-STD-105D, and MIL-STD-414 (military sampling by variables). The use of other information such as control chart evidence that the process is in a state of control is also briefly summarized.

4. J. M. Juran (ed.), "Quality Control Handbook," 2nd ed., McGraw-Hill Book Company, New York, 1962. Acceptance sampling plans specifically are covered in section 13 from pages 13-69 to 13-118. Material covered is about the same as the references above, but in the form and style of a manual or handbook. Section 8 entitled "Acceptance of Quality" covers such general subjects as inspection planning, interpretation of specifications, classification of quality characteristics, providing instruments, judging conformance, physical control of product, rejection of vendor-supplied product, fraud and collusion, flinching, and inadvertent shipment of defectives. This section covers practical problems and ramifications of operating the product acceptance function.



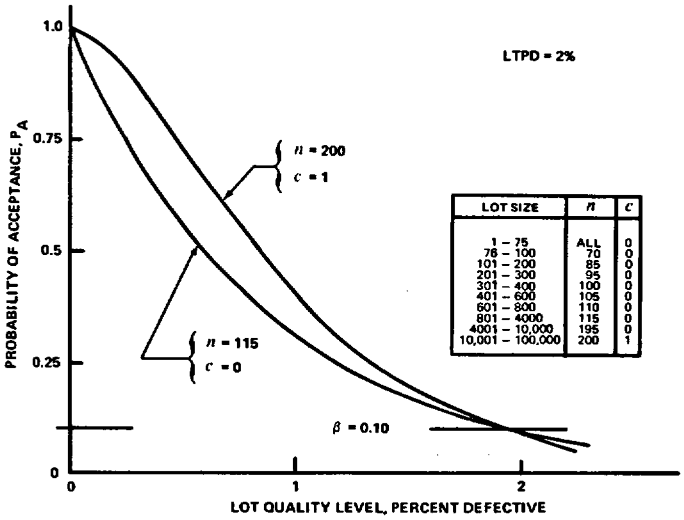
LOT SIZE	n	c
1 – 180	ALL	0
181 – 210	180	0
211 – 250	210	0
251 – 300	240	0
301 – 400	275	0
401 – 500	300	0
501 – 600	320	0
601 – 800	350	0
801 – 1000	365	0
1001 – 2000	410	0
2001 – 3000	430	0
3001 – 4000	440	0
4001 – 5000	445	0
5001 – 7000	450	0
7001 – 10,000	455	0
10,001 – 20,000	460	0
20,001 – 50,000	775	1
50,001 – 100,000	780	1

Figure 1. – Operating characteristic curves and sampling table for Lot Tolerance Percent Defective 0.5%.



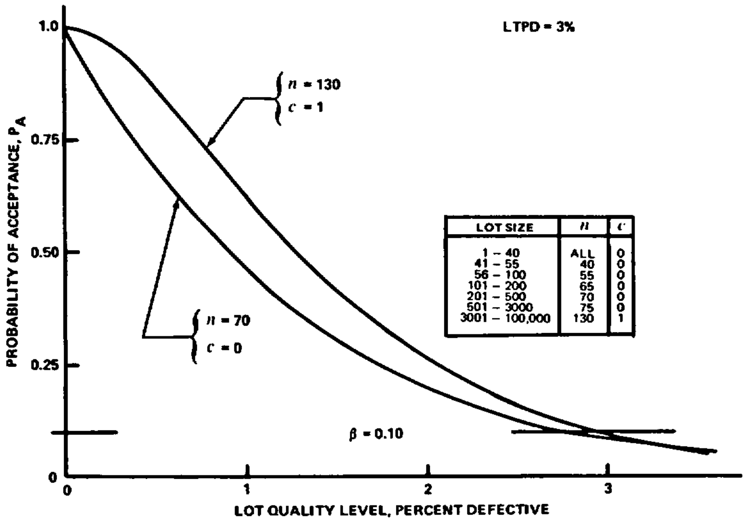
LOT SIZE	n	c
1 – 120	ALL	0
121 – 150	120	0
151 – 200	140	0
201 – 300	165	0
301 – 400	175	0
401 – 500	180	0
501 – 600	190	0
601 – 800	200	0
801 – 1000	205	0
1001 – 3000	220	0
3001 – 5000	225	0
5001 – 10,000	230	0
10,001 – 100,000	390	1

Figure 2. – Operating characteristic curves and sampling table for Lot Tolerance Percent Defective 1.0%.



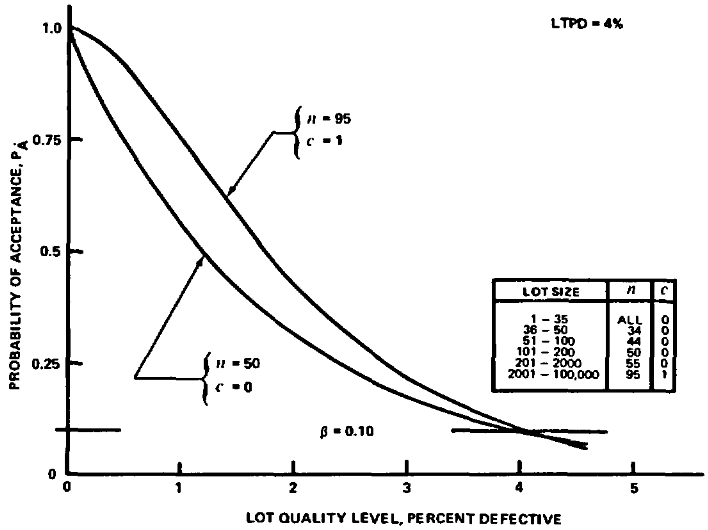
LOT SIZE	n	c
1 – 75	ALL	0
76 – 100	70	0
101 – 200	85	0
201 – 300	95	0
301 – 400	100	0
401 – 600	105	0
601 – 800	110	0
801 – 4000	115	0
4001 – 10,000	195	0
10,001 – 100,000	200	1

Figure 3. — Operating characteristic curves and sampling table for Lot Tolerance Percent Defective 2%.



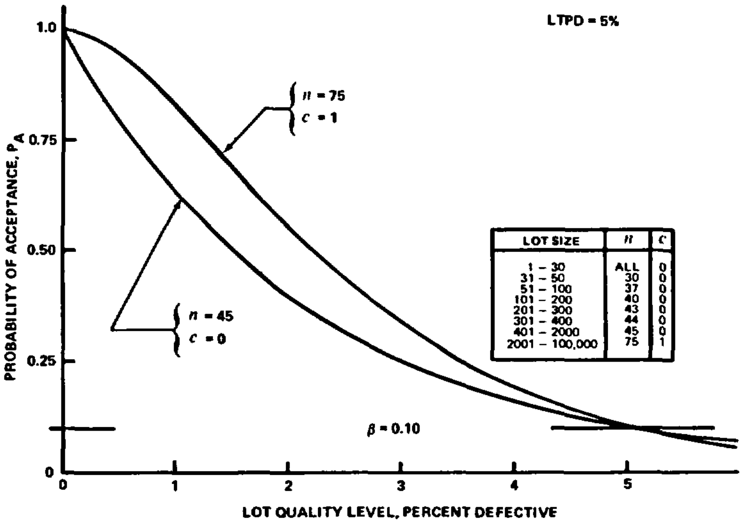
LOT SIZE	n	c
1 – 40	ALL	0
41 – 55	40	0
56 – 100	55	0
101 – 200	65	0
201 – 500	70	0
501 – 3000	75	0
3001 – 100,000	130	1

Figure 4. — Operating characteristic curves and sampling table for Lot Tolerance Percent Defective 3%.



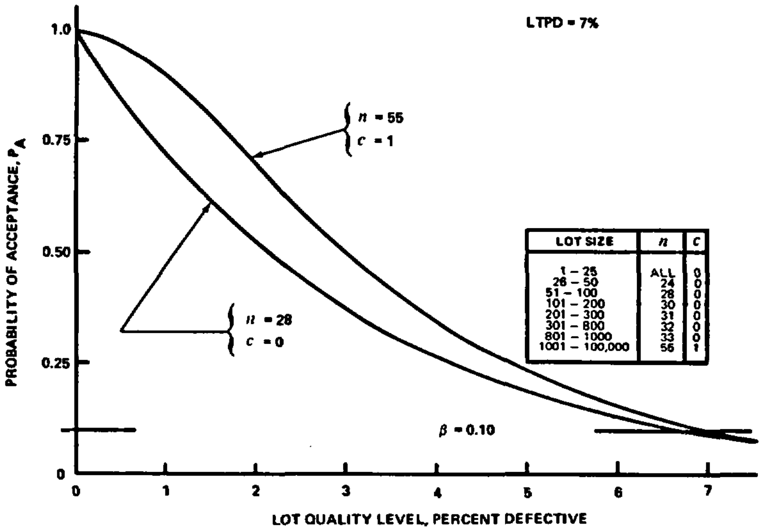
LOT SIZE	n	c
1 – 35	ALL	0
36 – 50	34	0
51 – 100	44	0
101 – 200	50	0
201 – 2000	55	0
2001 – 100,000	95	1

Figure 5. — Operating characteristic curves and sampling table for Lot Tolerance Percent Defective 4%.



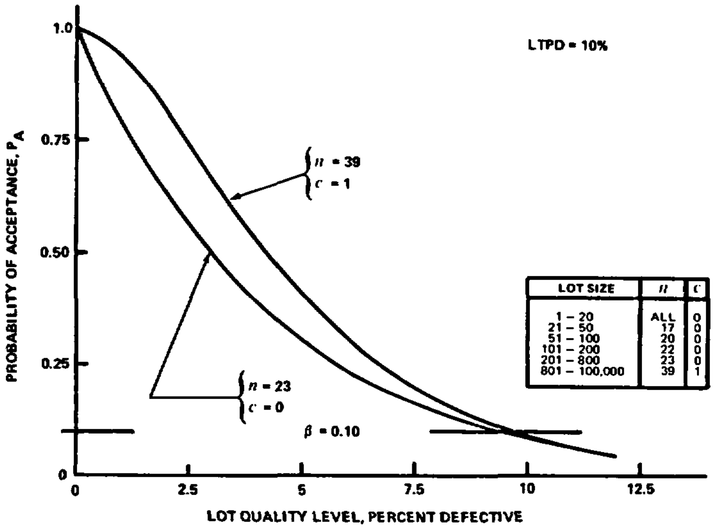
LOT SIZE	n	c
1 – 30	ALL	0
31 – 50	30	0
51 – 100	37	0
101 – 200	40	0
201 – 300	43	0
301 – 400	44	0
401 – 2000	45	0
2001 – 100,000	75	1

Figure 6. — Operating characteristic curves and sampling table for Lot Tolerance Percent Defective 5%.



LOT SIZE	n	c
1 – 25	ALL	0
26 – 50	24	0
51 – 100	28	0
101 – 200	30	0
201 – 300	31	0
301 – 800	32	0
801 – 1000	33	0
1001 – 100,000	56	1

Figure 7. — Operating characteristic curves and sampling table for Lot Tolerance Percent Defective 7%.



LOT SIZE	n	c
1 – 20	ALL	0
21 – 50	17	0
51 – 100	20	0
101 – 200	22	0
201 – 800	23	0
801 – 100,000	39	1

Figure 8. — Operating characteristic curves and sampling table for Lot Tolerance Percent Defective 10%.

U. S. ATOMIC ENERGY COMMISSION

(Reprint from Federal Register) 30 F.R. 3462, March 16, 1965

ATOMIC ENERGY COMMISSION

USE OF BYPRODUCT MATERIAL AND SOURCE MATERIAL

Products Intended for Use by General Public (Consumer Products)

Criteria for the approval of products intended for use by the general public containing byproduct material and source material. This notice sets forth the essential terms of the Commission's policy with respect to approval of the use of byproduct material and source material in products intended for use by the general public (consumer products) without the imposition of regulatory controls on the consumer-user. This is accomplished by the exemption, on a case-by-case basis, of the possession and use of the approved items from the licensing requirements for byproduct and source material of the Atomic Energy Act of 1954, as amended, and of the Commission's regulations "Licensing of Byproduct Material", 10 CFR Part 30 and "Licensing of Source Material", 10 CFR Part 40.

1. At the present time it appears unlikely that the total contribution to the exposure of the general public to radiation from the use of radioactivity in consumer products will exceed small fractions of limits recommended for exposure to radiation from all sources. Information as to total quantities of radioactive materials being used in such products and the number of items being distributed will be obtained through recordkeeping and reporting requirements applicable to the manufacture and distribution of such products. If radioactive materials are used in sufficient quantities in products reaching the public so as to raise any question of population exposure becoming a significant fraction of the permissible dose to the gonads, the Commission will, at that time, reconsider its policy on the use of radioactive materials in consumer products.

2. Approval of a proposed consumer product will depend upon both associated exposures of persons to radiation and the apparent usefulness of the product. In general, risks of exposure to radiation will be considered to be acceptable if it is shown that in handling, use and disposal of the product it is unlikely that individuals in the population will receive more than a small fraction, less than a few hundredths, of individual dose limits recommended by such groups as the International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), and the Federal Radiation Council (FRC), and that the probability of individual doses approaching any of the specified limits is negligibly small. Otherwise, a decision will be more difficult and will require a careful weighing of all factors, including benefits that will accrue or be denied to the public as a result of the Commission's action. Factors that may be pertinent are listed in paragraphs 9 and 10, below.

3. It is considered that as a general rule products proposed for distribution will be useful to some degree. Normally the Commission will not attempt an extensive evaluation of the degree of benefit or usefulness of a product to the public. However, in cases where tangible benefits to the public are questionable and approval of such a product may result in widespread use of radioactive material, such as in common household items, the degree of usefulness and benefit that accrues to the public may be a deciding factor. In particular, the Commission considers that the use of radioactive material in toys, novelties, and adornments may be of marginal benefit.

4. Applications for approval of "off-the-shelf" items that are subject to mishandling especially by children will be approved only if they are found to combine an unusual degree of utility and safety.

5. The Commission has approved certain long standing uses of source material, most of which antedate the atomic energy program. These include:

(1) Use of uranium to color glass and glazes for certain decorative purposes;

(2) Thorium in various alloys and products (gas mantles, tungsten wire, welding rods, optical lenses, etc.) to impart desirable physical properties; and

(3) Uranium and thorium in photographic film and prints.

6. The Commission has also approved the use of tritium as a substitute luminous material for the long standing use of radium for this purpose on watch and clock dials and hands.

7. The Commission has approved additional uses of byproduct and source material in consumer products. These include the following:

(1) Tritium in automobile lock illuminators;

(2) Tritium in balances of precision;

(3) Uranium as shielding in shipping containers; and

(4) Uranium in fire detection units.

8. In approving uses of byproduct and source materials in consumer products, the Commission establishes limits on quantities or concentrations of radioactive materials and, if appropriate, on radiation emitted. In some cases other limitations, such as quality control and testing, considered important to health and safety are also specified.

PRINCIPAL CONSIDERATIONS WITH RESPECT TO EVALUATION OF PRODUCTS

9. In evaluating proposals for the use of radioactive materials in consumer products the principal considerations are:

(a) The potential external and internal exposure of individuals in the population to radiation from the handling, use and disposal of individual products;

(b) The potential total accumulative radiation dose to individuals in the population who may be exposed to radiation from a number of products;

(c) The long-term potential external and internal exposure of the general population from the uncontrolled disposal and dispersal into the environment of radioactive materials from products authorized by the Commission; and

(d) The benefit that will accrue to or be denied the public because of the utility of the product by approval or disapproval of a specific product.

10. The general criteria for approval of individual products are set forth in paragraph 2, above. Detailed evaluation of potential exposures would take into consideration the following factors together with other considerations which may appear pertinent in the particular case:

(a) The external radiation levels from the product.

(b) The proximity of the product to human tissue during use.

(c) The area of tissue exposed. A dose to the skin of the whole body would be considered more significant than a similar dose to a small portion of the skin of the body.

(d) Radiotoxicity of the radionuclides. The less toxic materials with a high permissible body burden, high concentration limit in air and water, would be considered more favorably than materials with a high radiotoxicity.

(e) The quantity of radioactive material per individual product. The smaller the quantity the more favorably would the product be considered.

(f) Form of material. Materials with a low solubility in body fluids will be considered more favorably than those with a high solubility.

(g) Containment of the material. Products which contain the material under very severe environmental conditions will be considered more favorably than those that will not contain the material under such conditions.

(h) Degree of access to product during normal handling and use. Products which are inaccessible to children and other persons during use will be considered more favorably than those that are accessible.

(Sec. 161, 68 Stat. 948; 42 U.S.C. 2201, Administrative Procedure Act, sec. 3, 60 Stat. 238; 5 U.S.C. 1002)

Dated at Washington, D.C., this 8th day of March 1965.

For the Atomic Energy Commission.

W. B. MCCOOL,
Secretary.

[F.R. Doc. 65-2616; Filed, Mar. 15, 1965; 8:45 a.m.]

THE ROLE OF THE BUREAU OF RADIOLOGICAL HEALTH IN CONTROLLING RADIOACTIVITY IN CONSUMER PRODUCTS

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Under authority provided by the Public Health Service Act, the Bureau of Radiological Health may cooperate with State and local authorities on matters relating to the preservation and improvement of the public health. In 1966, the Secretary of Health, Education, and Welfare established the National Center for Radiological Health (now the Bureau of Radiological Health) for the explicit purpose of developing and carrying out a national program for the prevention and control of radiological hazards to the public. With the passage of the Radiation Control for Health and Safety Act of 1968, these responsibilities were expanded to also include the safe uses of non-ionizing radiation in consumer products. Under the most recent reorganization, this authority has been delegated to the Director, Bureau of Radiological Health, through the Commissioner of Food and Drugs. Within the Bureau, the Division of Radioactive Materials and Nuclear Medicine is responsible for the development of a comprehensive radioactive materials control program, including user protection at the State and Federal levels.

The objective of radiological health programing is to prevent or minimize exposure as a presumptive index for somatic injuries and to minimize the deterioration of the genetic constitution of the population. To achieve this objective, there must be consistent, uniform, and all-inclusive control of radioactive materials.

Radium, a naturally occurring radioactive element used since the turn of the century, has had the longest history of use of any radioactive material. Also, because it has a long half-life (>1600 years) and because it is a bone seeker like calcium, radium is more hazardous than most man-made radionuclides. Much of what is known of the biological effects of ionizing radiation in man is based on the crippling and lethal effects of radium ingested more than 40 years ago by watch dial painters. Many of these timepieces are still in use.

Materials that are made radioactive through the use of particle accelerators have come into increased use in medicine and industry in recent years. Approximately 875 particle accelerators are estimated to exist in the U.S., of which some 700 have been registered by the States.

In 1966, the U.S. Atomic Energy Commission (AEC) submitted a report on the extent of the uses of radionuclides in consumer products of various types. According to this report, the AEC authorized some 26 different radionuclides for use in more than a dozen separate products of various types. A patent was issued in 1967 for an air ionization device containing more than 10 μCi of Ra-226 or the curie equivalent of tritium for use as an "anti-fatigue" mechanism. It was reputed that, as a result of the ionization of the air, a higher performance from the work force in the exposed area would result. More mundane are such products as automobile lock illuminators, instrument dials, compasses, and aircraft exit signs, all of which contain either radium, promethium-147, krypton, or various byproduct radionuclides as the luminizing activator. The list could go on to include gauging and well-logging devices, ion generating tubes, vacuum tubes, etc. As is well known, oxides and salts of uranium and thorium are used extensively as coloring agents in glass and glazes of various types. Also, thorium is used as an agent to improve the refractory properties of photographic lenses. All too familiar is the use of uranium as a coloring agent in ceramics and ornamental glass. In addition, the fluorescent properties of uranium are used to imitate the fluorescence of natural teeth.

The need for some international guidelines regarding the uses of radioactive materials in consumer products was reflected in 1966 by the World Health Organization in announcing a world survey of such consumer products available to the general public and in use without the national authorities exercising regulatory controls over these products. IAEA (1967) and NEA (1970) publications include guidelines on an international scale for controls of radiation exposure to the public from radioactive consumer products.

Since the authority of the Nuclear Regulatory Commission to license and control source and byproduct materials does not include naturally occurring and accelerator-produced radioactive materials (NARM), the Bureau's program has concentrated in this area. Recently, in cooperation with other Federal and State radiation control agencies, the Bureau has drafted some guidelines for NARM that will be useful to the States in implementing their programs.

That the public is still concerned about potential radiation hazards from consumer products is reflected in "Fire Detectors and Safety," an article in the January 4, 1977 issue of the Washington Post. The Health Research Group, an organization of Raplh Nader, denounced ionization smoke detectors as being "mindless and dangerous." The group advocated the recall and disposal of some four million devices. Conversely, the Consumers Union, basing its position test data, advocated that such devices imposed little radiation hazard and, if recalled, could lead to tragic consequences resulting from the lack of such fire alarms.

REFERENCES

International Atomic Energy Agency (1967), "Radiation Protection standards for Radioluminous Time Pieces," Safety Series No. 23, International Atomic Energy Agency, Vienna.

Nuclear Energy Agency (1970), "Basic Approach for Safety Analysis and Control of Products Containing Radionuclides and Available to the Public," Nuclear Energy Agency, Paris.

EPA'S ROLE AND APPROACH IN CONTROLLING RISKS FROM NATURALLY OCCURRING RADIOACTIVITY IN CONSUMER PRODUCTS

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In the past, many papers addressing selected exposure situations have been published, but none has focused totally on the radiological aspects of consumer products.

Consumer products containing radioactive materials are not new. Radionuclides from the uranium and thorium series were present on the earth long before man's arrival. As a result, perhaps the first consumer products containing radioactivity were arrowheads, ceramic pots, and mineral waters used by our remote ancestors. Today, our daily activities and the environment in which we live are permeated with consumer products that emit radiation or contain radioactive materials. These include such plentiful, mundane products as concrete blocks, bricks, fertilizers, televisions, and luminous materials as well as such less prolific products as lightning rods, static eliminators, or smoke detectors.

Like our unaware primitive ancestors, very few members of the general public using these products are aware that they contain radioactive materials or produce radiation during operation. This places a special burden on manufacturers as well as government control agencies to ensure that adequate measures are taken to inform and protect the unsuspecting public.

In controlling risks from such consumer products, the Environmental Protection Agency (EPA) primarily addresses products that contain naturally occurring radionuclides. Such products principally contain radionuclides from the natural uranium and thorium decay series.

The Agency's authority for its program is derived from transferred functions of the Atomic Energy Act and the Public Health Service Act, as well as from the Clean Air Act, the National Environmental Policy Act, and the Safe Drinking Water Act. Our program focuses on:

(1) Development and promulgation of Federal radiation protection guidance,

(2) Investigations into the environmental levels and public health impact of these consumer products,

(3) Detailed review of environmental impact statements involving consumer products, and

(4) Technical assistance to the States in the conduct of their radiation control programs.

The EPA's definition of consumer product is quite broad, encompassing devices, commodities, materials, or other goods that are sold or otherwise directly or indirectly made available to the public. The purpose of this is to address items purchased or used by the general public in their normal activities, although they might not acquire these items from the corner store, e.g., materials like fertilizer, concrete, and wallboard and even the acquisition of property for home construction.

The EPA's basic goal with respect to consumer products containing naturally occurring radionuclides is to minimize any potential health impact by controlling population exposure to such sources. This goal is met by conducting a balanced program of investigative studies leading to the development and promulgation of criteria and guidelines to minimize risk in a cost effective manner.

In conducting this program, EPA begins with the assumption that any radiation exposure has a possible adverse health effect. Clearly, while some public exposure to radiation from consumer products is inevitable, no avoidable risk due to radiation exposure should occur to individuals, the population at large, or the environment without the existence of adequate offsetting benefits.

Consumer products containing naturally occurring radionuclides may have an environmental or public health impact during their useful life, after they have been disposed of as waste, or during both periods. For this reason, manufacturers and government radiation control agencies must ensure that such products are useful, that the alternatives to employing radioactive materials in the products have been considered, and that the design and engineered protective qualities of the product ensure no adverse impact on public health during their use. In addition, such products should not result in any significant long-term environmental dose commitment after they are thrown away. Since it is virtually impossible to ensure that special use or disposal procedures are employed by consumers for products containing radioactive materials, their design should preclude the need for such measures as much as possible. However, with increasing proliferation of consumer products containing radioactive materials, we are likewise increasing the potential long-term contamination of the environment. Consequently, to the extent feasible, product design and engineering should use radionuclides that would not persist in the environment for long time periods or present special health hazards to man or animals. Further, the form and packaging should be such as to minimize migration of the radionuclide under all conditions.

At present, the Agency is directing its resources in the consumer products area toward the assessment of products resulting from the operations of the phosphate and the construction materials industries. These studies are being used to determine the need for radiation protection criteria and guidance in these areas as well as to provide the technical basis for such guidance as might be necessary.

It is estimated that the average person in the United States spends about 90% of his time indoors. Over 78% of this time is spent in the home (Oakley, 1972). Studies of the radioactivity concentration in various building materials in several countries throughout the world have shown that construction products made from certain clays, slags, pumice, sands, and gypsums contain radium-226 concentrations up to 30 pCi/g along with similar concentrations of other members of the uranium series (Harvard, 1976). Such construction products can lead to structures that contribute to their occupants considerable gamma exposure as well as exposure to radon daughters. While external gamma exposures in structures due to the construction products probably do not double the normal control gamma exposure, the indoor radon levels could be several orders of magnitude higher than normal background. Average background radon daughter levels in the United States range from about 0.0002 to 0.006 WL, whereas in situations where high concentrations of uranium and radium-226 are present in or around the structures, levels on the order of 0.1-0.5 WL might be observed, as shown by the Agency's studies of the uranium mill tailings problem in the Western United States. As a consequence, radon-222 sources in construction products may potentially cause particularly elevated radon daughter levels in structures made with the products. Since epidemiological studies on uranium miners have demonstrated an increased lung cancer risk among miners exposed to increased radon daughter levels, the Agency is very concerned about this problem.

Situations where large areas of land contain high concentrations of radium--226 can also pose radon daughter health hazards to residents, as observed by the Agency on reclaimed phosphate mine lands in Florida. Such land could become a problem to an unknowing home owner if he purchased the land and constructed a house to find out to his surprise that the indoor radon daughter levels were excessive.

The Agency's study of the radiological aspects of consumer products from the phosphate industry overlaps our construction material's efforts because many of the phosphate industry's products such as by product gypsum (phosphogypsum) or slag could be or are used as construction materials. Calcium silicate slag from the production of elemental phosphorus has been widely used in and around Alabama as an aggregate for concrete block. The slag has also been used in Idaho under some structures and is still widely used there for road paving and several other applications, including the production of insulation. Phosphogypsum was used to make plaster and wallboard materials in the United States during the 1940's. However, at present no wallboard using phosphogypsum as a material is manufactured in the United States although several European countries and Japan do manufacture such wallboard.

On the other hand, fertilizer, the primary product of the phosphate industry, is extremely beneficial for maximizing food yields throughout the world. As a consequence, it is clearly a product of considerable social benefit. Nonetheless, the questions remain, is the radiological impact of this product significant and can it be cost effectively reduced? These are the issues we are presently evaluating.

The Office of Radiation Programs is investigating several other consumer product areas. The EPA has prepared two reports on the radiological impact of radon-222 from unvented home appliances that use natural gas and liquified petroleum gas. These studies indicate that this source may contribute to some increased general population exposure. The critical consumer groups involved would be those households near the gas wells where only a short period of time would be allowed for the decay of the radon and its daughters. The Agency's ORP is also investigating the impact of high radon-222 concentrations in potable water. Calculations and limited field studies suggest that concentrations in excess of 500 pCi/liter could contribute to a significant increase in airborne radon daughter levels in structures because of the release of the radon to the air during household or commercial activities. Considering that several areas of the United States have reported radon-222 concentrations up to several hundred thousand picocuries per liter, we believe that this source may contribute significantly to overall population exposure.

Some of these consumer product sources are of greater significance in certain States, e.g., fertilizer use in the Midwest. However, increased emphasis on conservation and efficiency by using byproducts from various mineral extraction industries accompanied by general increases in the mining of our natural resources leads the Agency to believe it has a firm responsibility to ensure that such uses are in accordance with sound radiation protection practice. In this regard, EPA has a positive commitment to aggressively assess the impact of such products and take radiation control action when necessary.

In conducting its program, the Agency recognizes the strong role of the individual States in controlling exposure from many of these sources. EPA plans to continue to work closely with the States, to continue its support of the Conference of Radiation Control Program Directors, and to cooperate with other Federal agencies with responsibilities in the area of consumer products such as the Bureau of Radiological Health, the Nuclear Regulatory Commission, and the Consumer Product Safety Commission. Together, and with open participation from the public, we can ensure that all consumer products will not present unknown or unnecessary radiation risks. However, to fully meet this objective, it may be necessary that Congress enact appropriate legislation to eliminate present gaps in Federal authority.

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NRC'S REGULATORY PROGRAM ON CONSUMER PRODUCTS CONTAINING BYPRODUCT, SOURCE, AND SPECIAL NUCLEAR MATERIAL

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The Nuclear Regulatory Commission has launched a program of aggressive solicitation of public input into the rule making process. The NRC as a new independent regulatory agency is taking a fresh and thorough look at its regulatory program for consumer products. NRC does not consider itself to be "boxed in" by anything AEC had done before. Based on present conditions and activities, NRC may decide to take a totally different approach, follow the past practices, or merely make some changes in its program for regulating consumer products.

CONSUMER PRODUCTS UNDER NRC'S REGULATORY CONTROL

NRC has authority to exempt consumer products containing source materials, byproduct materials, and special nuclear materials from regulatory control under certain conditions.

Source materials are materials essential to the production of special nuclear materials. This category covers uranium (including depleted uranium produced as tailings from the enrichment process) and thorium, both of which are naturally occurring and radioactive. Other radioactive materials that occur in nature along with uranium and thorium, such as radium and polonium, are not included under the Atomic Energy Act—presumably because they are not considered to be important to the common defense and security.

Special nuclear materials are materials capable of releasing substantial quantities of atomic energy. This category includes plutonium, uranium enriched in the isotope-235, uranium-233, and any material artificially enriched by any of these materials.

Byproduct materials are radioactive materials (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear materials. Although byproduct materials do include activation products from nuclear reactors and plutonium-beryllium neutron sources, they do not include activation products from other neutron sources such as californium-252 or accelerators.

At present, the possession and use of about 15 types or classes of consumer products containing byproduct materials and about an equal number of types containing source materials are exempt from NRC regulatory control. Although NRC received authority in August 1974 to exempt products containing special nuclear materials, there have been no petitions for such an exemption.

Table 1 gives distribution data for the most widely distributed consumer products containing byproduct materials. The first two columns indicate the number of units and quantity of radioactive material distributed in a one-year period between July 1975 and June 1976. The next two columns show the total amount transferred to

TABLE 1

TRANSFER OF CERTAIN CONSUMER PRODUCTS CONTAINING BYPRODUCT MATERIALS

(As Reported by NRC Licensees)

Products	July 1975 to June 1976		Thru June 1976	
	No. of Units	Activity (Ci)	Total No. of Units	Total Activity (Ci)
Timepieces (H-3)	6×10^6	6,400	1.3×10^8	1.4×10^5
(Pm-147)	2×10^6	100	1.4×10^7	620
Smoke detectors (Am-241)	3×10^6	22	5×10^6	71
Electron tubes (Kr-85)	1×10^8	4.3	6×10^8	110

date. For smoke detectors, about three-quarters of the total units were distributed last year, indicating the rapid growth of the market.

Similar distribution data for products containing source material are given in Table 2. Since reporting of the units and quantities transferred is not required for products containing unimportant quantities of source material, it is very difficult to obtain such data. The data presented in Table 2 were estimated based on information supplied by several manufacturers.

TYPES OF LICENSING ACTIONS

There are three types of licensing actions: exemptions, general licenses, and specific licenses.

Exemptions

The exemptions from the regulations and licensing requirements are set forth in detail in Parts 30 and 40 of the Commission's regulations. Of particular interest are the exemptions for small quantities of certain radioisotopes when incorporated in specified products. The manufacture and distribution of such products are generally subject to specific licensing requirements, but the possession, use, and transfer may be exempted. An example of a product that is exempted is a watch whose hands and dials are made luminous by application of the radioisotope tritium or promethium-147. The manufacture of these luminous watch dials, however, must be specifically licensed.

Exemptions are based mainly on a determination by the Commission that the exempted classes or quantities of radioactive material or the kinds of uses or users will not constitute an unreasonable risk to the common defense and security or to the public health and safety. Any person may apply to the Commission for an exemption, or the Commission may make an exemption on its own initiative.

TABLE 2

ESTIMATED PRODUCTION OF CERTAIN CONSUMER PRODUCTS CONTAINING SOURCE MATERIALS IN 1974

Products	No. of Units	Total Wt. (kg)
Incandescent mantles (Nat. Th)	2×10^7	5,000
Piezoelectric ceramic (Dep. U)	1×10^7	Not available
Photographic films, prints, and negatives (U or Th)	∿0	∿0
Fire detectors (U)	∿0	∿0

General Licenses

General licenses are effective without the necessity for applications or the issuance of licensing documents to particular persons. A general license permits the possession and use of specified kinds and quantities of radioisotopes, subject in some cases to certain regulatory requirements. In some instances, registration with NRC is required to use radioisotopes under a general license. Radioisotopes that may be used under general licenses are for the most part incorporated in products, devices, or equipment manufactured under specific licenses issued by the Commission or by an Agreement State.

Specific Licenses

Persons wishing to possess and use radioisotopes in a manner, form, or quantity not exempted from licensing and not covered by a general license may apply for and obtain a specific license from the commission or an Agreement State. The applicant for such a license may be an individual, firm, corporation, association, public or private institution, or agency. Depending on the interests and capabilities of the licensee, the activities authorized in the license can be very limited or can cover broad areas.

PETITIONER'S PROCEDURE FOR REQUESTING AN EXEMPTION

The Commission's general rules for filing a petition for rule making are set out in 10 CFR Part 2, "Rules of Practice."

The petition should be addressed to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Chief, Docketing and Service Branch. To ensure that there is no question about the letter being considered a petition for rule making, the petitioner should reference 10 CFR §2.802.

The petition should state the substance or text of the proposed new regulation or amendment and should state the basis for the request.

In the case of a petition seeking an exemption for a product containing a radionuclide, the petitioner must file 50 copies of an environmental report. The NRC staff has issued Regulatory Guide 6.7 to provide assistance to petitioners in their development of these environmental reports.

Among the subjects covered in the environmental reports are environmental effects of normal distribution, use, and disposal of the product; environmental effects of postulated accidents or misuse; alternatives; and potential benefits and possible costs. The last category, if documented with quantified benefits and costs or risks from safety and marketing studies, will be particularly helpful to the NRC staff in preparing an environmental impact statement. Description or narrative text, as well as tables, charts, graphs, and schematic drawings, should be used.

NRC'S PROCEDURES TO ESTABLISH AN EXEMPTION

In response to a petition, the NRC staff can initiate a rule making action to consider the possibility of establishing in the regulations an exemption from any or all of the licensing and regulatory requirements. The first action taken by the staff in response to a petition is to publish in the Federal Register a notice of receipt of the petition, together with a description of the request and an invitation for comments. The staff then performs a preliminary evaluation of the safety, environmental, legal, and administrative aspects of the petition in order to determine the appropriate process for handling it. If it appears that, for safety or legal reasons, the petition cannot by granted or if the petition is already answered in another way by the regulations, the process would tend toward denial. If a positive response is feasible, the next decision is how should the response be developed–via an exemption, a general license, or some other provision to be added to the regulations.

If the staff sees a need for an exemption, it can also initiate a rule making action on its own initiative.

Although all of this process is carried out within the NRC staff, only the Commission (that is, the five presidentially appointed Commissioners) can decide to deny a petition or to amend the regulations.

The staff makes a thorough, independent analysis of three primary factors for consideration by the Commission in making a determination about a petition. These factors are (a) administrative considerations, (b) radiation safety aspects, and (c) environmental impact. In some cases, a public meeting to discuss the pros and cons of approval may be considered desirable because of the nature of the issues involved. Preparation of the basis for denial or for the rule change can take a considerable amount of time and effort.

The analyses are submitted to the Commission for consideration and action. Under the new Sunshine Act, that action must be taken in a meeting that is open to the public and has been announced publicly (in the Federal Register) at least 28 days in advance. Subsequently, if approved by the Commission, the action is submitted to the Federal Register for publication–usually within two weeks.

In the case of an amendment of the rules to provide an exemption, for example, the initial action by the Commission is to issue a proposed rule, allowing 30 to 90 days for public comment. If an environmental impact statement has been prepared as part of the decision making process, the draft is distributed to interested Federal and State agencies and is made available to the public by placing a notice of its availability in the Federal register. Review and comments are encouraged.

The next step is to give careful and full consideration to the comments on the rule and on the draft environmental statement (if involved). Revisions to both the rule and the environmental impact statement are made as appropriate on the basis of those comments and any other information the staff may have.

If any of the comments or changes are significant, the revised rule must be resubmitted to the Commission. If approved, the rule is published in the Federal Register, usually to be effective in 30 days, and the Final Environmental Impact Statement is made available to government agencies and the public and its availability noted in the Federal Register.

The petition-for-rule-making process has about 9 months of built-in waiting time. If complicated legal or safety issues arise, it may take much longer.

It should be emphasized that the company or companies that petition for the rule change must provide the necessary data and information on safety and environmental impacts for the rule change. Once the rules are amended, these companies in a separate action must apply for a specific license to manufacture and distribute their product. Other manufacturers of the same type of product need only apply for a license to manufacture and distribute their products.

PROCEDURES TO OBTAIN A SPECIFIC LICENSE

The procedure just described is appropriate to obtain authorization for the possession, use, and transfer of a consumer product. Following is a review of the procedure involved in applying for and obtaining a specific license that is required to manufacture a consumer product.

The NRC safety evaluation of an application for a specific license is made on the basis of training and experience and the instrumentation, equipment, facilities, and procedures the applicant proposes to use for radiation protection and waste disposal. If employees are to handle radioisotopes, they must also have adequate training and experience, and this must be shown in the application.

The application must also include detailed information on the quantity, type, and chemical or physical form of radioisotopes to be used and the purpose for which radioisotopes will be used.

If an application is approved, the Commission will issue a license. Licensees must confine their possession and use of radioisotopes to the locations and purposes authorized in the license. Authorization of locations and purposes, however, may be quite broad, depending on the needs of the licensee.

The license carries with it, unless otherwise provided, the right to receive, acquire, own, and import radioisoptopes and to transfer them to other NRC or State licensees authorized to receive them.

Since there is such a wide range in the kinds of radionuclides, their uses, and the quantities involved, individual license applications occasionally present unusual considerations that require specialized licenses covering circumstances not contemplated in the regulations. In such cases, the Commission may include in a particular license specific requirements covering those matters not expressly defined in the regulations. If, after a license is issued, it is found that some aspect of the licensee's activity has not been appropriately covered by the regulations or by the conditions in the license, the Commission may issue an order imposing additional requirements on the licensee. On the other hand, a licensee may request amendment of his license to change or eliminate a condition when he feels that his operations warrant such consideration.

For example, requirements for labeling the product may be spelled out in the license. Some of the purposes that may be served by labeling and instructions that accompany devices are:

– Identification of the product and conditions of use,

– Alerting the buyer of certain properties or characteristics of the product so that the informed buyer can exercise choice in the purchase, and

– Warning of potential hazards associated with the product.

With respect to alerting the buyer, the AEC did not require a label on luminous dial watches because it was thought that most people, from past experience with radium luminous dials or simply because the dial was luminous, would recognize that some radioactivity was present.

In the case of smoke detectors, the label was required to be attached to that part of the assembly in which the radioactive material is present. Although a label is sometimes hidden when the detector is assembled and the buyer may not see it before he buys it, the label is required to be prominently displayed at a point that anyone disassembling a detector would see before the radioactivity would be accessible to him, thus fulfilling the warning purpose.

The small risk presented by some low-risk products can be reduced even further by recommended procedures (which are not requirements) such as return to manufacturer for disposal. Such is the case with smoke detectors.

OTHER REGULATORY PROGRAMS

In addition to the rule making and licensing procedures, NRC has several supplementary programs in the area of consumer products.

We have issued two regulatory guides in this area. One (6.6) describes the statistical sampling procedures for exempt and generally licensed items containing byproduct material, and the other (6.7) describes the information needed in environmental reports in support of petitions for rule making.

The NRC has prepared two draft and one final environmental impact statements on consumer products. In the case of spark gap irradiators containing cobalt-60 the NRC staff has had problems in documenting the benefits from the use of the irradiators in oil-burning furnaces to prevent spark delay. It is generally accepted that use of the irradiators saves money by preventing safety shutdowns, furnace puffs (smoke), and even explosions. But the preparation of a final environmental statement has been delayed because of lack of documentation to permit balancing of benefits against dollar costs and radiological risks.

In the case of personnel neutron dosimeters containing thorium, we issued a final environmental statement that used the same primary text as the draft statement. This is because we responded to the few comments on the draft in a special section on staff responses and did not have to revise any text of the draft statement.

We have established broad exemptions for classes of products containing small quantities of radioactive material, such as self-luminous products and gas and aerosol detectors; only licensing actions, instead of rule making actions, are required to approve a specific model of a product within those classes. This reduces the amount of time and effort required to process the approval of the product without compromising safety.

We are continually evaluating individual and population doses from the distribution, transfer, use, and disposal of consumer products. O'Donnell (1977) described the Oak Ridge National Laboratory (ORNL) computer program for estimating doses received by various segments of the population associated with consumer products, such as transport workers, sales personnel, and users.

Under contract with NRC, ORNL is also conducting a limited program under which consumer products, available on the market, can be tested and examined for safety. Several products have been tested in the past few years, including tests of static eliminators containing polonium–210.

The NRC is working with several foreign governments and international organizations in establishing international import and export control of consumer products containing nuclear materials.

In 1970 the European Nuclear Energy Agency (ENEA) published a "Basic Approach for Safety Analysis and Control of Products Containing Radionuclides and Available to the General Public." This document suggests that approval of the distribution of a product should be contingent on a demonstration that the radioactive product performs a function that can be fulfilled only by a radioactive method or that the radioactive method has clear advantages over any other practical method. Use of the specific radionuclide selected for the product should be justified. The ENEA report also recommends that the radiation dose to the average individual and the population from all exempt products should not exceed a small fraction of the ICRP limits; a dose apportionment based on risk–benefit considerations is offered to achieve that goal. In October of 1976, the U.S. became a full participating member in that international standards organization, now called the Nuclear Energy Agency.

AGREEMENT STATE PROGRAMS

Those who are located in any of the States that exercise regulatory authority by agreement with the Commission must apply to the particular State regulatory agency instead of the NRC for a license to possess and use radioisotopes. Such States are called "Agreement States." State licensing and regulation of nuclear material under agreement with NRC was authorized by Congress in 1959.

Under such agreements, the State exercises its own authority, which, in most States, covers all radioactive materials except those over which control is specifically retained by NRC, such as Federal activities, export and import activities, "critical" quantities of special nuclear material, sea disposal, production and utilization facilities, and transfer of exempt items.

The Agreement States already are responsible for issuing over 50 percent of all current licenses for the use of radioisotopes. The States also have jurisdiction over the use of other sources of radiation–radium, X-rays, and accelerator-produced radioisotopes–which are not covered by the Atomic Energy Act. Agreement State authorities carry out an onsite inspection program to determing whether licensees are complying with the State's regulations and the requirements of their licenses.

CONCLUSION

The current NRC regulatory program for consumer products is designed to protect public health and safety and the environment. It includes establishing regulations, standards, and guides; conducting rule making and licensing activities; and sponsoring safety research such as product safety testing and development of techniques for estimating individual and population exposures. We are seeking new ways to improve the regulatory program. For example, we are reevaluating the criteria published in 1965 for approval of consumer products in light of current technology and expect to update and revise these criteria. We encourage expression of concern by the public and we are looking for views and suggestions from the public, especially from people knowledgeable in the area of consumer products. As a result of better communication, we hope to improve the regulatory system and better serve the public.

ACTIVITIES AND ACCOMPLISHMENTS OF THE BUREAU OF RADIOLOGICAL HEALTH IN CONTROLLING RADIOACTIVITY IN CONSUMER PRODUCTS

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The Food and Drug Administration's Bureau of Radiological Health was organized as a distinct unit within the Public Health Service in July 1958 and has continued as such through a number of administrative reorganizations. Although the name of the Bureau has changed from time to time, the interest in control of radioactivity in consumer products has been continuous. This interest can be traced back to early forerunners, such as the Public Health Service physician who in 1923 investigated the effects on persons measuring radium preparations at the U.S. Bureau of Standards and the Public Health Service industrial hygienists who in 1929 studied radium deposition in workers at luminous dial plants. By 1945, the Public Health Service Division of Industrial Hygiene was involved in a project concerned with the disposal of surplus radioluminous instrument dials.

EARLY CONCERNS

Following its formation in 1958, the Division of Radiological Health (DRH) developed an assistance program providing personnel, equipment, and training for State radiation control programs. Early efforts were directed toward the registration of radium users, survey of facilities, source accountability, leak testing, and transportation incidents. On September 3-4, 1964, the Division of Radiological Health of the Public Health Service sponsored a conference on the management of radium and radium substances for medical uses. The conference report was published by the Public Health Service (1965) and the conclusion that naturally occurring and accelerator-produced radionuclides should be managed in a manner similar to that for reactor-produced radionuclides is noteworthy.

A procedure, known as the jar method, was developed for leak testing sealed radium sources in Georgia hospitals (Benson, 1967). In this procedure, the source is placed in a closed jar for a 24-hour period after which measurement of the alpha activity deposited on the inside jar cover can be quantitatively related to the rate of radon leakage from the source. The jar method permits rapid source handling and does not sacrifice reproducibility or sensitivity.

Several reports were published on the distribution and disposal of radium, including "Radium in Military Surplus Commodities" (Halperin, 1966). Using appropriate radiation detection instruments, physical surveys of military surplus property in California retail stores identified many items containing radioactive materials. Luminous dials, aircraft instrument panel components, electronics equipment, gauge dials, and meters were some of the products encountered, and radium was the radioactive material of most public health concern. The report recommended that these kinds of radioactive items should be removed by the military from the surplus property system and should not be released for public use.

STATE ASSISTANCE

The DRH, in an effort to assist the States, initiated a project in 1965 to collect and dispose of contaminated, leaking, or unwanted radium sources. Over a 2-year period, 624 sources totaling 42.5 g of radium in the form of sealed sources, luminous compound kits, and powders or tablets were disposed of.

Renamed the National Center for Radiological Health (NCRH) in 1967, this unit of the U.S. Public Health Service, in cooperation with the Pennsylvania Department of Health, directed the first full-scale decontamination of a private residence. The basement of the residence, used by a physics professor for processing radium between 1924 and 1944, had become grossly contaminated with radium and radon daughters. Approximately 30 mg of radium were removed from the house during the cleanup operations. Alpha measurements taken throughout the basement and the first floor indicated contamination levels in excess of 1 nCi/100 cm^2, with some readings higher than 2 μCi/100 cm^2.

In 1968, the NCRH collected, with State cooperation, 396 radium incident reports dating from the early 1900's through 1967. After analyzing the reports, the NCRH found that most reported incidents concerned the loss of radium sources from medical facilities. The analysis indicated that the losses occurred primarily during patient treatment or during removal of the sources from the patient. In those instances where the radium was found, 54 percent of the medical radium recoveries were from the trash system. Lost sources were not recoverable in 31 percent of all radium losses and thefts. A further finding indicated that sudden, overt source rupture was related to careless source handling and was the cause of 66 percent of all the reviewed radium contamination cases.

Analysis of radium losses during transport indicated that improper packaging for shipment of radium sources might have been due to the general lack of training in radiation protection for radium users as compared to byproduct material users (Schmidt, 1968). Apparently the primary cause for losing radium during shipment was the shipper's unfamiliarity with regulatory packaging procedures and container structural requirements for the transportation of radium sources. That positive closure devices be integral with the shield and that gastight, fireproof containers be used were recommended as procedures to minimize radium losses and contamination events during shipment.

Also in 1968, at the request of NCRH, 1,700 radium-dial pocket watches were removed from State and Federal surplus channels for evaluation and disposal. Measurements of the radium content, performed on 17 watches, gave values ranging from 0.60 to 1.39 μCi per watch (Klein, 1970). Estimates indicated that a pocket watch with a 1μCi radium dial would expose the male gonads to an annual dose of 60 millirads and would deliver 65 rads to the skin directly under the face of the watch under the same wearing conditions.

The extent of the use of radium in consumer products was detailed in another NCRH report (Robinson, 1968). Data were presented on items ranging from laboratory balances and electron tubes to various gauges and luminous products.

BUREAU OF RADIOLOGICAL HEALTH

In 1968 Congress amended the Public Health Service Act through enactment of the Radiation Control for Health and Safety Act. Shortly afterward, the National Center was retitled the Bureau of Radiological Health (BRH) and a major protion of its resources was directed under the Act toward developing a radiation control program for electronic products. Nevertheless, the Bureau continued to investigate and report on radioactivity in consumer items.

A limited survey of radiation source use at the secondary school level was performed in 1969 to assess the type, quantity, and use of potential or actual radiation-emitting sources in the science classroom. Recommendations for radiation protection in the classroom were directed to Federal and State radiation control programs, school authorities, and manufacutrers and distributors of scientific supplies that produce radiation (DHEW, 1969).

The Bureau reported on the early development, the present clinical use, and the disposal of gold radon seeds as a followup to three incidents of radiation exposure to individuals wearing contaminated radioactive jewelry (Boggs, 1969). No clear evidence was gathered to prove that radon seeds were sold to jewelry manufacturers. An ad hoc committee formed by the Bureau concluded that, based on available evidence, radioactive contamination in gold from spent radon seeds did not appear to be a widespread public health hazard. The committee also proposed several recommendations to prevent potential biological injuries from the misuse of the contaminated gold.

The Atomic Energy Commission, the Department of Health, Education, and Welfare, and the Department of Transportation in 1969 conducted a joint study of radioactive material transport at 23 terminals in the eastern part of the United States (Schmidt, 1972). Radiation levels from radioactive material packages were measured, the radiation exposure to transportation workers was evaluated, and the carriers' and shippers' information regarding transport regulations was checked. The radiation exposure by transportation workers under most conditions was within permissible limits.

Another Bureau report described the general principles of operation for gas chromatography devices and the kinds of radionuclides incorporated in the various units (Pettigrew, 1970). Radiation hazards during operation, cleaning, and handling were noted, and precautions for their minimization were suggested.

RECENT BRH ACTIVITIES

Alpha-emitting isotopes such as lead-210, americium-241, and radium-226 were compared in a 1974 report (Tapert, 1974). These radioisotopes are used for static elimination, aerosol detection, and luminosity activation in consumer and industrial products. An appropriate alpha source should possess a physical half-life commensurate with the design lifetime of the product to minimize replacement or disposal problems. Therefore, it is important that efforts be made to research the applicability of radionuclides whose half-lives and emission properties indicate their suitability. Lead-210 and actinium-227 appear to deserve more attention in these respects.

The BRH has also analyzed radioactive consumer product risk/benefit aspects (Paras, 1975). Consideration was given to the health and safety aspects of the radioactive materials that consumer products incorporate. The physical and biological half-lives, emissions, availability, and ease of fabrication of the radioactive material into a source were listed as aspects that needed to be appraised as well as the design, construction, use, labeling, disposal, and radiation dose to the consumer.

Occupational and public health concerns with radioluminous materials were investigated at the Georgia Institute of Technology under a contract with the Bureau (Moghissi, 1975). The safety, efficacy, and relative merits of commonly used radioluminous materials were studied. The risks/benefits of radium-226, promethium-147, and hydrogen-3 (tritium) were analyzed. These materials have been used most extensively in the dial-painting industry for illuminating timepieces and other instrument dials. In general, the occupational exposure from radium was found to be higher than that from tritium, whereas the occupational exposure from promethium-147 could not be measured with any significant accuracy and remained essentially an unknown. Data for the occupational and population exposure from radioluminous timepieces were presented.

The radiological health aspects of using uranium in dental porcelain were recently studied (Thompson, 1976). Particle emission rates for uranium and potassium-40, which is also present in teeth, were obtained. The annual doses to the individuals who wear porcelain prostheses were calculated as were the doses to persons occupationally exposed to the teeth and powders. Recommendations regarding the substitution of nonradioactive agents and interim guidelines on maximum permissible concentration for uranium in dental porcelain were given.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL CONCERNS

Initially, the Bureau's radioactive material programs were focused on radium because the Atomic Energy Commission (AEC) effectively controlled most other available sources. When accelerator-produced radioactive sources began appearing on the market, potential problems were noted with some of these materials. Regulation of these naturally occurring and accelerator-produced radioactive materials (NARM) had been left to the discretion of the individual States with no comprehensive program at the Federal level. The Radiation Control Act of 1968 specifically directed the Department of Health, Education, and Welfare to prepare an analysis of the control of radioactive material not controlled by the AEC. This assessment, undertaken by the Bureau, led to a legislative proposal for a Radioactive Materials Control Act that addressed all sources not covered by the Atomic Energy Act. The proposal was forwarded to the Office of the Assistant Secretary for legislation, but no further action was taken.

The States began to express increasing concern over the lack of uniform control through their Conference of Radiation Control Program Directors. Since none of the principal Federal agencies working in radiological health had the authority to regulate NARM, the Bureau of Radiological Health chose to act under Section 311 of the Public Health Service Act (42 U.S.C. 243) and provide assistance to the States in developing the elements of a uniform State program. These elements are discussed below.

Radioactive Materials Reference Manual (RMRM)

The RMRM is a catalog of NARM products and uses for administrative applications by State radiation control directors. The RMRM was first developed about 1970 in cooperation with the States' radiological health personnel for disseminating information on sources and devices whose radiation hazards and characteristics are not documented in the literature.

The main purpose of the RMRM is to transmit radiological product evaluations to State and local radiation control agencies. These evaluations in turn are used by the radiation control program directors in making regulatory decisions on products containing NARM. There are three kinds of RMRM transmittals:

a. "Evaluations" indicate acceptability for licensing or exemption by licensing States or BRH/State cooperative evaluation of a NARM source or device;

b. "Product indentifications" declare the existence of a NARM product or use problem;

c. "Advisory notices" request that regulatory action be applied to the control or surveillance of a specific NARM product.

All State and Federal radiological health agencies may contribute information for distribution via the RMRM. Approximately 250 transmittals, which evaluate, identify, or advise on NARM products or services available in the United States, have been issued. At least 18 separate States have contributed evaluations to the RMRM on such radioactive consumer products as electron tubes, jewelry, tape dispensers, smoke detectors, and star maps.

NARM Guides

The second element of the State uniform control program was initiated when the Conference of Radiation Control Program Directors in 1975 established a task force with resource personnel from the Bureau of Radiological Health, the Envoronmental Protection Agency, and the Nuclear Regulatory Commission to draft guidelines for evaluating NARM products and devices. This task force recently submitted to the Executive Directors of the Conference for approval the draft guidelines for the appraisal of some 12 different categories of products. These NARM guides give specific criteria for evaluation that are consistent with those used by the Nuclear Regulatory Commission for similar products. They include consideration of source activity, labeling and instructions, manufacturer's quality control procedures, and prototype testing for such diverse items as gas and aerosol detectors, gauges, static elimination devices, medical sources, and in vitro test kits. The guides have been integrated into the earlier format of the RMRM procedures for identification, evaluation, and recommendations.

The effect of the State uniform control program will be twofold. It will protect the consumer by requiring that products containing NARM sources be manufactured, assembled, and distributed in compliance with current radiological safety criteria and be periodically reviewed in this regard. The program will also provide manufacturers with a single set of criteria for their products so that approval of an item by any participating State will preclude the necessity as having that item evaluated again before distribution in another State. In addition, there will be no difference in the requirements for NARM and NRC-licensed products.

Suggested State Regulations for the Control of Radiation

Implementation of the State uniform control program will also be pursued through amplification of the Suggested State Regulations for the Control of Radiation. These are model regulations for State program administration produced and revised in a continuing cooperative effort between the States and the concerned Federal agencies, i.e., the Environmental Protection Agency, the Nuclear Regulatory Commission, and the Bureau of Radiological Health. The Suggested State Regulations are adopted in whole or in part by the States in drafting their regulations for licensing radioactive materials and registering other sources of ionizing radiation, e.g., x-ray machines and accelerators. Recently proposed revisions defining State licensing activities for NARM products place them on an equivalent basis with NRC-licensed products.

In addition, the Executive Board of the Conference of Radiation Control Program Directors has asked for the developemnt of a mechanism for the formal review and sanction of State NARM licensing programs. FDA'S Bureau of Radiological Health and the Executive Director of Regional Operations have offered to assist with personnel for the review team.

SUMMARY

The Bureau of Radiological Health has provided leadership in the area of radioactive consumer products as evidenced by its activities in transport, decontamination, source disposal, risk/benefit analysis, and comprehensive reports on two subjects with large public health implications, i.e., radioluminous materials and uranium in dental porcelain. When appropriate, Bureau activities have been coordinated with the Nuclear Regulatory Commission, the Consumer Products Safety Commission, the Environmental Protection Agency, the National Bureau of Standards, and the American National Standards Institute.

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REGULATIONS OF THE CONSUMER PRODUCT SAFETY COMMISSION

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The Consumer Product Safety Commission (CPSC) was established in 1973 by the Consumer Product Safety Act (CPSA). It is an independent regulatory agency, with jurisdiction over a wide variety of consumer products. The only product classes not covered by the Commission under the CPSA are those product classes specifically exempted such as tobacco, motor vehicles and equipment, economic poisons (insecticides), articles subject to specific taxes (e.g., alcohol), aircraft (including components and appliances), boats, drugs, medical devices, cosmetics, or foods. The Commission also may not regulate under CPSA any risk of injury associated with consumer products if such risks could be eliminated or reduced to a sufficient extent by actions taken under the Occupational Safety and Health Act (OSHA), the Atomic Energy Act, the Clean Air Act, or the Public Health Service Act (CPSC, 1973) for electronic product radiations as defined therein. The Commission was given jurisdiction over four earlier acts still in effect. These are the Federal Hazardous Substances Act (FHSA), the Flammable Fabrics Act (FFA), the Poison Prevention Packaging Act (PPPA0, and the Refrigerator Safety Act (RSA)(CPSC,1973).

The Commission consists of five Commissioners who serve for staggered 7-year terms. No more than three Commissioners may be from any one political party. The Commissioners are appointed by the President, subject to confirmation by the Senate. The Chairman is designated by the President and when so designated serves until the end of his term as Commissioner. He may not be removed by the President except for neglect of duty or malfeasance in office. The Vice-Chairman is elected to that position by his fellow Commissioners in May of each year.

In the following paragraphs each of the Acts is discussed briefly, in the order of their enactment.

The Flammable Fabrics Act (FFA) was passed in 1953 and amended in 1954 and 1967 (CPSC, 1973). It was intended to regulate the flammability of fabrics both in apparel and in interior furnishings. At the time of its enactment, the FFA'S jurisdiction over flammable fabrics was shared by three agencies: (1) The Department of Health, Education, and Welfare was charged with undertaking investigations to determine the risks of injury, (2) the Department of Commerce developed and issued regulations, and (3) the Federal Trade Commission enforced them. All three activities are now under the jurisdiction of the CPSC. Examples of regulations issued under the FFA include regulations for children's sleepwear, carpets and rugs, and mattresses (16 CFR II, 1977). A draft regulation for upholstered furniture is now under development. Regulations for general wearing apparel, which are enforced by the Commission, were enacted into law by Congress in 1953 (16 CFR II, 1977).

The Refrigerator Safety Act (RSA) was passed in 1956, (CPSC, 1973). It was enacted in order to reduce the risk of injury to children trapped inside old refrigerators. It mandates that all refrigerators be easily opened from the inside, either by a moderate push or by easy turning of a knob. Most refrigerators today use a magnetic latch to meet the requirements of the RSA.

The Federal Hazardous Substances Act (FHSA) was enacted in 1960 and amended in 1966 and 1969 (CPSC,1973). It began as a labeling law only; in fact, its original name was the Federal Hazardous Substances Labeling Act (CPSC,1973). The original law provided for establishing definitions for toxic, highly toxic, corrosive, irritant, strong sensitizer, flammable, combustible, extremely flammable, and radioactive substances. Materials that met the definitions or test protocols developed and were capable of causing substantial personal injury or illness were required to bear certain prescribed cautionary labeling. The Act also provided for special labeling when labeling according to the general provisions of the Act was not considered adequate for the protection of the public health and safety.

In a subsequent amendment, two provisions that permit the banning of certain household substances were added (CPSC, 1973). First, if the Commission determines that, notwithstanding such cautionary labeling as may be required for a particular substance, the degree or nature of the hazard involved is such that the objective of the protection of the public health and safety can be adequately served only by keeping such substance out of the channels of interstate commerce, the substance can be termed by regulation a banned hazardous substance and can be prohibited from distribution in interstate commerce. Second, if the Commission finds that a substance presents an imminent hazard to the public health, it may prevent its distribution in interstate commerce until formal rulemaking proceedings have been completed.

Other amendments to the FHSA brought toys and other children's articles under the jurisdiction of the Act by extending to these article the labeling and banning authority of the Act (CPSC, 1973).

A unique feature of the FHSA, is the repurchase feature, which provides that banned hazardous substances or articles are subject to repurchase throughout the chain of distribution. This means that retailers must post notices to permit consumers to return such goods. Each earlier party in the distribution chain is required to repurchase the product form the next lower level of distribution unless the product, with the consent of the owner, is modified or replaced.

As with the Consumer Product Safety Act, the Federal Hazardous Substances Act does not include source materials, special nuclear materials, or byproduct materials as defined in the Atomic Energy Act,(CPSC,1973). It does,however,give the authority to the Commission to regulate other radioactive materials as they appear in various household substances or toys or children's articles.

Many substances are labeled to indicate the specific hazards defined in the FHSA. Examples of special labeling include recommendations against swallowing ethylene glycol and petroleum distillates, the hazards of carbon monoxide if charcoal is used indoors, and instructions for the use of certain fireworks (16 CFR II, 1977). Banning regulations have included household substances containing carbon tetrachloride, certain fireworks, vinyl chloride, lead-containing paint, toys, and other children's articles (16 CFR II, 1977). Examples of toys banned by regulations include rattles, dolls, stuffed animals, noisemaking toys with small squeakers; caps above certain noise levels; and electrical toys (16 CPR II, 1977). Examples of other children's articles banned by regulation include cribs and bicycles that do not meet specific requirements set out in the regulations (16 CFR II, 1977).

The Poison Prevention Packaging Act (PPPA) was passed in 1970 (CPSC, 1973). The intent of the PPPA was to provide for special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances. The PPPA provides that the Commission may establish standards for the special packaging of any household substance if it finds that the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness. Household substances covered by the PPPA include hazardous substances as that term is defined in the Federal Hazardous Substances Act (CPSC, 1973); foods, drugs, or cosmetics, as those terms are defined in the Federal Food, Drug, and Cosmetic Act (CPSC, 1973); and substances intended for use as fuel when stored in portable containers and used in the heating, cooking, or refrigeration system of a house. The PPPA provides that any product for which special packaging is mandated can be sold in one package form that does not comply with the special packaging requirements as long as at least one other form is provided in special packaging. The noncomplying package must be clearly labeled that it should not be used in households in which children are present.

Regulations issued under the PPPA established the test protocols to be used (16 CFR II, 1977). Two hundred children under 5 years of age are given a package to open. If 85 percent of this panel of two hundred children under 5 years of age are unable to open a package without demonstration, if 80 percent of them are unable to open the package with demonstration, and if 90 percent of a panel of 100 adults are able to open the package, the package may be used as a special package.

Examples of regulations issued under the PPA include packaging for oral prescription drugs, aspirin, and drain cleaners (16 CFR II, 1977). It should be noted that, for precription drugs, if either the doctor or patient requests the pharmacist to use ordinary packaging, such requests may be honored.

The Consumer Product Safety Act (CPSA), which established the Commission, was enacted in 1972 (CPSC, 1973) and amended in 1976 (U.S. Statutes, 1976). Its goal is to protect consumers against unreasonable risks of injury. Unique features of the CPSA include its procedure for development of consumer product safety standards, its petition procedures, and its so called "tattle tale" provision.

When the Commission decides to initiate a regulatory development proceeding for a particular product, it first makes a preliminary finding that an unreasonable risk of injury exists and that a consumer product safety standard is necessary to reduce or eliminate the unreasonable risk of injury. The expression "unreasonable risk of injury" is not specifically defined, but the legislative history indicates that the determination of unreasonable hazard will involve the Commission in balancing the probability that risk will result in harm as well as the gravity of such harm against the effect on the product's utility, cost, and availability to the consumer. When the Commission decides to begin a standard development proceeding, it publishes a notice containing preliminary findings, an evaluation of existing standards, and an invitation to any organization or person to submit an existing standard as a consumer product safety standard or to offer to develop a standard. If the Commission chooses to have an offer or develop the standard, that offeror must conduct the standard development as a public procedure and must provide a plan to ensure direct, adequate consumer participation in the development of the standard. The offeror has 150 days from acceptance of the offeror to develop such standard, unless the development period is extended by the Commission for good cause. After the offeror has completed his work, the Commission reviews the recommended standard, revises if necessary, and proposes the standard as a consumer product safety standard. After the standard has been proposed, a period for written comment is provided. The Commission must also provide for oral presentation of data, views, and arguments if requested. On the basis of these comments, oral presentations, and the rest of the record that has been developed, the Commission must make specific findings about the risk of injury and the potential effect of the standard on the product's cost, utility, and availability to consumers. A ban can also be issued by the same procedure of comment, oral presentations, analysis of comments, and making of specific findings, but only if the Commission is able to determine that no standard is feasible. Commission findings must be supported by substantial evidence on the record as a whole rather than by the traditional administrative procedure guideline that rules not be arbitrary and capricious.

The CPSA, like the Federal Hazardous Substances Act, also provides the Commission with the authority to declare a product an imminent hazard (CPSC, 1973). However, under the CPSA, that declaration can only be issued when the Commission brings suit before a court for such a ruling. If the court grants the Commission its request, the product is classified as imminently hazardous and may be seized and/or subject to public notice and recall. In the case of an imminent hazard ban, the Commission is required to begin rule development promptly.

The CPSA provides that any interested person may petition the Commission to begin a proceeding for the issuance, amendment, or revocation of a consumer product safety rule. The petition must set forth facts which, it is claimed, establish that the action is necessary and a brief description of the rule or amendment which, it is claimed, should be issued. If the Commission grants the petition, it must promptly begin the appropriate proceeding. If the Commission denies the petition, it must publish its reasons for denial in the Federal Register. If the petition is denied or the Commission fails to make a decision within 120 days of filing, the petitioner may begin a civil action in a United States district court to compel the Commission to initiate a proceeding to take the action requested. The burden of proof, however, is on the petitioner. Three of the six standards development proceedings begun to date under the CPSA were initiated by petition, although the great majority of petitions have been denied.

Another unique feature of the CPSA is the substantial hazard, or so called "tattletale" provision. It provides that, if a manufacturer, distributor, or retailer of a consumer product obtains information reasonably supporting the conclusion that such product fails to comply with an applicable consumer product safety rule or contains a defect that could create a substantial product hazard, that party shall immediately inform the Commission of such failure to comply or of such defect. If the Commission determines through administrative procedures that such a product does present a substantial product hazard, it can require the manufacturer, distributor, or retailer to give notice of the defect or failure to comply or to mail notice to each person who is a manufacturer, distributor, retailer, or consumer of the product. It also provides for the manufacturer, distributor, or retailer to bring such product into conformity by repair, replacement, or refund of the purchase price. In practice, very few of these notification procedures have gone through the full administrative procedure; generally, correction plans are handled voluntarily by negotiations between the staff and the manufacturer with the final approval of the Commission.

As with the Federal Hazardous Substances Act, the Commission is excluded in the Consumer Product Safety Act from regulating any risk of injury that could be reduced or eliminated under actions taken under the Atomic Energy Act (CPSC, 1973). This has the effect of excluding the Commission from regulating source materials, special nuclear materials, or byproduct materials.

As of this writing, three consumer product safety standards have been issued under the CPSA, i.e., one for swimming pool slides, one for architectural glazing materials, and one for matchbooks (16 CFR II, 1977; Federal Register, 1977a). A standard for power lawn mowers has been proposed, commented on, and is being revised prior to issuance (Federal Register, 1977b). Regulations for television receivers, aluminum wiring, and Christmas tree lights are in various stages of development. Under the substantial hazard section of the CPSA, about 500 notifications by manufacturers have been made to the Commission. Many of these were considered by the Commission not be be substantial hazards, and most of the others were disposed of voluntarily to the Commission's satisfaction. Specific actions of interest include Commission moves against gas detectors advertised as smoke and fire detectors and against smoke and fire detectors which themselves could catch fire because of improper circuitry. In the first situation, the Commission is currently developing additional hazard information; in the latter, the manufacturer has changed his circuit design and is retrofitting models already in place.

The issue of agency consideration of radioactive materials in consumer products first surfaced when the Bureau of Radiological Health asked the Bureau of Product Safety to consider issuance of a labeling regulation under the Federal Hazardous Substances Act for consumer products containing radium. The request could be conveniently made because both Bureaus were then under the Food and Drug Administration. In addition, the Bureau of Radiological Health does not have regulatory authority over radioactive materials, whereas in this particular area the Federal Hazardous Substances Act did provide the mechanism for issuing regulations. When the Bureau of Product Safety was absorbed into the Consumer Product Safety Commission, the staff expanded the discussion to the possibility of a ban as well as a labeling regulation but indicated to this new Commission that the hazard was low, that the commission could only move against natural or accelerator-produced radioisotopes (most specifically radium-226), and that the majority of the products that the Commission might want to proceed with were converting to the use of isotopes that the Commission could not regulate, i.e., promethium-147 and tritium in timepieces and americium-241 in smoke and fire detectors. On the basis of that information, the Commission declined to proceed with any regulations, although it encouraged voluntary activities to reduce the use of some of the natural radioactive isotopes, primarily radium.

That decision by the Commission was a refusal to take action on radioactive materials in consumer products generically. However, there are instances where the Commission might still regulate radioactive materials on a case-by-case basis. For instance, the Commission staff is now considering developing a regulation for proper operation of smoke and fire detectors. In doing so, the major intent would be to ensure proper electronic operation of smoke and fire detectors so that the detectors themselves would not catch fire and so that the consumer's confidence in such products to protect him would not lead to unreasonable risks of injuries from fire.

However, if such a regulation were to be developed, the Commission could consider regulating or banning the use of radium in ionization-type smoke and fire detectors. Such an action would not be inconsistent with the generic decision listed above. It is possible to argue that an unreasonable risk of injury does exist from the use of radium in consumer products, primarily because it does not appear that there would be a cost increase or a utility decrease to consumers if products containing radium were banned and because inexpensive and technically adequate substitutes do exist. As mentioned above, because of the low overall level of risk, radioactivity hazards in general do not have a high priority. However, if the Commission were to regulate a specific product such as smoke and fire detectors, the specific hazard could be addressed at relatively little additional commitment of Commission resources. A similar approach would be possible for any other situation where regulation of radioactive materials subject to the Commission's jurisdiction could be considered as part of overall Commission regulation of that product. However, the staff has not briefed the Commission on any of these issues, and the Commission has not decided on them. The scenarios are mentioned only as examples of ways in which the Commission could act.

The views expressed in this paper are the author's and do not necessarily represent an official position of the Consumer Product Safety Commission.

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RADIATION CONTROL REGULATIONS OF THE STATES

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INTRODUCTION

In order to appreciate the action, or lack of action, of state radiation control programs with regard to radioactive materials in consumer products, one must understand how these programs developed, what type of people they employ, under what Federal constraints they operate, and how they are going about remedying problems that they feel exist in the present regulatory scheme.

Although as a collection, the ideas expressed in this paper are certainly not universally accepted by state radiation control programs, they do represent a montage of ideas gathered from the various programs. The tenor of this paper is critical of state radiation control programs, because it is felt that only by critical analysis can the present system of regulation be improved.

HISTORICAL BACKGROUND

State radiation control programs to a large extent evolved from existing groups within state health departments, quite often the sanitary engineering section or civil defense organization, in the late 1950s and early 1960s. For the most part, the individuals involved had received their college degrees in fields only slightly, if at all, related to nuclear physics or engineering or health physics. These people, many of whom are still associated with state radiation control programs, received their training in health physics through U.S. Public Health Service (PHS) and U.S. Atomic Energy Commission (AEC) short courses, and many received graduate degrees in health physics through state, PHS, and AEC educational grants. However, their attitudes toward regulation were rooted in the traditionally conservative approach prevalent among state health departments. Violators of regulations and guidelines were more often cajoled into compliance than forced; the regulations were carefully written to avoid direct conflict with those to be regulated.

Today, state radiation control programs appear to be taking a new tack. As these programs grow and begin to hire more and more people who studied nuclear engineering or health physics in college, a new outlook seems to be developing. They feel confident to confront their Federal counterparts in technical discussions; they perceive problems and generate their own suggested solutions.

As the individuals in the state programs have developed, so have the responsibilities of the programs. The programs began as advisory programs to assist industry and practitioners of the healing arts to use sources of radiation safely. Regulatory programs for x-ray and naturally occurring radioactive materials such as radium were established.

When offered in the early 1960s, several states quickly accepted the responsibilities of "Agreement State" status as presented by the AEC under a 1959 amendment to the Atomic Energy Act of 1954. Over the years more states have accepted

"Agreement" status until today there are 25 Agreement States. Each Agreement State has promulgated regulations which are applicable to all sources of radiation, including x-ray machines and radium in addition to the so-called "agreement materials" (i.e., byproduct, source, and special nuclear materials). Unfortunately, only five states (Illinois, Maine, New Jersey, Pennsylvania, Virginia) other than the Agreement States have promulgated comparable regulations covering the naturally occurring and accelerator-produced radioactive materials (NARM). These five states plus the 25 Agreement States are designated as Licensing States for the Control of NARM by the Conference of Radiation Control Program Directors (1977). NARM are "non-agreement materials"; hence the manufacture, distribution, and use of NARM sources are not controlled by the Federal government. Rather, the regulation of NARM has been left to the discretion of each state.

The Council of State Governments (1961) with the cooperation of the AEC, PHS, and others published criteria for the model *State Radiation Control Act* and the *Suggested State Regulations for the Control of Radiation* (SSRCR) (1962). These were not only "compatible" with the regulations of the AEC, but, fortunately for the states, also included all sources of radiation. Each of the Agreement States adopted regulations that were substantially identical to the SSRCR. The AEC, presently the U.S. Nuclear Regulatory Commission (NRC), required each Agreement State to maintain an "adequate" program and to have regulations that were "compatible" with those of the AEC. The "adequacy" and "compatibility" were assured through the Annual Agreement States Meeting and the Annual Exchange of Information meeting in each state.

In the early years, these meetings usually consisted of the AEC telling the Agreement States what they had to do to remain adequate and compatible. As the number of Agreement States increased and training and experience of state people improved, the Agreement States began to question the AEC's policies, procedures, and regulations. This, combined with the problems associated with dealing with many Federal agencies such as NRC, Bureau of Radiological Health, Food and Drug Administration (BRH), U.S. Environmental Protection Agency (EPA), U.S. Department of Transportation (DOT), U.S. Department of Labor (OSHA), Energy Research and Development Administration (ERDA), National Bureau of Standards (NBS), etc., gave the impetus for the establishment and consolidation of the Conference of Radiation Control Program Directors, Inc. (CRCPD).

The CRCPD afforded the states an organization through which they could present the unified views of the states to the Federal agencies. Problems beyond the capabilities of an individual state can be addressed through task forces and workshops of the CRCPD. The review and updating of the SSRCR became a major effort of the CRCPD working in cooperation with NRC, BRH, EPA, and lately NBS. The CRCPD was originally sponsored by the BRH. Later EPA, NRC, and NBS gave support. Now the CRCPD is funded by membership dues and a contract with the Federal government with funds being contributed to the contract by BRH, EPA, and NRC.

CONSUMER PRODUCTS

For the purposes of this review, a consumer product is considered to be any item containing radioactive material that can be given, sold, leased, or otherwise transferred to a person without some regulatory agency having given its prior approval of the transfer by the issuance of a specific license. The receiver may or may not be aware that the item contains radioactive material. He may have little or no training and experience in handling or using radioactive materials.

Consumer products containing radioactive materials can be divided into the following categories:

I. Naturally Radioactive Products (NRAP),
II. Technologically Enhanced Naturally Radioactive Products (TENRAP),
III. Recreational, Entertainment, and Health Naturally Radioactive Products (REHNRAP),
IV. Contaminated Products,
V. Exempt Products, and
VI. Generally Licensed Products.

Products from the first three categories contribute to what has been called the technologically enhanced natural radiation (TENR) environment, and, with the exception of uranium mill tailings and drinking water, have remained for the most part unregulated (Gesell, 1975a). For the last three categories, if the radioactive materials are byproduct, source, or special nuclear materials, they are regulated by the NRC and the Agreement States, and if they are NARM, by the Licensing States.

NATURALLY RADIOACTIVE PRODUCTS

Consumer products which, without any concentration of the naturally occurring radioactive materials due to processing, contain radioactive materials that may approach hazardous levels can be called "naturally radioactive products" (NRAP). These include such commodities as natural gas, coal, water, building materials like granite and bricks, and foods and animal feeds. With the exception of drinking water, no Federal or state standards have been set for the permissible concentrations of radioactive materials in these products.

The burning of natural gas in space heaters can result in significant indoor radon levels (Gesell, 1974). The solution to this source of exposure to the consumer is simple albeit expensive. It required only that the natural gas be circulated through storage tanks long enough to allow the radon to decay to lower levels. Still, neither the Federal government nor any state has standards for the maximum permissible concentration of radon in natural gas.

The burning of coal in commercial power plants has been shown in some cases to release as much radioactive material into the atmosphere as nuclear power reactors of the same size are permitted to release (Eisenbud, 1964), yet no standards have been set for the release of radioactive materials by coal-fired plants.

Geothermal power plants may result in additional exposure to the population from radon (Gesell, 1975b). Similarly, building materials have been studied (USEPA, 1976a), but no standards exist concerning the permissible concentrations of radioactive materials in them.

The permissible concentrations of radioactive materials in drinking water have existed for several years in the drinking water standard of the US PHS (USPHS, 1962). This standard, in theory at least, applied only to bottled water and that used on interstate carriers. EPA, after some discussion, has adopted standards (CFR, 1977) for public water supplies.

Although several water suppliers across the nation have been shown to exceed the EPA standard (FR, 1976a), none has been forced to seek alternative sources or treat the water to lower the concentration to levels below the standard. In Texas at least one school and one family (Wukasch, 1974) have been persuaded to switch to water supplies with lower concentrations of radioactive materials. Also, EPA began conducting studies to determine the feasibility of removing radon and radium from water (US EPA, 1976b).

Since these products can be produced or processed in any state and shipped into another state, it would appear that no single state could establish limits that could be effectively enforced in that state, much less throughout the nation. It is felt that Federal standards for all of these products are needed.

TECHNOLOGICALLY ENHANCED NATURALLY RADIOACTIVE PRODUCTS

Technologically enhanced naturally radioactive products (TENRAP) are consumer products in which naturally occurring radioactive materials have been concentrated because of processing of the raw materials of the product. Included in this category are liquefied petroleum gas, building materials such as gypsum wallboard, fertilizer, and mill tailings used for fill or construction materials. No state or Federal regulations address any of these materials except mill tailings. The usage of uranium mill tailings for fill or construction materials is now prohibited by the NRC and the Agreement States. Uranium mill tailings were not always so carefully regulated by the AEC, but it appears that no uranium tailings under the regulatory control of state radiation control programs have been used for fill or construction materials. Tailings from other milling operations have not been regulated. The Louisiana Board of Nuclear Energy (LBNE, 1976) is the only regulatory agency that has initiated measures to control mill tailings other than those from uranium milling. EPA has issued "Interim Recommendations for Radiation Levels" for use in connection with the building of homes on reclaimed phosphate mine land (FR, 1976b).

RECREATIONAL, ENTERTAINMENT, AND HEALTH NATURALLY RADIOACTIVE PRODUCTS

These consumer products containing radioactive materials include such diverse items as mineral baths, cave tours, and various "medicinal" devices.

The incorporation of uranium ores and radium and its daughters into "cure-all" medical devices and patent medicines was early recognized as a potential health hazard. The distribution of drugs and ointments containing, or claiming to contain, radium and "Thorium X" was curtailed by the Federal Food, Drug and Cosmetic Regulations. In Texas, the use of the Thomas Radioactive Cone and carnotite-lined water storage crocks to saturate drinking water with radon was discouraged by a media campaign and confiscation of the cones and crocks in the early 1960s (Wukasch, 1964). Although this campaign was highly successful, two additional cones and one additional crock were discovered and confiscated during 1976.

Mineral baths and drinking water containing radon were touted as late as the early 1970s. Hot Springs National Park operated by the U.S. National Park Service was still distributing literature entitled "Thermal Waters of Hot Springs National Park" (1962) at the visitor's center praising the radon content of the hot springs' water and the water's curative power.

Similarly the radon content of the air in caves, some operated by the U.S. National Park Service, has been studied (Wilkening, 1976; Haygood, 1976), but no regulatory guidance has been developed.

CONTAMINATED PRODUCTS

Contaminated products are those into which radioactive materials have been introduced in low concentrations normally to study process characteristics. The steel industry sometimes uses radioactive sources in the refractory lining of blast furnaces to measure the loss of lining, and this may result in slightly contaminated steel. The petrochemical industry sometimes uses radioactive tracers to measure flow and reaction rates, and this may result in slightly contaminated petrochemicals and plastics. As long as the radioactive materials used in the study are not NARM, the introduction is closely regulated by NRC or an Agreement State to insure that the resulting product does not exceed the concentration limits set forth in 10 CFR §30.70 or the equivalent section of the Agreement State's regulations. In the other 20 states, the degree of use and regulation of the introduction of NARM such as radium are uncertain.

EXEMPT PRODUCTS

The regulations of NRC and the Agreement and Licensing States exempt persons who possess and use certain products containing radioactive materials from regulation. The presumption is that the radioactive material, because of its quantity or method of incorporation into the product, poses no significant hazard to the user and therefore the use and disposal of the product need not be regulated. This presumption is based upon data submitted by the manufacturer or distributor in an application to distribute the product. The application would normally detail the materials and methods of construction of the product, the labeling of the product, the quality control procedures to be followed, and the environmental impact of the product. In the environmental report (USNRC, 1976), the applicant must compare the product containing the radioactive material with other products intended for the same purpose. As a general rule, radioactive material will not be permitted in "frivolous" products such as toys, adornments, foods, beverages, or cosmetics.

Table I lists the types of products that may be distributed to persons exempt from regulation. If the radioactive material incorporated is "agreement material," the distribution of these products can only be licensed by NRC; an Agreement State cannot issue a license for the distribution of these products if they contain byproduct, source, or special nuclear materials. Similarly, no state can prohibit their distribution. If the radioactive material is NARM, however, the NRC has no authority to regulate it, and the job of licensing and regulating its distribution is left entirely to the states.

Until now, the regulation of the distribution of these products if they contain NARM has not been uniform. The Licensing States used essentially the same criteria for licensure of NARM as the NRC used for the "agreement materials"; however, most of the other 20 states did little or no evaluation of NARM products. The manufacturers and distributors in these states had no mechanism whereby they could get their product evaluated or get licensed to distribute the product. It is doubtful that any regulatory action was taken against them for failure to meet acceptable standards or for unauthorized distribution.

Realizing the inadequacies then inherent in the regulatory control system with regard to products containing NARM, the CRCPD established a task force in 1975 to develop a system to uniformly regulate the distribution of NARM and to write guides

TABLE I
CONSUMER PRODUCTS CONTAINING EXEMPT RADIOACTIVE MATERIALS

Type of Consumer Product	Possession & Use Exempted By	Distribution Licensed By
I. BYPRODUCT MATERIAL		
1. Timepieces (Watches & Clocks)[1]	30.15(a)(1)	32.14
2. Automobile Lock Illuminators[2]	30.15(a)(2)	32.14
3. Balances of Precision	30.15(a)(3)	32.14
4. Automobile Shift Quadrants[2]	30.15(a)(4)	32.14
5. Marine Compasses and Navigational Instruments[1]	30.15(a)(5)	32.14
6. Thermostat Dials and Pointers[1]	30.15(a)(6)	32.14
7. Electron Tubes	30.15(a)(8)	32.14
8. Ionizing Radiation Measuring Instruments[1]	30.15(a)(9)	32.14
9. Synthetic Plastic Resins for Sand Consolidation in Oil Wells[3]	30.16	32.17
10. Exempt Quantities[1]	30.18	32.18
11. Self-Luminous Products[1]	30.19	32.22
12. Gas and Aerosol Detectors[1]	30.20	32.26
II. SOURCE MATERIAL (so called "unimportant quantities")		
1. Incandescent Gas Mantles	40.13(c)(1)	40.13(c)
2. Vacuum Tubes	40.13(c)(1)	40.13(c)
3. Welding Rods	40.13(c)(1)	40.13(c)
4. Electric Lamps for Illuminating Purposes	40.13(c)(1)	40.13(c)
5. Germicidal Lamps, Sunlamps, and Lamps for Outdoor or Industrial Lighting	40.13(c)(1)	40.13(c)
6. Personnel Neutron Dosimeters	40.13(c)(1)	40.13(c)
7. Glazed Ceramic Tableware	40.13(c)(2)	40.13(c)
8. Piezoelectric Ceramic	40.13(c)(2)	40.13(c)
9. Glassware, Glass Enamel, and Glass Enamel Frit	40.13(c)(2)	40.13(c)
10. Photographic Film, Negatives, and Prints	40.13(c)(3)	40.13(c)
11. Finished Magnesium-Thorium Alloy Products or Parts	40.13(c)(4)	40.32
12. Uranium Counterweights Installed in Aircraft	40.13(c)(5)	40.32
13. Uranium as Shielding in Shipping Containers	40.13(c)(6)	40.13(c)
14. Thorium in Finished Optical Lenses	40.13(c)(7)	40.32
15. Thorium in Finished Aircraft Engine Parts	40.13(c)(8)	40.13(c)
16. Uranium in Fire Detection Units	40.13(c)(9)	40.32

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[1] Products may contain NARM. If it does, its distribution is licensed by the Agreement and Licensing States.

[2] No known usage.

[3] Only one known licensee.

for the states to use in the evaluation of products containing NARM. This task force has written NARM Guides (CRCPD, 1977) for the evaluation of the following categories of products:

1. Calibration and Reference Sources Containing Radium-226 for Distribution to Persons Generally Licensed Pursuant to C.22(g), SSRCR
2. Sealed Sources
3. Gas and Aerosol Detectors for Distribution to Persons Exempt From Regulation Pursuant to C.4(c)(3), SSRCR
4. Measuring, Gauging, or Controlling Devices
5. Radioactive Material for Distribution to Persons Exempt from Regulation Pursuant to C.4(b), SSRCR
6. Static Elimination and Ion Generating Devices
7. Radioluminous Products
8. Electronic and Electrical Devices
9. Leak Test Kits and Services
10. Medical Sources
11. Radiopharmaceuticals
12. *In Vitro* Test Kits.

The NARM Guides are the basis of a program aimed at attaining uniformity in the evaluation and distribution of NARM sources and products through the cooperative efforts of the states and Federal Agencies, in particular, BRH. These guides provide for the uniform classification and evaluation of NARM sources and products by radiation control agencies and are intended to be used in conjunction with the Radioactive Material Reference Manual (RMRM), which is maintained and coordinated by BRH for distribution to state and Federal Agencies and the Suggested State Regulations for Control of Radiation (SSRCR).

As the uniform NARM control system is realized, each NARM source or product intended for distribution in the United States will be evaluated according to the appropriate NARM Guide prior to routine distribution. The Licensing State will determine that each NARM source or product has been evaluated in accordance with the NARM Guides prior to licensing its possession and use. Any state can enjoin or otherwise prohibit a distributor from distributing an "exempt" product until it is evaluated. The issuance of a RMRM evaluation sheet is evidence that such an evaluation has been performed. The manufacture, assembly, or distribution of NARM sources and products will continue to be licensed in Licensing States.

In states that do not license NARM, the appropriate authority will issue a letter of authorization (or other document) for the manufacture, assembly, or distribution of a NARM source or product. The letter of authorization will set forth appropriate operating conditions to insure that the manufacture, assembly, or distribution of the NARM source or product has been performed in accordance with applicable provisions of the SSRCR and the relevant NARM Guide.

The NARM Guides were written to be compatible with the standards, criteria, and requirements placed upon "agreement materials" by the NRC in its licensing process and as such may suffer from some of the same weaknesses.

GENERALLY LICENSED PRODUCTS

In contrast to exempt items, the Agreement States can license the distribution of generally licensed products.

The Agreement States are required by their regulatory transfer agreements to remain compatible with the regulations of the NRC. In view of this, the Agreement States have applied the same criteria as the NRC in licensing companies to distribute these products regardless of whether or not the radioactive material is "agreement material" or NARM. This practice is continued in the previously described NARM Guides.

Table II lists the types of products that may be distributed to persons generally licensed. For convenience, all regulatory references are to NRC regulations; however, comparable regulations are specified in the SSRCR for NARM.

One might question the inclusion of "generally licensed" devices in the category of consumer products; however, if one were to review the training and experience of the users of these devices, one would find that as a rule, the user's knowledge of radiation and radioactive materials is limited to what he has been told by the device distributor's representative. Therefore, "generally licensed" devices should be categorized as consumer products.

At the present time, neither the NRC nor the Agreement States (with the possible exception of North Carolina) routinely inspect the generally licensed user of these devices. Therefore, no one is really sure that the devices are being properly used, leak tested, and disposed.

Chairmen of the past several Agreement States Meetings (USNRC, 1974, 1975, 1976) and the CRCPD (CRCPD, 1975, 1976), have asked that NRC reexamine the general licensing of gauges containing multicurie quantities of radioactive materials. Certain Agreement States would favor specific licensure of these gauges and gauges with millicurie quantities of radioactive materials that are used in the food and beverage processing industry.

CONCLUSIONS

State radiation control programs are beginning to more fully appreciate the radiological health and public information implications of radioactive material in consumer products. They are, however, limited in their ability to implement significant changes in the regulatory practices associated with these products because of lack of nationwide regulatory jurisdiction, inadequate research staffs and laboratories, and existing regulations of Federal agencies.

There need to be thorough, coordinated studies of the implications of radioactive materials in NRAP, TENRAP, and REHNRAP. Based upon the results of these investigations, regulations need to be promulgated that either regulate the products or exempt them from regulations.

The regulation of exempt and generally licensed products needs to be closely examined to ensure that all of these products really need the "exempt" or "generally licensed" status and that the standards and criteria under which they are licensed, manufactured, and distributed are adequate. This review should result in the regulatory changes that:

1. Ensure that the products are manufactured and distributed in such a manner as to adequately protect the health and safety of the user and to prevent contamination of the environment. (This is an area that is currently being done fairly well.)
2. Result in the consumer being informed of the presence of radioactive material in the product he intends to purchase and provide him with enough information to make a decision on whether or not he wants to buy the product. (This is an area that is currently being miserably handled by regulatory agencies.)

TABLE II
GENERALLY LICENSED PRODUCTS

Type of Product	Possession & Use Generally Licensed By	Distribution Licensed By
I. BYPRODUCT MATERIALS		
1. Static Elimination Device[1]	31.3(a)	Not Specific
2. Ion Generating Tube[1]	31.3(d)	Not Specific
3. Certain Measuring, Gauging, or Controlling Devices	31.5	32.51
4. Luminous Safety Devices for Use in Aircraft	31.7	32.53
5. ^{241}Am Calibration or Reference Sources	31.8	32.57
6. ^{90}Sr Ice Detection Devices	31.10	32.61
7. *In Vitro* Laboratory Studies	31.11	32.71
8. Certain Medical Uses	35.31	32.70
II. SOURCE MATERIAL (so called "small quantities")		
1. Pharmacists' Usage	40.22(a)	40.32
2. Physicians' Usage	40.22(b)	40.32
3. Patients[2]	40.22(c)	40.32
4. Commercial and Industrial Firms and Research, Educational, and Medical Institutions' Usage	40.22(d)	40.32
III. SPECIAL NUCLEAR MATERIAL		
1. Pu Calibration or Reference Sources	70.19	70.39

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[1] Distribution can only be licensed by the NRC.

[2] It is interesting to note that no similar general license is provided for patients who are given radiopharmaceuticals containing byproduct material.

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NUCLEAR ENERGY AGENCY'S EXPERIENCE IN DEVELOPING GUIDES AND STANDARDS FOR RADIOACTIVE CONSUMER PRODUCTS

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The Nuclear Energy Agency (NEA), in existence since 1958, is a specialised body of the Organisation for Economic Co-operation and Development (OECD) based in Paris. The membership of NEA now comprises 23 industrialised countries, i.e., all the Western European nations, Japan, Australia, Canada, and the United States.

The main objective of NEA is to promote international co-operation within the OECD member nations for the development and application of nuclear power for peaceful purposes through international research and development (R&D) projects and exchanges of scientific and technical experience and information. An expanding part of the Agency's work is devoted to the safety and regulatory aspects of nuclear energy, including the development of uniform standards governing safety and health protection and of agreement among nuclear legislative bodies.

The co-operation that NEA seeks to develop among its member countries may take a variety of forms including (1) exchanges of information on nuclear scientific and technical subjects, (2) co-ordination of research, (3) setting up of R & D programmes, (4) establishment of joint undertakings, (5) development of guides and standards, especially in the field of safety, and regulatory aspects of nuclear activities.

Although not binding, these standards, which are being jointly developed on the basis of mutual understanding, are recommended for adoption by member countries to serve as a basis for their national regulations.

BASIS OF NEA WORK ON RADIOACTIVE CONSUMER PRODUCTS

Following a joint agreement among three international organisations (International Atomic Energy Agency [IAEA], World Health Organisation [WHO], and NEA), a study was initiated in 1965 with a view to identifying products containing radioactivity available to the general public which, after distribution to the consumer, were used and disposed of without any regulatory control being exercised by the relevant national authority. The aim of this study was to determine the acceptability of such products from the radiation protection standpoint and to indicate whether it might be desirable and feasible to establish international safety standards. As a result of this study, the following recommendations were presented to NEA in 1969:

1. The adoption of a guide as a common basis for defining consistent policies at the national level and for the safety evaluation of radioactive consumer products.
2. The development, in accordance with the principles set down in the guide, of international safety standards for specific classes of products.

3. The establishment of an international programme for information exchange on exempt products.

4. The review by NEA, at appropriate intervals, of the data gathered through the international exchange programme.

THE NEA "GREEN" GUIDE

In accordance with the first recommendation of 1969, the basic guide was published by NEA in 1970 (European Nuclear Energy Agency, 1970). This guide, referred to simply as the NEA "green" guide, defines the general radiation protection principles and safety considerations to be taken into account in authorising the distribution, use, and disposal of products containing radionuclides intended for the general public. This guide should serve as a common basis for establishing consistent national policies for using such products and for conducting adequate safety evaluations prior to authorising their use; it should also facilitate international trade.

According to this guide, two main considerations should govern national policies regarding the distribution of products containing radionuclides:

1. Approval of a product should be contingent upon

   (a) An adequate demonstration that the radioactive product performs a function that can be fulfilled only by a radioactive method or so fulfilled that the radioactive method has clear advantages over any other practical method, and

   (b) a justification for the use of the specific radionuclide selected.

2. Generally, the radiation dose to the average individual user and to the population from all exempt products should not exceed a small fraction of applicable International Commission on Radiological Protection (ICRP) limits.

Decisions concerning the approval of a product submitted for exemption should take into account the anticipated individual and population doses, together with an assessment of the benefit to be expected from using the radionuclide in the product since any exposure to radiation is assumed to entail a risk of deleterious effects.

The benefits that might be derived from the use of different exempt products will vary significantly. These benefits range from possible saving of life and prevention of injury or loss of property to improving the reliability of the product and lower-order benefits. It was felt desirable to allocate for each order of benefit a certain fraction of the ICRP dose limits. Tentative values that might be used as a basis when establishing a risk/benefit balance are given (see Table 1). Nevertheless, the guide recognises that the allocation of the portion of the ICRP population dose limit that might be permissible from exempt products will depend on national, economic, and social considerations, which vary from country to country, and should be established by the relevant national authority.

RADIATION PROTECTION STANDARDS FOR CLASSES OF PRODUCTS IN WHICH THE USE OF RADIONUCLIDES IS INTENTIONAL

According to the second 1969 recommendation, NEA has prepared or is preparing the following radiation protection standards for classes of products in which the use of radionuclides is intentional: radiation protection standards for radioluminous timepieces, gaseous tritium light devices, and ionization chamber smoke detectors. They follow the principles of the NEA green guide. Their main objective is to serve as a basis for setting up national rules and regulations concerning the radiation

TABLE 1

Dose Apportionment for Exempt Products Based on Risk/Benefit Considerations expressed as fraction of ICRP limits*

Order of benefit	Individual dose	Population dose
Lifesaving devices	<0.1	$<10^{-4}$
Safety and security devices, improve reliability of the devices	<0.01	$<10^{-4}$
Lower order of benefit	<0.001	$<10^{-5}$

*This table has not been derived from precise technical information and should be regarded as provisional only.

protection aspects of radioactive products and to inform producers and importers of such products.

These radiation protection standards are based on the scientific recommendations of the ICRP, which for nearly half a century has reviewed and assessed research on the effects of ionizing radiation and reported on the fundamental principles for health protection against such radiation. However, interpretation of ICRP recommendations is left to the national bodies responsible for formulating regulations and codes of practice. The various NEA standards and guides comprise an intermediate step in this chain of interpretation.

The main features of these standards include requirements for the manufacture, use, and import of the product, recommendations concerning administrative control, prototype tests, radiation protection considerations, and technical information.

Radiation protection standards for radioluminous timepieces

This document, the first of its kind produced by NEA, was prepared in collaboration with the IAEA, which is based in Vienna (IAEA, 1967). This publication affected an important dose reduction to the general public and has been incorporated into the national regulations of many countries. The main features of these standards are well known and are summarised in Table 2.

A revision of these standards is on the NEA programme because (1) new scientific evidence concerning tritium is available, (2) gaseous tritium lights are being used in timepieces, and (3) most producers have abandoned the use of radium, although at one time the major part of the doses to the population from radioactive consumer products came from watches containing radium.

TABLE 2

Activity Limits for Timepieces

Maximum 147$_{\mathrm{Pm}}$ Activity 226$_{\mathrm{Ra}}$	7.5 mCi 150 μCi 0.15 μCi	7.5 mCi 150 μCi –	10 mCi 200 μCi 0.2 μCi	25 mCi 500 μCi 1.5 μCi
Marking	no	no	no	T, Pm, Ra + activity
Use	unrestricted			T: may be exempted Pm, Ra: notification or registration
	wrist	pocket	clock	special

Radiation protection standards for gaseous tritium light devices

These standards, published by NEA (NEA, 1973), are also widely applied and will be briefly summarised. The activity of tritium used in devices should be as low as practicable, and no source should be directly accessible. Gaseous tritium light devices must not be used in toys, for personal adornment, or for frivolous purposes. Some requirements concerning the tritiated water content of sources are also given.

An authorisation for the manufacture of a gaseous tritium light device should be contingent upon an adequate demonstration that it performs a function that can be fulfilled only by using a radioactive substance or that the use of a radioactive substance to fulfill the function has evident advantages over any other practical method.

Requirements for the use of gaseous tritium light devices are given in Table 3.

Radiation protection standards for ionization chamber smoke detectors

The preparation of the NEA standards for this product is well advanced, but, since the final draft has not yet been adopted, only tentative information can be given.

The source activity must be as low as practicable consistent with reliable function. Only sealed sources conforming to the relevant requirements of the International Standards Organisation (ISO) standards may be used. Under normal conditions of use, direct contact with the source should be impossible. The exemption requirements are given in Table 4. Only radionuclides currently being used have been considered. Other radionuclides may be accepted if they offer a similar degree of safety. A set of tests to be performed on the whole detector will be required in order to satisfy the relevant national authorities that the source will not become detached or suffer loss of integrity.

TABLE 3

Activity Limits for Gaseous Tritium Light Devices

Maximum Activity	500 mCi	2 Ci	more than 2 Ci
Marking	T	T . . . . Ci colour code label for recovery or disposal requirements, trefoil symbol	
Use	unrestricted	may be exempted	notification or registration
Requirements	– possible saving of life – protection against personal injury – advantage judged of equal importance		

TABLE 4

Activity Limits for Ionization Chamber Smoke Detectors (Tentative)

Maximum Activity	^{241}Am: 1 μCi (5 μCi) ^{226}Ra: 0.1 μCi	^{241}Am or ^{238}Pu: 20 μCi ^{226}Ra: 1μCi ^{85}Kr or ^{63}Ni: 0.5 mCi	higher activities
Maximum dose rate	0.1 mrem/h at 0.1 m		higher dose rate
Marking	trefoil symbol and/or label	trefoil symbol and label	
Use	unrestricted	recovery and disposal requirements	notification or registration
	single station for private home	industrial use	

The appendices of the document will contain radiation protection considerations, including dose evaluation and an accident analysis based on a list of all known incidents, e.g., theft, different kinds of fire, bomb explosion, mutilation of detectors and sources, involving ionization chamber smoke detectors in the United Kingdom. The problem of disposal of exempted single-station detectors is also considered. Finally, a comparison is made of the various types of fire detectors, both radioactive and nonradioactive.

Other radiation protection standards

The NEA green guide recognises that products containing isotopic batteries require special safety standards. The development and possible uses of isotopic batteries are also dealt with by NEA. In this respect, it should be noted that a certain number of countries are opposed to the use of isotopic batteries in consumer goods. In 1974, NEA published a report dealing with interim radiation protection standards for the design, construction, testing, and control of radioisotope cardiac pacemakers (NEA, 1974). These standards are solely intended to provide the basis for national authorities to establish practices and procedures by which the radiation risks to the nonpatients involved can be kept to a minimum. Since this risk results mainly from the low possibility of fuel release (^{238}Pu) due to containment failure in the event of an unusual incident, very careful attention has been devoted to the design requirements. The recommended prototype testing procedures have been established according to the results of an accident analysis based on death statistics.

In view of the limited practical experience with the actual performance of radioisotope-powered cardiac pacemakers, it was recognised that the standards should have a provisional character. An ad hoc group of experts has recently been set up to assess the performance of implanted radioisotope cardiac pacemakers as well as the administrative and regulatory problems confronting member countries that base their practices on these standards.

Although the NEA green guide does not deal with products in which the presence of radionuclides is unintentional, NEA is preparing a report dealing with radiation protection standards for building materials containing naturally occurring radioisotopes. It should be noted that some natural building materials that have been used for a considerable length of time in large quantities may result in higher doses for individual members of the public than those from nuclear power stations and consumer goods. This constitutes a particular difficulty in the preparation of these standards.

A first draft of this report has been prepared by European experts. The main idea expressed is that a "non-action level" should be found for activity concentration in new building materials to be introduced on the market. All "normal" materials (e.g., concrete, brick) should fall below the non-action level while "artificial" materials (e.g., materials based on tailings, byproduct gypsum, light concrete from uranium-rich shale) could well be above the level. Materials below the limit should be free from all restrictions; above the limit, they should be subject to evaluation, authorisation, and control.

The expert group will soon reconvene with U.S. experts participating, to consider the recent U.S. achievements in this field. As a result, the first draft may be significantly modified.

Agreement was reached in the expert group on the desirability of comparing methods for measuring radon daughter concentrations in air or activity concentrations in building materials. Such comparisons are now in progress or will be organised by circulating instruments and measurement samples.

IMPORT CONTROL AND INFORMATION EXCHANGE ON EXEMPT PRODUCTS

The third recommendation made to NEA in 1969 concerned the establishment of an international programme for information exchange on exempt products. This has not yet been implemented because higher priorities in the NEA programme caused a redeployment of resources.

Nevertheless, controlling imports is a growing problem in most countries. Although the import of radioactive consumer products is subject to licensing, such products are often imported and distributed to the public without notice to the relevant national authorities. In some cases, the importer himself is not aware that the product contains radionuclides. Several cases of illegal import of radioactive products with broad potential diffusion to the public have been mentioned recently to NEA by governmental officers of member states. The problem is not new, but no satisfactory solution has yet been found. It is not practicable to increase the number of controls at Customs. Prohibition of these products, especially of those normally accepted in other countries, may prove to be worse than a more liberal attitude that maintains frequent contacts between responsible national authorities and importers.

International cooperation may certainly improve the situation with agreements among NEA member nations on radiation protection standards and possibly with an information exchange on exempt products on a much more restricted basis than the system previously envisaged.

REVISION OF THE NEA GREEN GUIDE AND INTERNATIONAL COOPERATION PROBLEMS

The importance of keeping products containing radionuclides under control has now been recognised in most OECD member countries, but there are still questions needing better answers. The experience gained with the development of the NEA standards and the evolution of ideas on this subject within the respective national authorities in member countries suggest that the time has come to consider a revision of the green guide to assess the validity of the radiation protection criteria in the light of experience and, possibly, to develop new concepts.

An expert group will shortly be set up to deal with this revision. It will have to take into account the new ICRP basic recommendations (ICRP, 1977). A review of the radioactive consumer product situation in NEA member countries as well as an enquiry on the implementation of NEA standards should be undertaken and would satisfy the fourth recommendation of 1969. The danger with dose apportionment is a tendency to go as nearly as possible to the limit whereas the present trend gives more importance to the justification of an engaged dose. Some countries will be in favour of dose apportionment for planning purposes because such a concept facilitates the task of responsible national authorities who may be prevented by regulations from withdrawing a license after it has been granted.

Another important point to be discussed is the selection of criteria for deciding whether to exempt a product or not. It is recommended that such decisions should be based on a risk/benefit analysis, but decisions are most frequently not made this way. A small risk should result in the acceptance of a product presenting a small benefit, but many national authorities reject a product if the benefit is not important. The present version of the NEA green guide specifies that a radioactive product must be rejected if a nonradioactive product can fulfill the same function. But in some cases the use of a nonradioactive method may also present some degree of risk and therefore the principle that "nothing is worse than radioactivity" is no longer generally accepted.

The following criteria for accepting a product for exemption have been proposed, although no general agreement on them has yet been achieved: the benefit is larger than the risk, the dose due to normal use and disposal equals a very small fraction of ICRP limits, and the dose due to abuse and accident does not approach ICRP limits (for example $< 1/10$ of ICRP limits).

Many difficulties encountered in an international approach to the problem of consumer goods originate from the fact that countries differ in their history, culture, and way of life. In some countries, a label advising that an obsolete product should be sent to a disposal centre is sufficient to recover a large part of these products. Nevertheless, many national authorities will hestitate to rely on such a system. Geological peculiarities may need to be considered; for example, a country with a very low natural radioactive background will be reluctant to authorise the use of building materials with relatively high natural activity contents. The history of a product in a country is also important. For example, relevant national authorities may have to demonstrate the ineffectiveness of radioactive lightning conductors if they want to withdraw the license; on the other hand, it will be up to the producer to prove the efficiency to obtain a new license. In fact, the lack of field experiments forced NEA some years ago to abandon a project on standards for lightning rods.

The legal structure governing radiation protection in general and radioactive consumer products in particular varies from one country to another. For example, control of distribution may be legally impossible, or licensing decisions may be made at either the Federal or the provincial level.

Economic competition plays a very important role; and there will be pressures on national authorities to support or promote national industry.

All the above comments make it clear that an international approach to the problem must be pragmatic to some extent.

CONCLUSIONS

Radiation protection considerations are an important factor in the orderly development of nuclear energy for peaceful purposes, and it is essential to understand the relative significance of all potential sources of radiation exposure of the population. A recent study published by NEA on this subject (Pochin, 1976) clearly shows that doses due to radioactivity in consumer products cannot be neglected.

The development of industrial uses of radionuclides, in particular as products or devices intended for use by the general public, makes it necessary to define well-devised national policies that should provide adequate protection of the public without unduly restricting the use of ionizing radiation and the benefits that might be derived for man. These policies should furthermore be sufficiently consistent in order not to unnecessarily hinder international trade in this field.

Because of its very flexible structure and because its member countries have similar problems and interests, the NEA's object is to facilitate the task of the national authorities by providing them with the opportunity to meet so as to achieve mutual understanding and solve their problems on the basis of internationally recognised and accepted concepts.

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RADIOACTIVITY IN CONSUMER PRODUCTS IN THE UK

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Over the last few decades, some changes have inevitably occurred in the UK system for dealing with sources of radiation that may affect the general public. These changes have had their impact on the attitudes adopted and the decisions made. Some further changes will occur as a result of the obligations being placed on the UK by a directive (Euratom, 1976) of the European communities prepared under the Euratom Treaty. This paper will trace the development of consumer protection practice in the UK, both generally and specifically with regard to radioactive consumer products. The current approach in dealing with radioactive consumer products will also be discussed as will the implications of the Euratom directive.

THE UK SYSTEM OF CONTROL OF RADIOACTIVE CONSUMER PRODUCTS

Prior to the advent of the nuclear energy industry, only naturally occurring radioactive materials were available for use in consumer products. The most common application was the use of radium-226 in radioluminous devices. At that time, relatively little was known about the possible long-term effects of exposure to ionising radiations, and concern was centred on the protection of workers. It is not surprising, therefore, that the Radioactive Substances Act 1948, which set up the Radioactive Substances Advisory Committee, makes no mention of consumer protection.

The increasing concern over possible long-term effects from low doses of ionising radiation and the realisation that there was no specific control over radioactive consumer products led the Committee to set up the Miscellaneous Sources Panel during the 1950's. This Panel was given the function of surveying the various sources of radiation to which the public are exposed and informing its parent Committee of any undue proliferation of such sources and any action needed. The Panel also gave expert advice to manufacturers and distributors of such products prior to their distribution, if possible. This advice was given informally and with a view to avoiding exposure of the public without adequate justification. The Panel had no statutory power to give approval to commercial products.

The Radiological Protection Act 1970 transferred the functions of the Radioactive Substances Advisory Committee and hence those of the Miscellaneous Sources Panel to the National Radiological Protection Board. The Board was set up, inter alia, "to provide information and advice to persons (including government departments) with responsibilities in the UK in relation to the protection from radiation hazards either of the community as a whole or of particular sections of the community." The Board has continued to provide manufacturers and distributors with advice on the acceptability of their products but has no statutory power to grant approval or insist on the withdrawal of unsatisfactory products.

The recently revised directive (Euratom, 1976) prepared under Article 31 of the Euratom Treaty will require the UK to institute a statutory system of prior authorisation for some classes of consumer goods. The detailed arrangements by which this will be implemented are not yet clear, but the procedures used by the Board to give advice based, when appropriate, on national and international standards and recommendations seem likely to be used as the basis for official approval. The advice given at present by the Board is well received by the firms concerned, and they are unlikely to have much difficulty with the transition from voluntary to statutory controls. However, some care will be needed to ensure consistency and continuity of approach and to avoid the unjustifiably restrictive attitudes that might be associated with a statutory system of control.

The system of control over radioactive consumer products may be contrasted with that adopted for consumer products in general. In the UK, approximately 7,000 people die each year from accidents in the home and residental institution, and many more receive hospital treatment. Although many of these deaths and injuries result from accidents unrelated to any particular product, there are a substantial number of cases for which products are partly or wholly responsible. The Consumer Protection Act 1961 was intended to give the government power to take effective action when any products are likely to affect public safety. Under this Act, regulations can be made imposing requirements that must be met by any class of consumer goods to prevent or reduce the risk of death or personal injury. It is an offense to sell, in the course of doing business, goods that do not comply with regulations made under the Act. A number of regulations have been made covering such matters as the lead content of paints on pencils, certain electrical appliances, and the flammability of nightdresses. The need for making regulations under the Act is established by collecting information about home accidents, an "after–the–event" approach. In this respect, the Act has limitations; there is no provision to ban outright any particular type of product (i.e., one that might be intrinsically dangerous), and there is no provision for prior authorisation of any type of product.

EXISTING APPLICATIONS OF RADIOACTIVITY IN CONSUMER PRODUCTS

Inevitably, there are some products in circulation that have not been subjected to the close scrutiny now normally applied to new products. Some of these are no longer manufactured but are still in the possession of members of the public; others are still being manufactured and marketed.

The Board has examined many old watches luminised with radium-226; the activity levels are usually below 0.1μCi, which is the average level now permitted by both international (IAEA,1967) and British (BSI, 1968) standards. The policy adopted in dealing with these watches received from the public is summarised in Table 1. The Board has always dealt with enquiries on a case-by-case basis and has regarded further general action as unjustified. The effort required to call in unsatisfactory timepieces would produce only a minimal benefit; this would be out of all proportion to the resulting public anxiety.

Some other products that were permitted in the past and are still being manufactured and marketed raise different considerations. It is irrelevant to a large extent whether or not the product, if treated as a new proposal, would be considered acceptable and fully justified.

TABLE 1

Board Action on Old Timepieces Sent in by Members of the Public

Situation	Action
Annual Does < Dose Limit	Return timepiece with reassurances
Annual Dose > Dose Limit but < Maximum Permissible Dose	Return timepiece but recommend that thought be given to obtaining a modern replacement
Annual Dose > Maximum Permissible Dose	Recommend leaving timepiece with Board for controlled disposal

In such cases, very substantial reasons are necessary for advising that the product should no longer be marketed. The possibility of exceeding the International Commission of Radiological Protection (ICRP) dose limits either under normal conditions of use or as a result of accidents and misuse would usually be considered a sufficient reason, particularly if there is little justification for the product. In recent years, the Board had advised against only two existing applications on the ground that the ICRP dose limits applicable to members of the public might be exceeded. In one case, which concerned the use of antistatic brushes containing polonium–210, radiological safety tests indicated that intakes of radioactivity could lead to doses in excess of the ICRP limits in extreme but credible circumstances (Webb et al., 1975). In the other case, which concerned the use of uranium as a fluorescing agent in dental porcelains, the doses were likely to exceed the ICRP limits during normal use (O'Riordan et al., 1974).

With other existing applications, the Board's attitude is to encourage the development of appropriate radiation protection standards such as those mentioned above for radioluminous timepieces. Such standards must have as their basic objective the reduction of real and potential doses from normal use, accidents, abuse, etc., to levels that are as low as are reasonably achievable. The standards and guidelines recommended by international organisations such as the Nuclear Energy Agency (NEA) of the Organisation for Economic Co-Operation and Development and the International Atomic Energy Agency (IAEA) have been found to be particularly valuable.

NEW RADIOACTIVE CONSUMER PRODUCTS

Decisions in radiological protection should ideally be based on the procedures of cost-benefit analysis as discussed in ICRP Publication 22 (ICRP, 1973). The process consists of two basic steps, given the overriding requirement of compliance with the ICRP recommendations for limitation of individual doses:

1. initial risk-benefit analysis to determine whether the benefit from the product is likely to exceed the risk and
2. optimisation of the features of the product and comparison with other optimised alternatives in order to choose the best.

In the initial assessment, both benefits and risks (expressed in terms of dose) are usually found to be low. Decisions are therefore likely to be subjective, and what may be accepted in one country may not be accepted in another. Some advise on decisionmaking has been given in a guide issued by the European Nuclear Energy Agency (ENEA,1970). It suggests, for example, prohibiting the intentional addition of radionuclides to foodstuffs, beverages, and cosmetics. A similar prohibition is also implied for toys, articles for personal adornment, and other substances for domestic use. Examples of benefits are possible saving of life, prevention of injury or loss of property, improving reliability or dependability of the product, improving technology, advancing education, and providing social amenities. The guide recommends that the assessment of proposals should involve a consideration of doses resulting from use, disposal, handling, credible abuse, and accidents including fire. This is necessary since there is no effective way of controlling any product after sale to the public.

The evaluation of doses from any particular application of radioactivity may involve theoretical assessment alone but more commonly will include practical testing. Such testing will obviously cover the measurement of external radiation dose rates and radioactive contamination but should also include temperature, mechanical, and corrosion tests that will be aimed at simulating the effects of long-term and adverse environmental conditions. If a sufficient range of comparable products is available, testing may also be used to provide information for the optimisation process (Hill et al., 1976).

APPROVED PRODUCTS

Gaseous Tritium Light Devices (GTLDs)

In recent years, most inquiries received by the Board have related to the use of gaseous tritium light sources (GTLSs), which are sealed glass tubes coated internally with a phosphor and filled with tritium gas. They are in general a more satisfactory means of luminising than are radioluminous paints, notwithstanding the rather higher activity levels needed for a given luminosity.

In normal use, any external radiation is solely due to very low energy bremsstrahlung and is therefore strongly attenuated by the device in which the GTLS must be incorporated. Most devices measured in the UK give dose rates that do not exceed 0.1 mrad h^{-1} at or near the surface.

Internal exposure due to tritium can only arise as a result of GTLS breakage. In the experience of the Board, GTLS breakage is extremely rare but, should it occur, the limiting hazard will be due to the intake of tritiated water. The NEA standards (NEA,1973) require that the tritiated water content of GTLSs should not exceed 2%

of the total tritium activity (1 mCi in the case of sources with less than 50 mCi tritium gas). On the basis of simple assumptions, the intakes given in Table 2 may be calculated for various GTLS activities. Only under very exceptional circumstances is the intake likely to approach the maximum permissible annual intake of 5 mCi (Vennart, 1969) applicable to members of the public.

Another matter for consideration is the collective dose associated with the disposal of a large number of GTLDs. Assuming GTLDs containing a total of 10^6 Ci of tritium were to be disposed of each year, the equilibrium collective dose rate to the UK population has been calculated to be 10 manrad y^{-1} (Wrixon, 1974).

In some applications of GTLSs the benefit is clear; for example, their use in safety and emergency signs. These applications are immediately acceptable. In addition, because of the low risk associated with the use of GTLSs, other applications with a lower order of benefit have also been accepted either by the Board or earlier by the Miscellaneous Sources Panel. These applications include the use of GTLSs in illuminating telephone dials, liquid crystal digital watches, camera range and view finders, and fishing floats and fishing rod tips.

Although the risk of GTLS is low, it can often be reduced still further by simple and cheap methods. For esample, the NEA standards (NEA, 1973) require that GTLSs be incorporated in a device and not directly accessible. Such

TABLE 2

Assessment of Intake of Tritiated Water Due to Breakage of a Gaseous Tritium Light Source

GTLS activity (Ci)	2*	0.2	0.05
Intake in 1 h (Ci)	1.7×10^{-3}	1.7×10^{-4}	4.3×10^{-5}
Intake in 2 h (Ci)	2.3×10^{-3}	2.3×10^{-4}	5.8×10^{-5}

*Maximum exempt activity (see NEA, 1973).

Assumptions: Tritiated water content = 2%

Room volume = 30 m^3

Ventilation rate = 1 air change h^{-1}

Breathing rate = 1 m^3 h^{-1}

Equal intake by skin absorption and inhalation requirements obviously reduce the possibility that a GTLS may become detached or broken. Other information that can be used to improve designs can be obtained through simple measurements and tests. Measurement of external bremsstrahlung dose rates could lead to better shielding of the sources. Mechanical tests such as drop and impact tests show whether the sources will be easily detached or broken when the devices are in use. Measurements are also made on the tritiated water content of the sources to ensure that the 2% limit set by the NEA standards is not exceeded.

Ionisation Chamber Smoke Detectors (ICSDs)

In the UK, these devices have been widely used on industrial premises, e.g., shops and warehouses, mainly to protect property. In recent years they have been installed in hotels and residential institutions to save lives. Only during the last year or so have substantial efforts been made to place them in private homes.

A person at an average distance of 4 m from an ICSD containing 5μCi ^{241}Am will receive an annual external dose of about 30 μrad. This extremely small dose does not merit further consideration; it is indistinguishable from minor perturbations in the natural background radiation.

Only in the event of an accident or misuse is there a likelihood of contamination that might lead to an intake of radioactive material and a subsequent internal dose. On the basis of some simple assumptions, the intakes given in Table 3 have been calculated for a 5μCi ^{241}Am domestic ICSD. The maximum permissible annual intakes of 3 μCi (via ingestion) and 1.5×10^{-3} μCi (via inhalation) for the more restrictive transportable form of ^{241}Am are therefore most unlikely to be reached. This conclusion is supported by experience with industrial ICSDs involved in a variety of incidents. The Board is often called in following these incidents and in no case has any detectable internal contamination been found (Jackson, 1974; Mullarkey, 1975; Croft, 1975).

The UK fire authorities have estimated that more than one-third of the current fatalities due to fire might not occur if fire detection systems were universally installed (Rasbash, 1972). Since a large number of these fatalities occur in private homes, usually while individuals are asleep, it is clear that the benefit from the domestic use of ICSDs would be substantial.

The Board has therefore concluded that the benefit from the domestic use of ISCDs vastly outweighs any associated radiological risk. Although this conclusion was necessary, it is not in itself sufficient to justify general acceptance. Additional points to be considered are:

1. are there any nonradioactive alternatives that are equally satisfactory or better?
2. are the risks as low as are reasonably achievable?

Only optical smoke detectors can be considered as real alternatives to ICSDs. In general, optical types respond better to the large particle size aerosols produced by smouldering fires while ICSDs respond to the smaller invisible particles produced by clear-burning fires. In a real fire situation, the performance of the two types tends to be broadly equivalent. Until recently ICSDs have had certain practical advantages, including lower installation costs, better compatibility with batteries, and no problem of lamp failures. With the recent introduction of light-emitting diodes, these advantages are no longer so pronounced. However, according to the British

TABLE 3

Assessment of Intake of ^{241}Am Due to Incidents Involving Ionisation Chamber Smoke Detectors

Incident	Activity Inhaled (μCi)	Activity Ingested (μCi)
During fire[I]	5×10^{-6}	–
Following fire[‡]	10^{-8}	–
Misuse*	–	0.05

Assumptions: ICSD activity 5-μCi ^{241}Am

[I] Airborne activity	0.1%
Amount of airborne activity inhaled	0.1%
[‡] Resuspendable activity	1%
Contaminated area	100 m^2
Resuspension factor	2×10^{-6} m^{-1}
Time for cleanup operation	8 h (one working day)
Breathing rate	10 m^3 during a working day
*Amount of activity transferred to fingers and subsequently ingested	1%

N.B. Only the critical pathways of exposure have been covered in this assessment.

manufacturer's association (BFPSA, 1976), it has not yet been demonstrated that optical detectors can be engineered, produced, and applied in large numbers with comparable overall effectiveness. According to the US testing authorities (Bright, 1976), it is still too early to foresee potential problems and "much work remains to be done before an unequivocal opinion can be rendered." In view of these opinions, it cannot yet be concluded that optical detectors are as good as or better than ICSDs in all respects.

There are a number of matters that should be taken into consideration when attempting to improve the design of detectors. Some of these are obvious even before the prototype stage and include:

1. selection of the least hazardous radionuclide with a half-life consistent with the useful life of the product;
2. keeping the activity as low as is necessary for the adequate functioning of the device;
3. Use of shielding, where appropriate, particularly where β-radiation is involved;
4. Limiting access to the source; and
5. Appropriate choice of source form.

Of the readily available α-emitters that could be used, ^{241}Am emits little external radiation and therefore is best for use in ICSDs. The required activity appears to be a few microcuries. Since ^{241}Am is highly radiotoxic, the source should not be readily accessible. This objective can be achieved by requiring the use of special tools or by sealing the ionisation chambers. In addition, the source should be of high integrity and in nondispersible form.

Perhaps less obviously, information on minimising doses can be obtained from appropriate tests on prototypes. The Board has been extensively testing ICSDs in accordance with a provisional testing programme (Hill et al., 1976). The tests are intended to simulate the damage and effects produced by long term use or as a result of accidents and abuse. The most interesting and useful results have come from the fire test.

A 600°C fire test for domestic detectors was chosen as typical of the temperature reached in house fires. The test was carried out for 1 hour at the required temperature in a standard airflow. Ideally, complete ICSDs should be tested but, because of the practical difficulties involved, the tests were carried out on sources mounted in their holders in the presence of representative parts of the complete ICSD. After the test any airborne activity was measured, the ICSD debris was examined for radioactive contamination, and the source and their holders were wipe-tested. Only ICSDs using foil sources have yet been tested. ICSDs intended for both domestic and industrial application have been tested to obtain as much information as possible.

Although the sources in the ISCDs were all of similar construction, the results obtained varied greatly and depended more on the materials used in the construction of the source holder than on the activity of the source. With a few exceptions, no activity became airborne, and there was no significant contamination of the detector debris. However, wipes of the sources and their holders ranged from "no detectable activity" (i.e., less than a few pCi) in the best cases to several hundred nCi in the worst cases. In general, stainless steel and aluminium source holders gave lower wipe test results than brass—or tin–plated materials. The only exception involved a stainless steel holder, but in this case further investigations by the Radiochemical Centre (Hunt, 1976) revealed that burning of the plastic housing of the detector caused the damage to the source. The results of the sources following the tests are summarised in Table 4.

The fire-test results confirm that both during and following a fire the hazard to individuals is very low. The absence of airborne activity during the tests shows that the assumptions made in the initial risk-benefit analysis (see Table 3) of inhaled activity during a fire were extremely conservative. The activity removed on wiping the sources following the test gives an indication of that which might be resuspended during the cleanup operations following a fire. Most of the results obtained are well below the 1% assumed in the initial risk-benefit analysis (see Table 3). Even where the values are higher, the inhaled activity is unlikely to exceed that calculated by more than one order of magnitude and cannot be considered a serious health hazard. However, in order to ensure that doses are kept to levels as low as are reasonably achievable, the Board has established as one of its criteria for acceptance of any particular type of ICSD a requirement that not more than 5 nCi of the total activity should be detectable in the debris and removed by wiping the source and holder after the fire test.

NON-APPROVED PRODUCTS

The Board had advised against the use of radioactivity in a number of applications. Proposals to use GTLSs as art forms around picture frames, in paperweights, and on the walls of swimming pools, as well as a proposal to make available loose GTLSs in do-it-yourself kits for making fishing floats, have been discouraged. The Board has also advised against several proposals to use radioactive tracers to mark products in such a way as to distinguish one manufacturer's products from those of a competitor; practicable alternatives are available for this purpose.

DISCUSSION

The basic aim of any consumer protection policy should always be to ensure that the rights of consumers are respected and that their health, safety, and economic interests are taken into proper account.

When dealing with matters of health and safety, the relevant authorities should not only be fully aware of the hazards associated with a particular product but should also be sensitive to the needs and desires of the consumer. An approach relying on the identification of unsatisfactory products through the collection of accident statistics and encouraging the development of appropriate safety standards is adequate for most consumer products. A system of prior authorisation for every type of consumer product would be impracticable and unnecessary.

TABLE 4

Fire-Test Results* for Ionisation Chamber Smoke Detectors (600°C for 1 hour)

Detector Type	Wipe Results (nCi)		Comments
	Before Test	After Test	
A	NDA**	NDA	Stainless steel holder
	NDA	NDA	Stainless steel holder
B	0.09	0.04	Stainless steel holder
	0.01	0.01	Stainless steel holder
C	1.28	0.4	Aluminium holder
D	0.20	275	Tin-plated brass holder
E	NDA	91, 10***	Tin-plated mild steel holders
	NDA	200, 409***	Orientation of sources and holder geometry may account for differences
	NDA	0.4 3***	Stainless steel holder
	NDA	0.9 0.3***	Stainless steel holder
F	0.19	0.47	Gold-plated plastic holder
	0.16	1.66	Mild steel holder
G	0.10	0.04	Aluminium holder
	0.10	0.01	Aluminium holder
H	1.05	NDA	Stainless steel holder
I	0.01	0.13	Stainless steel holder
J	NDA	4.3	Aluminium holder
K	NDA	97	Stainless steel holder. High results due to reaction with plastic material of detector
	NDA	345	
L	0.08	120	Brass holder. High result possibly due to solder melting and attacking foil
M	0.06	15	Brass holder
N	0.06	12	Brass holder

*The numberical results reported here are the activities removed on wiping the sources with an alcohol-moistened cotton swab.

**NDA = no detectable activity.

***Repeat tests with another detector.

Radioactive consumer products need to be treated somewhat differently. At the levels of radiation normally involved, no health effects would ever be observed. For radiation protection purposes, it is conventionally assumed that any radiation dose entails some risk of deleterious effects, and all doses, at least in principle, must be justified in terms of the benefits to be accrued. This automatically suggests a system of prior authorisation or licensing. The controlling authority may be expert in estimating risk but not necessarily expert in determining benefit. Preoccupation with risk can result. It is perhaps for this reason that certain minor applications appear to have been treated dissimilarly in different countries.

The UK is considering this carefully in the light of the requirements of the Euratom directive. If risk-benefit analysis is to be used as the basis for decision-making under some statutory prior-authorisation procedure, it must be recognised that there are benefits other than that of lifesaving. Even the application of radioactive materials for recreational purposes, for example, should not be prohibited without at least some consideration. A guiding principle might be that action should not be taken to prohibit radioactive consumer goods that the consumers themselves would accept if they were in full possession of the facts about the potential hazard.

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LEGAL AND PRACTICAL ASPECTS OF RADIOACTIVITY IN CONSUMER PRODUCTS IN THE FEDERAL REPUBLIC OF GERMANY

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In the Federal Republic of Germany (FRG), the use of consumer products that contain radioactive substances is primarily controlled by the first radiation protection ordinance (FRG, 1965), the second radiation protection ordinance (FRG, 1964), and the ordinance on the approval of drugs that have been treated with ionizing radiation or that contain radioactive substances (FRG, 1971). In October 1976, a new radiation protection ordinance was published (FRG, 1976). This new ordinance replaced the regulations of the first and the second radiation protection ordinances. In this paper, the old regulations and the most important changes according to the new radiation protection ordinance are discussed.

According to the radiation protection legislation of the FRG, the handling of radioactive substances i.e., the extraction, production, storage, treatment, processing or any other use, and the disposal of this material, is subjected to a system of licensing. The use of radioactive substances, or goods containing such substances, without a license is permitted only if certain specified provisions for exemptions are fulfilled. The exemptions can be summarized as follows:

1. A license is not required by any person using an apparatus, product, or other equipment containing sealed sources, provided the apparatus, product, or equipment is of an approved design.

2. A license is not required by any person

–handling an apparatus containing scales or dials with firmly adhering radioactive luminous paint, provided the paint and the shielding fulfill certain specific conditions.

–storing, using, or disposing of glassware containing uranium, provided the content of natural or depleted uranium does not exceed 10% of the weight of the glass.

–storing, using, or disposing of glazed ceramic articles, porcelains or glassware, provided the glazing does not contain more than 20% of natural or depleted uranium or the uranium content per unit area of the painted surface does not exceed 2 mg/cm^2 of uranium in the case of underglaze painting and 0.1 mg/cm^2 in the case of overglaze painting.

–storing, using, or disposing of electronic components, provided each individual component contains only radioactive substances of an activity below the general exempted quantity and the dose rate at a distance of 0.1 m from the accessible surface of the component does not exceed 0.1 mrem/h. The general exempted quantities are given in Annex I of the first radiation protection ordinance; they depend on the radiotoxicity of the radionuclide and have values between 0.1 μCi and 100 μCi.

–storing, using, or disposing of electrotechnical or other devices designed for purposes of illumination, provided the conditions given in the previous case are valid.

3. A license is not required by any person

–handling radioactive substances, provided the activity does not exceed the general exempted quantities.

–handling solids containing natural radioactive substances, provided the concentration of activity does not exceed 10 nCi/g.

–handling substances, provided the concentration of activity does not exceed 2 nCi/g, and provided further the radioactive substances are not (a) used for medical purposes, (b) added to drugs or foods, (c) used in the production of goods designed for domestic use, or (d) used in the production or application of plant sprays, insecticides, fertilizers, or soil improvement agents in such a way that the product contains radioactive substances, other than those of natural origin, in a concentration of more than 2 nCi/g.

4. A license is not required by any person handling natural thorium up to 100 g for purposes of chemical analysis or chemical synthesis.

5. A license is not required by any person handling

–natural potassium.

–medicinal waters originating from natural sources having a normal concentration of radioactive substances of natural origin.

--dental porcelain or porcelain teeth colored with natural or depleted uranium, provided the concentration of uranium does not exceed 0.1% by weight.

The new radiation protection ordinance brings some essential changes. The most important point is the introduction of a notification for certain cases of handling radioactive substances that are not subjected to the system of licensing. The new system is a three-step graduated system of regulation–free use, notification, and licensing, depending on the hazard expected in the handling of substances or equipment containing radioactive materials. The use of equipment that is of approved design will be free from licensing only if the activity contained in the device is not higher than ten times the general exempted quantities. Handling an apparatus containing scales or dials with radioactive luminous paint is allowed without notification only if the apparatus contains no more than 5 mCi of tritium. Storage, use, and disposal of other consumer products enumerated under point 2 are permitted; however, electronic components and devices designed for purposes of illumination are not permitted if they contain radionuclides of the highest class of radiotoxicity, e.g., Ra-226 or Am-241. Further changes include special regulations for ionisation smoke detectors. Also, the use of uranium counterweights installed in aircraft is possible without license or notification.

In this paper, only consumer products that fall under points 1, 2, and 3 of the enumeration given previously are discussed. Provisions referred to under point 4 cannot be applied to the production of consumer products, and point 5 is derived from the ordinance on the approval of drugs (FRG, 1971), which is under the jurisdiction of the Federal Ministry of Health. This applies also to radioactive pharmaceutical products, which are not discussed in this paper.

Table 1 contains a list of all types of equipment of approved designs. Three groups have to be distinguished:

a. Devices destined for use in schools. Various types of equipment of this group, e.g., neutron generators, X-ray generators, and sources containing radioactive substances, have to fulfill particular conditions that are described in the second radiation protection ordinance.

b. Calibration sources for controlling radiation protection measuring devices. For these sources, also, there are detailed conditions of approval in the first radiation protection ordinance.

TABLE 1
EQUIPMENT OF APPROVED DESIGN IN THE FRG FROM 1960 TO 1975

Type of equipment	Number of approvals	Activity and radionuclide	Number of pieces produced 1975*
Equipment for use in schools:			
Neutron generators	4	3-10 mCi Ra-226	21
X-ray generators	4		?
Sources with radioactive substances	24	0, 1-500 μCi Na-22, Co-60 Kr-85, Sr-90, Cs-137, Tl-204, Po-210, Ra-226, Th_{nat}, Am-241	1,040
Calibration sources	26	0, 1 μCi-50 mCi C-14, Na-22, Co-60, Sr-90, Ba-133, Cs-137, Pb-210, Ra-226	169
Other equipment:			
Gaseous tritium light devices	3	10 mCi-2 Ci H-3	?
Electronic tubes	19	4-200 μCi H-3, 0, 4 μCi Ni-63 3-150 nCi Co-60 3-30 μCi Pm-147 8-50 nCi Ra-226	732,000
Antistatic devices	2	50-125 μCi Po-210	?
Electron capture detectors	4	2-10 mCi Ni-63	32
Smoke and fire detectors	20	0, 1-4 μCi Ra-226 0, 5-72 μCi Am-241	106,000
Density measurement devices	2	50-500 mCi Am-241	1
Other devices (e.g., fluorescence analyzers, devices for dust and condensation point measurements)	8	80 μCi-50 mCi Fe-55, Kr-85, Pu-238, Am-241	8

*Hesse and Northrhine-Westphalia are not included.

c. Other equipment containing sealed sources. In this group, the conditions for the approval of the design have a very general form. The first radiation protection ordinance required only that the equipment contain a sealed source, that the source could not be touched, and that the dose rate at a distance of 0.1 m from the surface of the equipment did not exceed 0.1 mrem/h. If these conditions are met, there is no requirement to obtain an approval of the design.

In addition, each state (land) of the FRG has the right to grant or refuse an approval. In general, such a decision is discussed by a commission of the respective authorities of all states, chaired by the Federal Ministry of the Interior. During recent years, many devices containing gaseous tritium lights that, in general, complied with the conditions given above did not receive an approval of the design. Between 1960, when the first radiation protection ordinance became effective, and 1975, approval of the design was given for 116 different types of equipment. In Table 1 are listed, for each type of equipment, the number of approvals issued, the type of radionuclides and the range of the activities used, and the number of pieces produced in 1975. Many of the older approvals are no longer used today, and therefore few of the 116 approvals contribute to the numbers given in the last column. This is especially valid for electronic tubes. As a result of changes in the rules of the first radiation protection ordinance in 1965, nearly all electronic tubes do not at present need an approval of the design, as they fall under the exemptions given under point 2.

The numbers given in the last column of Table 1 do not contain the pieces produced in Hesse and Northrhine-Westphalia. A question mark means that, at present, this type of equipment is produced only in these two states.

Table 2 contains a comprehensive list of consumer products falling under point 2 of the enumeration given above. Although these products are free to be stored, used, or disposed of in the FRG, they can be produced only with a license. Up to the present, there is no general system of notification that would force the manufacturers of these products to provide production and activity data for each type of consumer product to the appropriate authorities. The numbers given in columns 2, 3, and 4 of Table 2—and also the numbers in Table 3—are derived from questionnaires sent to the manufacturers of consumer products containing radioactive substances at the end of 1974. Because this survey was done on a voluntary basis, not all producers filled out the questionnaires completely, and some firms did not respond at all. The data certainly give a qualitative view of these consumer products and supplement figures given in the study of the European Communities (Washsmann, 1976) for the FRG. According to the first radiation protection ordinance, importers of consumer products falling under point 2 of the enumeration given above have to report to the "Bundesamt für gewerbliche Wirtschaft" in Frankfurt. The last column of Table 2 contains values for 1973 derived from information from that office.

Consumer products falling under point 3 of the enumeration given above can be classified into three categories:

a. The radioactive substances are added intentionally to the consumer products, for instance, to improve the quality of a material. Table 3 contains a comprehensive list of the consumer products produced in 1973 in the FRG by making use of the exempted concentrations given under point 3. Table 3 can be regarded as a supplement to Table 2. The wording of the regulations is such that these consumer products cannot be classified under point 2. For example, the addition of thorium to glassware is dealt with in Table 3, whereas the addition of uranium to glassware is

TABLE 2
CONSUMER PRODUCTS, PRODUCED AND IMPORTED IN 1973 IN THE FRG UNDER THE EXEMPTIONS GIVEN IN POINT 2 OF THE PAPER

Type of consumer product	Produced in the FRG			Imported into the FRG
	Number of pieces or weight of the product	Total activity and radionuclide used	Exported	Number of pieces
Apparatus containing scales or dials with luminous paint	$14 \cdot 10^6$	1200 Ci H-3 300 Ci Pm-147	50%	$841 \cdot 10^3$ with H-3 $116 \cdot 10^3$ with Pm-147
Glassware containing uranium	4 tons	50 mCi U-238	50%	$326 \cdot 10^3$
Articles with uranium paints	$0,3 \cdot 10^6$	16 mCi U-238	50%	$1030 \cdot 10^3$
Electronic components containing radioactive substances	$40 \cdot 10^6$ $11 \cdot 10^6$ $3 \cdot 10^6$ $2 \cdot 10^3$	5100 Ci Kr-85 350 Ci H-3 or Pm-147 5 mCi Th-232 0.3 mCi Ni-63	40%	$31 \cdot 10^3$
Apparatus designed for purposes of illumination:				
High-pressure mercury lamps	$7 \cdot 10^6$	0.4 Ci Th-232	20%	–
Ignition device for fluorescent lamps	$26 \cdot 10^6$	77 Ci Kr-85	50%	–

TABLE 3
CONSUMER PRODUCTS PRODUCED IN 1973 IN THE FRG UNDER THE EXEMPTIONS GIVEN IN POINT 3 OF THE PAPER*

Type of consumer product	Produced in the FRG		
	Weight of the product	Total activity and radionuclide used	Exported
Glassware containing thorium	16 tons	190 mCi Th-232	10%
Steel/thorium alloys	?	140 mCi Th-232	?
Tungsten and molybdenum/ thorium alloys	37 tons	50 mCi Th-232	30%

*Radioactive substances are added intentionally to improve the quality of the material.

shown in Table 2. For the products falling under point 3, there is no requirement for notification of imported products; therefore, there are no import data given in Table 3.

b. The radioactive substances are used to improve the process of production of the consumer goods and may be incorporated into the consumer goods. Examples include the use of Co-60 sources for checking wear of blast furnace lining and the monitoring of glass-melting processes by the addition of Na-24 and Sc-46.

c. The radioactive substance is carried unintentionally into the consumer product with the raw material or with added substances. We have given greater attention to this group of materials in recent years because these materials most likely give rise to the highest population doses of all consumer products. Examples are building materials and fertilizers. In a separate paper presented elsewhere in this book, Dr. Kolb has discussed details of the study on building materials. A summary of a study on phosphate fertilizers sponsored by the Federal Ministry of the Interior and performed by the Radiological Institute of the University of Erlangen-Nürnberg (Pauley, 1976; Pfister, 1976) is given below. The study included a gamma spectrometric analysis of inorganic fertilizers containing phosphate for uranium, thorium, and Ra-226.

The analysis included 86 different trademarks representing about 70% of all fertilizers of this type permitted for use in the FRG. The results of these measurements are given in Table 4. The 86 trademarks are summarized in six different types of fertilizers, three pure phosphates and three mixed fertilizers. The percentage of use in the agricultural year 1973/74 in the FRG is given for the different types of fertilizers in the third column of the table. In the last line of the table, the mean specific activities weighted with the percentages of the third column are given. These values are used for the further assessments. In the agricultural year 1973/74 in the FRG, 0.92 million tons of P_2O_5 were used. This means that 53 Ci of U_{nat}, 36 Ci of Ra-226, 2 Ci of Th_{nat}, and 536 Ci of K-40 were spread over fields,

TABLE 4
SPECIFIC ACTIVITIES OF PHOSPHATE FERTILIZERS USED IN THE FRG

Type of fertilizer	Number of measured trade-marks	Quota of use in agriculture in 1973/74 in %	Specific activity in nCi/kg P_2O_5			
			U_{nat}	Ra-226	Th_{nat}	K-40
Pure phosphate:						
Superphosphate	3	1.9	77.7	78.1	2.4	20.4
Thomasphosphate	1	28.0	(1.0)	1.0	0.3	0.6
Others	7	8.0	64.2	46.4	2.5	10.9
Mixed phosphate and potassium	20	25.3	67.7	61.7	2.2	1011.3
Mixed phosphate and nitrogen	7	5.5	88.7	30.4	2.7	4.0
Mixed phosphate potassium and nitrogen	50	31.3	92.4	55.1	2.9	1044.4
Mean value of all phosphate fertilizers			57.8	40.0	1.9	584.4

meadows, and gardens. Considering that 134 billion square meters of land are used in the FRG for agricultural purposes, this gives a mean concentration of 0.4 nCi/m^2 for natural uranium, 0.3 nCi/m^2 for radium-226, 0.01 nCi/m^2 for natural thorium, and 4 nCi/m^2 for potassium-40. But we must bear in mind that there are considerable differences in the manner of fertilizing in the different districts and for the different kinds of cultural areas. For instance, if we look only at the district of Würzburg, we find mean concentration values that are a factor of 22 higher than the values given for the FRG. So we can assume that, in some agricultural areas of the FRG, the radium-226 that is spread yearly by fertilizers is of the order of 10 nCi/m^2. This is one-tenth of the limit given for this radionuclide for surface contamination of objects coming out of restricted areas. Further investigations on the retention of uranium and radium in the soil and the uptake by plants are projected to assess the contribution of these radionuclides to the internal radiation exposure of the population. The external radiation exposure of members of the population that are not handling fertilizers occupationally is very small. A very conservative estimate gives values on the order of 0.1 mrem/yr. A second study (Pauly, 1976; Pfister, 1976) by the same institute deals with the external radiation exposure of persons working in areas where rock phosphates or phosphate fertilizers are present in greater amounts. Whole-body doses of 20 and 11 mrem/yr were obtained for persons working in production plants and fertilizer storehouses, respectively, with a maximum of 45 mrem/yr in both cases. Rough estimates showed that the whole-body dose can reach about 30 mrem/yr for persons working in rock phosphate and transport in some special cases, whereas the exposure of agricultural workers is negligible compared to this value. The internal exposure of these persons due to the inhalation of radon and of phosphate fertilizer dust may be more significant. Further investigations are also concerned with this problem.

Present estimates of the average annual population dose in the FRG from consumer products are not accurate. In the latest annual report, "Environmental Activity and Radiation Exposure," edited by the Federal Ministry of the Interior, a value of less than 1 mrem/yr is given for "industrial products." In practice, this term includes all products given in Tables 2 and 3 of this paper and some devices named in Table 1. Most of the equipment listed in Table 1 will fall under the term "use of radioactive sources in industry and research," which in the report is estimated to have a value of less than 1 mrem/yr, also. The contribution from building materials in the report is listed under "natural exposure" and amounts to about 20 mrem/yr, which is the difference between the mean exposure inside and outside buildings.

Further actions by the Federal Ministry of the Interior in the field of consumer products containing radioactive substances are in two categories.

The first category includes all products in which the presence of radionuclides is intentional. For this category, we have a detailed legal system of exemptions that should be revised from time to time to ensure that:

a. New applications for the use of radioactive substances in consumer products are favorably considered, provided the benefit is high compared to the risk,

b. Radionuclides of high radiotoxicity are replaced, as far as possible, by less dangerous radionuclides, and

c. Antiquated techniques or applications of radioactive substances that have proved to be useless are eliminated.

The surveillance of manufacturers of consumer products containing radioactive substances has to be improved by:

a. A system of quality control for those products that are of approved design, and

b. A system of notification for the other exempted products.

The system of quality control provided in Section 24 of the new radiation protection ordinance must be put into practice. The system of notification, already mentioned, should ensure that the appropriate authorities have a good overview of the exempted products that are not of approved design. This is an important basis for better and more elaborate assessments of population doses from consumer products.

External and internal exposure to individual members of the public and to the general public resulting from distribution, normal use, maintenance and disposal of the product and from abuse and accidents should be assessed. In all cases where uncontrolled disposal of the products is allowed, the exposure resulting from that pathway should be checked carefully. This is due to the fact that, at least in Germany, waste incineration and waste recycling become more and more important and therefore new pathways of potential exposure are created.

The second category includes those consumer products that contain the radioactive substances unintentionally through the raw material or added substances. At present, we have no detailed regulations for this category, in particular as related to radionuclides of natural origin. But we know that consumer products in this category contribute much more to the population dose than those of the first. For example, the large-scale survey of building materials described in Dr. Kolb's paper presented elsewhere in this book shows that the annual exposure in houses of Saarland built after 1900 is 20 mR higher than in those built before 1900, whereas, in nearly all other States, the exposure in new buildings is lower than in older buildings. This is caused by the fact that, since the beginning of this century, bricks made from furnace slag with a relatively high content of Ra-226 and Th-232 are produced in Saarland. As a result of the use of this special building material, the mean whole-body dose of the population of Saarland was increased by about 10 mrem/yr. We believe regulation of the radioactive content of building materials is needed and intend to prohibit the production and the import of building materials containing Ra-226 and Th-232 in a concentration exceeding 20 pCi/g. To provide the legal means for this decision, we have incorporated into our new atomic law the authority to prohibit the use of radioactive substances for certain purposes, where necessary to protect the population. We are not sure whether we need an additional system of notification or licensing for building materials with lower activity concentrations. For the time being, we will have a voluntary system of control for such materials with an occasional check on the radioactive content of building materials on the market. In addition, further large scale surveys of buildings are being considered.

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THE U.S. ENVIRONMENTAL PROTECTION AGENCY'S REVIEW PROCESS FOR ENVIRONMENTAL IMPACT STATEMENTS

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In the belief that factual communication between the Federal government and those affected by Federal government decisions is beneficial to both, this paper briefly outlines the review procedures and issues examined by the U.S. Environmental ProtectionAgency (EPA) in its review of environmental impact statements (EISs) concerning consumer products containing radioactive material. The goal is to indicate the procedures and issues considered by EPA during its review of an EIS on consumer products containing radioactive material, an important step toward the realization of the proposed action. To accomplish this goal, four questions need to be answered:

a. Why is EPA involved in these reviews?
b. What entity within EPA manages the reviews?
c. What issues are addressed by EPA?
d. What actions can EPA take following their review?

The review of EISs on consumer products containing radioactive material is one method used by EPA in fulfilling its mission of protecting the public health and environmental quality. Under the provisions of the National Environmental Policy Act of 1969 (Public Law 91-190), Federal agencies must file a written analysis of the environmental impact of any proposed major action, together with a discussion of any adverse environmental effects that cannot be avoided should the proposal be implemented. The impact statement must also discuss the alternatives for the proposed action, and any irreversible or irretrievable commitment of resources must be specified. In the preparation of these statements, the Federal agencies have been directed by Congress to consult with and to obtain relevant comments from other agencies having jurisdiction over or special expertise on the subject matter involved. EPA is required to comment on draft impact statements that fall within the agency's special expertise before the final statement is issued. And further, Section 309 of the Clean Air Act of 1970 (42 U.S. Sec. 1857-7) requires EPA to review and comment on the environmental impact of any major Federal agency action, including guidelines, regulations, and proposed legislation.

Within EPA, the Office of Radiation Programs (ORP) has the lead responsibility for reviewing EISs in which radiation impact is the main concern. To date, EPA has reviewed two consumer product EISs with both being managed by the ORP-Headquarters staff; this management practice is expected to continue.

Once a Federal agency has prepared an EIS, it is released in draft form to the public and appropriate Government agencies for comment. EPA receives the draft EIS in a section of the Administrator's office known as the Office of Federal Activities. Here the subject of the statement is noted and the statement referred to the proper program activity within the Agency.

Upon reaching the ORP, the draft EIS is assigned to a project officer who manages the review among selected EPA personnel. Initially, the EPA project officer determines the need for assistance from outside the radiation discipline, such as from EPA specialists in water pollution, and requests the necessary assistance. Similarly, ORP personnel with appropriate expertise are assigned to the review.

With the distribution of EISs completed, the technical review begins. A basic guide used to evaluate a statement is the Council on Environmental Quality (CEQ) guidelines for EIS preparation (40 CFR 1500). These consist, briefly, of several requirements: (1) to describe and state the purpose of the action and provide sufficient information to allow the assessment of potential environmental effects; (2) to discuss the land-use plans for the area; (3) to assess the probable impact of the proposed action on the environment; (4) to discuss alternatives to the planned action; (5) to list unavoidable adverse environmental effects; (6) to discuss the long-term versus the short-term uses of the environment; (7) to identify the irreversible and irretrievable commitments of resources; and (8) to review Federal policy needs supported by the action. Specific regulations (10 CFR § 51.23) require the inclusion of a cost-benefit analysis, also an important factor in EIS evaluation, in all EISs issued by the Nuclear Regulatory Commission.

Using these guidelines as a basis, the draft EIS is reviewed to determine if these areas are adequately addressed. With consumer products it is expected that areas 2, 6, 7, and 8 will generally not be of major consequence, and they will not be discussed here. The four areas that have received the most attention in the reviews thus far are: (1) the radiation dose to individuals and the general population, (2) the demonstrated need for the product, (3) the depth of the analysis of alternatives, and (4) the overall cost-benefit analysis.

Approximately three weeks after distribution of the draft EIS to EPA personnel, the project officer receives their comments, edits them, and assembles a comment package. On the basis of this package, the project officer recommends separate ratings for the adequacy of the information provided in the EIS and for the environmental impact of the action. Ratings used for indicating the adequacy of the EIS are Category 1 (satisfactory), Category 2 (insufficient information), or Category 3 (inadequate); similarly for the environmental impact, the ratings are lack of objections (LO), environmental reservations (ER), or, environmentally unsatisfactory (EU).

The comment package, following concurrence by the Deputy Assistant Administrator for Radiation Programs and the Assistant Administrator for Air and Waste Management, is returned to the Office of Federal Activities. Here it undergoes policy review and is then sent to the originating agency. If the review results in either a Category 3 or EU rating. the package is also sent to the CEQ for consideration. CEQ is the White House-level organization directly responsible to the President on environmental matters and is the final authority, short of the President, regarding environmental disputes between Federal agencies. Although it is not mandatory, a poor rating on a draft EIS will generally result in a meeting of EPA, CEQ, and the originating agency to discuss EPA's concerns and possible resolutions of them.

When the final statement is issued, the EPA review is the same as for the draft statement except that the purpose differs. The purpose in reviewing the final is to determine if the problems found in the draft have been substantially resolved. The final statement receives a single rating from 1 (no comment) to 5 (unresponsive).

Following the same procedure as the comments on the draft, the final comments, if any, and rating are issued to the originating agency and CEQ; any comments are also sent to the *Federal Register* for publication.

EPA has no power to force changes in an action; however, if serious problems do exist, the matter can be referred to CEQ by EPA for a decision on further action. If CEQ agrees with EPA's analysis, changes in the action or the final EIS will usually take place. The review process would then proceed as before. However, if CEQ decides against EPA's analysis, it marks the end of EPA's involvement in the EIS review process.

Both consumer product EIS's being reviewed by EPA are presently at the stage in their development of having been issued and reviewed in draft form with the final EIS yet to be issued. A summary of their reviews shows two contrasting examples and should yield insight into EPA's evaluation process.

The reviews generally revolve around EPA's position that any unjustified radiation exposure should be avoided; therefore, there must be a clearly defined and demonstrable need for the product and the product must have distinct advantages over nonradioactive alternatives. Further, safeguards must ensure that discharges of radioactive material and radiation exposure of the public are kept as low as reasonably achieveable. Regarding the analysis of costs and benefits, it is known that some factors defy monetary quantification, such as radiation exposure, and yet could be the key to a decision on the action. In the field of consumer products where unquantifiable factors can vary greatly from product to product, each product must be assessed in relation to its own circumstances. Therefore, EPA necessarily addresses cost-benefit analyses on a case-by-case basis.

The two consumer product EIS's that EPA is currently reviewing provide good examples of this case-by-case approach. Both were issued as the result of petitions from companies seeking exemptions from licensing requirements. One deals with personnel neutron dosimeters containing thorium. The other concerns spark-gap irradiators that utilize cobalt-60.

The thorium neutron dosimeter is a device that will be used as a personnel dosimeter for fast neutron dosimetry purposes. It consists, basically, of a thorium foil, a polycarbonate foil used for recording the passage of fission fragments from the thorium, and a case in which the foils are enclosed.

The rating given the draft EIS on thorium dosimeters (NRC, 1976) was LO-2. The LO indicates EPA's opinion that there will be no major adverse environmental impact; however, this was partly based on information and/or analysis by EPA and not presented in the EIS. Therefore, a Category 2 rating, a request for additional information to add to EPA's information base and confirm the estimated environmental impact, was assigned. In the review it was seen that the dose to individuals and populations were quite low; only in two very conservative cases during distribution and disposal did the maximum individual dose exceed 1 mrem/year. In this case the doses presented did not, in EPA's opinion, represent a cause for concern. In following the linear dose-effect theory, EPA believes that any radiation exposure is potentially harmful; however, there is the realization that benefits may exist that justify the exposure. By comparing the thorium dosimeter with the present and predominant neutron dosimetry, nuclear track film, it was shown that the new product was an improvement over the film. The depth of the analysis of alternatives was sufficient to show that the proposed dosimeter was the optimum alternative at this time. The overall costbenefit analysis of this action emplasizes the point made earlier about unquantifiable factors. The benefits to be realized over the present system are all unquantifiable factors, i.e., better accuracy and greater reliability and sensitivity. The costs of the dosimeter include the unquantifiable radiation exposure of people and the higher price of the dosimeter compared to the film. Overall, the unquantifiable benefits were judged to be sufficient to justify the costs, monetary and non-monetary, and EPA expressed no objection to the action.

The draft EIS on Co-60 spark-gap irradiators (NRC, 1975) presents a contrasting case. The spare-gap irradiator is a circular, oil-tempered, spring-steel clip with a flattened end onto which one microcurie of cobalt-60 has been electrodeposited. The radiation ionizes the air between the ignition electrodes in commercial-sized oil burners to aid in the ignition of the fuel.

The draft statement on the irradiator received a Catetory 3 rating, which indicates that sufficient information to allow a determination of the environmental impact was not presented. The major deficiencies cited by the EPA comments were the lack of a population dose analysis, insufficient analysis of alternatives, and a lack of data to support the benefits claimed.

The inclusion of individual and population dose analyses is essential. EPA believes the exclusion of one or both is totally unacceptable. The analyses should include accident scenarios as well as the normal scenario.

The alternatives analysis was believed by EPA to be too shallow to adequately demonstrate that this device was the optimum device available to relieve the problem for which it was designed. In ruling out an alternative, a one-sentence explanation is rarely adequate to dismiss that alternative. Explanations incorporating sufficient documentation and detail are essential to allow a proper evaluation of the plausibility of alternatives.

The final major problem listed by EPA was the lack of data supporting the benefits claimed. There is apparently a need for such a product since such a device seems to have the capability of reducing financial costs incurred by the public. However, there were insufficient data presented to substantiate the claims of benefits. Despite the fact that the device had been is use, under license, for 10 years, there was apparently no written record kept of its effect on the performance of the products in which it was used. In addition, the petitioner estimated that only 1% of the products that used the device would benefit. Therefore, 99% of the irradiators would accrue costs while yielding no benefits. While the costs, here mainly the radiation exposures, were not large on an absolute scale, one must carefully assess the situation and decide whether the benefits accrued by the 1% justify the costs incurred by all 100%.

In EPA's opinion, that situation was on the borderline between acceptable and unacceptable. It was felt that hard data were necessary to provide a more solid basis, where only estimates of benefits had been given in the draft EIS, to show that the exposures were justified. It was known that the draft EIS did not present such data and therefore the Category 3 rating was given. A meeting of the U.S. Nuclear Regulatory Commission, EPA, and the CEQ took place where EPA's concerns were discussed. EPA is now awaiting issuance of the final EIS to determine if our concerns have been addressed.

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HISTORICAL OVERVIEW OF RADIATION EXPOSURE GUIDANCE ON RADIOACTIVE CONSUMER PRODUCTS

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With the recent arrival of home smoke detectors, products containing radioactive materials have again become popular consumer items. During the past two generations other products such as radioluminous watches, clocks, compasses, lightswitch markers, and thermostat dials have been brought into homes and have exposed members of the general pulbic to radiation. These kinds of items can be distinguished as radioactive consumer products; however, there is not a specific radiation exposure guide addressed expressly to the consumer. Absence of such a guide may be partly explained by previous treatment of the many-faceted nature of the consumer as a single entity.

During the past decade several commissions, committees, and agencies have advocated various numerical exposure guides or limits in the interest of restricting the radiation dose to members of the population at large. Some of these groups are the International Commission of Radiological Protection, International Atomic Energy Agency, Federal Radiation Council (U.S.), Nuclear Energy Agency (formerly the European Nuclear Energy Agency), National Council on Radiation Protection and Measurements (U.S.), Food and Drug Administration (U.S.), Conference of Radiation Control Program Directors (U.S.), and the U.S. Nuclear Regulatory Commission.

Recommendations of the International Commission on Radiological Protection (ICRP, 1958) specified four basic categories of radiation exposure. These categories are called occupational, special groups, population-at-large, and medical. The population-at-large category is the exposure group of interest and is numerically the largest category. It is noteworthy that in 1958 ICRP associated the use of such well-known consumer products as wristwatches and television receivers to the population-at-large category.

As guidance, the ICRP suggested 2 rems (with a long-term reserve of 1.5 rems for possible eventualities) over a 30-year interval as the maxium genetic dose for the population at large. Hence, the dose limit for a member of this group could be as small as 67 mrem annually. Of course, the ICRP indicated that this dose is in addition to annual contributions received from medical or occupational exposure to radiation. In addition to genetic dose limits the ICRP also discussed aspects of somatic, internal, external, single organ, and whole-body dose implications and described controlled and non-controlled areas. There are important distinctions in the definitions of these terms, particularly genetic dose and wholebody dose. However, explanation of these distinctions is outside the scope of this overview.

For the purpose of this presentation, consumers of radioactive products should be assigned to the population-at-large category. Also, one may casually relate genetic dose with whole-body dose in order to simplify the above terminology as some whole-body doses may be genetic. The term "whole body" includes the gonads as well as head and trunk, active bloodforming organs, and lens of the eyes. One can further simplify matters by only relating external radiation aspects to consumer products. Ordinarily products deemed acceptable or approved for ingestion or inhalation are considered medical items. With these qualifications in mind, let us proceed to examine other suggestions that may be related to exposure of the consumer during the use of radioactive products.

The Federal Radiation Council (FRC, 1960) published their Report No. 1 on radiation protection standards. This report has a category expressly for the general population. The FRC basic recommendation that the wholebody dose to members of the general population, excluding medical, should be far below 0.5 rem per year agrees with ICRP. However, FRC proceeds one step further toward refining the average population dose concept. The FRC assumed that most individuals of a population do not differ biologically from the average individual by more than a factor of three and recommended that 170 millirem per year be the upper limit for the whole-body exposure to members of average population groups. The FRC cautions that the average dose concept be judiciously applied; for example, averaging the dose between children and adults is not appropriate.

The International Atomic Energy Agency (IAEA, 1962) formulated "Basic Safety Standards for Radiation Protection" for its member States as a framework for promoting national regulations or recommendations. The IAEA protection standards treated the use of natural and artifically produced radioactive substances, including processing, handling, storage, transport, and disposal. Although the primary concern of the IAEA limits if directed toward protecting the radiation worker, a maximum dose of 0.5 rem per year for the whole body was specified for the category called "Individual Members of the Public."

The IAEA (1967) recommended "Radiation Protection Standards for Radioluminous Timepieces" for international application. The IAEA standard restricted the amounts of hydrogen-3, promethium-147, and radium-226 that could be applied to the hands and dials of ordinary and special timepieces. Marking of special timepieces, those worn to produce greater luminosity necessary for particular purposes, was required to indicate the kind and amount of radioactivity on the product. The standard recommended the perference of hydrogen or promethium rather than radium and that radium was not to be used for pocket watchers.

The European Nuclear Energy Agency, (ENEA, 1970) published a guide entitled "Basic Approach for Safety Analysis and Control of Products Containing Radionuclides and Available to the General Public," The ENEA is currently called the Nuclear Energy Agency (NEA), and this report is sometimes known as the "NEA Green Guide." The NEA recognized that even though a single radioactive exempt product by itself represents a very small radiation dose to the general population, the distribution of these kinds of products irreversibly commits the population to radiation exposure. The NEA postulates that radioactive consumer products are manufactured under control of the national authority and that their distribution, use, and disposal should be controlled similarly. The NEA expert group also suggested several control procedures such as surveillance, tests, instructions, and product identification. Most significantly, the NEA expert group recommended an order of benefit approach based on risk-benefit considerations of the product and allocated a range of doses depending on the particular order of benefit associated with the radioactive product. The NEA basic approach is given in Table 1.

The National Council on Radiation Protection and Measurements (NCRP, 1971) recommends dose limits for members of the public, occasionally exposed individuals, students, and other groups identified. Students in this case are regarded as individuals undergoing education or training who are less than 18 years of age. The NCRP states that students should be limited to a maximum dose of 100 mrems in any one year. Occasionally exposed individuals, as regarded by NCRP, are persons who perform occasional work with radiation or periodically enter controlled areas. Visitors, service men, and delivery men are examples of occasionally exposed individuals. The NCRP recommends that members of the public and occasionally exposed individuals should be limited to a maximum dose of 500 mrems in any one year.

The National Academy of Sciences (NAS, 1972) prepared a report on the biological effects of ionizing radiation, commonly referred to as the "BEIR" Report. The BEIR Report states that there should be a maximum limit for man-made sources of non-medical radiation exposure to individuals of the general population, so that risk of serious somatic effects is reduced to a very small value relative to those risks that are accepted as a matter of routine. Again, there is agreement with the other advisory groups in that the radiation dose to the whole body of members of the general population should not exceed 0.5 rem per year. This advice excludes natural background and deliberate healing arts radiations. The BEIR Report also expresses concern that the annual whole-body dose for average population groups should not exceed 170 mrems. The BEIR Report recommends the formulation of an additional limit that considers the (mathematical) product of the radiation dose magnitude received by individuals and the number of individuals so exposed. For expressing this product the term person-rem is introduced.

All U.S. States can regulate the use of naturally occurring and accelerator-produced radioactive materials (NARM). The States can also regulate certain uses of byproduct, source, and special nuclear material via a formal agreement with the U.S. Nuclear Regulatory Commission (NRC). Currently, 25 States operate agreement programs. The Suggested State Regulations for the Control of Radiation (SSRCR) is a set of model regulations that have been distributed to assist the States in developing uniform radiation control regulations. The edition of the SSRCR printed by the U.S. Department of Health, Education, and Welfare (DHEW, 1974) contains suggested regulations for licensing the possession, use, manufacture, distribution, storage, and disposal of radioactive materials and registration of radiation machines, and specifies general standards for radiation protection. By implementing these model regulations, the regulations of the States remain compatible with Federal regulations. The SSRCR states that the permissible dose from external sources of radiation in unrestricted areas shall not be in excess of 2 mrems in any one hour for continuous exposure, 100 mrems while being exposed for 7 consecutive days, or 500 mrems during an exposure interval of any one year. The maximum of 500 mrems in any one year is consistent with the whole body dose permitted for a member of the general public by the groups previously cited.

TABLE 1

Basic Approach For Safety Analysis and Control Of Products Containing Radionuclides and Available to the General Public

Dose Apportionment for Exempt Products
Based on Risk/Benefit Considerations[1]

Order of Benefit	Individual[2] Dose	Population[3] Dose
Outstanding benefit (such as life-saving devices)	<0.1 ICRP dose limits	$<10^{-4}$ ICRP dose limits
Safety and security devices Improve reliability or dependability of technical devices Special technical devices	<0.01 ICRP dose limits[4]	$<10^{-4}$ ICRP dose limits[4]
Lower order of benefit	<0.001 ICRP dose limits[4]	$<10^{-5}$ ICPR dose limits[4]

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[1] The dose limits established in this chart were not derived from precise technical information. The figures have been estimated on the basis of normal use of the product. This table should be regarded as provisional only and is likely to undergo changes depending on developments in the nuclear industry and on social and economic needs.

[2] Refers to a single article.

[3] Refers to the total distribution of the article under consideration.

[4] It is recommended that the total exposure from all exempt products (except for those with outstanding benefit) should not exceed 10% of the dose limit recommended by ICRP for individual members of the public and 1% of the population dose limit. The ICRP whole-body limit for the individual dose is given as 0.5 rem in a year.

The Bureau of Radiological Health (BRH) recently evaluated a piece of jewelry incorporating uranium ore which produced a beta dose rate of 12 mrems per hour at contact. Measurements were performed on the sample using a lithium drifted germanium gamma detector, multichannel analyzer, and uranium oxide standard. Mass equivalents of natural uranium, uranium oxide, and radium-226 in the sample were determined from the gamma spectrum. Beta emission rates from the sample were determined using a gas flow proportional counter. In the instance of wearing the jewelry the radiation dose to an individual would come primarily from the beta emission. Wearing this particular jewelry is analogous to creating a radiation level in an unrestricted area which is six times in excess of the level permitted by the SSRCE. The recommendation in the BRH evaluation stated that although the dose to a person wearing the jewelry is nominal, the risk from wearing such an item is a dubious benefit; therefore, unregulated distribution of such objects should not be permitted.

The Conference of Radiation Control Program Directors (CRCPD) is an organization of the State Radiation Control Directors. The CRCPD maintains committees that periodically review various aspects of radiation control. In 1975, the CRCPD established a task force to develop uniform national guidelines for evaluating NARM sources and products. The CRCPD task force developed a set of NARM guides which present a basis for attaining uniformity in the evaluation and distribution of NARM products. The BRH published a report on the NARM Guides (DHEW, 1977). The part of the SSRCR on radioactive material licensing is essential to the application of the NARM Guides. These Guides classify NARM products into 12 categories and provide information on each evaluation item regarding manufacturer identification and model number, results of radiation measurements, labeling of name and amount of radioactive material, and licensing recommendation for product control. The NARM Guide categories are given in Table 2.

TABLE 2

NARM GUIDE CATEGORIES

1. Calibration and Reference Sources Containing Radium-226 for Distribution To Persons Generally Licensed Pursuant C.22(g), SSRCR

2. Sealed Sources

3. Gas and Aerosol Detectors For Distribution To Persons Exempt From Regulation Pursuant To C.4(c)(3), SSRCR

4. Measuring, Gauging, or Controlling Devices.

TABLE 2

NARM GUIDE CATEGORIES (CONT.)

5. Radioactive Material For Distribution To Persons Exempt From Regulation Pursuant To C.4(b), SSRCR
6. Static Elimination and Ion Generating Devices
7. Radioluminous Products.
8. Electronic and Electrical Devices
9. Leak Test Kits and Services
10. Medical Sources
11. Radiopharmaceuticals
12. *In Vitro* Test Kits

The NRC (1977) continues to delineate in their standards for protection against radiation permissible radiation doses for minors as well as adults. The NRC standard states that any individual less than 18 years of age is a minor and while in a restricted area can not be permitted to receive more than 125 mrems in a calendar quarter, 13 weeks. Also, there is a high degree of compatibility between NRC and SSRCR regulations, regarding the matter of time interval for receipt of the radiation dose, since some parts of the SSRCR were patterned after the U.S. Atomic Energy Commission (AEC) regulations.

The NRC has specified several restraints over the years for various radioactive products that are exempt from certain regulatory requirements. Examples of some of these products are incandescent gas mantles, vacuum tubes, welding rods, glazed ceramic tableware, counterweights with uranium, optical lenses with thorium, timepieces, lock illuminators, compasses, thermostat dials, and gas and aerosol detectors.

NRC requirements appear unique by applying both radioactive quantity and radiation emission rate limits to some consumer products in order to protect the user. An example of this kind of limit is the requirement that as much as 60 microcuries of promethium-147 can be affixed to a watch dial provided the radiation level does not exceed 0.1 millirad per hour at a distance of 10 centimeters from any surface on the wristwatch. A manufacturer who distributes exempt quantities of byproduct radioactive material is required by the NRC to label the product. In addition to labeling on the container, the container or accompanying brochure for an exempt quantity is required to bear the words "Radioactive Material–Not for Human Use–Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or Into Products Manufactured for Commercial Distribution is Prohibited–Exempt Quantites Should Not be Combined."

The figures of 500, 170, and 67 mrems per year have been presented as prospective maximum permissible whole body annual dose limits for consumers. Comparing the 67 and 500 mrems as extremes of the overall range, the extremes agree within an order of magnitude. Although the 500 mrems remains firmly established as the annual whole-body dose limit, the annual exposure to the consumer should be kept far below the 500 mrems limit as recommended by the FRC.

Therefore, it is apparent that the basic dose guidance for a member of the public regarding external whole-body radiation has been proceeding in a discreet manner during the past decade. During this period the guidance has been extended in several instances to apply directly to the radioactive product.

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RADIUM IN CONSUMER PRODUCTS: AN HISTORICAL PERSPECTIVE

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An overall view of radium or any radioactive material in consumer products would be incomplete and erroneous unless it is viewed in the perspective of history. The most important elements of this perspective are the changing views of the general public toward radium, the communications that generally formed these views, and the scientific knowledge that was available at the time.

During the period from the first discoveries of the Curies until sometime in the 1930s, radium was considered almost magical. In this early period, the public believed that cures for cancer and other ills were possible with radium, and that many new scientific discoveries were imminent.

But from the 1930s until the beginnings of the Nuclear Age in the 1940s, the public view began to change as reports of many previously unknown hazards began to be recognized—or more importantly—to be publicized. Such exciting prospects as unlimited low-cost power and innovations in medicine and science through radium were soon replaced by a growing feeling that *anything* radioactive was in some way associated with the awesome effects of the atomic bomb. It is therefore within this capsule of history and changing public opinion that the long and complex story of radium in consumer products can best be understood.

In briefly reviewing the various products, or attempts to produce products with radium, the phenomenon of radioluminosity is the most important. The actual starting clues to the discovery of radioactivity began with the observations of Becquerel of various light-producing minerals. Then, soon after the first production of radium by the Curies, experimenters in Europe and the United States began trials of the activation of phosphors by radium. One of the first methods of counting alpha particles was to count the flashes from zinc sulphide screens. The classic thesis of Marie Curie (1961) contains a section in which she thoroughly investigated these luminous effects.

It was obvious, therefore, that the first major use of radium would be in luminescence. And, from 1910 to 1914, luminous compounds began to be available in Germany, France, and the United States. These were used first in watch, clock, and later, aircraft instrument dials.

At this point, it might be well to digress a bit and recount the history of radium production in the United States. Time is not available to tell the complete story, which can be found in old publications (e.g., *The Story of Pittsburgh*, 1921). But, basically, it began when J.M. Flannery, the developer of the vanadium industry in the United States, determined to produce radium from low-grade uranium ores in Colorado after the Austrian government imposed a monopoly control over the Joachimstal mines, the Curies' source of radium. The ores were obtained in the Colorado Rockies by primitive mining methods, then transported by mules and wagons to the nearest rail line for shipment to Canonsburg, Pennsylvania, where the initial refinery was located. After basic refining, the final purification was accomplished in the laboratories in Pittsburgh.

From 1913 to 1920, approximately 70 grams of radium were produced and sold at an average price of $120 per milligram. It is interesting to note that, in 1920, 18.5 grams were produced; of this, 1.2 grams were used to make luminous compounds.

In the perspective of history, it should be noted that luminous dials were vital for early aircraft, which did not possess electrical systems. The only choice for night flying was between a flashlight held by the pilot (who needed two hands to fly the plane) or luminous instruments. Another necessary use was the luminous alarm clock. In the 1920s, when many American homes were still without electric lights, a luminous clock was more than a convenience!

The early luminous compounds contained a much higher ratio of radium than the currently available types, which use more efficient phosphors. It was not unusual for the early "government specification" grades to contain 100 micrograms of radium per gram of phosphor, and for a watch or aircraft dial to have an activity in excess of 1 microcurie.

Other devices produced in the 1920s found wide consumer use, too. Principally, a small luminous pendant for attachment to the pull chains of electric lights, as wall switches were still not in general use. Another popular device was a luminous ring for attachment to the knob of a chamber pot cover. The people who study the risk and benefit aspects of radioactivity today might have an interesting time evaluating the risk versus benefit here!

Religious pictures, statues, and small shrines treated with luminous paints were produced in quantity by small shops for local markets, and may still be sold in a few places in the world.

One unusual consumer product, produced in mass in the 1920s and 1930s, is now an antique collector's item—not for its radioactive content, but for its art-deco beauty. It is the famous California orange fiesta dinnerware. And while the product used uranium oxide to achieve the bright ceramic orange color, it was an outcome of radium refining. For in that period, radium was the desired extraction element and the parent uranium was discarded as having virtually no commercial value. Today, this would be considered an impossible use of a radioactive substance. But in the perspective of history, millions of sets of this dinnerware, with a uranium content averaging 20,000 dpm of alpha activity were made, sold, and used.

The luminous telephone dial is a prime example of a device that is reinvented at least once a year, always with the fond expectation of the inventor that he has hit upon a million dollar idea. Luminous fishing lures have been tried for many years with varied claims for their effectiveness.

Luminous tapes, dots, and buttons have had limited consumer uses as step locators in theatres and other public buildings. But they have had a major military use as mine field locators or vehicle markers or in such areas as naval vessel gangways where light under blackout conditions is desired.

A few novelties that have had sales in the hundreds of thousands have been produced. One is the famous Buck Rogers Mystery Ring of the 1950s, in which scintillations of a small bit of zinc sulphide activated with polonium could be observed. This is considered to be one of the most successful cereal box top premiums ever offered.

Other consumer uses of radium tried or used in the past that do not depend on luminous effects fall into several categories. Some are still considered valid; others, in our present perspective, are labeled medical quackery. First, for the medical types. In the 1920s, it must be remembered, even the most respected medical authorities believed that the remarkable properties of radium had many more uses than in cancer therapy. There were serious proposals that the government should establish radium hospitals under the Public Health Service for treatment and research in arthritis and a host of other diseases. The serious approach to the mysteries of radium was, of course, soon invaded by the quacks and promoters who produced radium water and radium emanators. These they sold by using all the techniques of the medicine show and snake oil people. The deviation is not unusual, as nearly every novel medical discovery has had parallel promotional problems.

The valid uses largely depend on ionization, either in electronics or for removal of static charges. Except for the antistatic devices, which ordinarily use polonium rather than radium because of cost, the electronic uses are probably too specialized to be labeled consumer uses. One exception might be the lightning rod that contains radium (another interesting risk versus benefit analysis).

The primary objective of this discourse was not to catalog or to date the development of each use or device, but to try and place the developments and uses in an historical perspective that may often be overlooked when consumer uses of radium or other radioactive materials are discussed or studied.

Radium is now considered taboo for consumer items. But again, in recent perspective, it was only 25 years ago that strontium-90 was proposed by some as the ideal activator for luminous paints. And, presently, Pm-147 is being widely proposed, with virtually no large-scale industrial experience, and some problems such as happened with radium 50 years ago could conceivably develop.

One other point should be kept in perspective, and that is the relative efficiencies of radium as compared to radium substitutes in the activation of luminous compounds. A luminous clock that is acceptable to the consumer can be produced with approximately 0.5 microcurie of radium, or somewhat less, depending on the design of the dial and hands.

If tritium is used, the present regulations allow the use in a single timepiece of 25 millicuries of tritium, although most clocks are produced using less than half this quantity. The allowable limit for promethium-147 is 200 microcuries.

In considering all factors, the ease of detectability of radium should be recognized in comparison to the difficulty of detection of tritium. The effects of radium on people in the luminous industry have been studied extensively by the Institute of Human Radiobiology at Argonne, whereas no comparable studies of tritium have been made. And, for promethium-147, not only have there been no studies, but there is no effective bioassay method.

Again, for an interesting note concerning radium, if it were not for the discovery of radium and the subsequent discovery of neutrons with the use of a radium-beryllium source, there would not be a nuclear age.

For a brief summary, an attempt has been made to show in historical and technical perspective how radium began to be used in consumer products and how changing conditions in technology and regulations have greatly modified the use of radium. In addition, the various uses of radium that have been tried or have been used in consumer products have been described, and wherever possible, the historical perspective has been used to show when devices were needed and when changing conditions caused the products to be no longer required. The final portion is an attempt to bring the historical perspective attitude into use in the evaluation of the risks and benefits of radium in comparison to radium substitutes.

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EXCERPTS FROM

GUIDES for NATURALLY OCCURRING and ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS (NARM)

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NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

INTRODUCTORY NARM GUIDE

A. Scope

NARM Guides provide uniform criteria for the evaluation of sources and products that incorporate naturally occurring or accelerator-produced radioactive materials (NARM). As used herein, NARM does not include byproduct, source, or special nuclear material. This Guide is a general introduction to NARM Guides 1 - 12 and presents background information and instructions on their use. NARM Guides 1 - 12 provide evaluative criteria for the following categories of sources and products:

GUIDE NO.	GUIDE TITLE
1.	Calibration and Reference Sources Containing Radium-226 for Distribution to Persons Generally Licensed Pursant to C.22(g), (SSRCR)*
2.	Sealed Sources
3.	Gas and Aerosol Detectors for Distribution to Persons Exempt from Regulation Pursuant to C.4(c) (3), SSRCR
4.	Measuring, Gauging, or Controlling Devices
5.	Radioactive Material for Distribution to Persons Exempt from Regulation Pursuant to C.4(b), SSRCR
6.	Static Elimination and Ion Generating Devices
7.	Radioluminous Products
8.	Electronic and Electrical Devices
9.	Leak Test Kits and Services
10.	Medical Sources
11.	Radiopharmaceuticals
12.	*In Vitro* Test Kits.

B. History

The manufacture, distribution, and use of NARM sources and devices are not covered by the Atomic Energy Act of 1954, as amended, and therefore are not regulated by the U. S. Nuclear Regulatory Commission. Rather, the regulation of NARM has been left to the discretion of each State. As such, the degree of regulation for NARM varies from State to State. To promote national uniformity, the Conference of Radiation Control Program Directors, Inc. in 1975 established a Task Force to develop uniform guidance for the evaluation of NARM sources and products. The Bureau of Radiological Health/FDA (BRH) funded Task Force activities. In support, the Bureau

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*Suggested State Regulations for Control of Radiation

of Radiological Health, the Nuclear Regulatory Commission, and the Environmental Protection Agency participated in the deliberations of the Task Force.

C. Purpose

The NARM Guides are the basis of a program aimed at attaining unformity in the evaluation and distribution of NARM sources and products through the cooperative efforts of the States and the Federal agencies. These guides provide for the uniform classification and evaluation of NARM sources and products by radiation control agencies and are intended to be used in conjunction with the Radioactive Materials Reference Manual (RMRM) and the Suggested State Regulations for Control of Radiation
(SSRCR).

D. Regulatory Process

Uniform application of the NARM Guides by radiation control agencies will promote radiological safety in the design and construction of NARM sources and products. Each NARM source or product intended for distribution in the United States shall be evaluated according to the appropriate NARM Guide prior to routine distribution.

A Licensing State should determine that each NARM source or product has been evaluated in accordance with the NARM Guides prior to licensing its possession and use. The issuance of a RMRM evaluation sheet is evidence that such an evaluation has been performed. The manufacture, assembly or distribution of NARM sources and products shall be licensed in Licensing States. In other States the appropriate authority shall issue a letter of authorization (or other document) for the manufacture, assembly, or distribution of a NARM source or product. The letter of authority shall set forth appropriate operating conditions which establish that the manufacture, assembly, or distribution of the NARM source or product will be performed in accordance with applicable provisions of the SSRCR and the relevant NARM Guide.

Prior to the issuance of the letter of authorization (or other document) the State shall assure, either by regulations or written agreements between the State and the manufacturer, assembler, or distributor that:

1. the State has the right to inspect the facilities, quality assurance and records of the manufacture, assembly, or distribution of the NARM source or product:
2. the manufacturer, assembler or distributor shall comply with the applicable requirements of the SSRCR; and
3. the manufacturer, assembler, or distributor shall meet the applicable provisions of the relevant NARM Guide.

E. Evaluation Process

The evaluation of NARM sources and products may be accomplished as follows:

1. State only - A State may, at its discretion, identify, evaluate, and prepare RMRM evaluation sheets on any NARM source or product whose place of manufacture, assembly, or distribution is located within that State's jurisdiction.
2. State with BRH assistance - A state may, at its discretion, request assistance from BRH for a cooperative evaluation (including preparation of RMRM evaluation sheet) of a NARM source or product whose place of manufacture, assembly, or distribution is located within that State's jurisdiction. This request shall be in writing.

3. BRH at the request of a State - A State may, at its discretion, request BRH to perform an evaluation (including preparation of RMRM evaluation sheet) of a NARM source or product whose place of manufacture, assembly, or distribution is located within that State's jurisdiction. This request shall be in writing.

The evaluating agency shall require the manufacturer, assembler, or distributor to submit in writing all information specified by the appropriate NARM Guide. In the event that a product or device contains a source which has previously been evaluated and included in the RMRM, no further evaluation of the source need be made provided the proposed source use is specific to that of the previously evaluated source.

A State shall not issue an RMRM evaluation sheet on a NARM source or product that is not acceptable for routine distribution under the suggested level of regulatory control.

A State shall not issue an RMRM evaluation sheet on a NARM source or product being manufactured in, assembled in, or distributed from another State.

F. Instructions for Completing and Submitting RMRM Sheets

The RMRM contains three types of sheets:

1. Evaluation (white sheets) - Indicates that an evaluation of the source or product has been made and recommends the suggested level of routine regulatory control to be applied to it, i.e., specific license, general license, or exemption. A suggested format for an evaluation sheet is shown in Appendix A.

2. Product Identification (green sheets) - Declares the existence of a NARM source or product for which an evaluation sheet does not exist. The radiation control agency noting the existence of the unevaluated NARM source or product shall issue a Product Identification sheet on it. If possible the State identifying the NARM source or product should notify the State of jurisdiction. A suggested format for a Product Identification sheet is shown in Appendix B.

3. Advisory Notice (pink sheets) - Advises of NARM source or product defects, misuses, or problems. The radiation control agency noting the defect, misuse, or problem shall issue an Advisory Notice sheet on it and notify the State of jurisdiction. A suggested format for an Advisory Notice sheet is shown in Appendix C.

Advisory Notices, Evaluations, and Product Identifications pertaining to NARM sources and products for distribution via the RMRM shall be sent to:

Director, Division of Radioactive Materials
and Nuclear Medicine (HFX 300)
Bureau of Radiological Health/FDA
5600 Fishers Lane
Rockville, Maryland 20857
Attention: Assistant Chief for Radioactive Products

BRH will duplicate and forward copies of each RMRM sheet to all States.

G. List of States by Degree of NARM Regulation

Basically there are three kinds of radiation control programs for NARM and other radioactive materials operated by the States. These are:

1. Agreement State - Licenses byproduct, source, and special nuclear material (agreement materials).
2. Licensing State - Licenses NARM.
3. Registration State - Registers NARM.

Licensing States

Alabama*
Arizona*
Arkansas*
California*
Colorado*
Florida*
Georgia*
Idaho*
Illinois
Kansas*
Kentucky*
Louisiana*
Maryland*
Michigan
Mississippi*
Nebraska*
Nevada*
New Hampshire*
New Jersey
New Mexico*
New York*
North Carolina*
North Dakota*
Oregon*
Pennsylvania
South Carolina*
Tennessee*
Texas*
Virginia
Washington*

*Also an Agreement State

Registration States

Alaska
Connecticut
Hawaii
Indiana
Maine
Massachusetts
Minnesota
Missouri
Ohio
Oklahoma
South Dakota
Utah
Vermont
West Virginia
Wisconsin
Wyoming

Other States

Delaware
  (issues permit)
District of Columbia
  (registers radium)
Iowa
  (no program)
Montana
  (registers radium)
Puerto Rico
  (no program)
Rhode Island
  (no program)
Virgin Islands
  (no program)

H. Availability of Documents Referenced in Guides

1. American National Standards Institute (ANSI) publications are available from:

   American National Standards Institute
   1430 Broadway
   New York, New York 10018

2. "NARM Guides" are available from:

   Director, Division of Radioactive Materials
   and Nuclear Medicine (HFX-300)
   Bureau of Radiological Health/FDA
   5600 Fishers Lane
   Rockville, Maryland 20857
   Attention: Assistant Chief for Radioactive Products

3. National Council on Radiation Protection and Measurements (NCRP) reports are available from:

   NCRP Publications
   P. O. Box 30175
   Washington, D. C. 20014

4. "Suggested State Regulations for Control of Radiation" (SSRCR) are available from:

   Bureau of Radiological Health (HFX-25)
   Food and Drug Administration
   5600 Fishers Lane
   Rockville, Maryland 20857

I. Mechanism for Effecting Changes to Guides

Comments and recommendations regarding changes to these Guides should be sent to the Chairman, Conference of Radiation Control Program Directors via:

Director, Division of Radioactive Materials
and Nuclear Medicine (HFX-300)
Bureau of Radiological Health/FDA
5600 Fishers Lane
Rockville, Maryland 20857
Attention: Assistant Chief for Radioactive Products

APPENDIX A

Evaluation Sheet

(present information on following items)

Manufacturer	Distributor
(name and address)	(name and address)
Radioactive Material	Activity
(name and mass number)	(Curie sub-units)

Model Number

Use

Source/Device Description

physical appearance
describe construction
give results of prototype testing

Radiation Measurements

Quality Control

Include ANSI Classification as applicable

Labeling and Instructions

Licensing Recommendations

Evaluation by

(name and address of agency)

Note: See RMRM for sample

APPENDIX B

Product Identification Sheet

(present information on the following items)

Manufacturer	**Distributor**	
(name and address)	(name and address)	
Radioactive Material	**Activity**	**Model No.**
(name and mass number)	(Curie sub-units)	

Use

Agency Making Identification

(name and address)

Note: See RMRM for sample.

APPENDIX C

Advisory Notice Sheet

TO: All Radiation Control Agencies

FROM: State of ______________________________

(Division of Radiological Health)

SUBJ: Product ____ Model ____ containing (name and mass number of NARM)

Give name and address of manufacturer, assembler, or distributor whose product or source has an actual or potential problem or defect.

State the problem, defect or misuse regarding the product, e.g.

radiation level
user instructions
wipe test results
malfunction
product labeling or mislabeling
packaging aspects

Specify the action to be taken on the problem to limit or correct any immediate or potential radiological hazard.

Note: See RMRM for sample.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

NARM GUIDE 1

CALIBRATION AND REFERENCE SOURCES CONTAINING RADIUM- 226 FOR DISTRIBUTION TO PERSONS GENERALLY LICENSED PURSUANT TO C.22(g) SSRCR*

A. Scope

This Guide provides criteria for the evaluation of calibration and reference sources containing radium-226 for distribution to persons generally licensed pursuant to C.22(g) of the SSRCR. The sources subject to this guide are designed for use as radiation sources per se and not as a component within a device. These sources may be sealed sources or plated alpha sources.

B. Definitions

1. Capsule - Protective envelope used for prevention of leakage of the radioactive material.
2. Device - Any piece of equipment designed to utilize sealed source(s).
3. Plated alpha source - A source which has radioactive material plated, deposited or otherwise bonded to a rigid backing in such a manner as to prevent leakage or escape material (Ra-226).
4. Sealed source - Radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.
5. Source holder - Mechanical support for the source.

C. General Criteria

The manufacturer, assembler, or distributor shall submit sufficient information regarding each type or model of source for the evaluation of the source. Such information shall include:

1. Identification

Identify the source by model number or other specific model designation.

2. Proposed Use

Describe the proposed use and type(s) of radiation emitted from the source. Define or identify the environments and operating conditions expected during normal use. Indicate the expected useful life of the source.

3. Radioactive Material

Identify the radioactive material, maximum activity per source, chemical and physical form of the radioactive material, and the details of the method of incorporation and binding of the radioactive material in the source.

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*Suggested State Regulations for Control of Radiation

4. Construction

Submit engineering drawings of the source, identifying all materials of construction, dimensions and methods of sealing the source, if any. Submit drawings of the source holder, if any, identifying materials of construction, dimensions and methods for mounting the source in the holder.

5. ANSI Classification

State the American National Standards Institute (ANSI) classification designation for the source.

6. Labeling

Submit facsimiles of labeling or marking to be placed on each source and copies of instructions for use that will accompany the source.

7. Additional Information

Submit any additional information, including experimental studies and tests which will facilitate a determination of the safety of the source.

D. Maximum Quantity

Each source shall contain a quantity not to exceed 5 microcuries of radium-226.

E. Prototype Evaluation

The manufacturer, assembler, or distributor shall submit information including:

1. For any type of source which is designed to contain more than 0.005 microcurie of radium-226, prototype tests shall be conducted on each of five prototypes of such source in the following sequence:

   (a) Initial measurement. The quantity of radioactive material deposited on the source shall be measured by direct counting of the source.

   (b) Dry wipe test. The entire surface of the source shall be wiped with filter paper with the application of moderate pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper.

   (c) Wet wipe test. The entire surface of the source shall be wiped with filter paper, moistened with water, with the application of moderate pressure. Removal of radioactive material from the source shall be determined by measuring the radioactivity on the filter paper after it has dried.

   (d) Water soak test. The source shall be immersed in water at room temperature for a period of 24 consecutive hours. The source shall then be removed from the water. Removal of radioactive material from the source shall be determined by measuring the total radioactivity in the water in which the source was immersed.

   (e) Dry wipe test. On completion of the preceding tests (a) through (d) above, the dry wipe test described in (b) shall be repeated.

2. Removal of more than 0.005 microcurie of radioactivity in any test as prescribed in (a) through (e) above shall be cause for rejection of the source design. Results of prototype tests submitted shall be given in terms of microcuries and percent of removal from the total amount of radioactive material deposited on the source.

F. Quality Control

1. Each manufacturer, assembler, or distributor shall describe the quality control procedures to be followed in the fabrication of production lots of the sources, as applicable, and the quality control standards for maintaining source design specifications.

2. Each manufacturer, assembler, or distributor should describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

3. Each manufacturer, assembler, or distributor shall perform a dry wipe test upon each source containing more than 0.05 microcurie of radium-226 prior to transferring the source to a general licensee. This test shall be performed by wiping the entire surface of the source with a filter paper with the application of moderate pressure. The radioactivity on the filter paper shall be measured by using radiation detection instrumentation capable of detecting 0.0005 microcurie of radium-226. If any such test discloses more than 0.005 microcurie of radioactive material, the source shall be deemed to be leaking or losing radium-226 and shall not be transferred to a general licensee.

G. Labeling and Instructions for Use of Sources

1. Each manufacturer, assembler, or distributor shall affix or attach to each source, source holder, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include, as a minimum, the following statement or a substantially similar statement:

> The receipt, possession, use and transfer of this source, Model ________,
> Serial No. ________, are subject to a general license and the regulations of
> Licensing States. Do Not Remove This Label.
>
> CAUTION - RADIOACTIVE MATERIAL - THIS SOURCE CONTAINS
> ________________ MICROCURIES RADIUM-226. DO NOT TOUCH
> (Specify quantity) RADIOACTIVE PORTION OF THIS SOURCE.
>
> ____
> (Name of manufacturer, assembler, or distributor)

2. Each distributor shall provide with each source:

   (a) A certification that the sealed source has been appropriately tested for leakage and contamination within six (6) months of date of transfer.

   (b) A certificate of assay which gives the amount of activity, accuracy and date of assay for each source.

   (c) Instructions for the safe handling and usage of the source.

H. Transfer Reports

Each manufacturer, assembler, or distributor shall file an annual report in duplicate with the State specifying the total quantity of radium-226 transferred. The report shall identify the recipient by name and address, state the kinds and numbers of sources transferred, and specify the activity of each source. Each report shall cover the calendar year and shall be filed by January 31 of the following year. If no transfers of radium-226 have been made during the reporting period, the report shall so indicate. The State will forward one copy of the report to the Bureau of Radiological Health, Food and Drug Administration, Rockville, Md., 20857. The Bureau of Radiological Health will send copies of the report to all States.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

NARM GUIDE 2

SEALED SOURCES

A. Scope

This Guide provides criteria for the evaluation of all sealed sources containing radioactive material unless a more specific NARM Guide exists. The sealed sources subject to this Guide are designed for use as radiation sources per se or as a component within a device.

B. Definitions

1. Capsule - Protective envelope used for prevention of leakage of the radioactive material.
2. Device - Any piece of equipment designed to utilize sealed source(s).source(s).
3. Sealed source - Radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.
4. Source holder - Mechanical support for the sealed source.

C. General Criteria

The manufacturer, assembler, or distributor shall submit sufficient information regarding each type or model of sealed source for the evaluation of the sealed source. Such information shall include:

1. Identification

Identify the source by type or model number or other specific model designation.

2. Proposed Use

Describe the proposed use of the source. Define or identify the environments and operating conditions expected during normal use. Indicate the expected useful life of the source.

3. Radioactive Material

Identify the radioactive material, maximum activity per source, chemical and physical form of the radioactive material, and the details of the method of incorporation and binding of the radioactive material in the source.

4. Construction

Submit engineering drawings of the source capsule identifying all materials of construction, dimensions and methods of sealing the source. Submit drawings of the source holder, if any, identifying materials of construction, dimensions and methods for mounting the source in the holder.

5. ANSI Classification

State the American National Standards Institute (ANSI) classification designation.

6. Labeling

   Submit facsimiles of the labeling to be engraved, etched, imprinted or printed on the sealed source, or on a tag to be attached to the source.

7. Additional Information

   Submit any additional information, including experimental studies and tests which will facilitate a determination of the safety of the source.

D. Maximum Quantity

Not applicable for this Guide.

E. Prototype Evaluation

The manufacturer, assembler, or distributor shall submit information including:

1. Maximum radiation levels at 5 and 30 centimeters from any external surface of the source averaged over an area not to exceed 100 square centimeters, and the method of measurement or calculation;

2. Submit results of tests performed on prototype sources that establish the integrity of the source construction and seal under the most adverse conditions of use to which the source is likely to be subjected. These prototype tests should insofar as possible, reflect the actual conditions of use and as a minimum shall meet the designated usage classification according to the current ANSI Standard entitled "Classification of Sealed Radioactive Sources," provided the means for assigning such a classification is described.

F. Quality Control

1. Each manufacturer, assembler, or distributor shall describe the quality control procedures to be followed in the fabrication of production lots of the sources, as applicable, and the quality control standards for maintaining source design specifications.

2. Each manufacturer, assembler, or distributor shall describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

3. Each manufacturer shall perform a leak test on each source by applying procedure(s) in the current ANSI Standard entitled "Classification of Sealed Radioactive Sources" or "Leak-Testing Radioactive Brachytherapy Sources",as appropriate. Acceptability of source leakage shall be indicated by removal of less than 0.005 microcurie of radioactive material. In the case of radium-226 sources intended for brachytherapy, in addition to the above requirement, acceptability is indicated by a leakage rate of less than 0.001 microcurie of radon in 24 hours.

G. Labeling and Instructions for Use of Sources

1. Ideally, source labeling should include the words: "CAUTION -RADIOACTIVE MATERIAL," manufacturer's trademark or unique serial number, radionuclide, activity, assay date, and the radiation symbol. Where labeling the source is impracticable, a tag containing the above information should be attached to the source, unless the attachment of such a tag is also impracticable. When a sealed source is permanently mounted in a device, source labeling is not required provided the device is labeled as specified above.

2. Each distributor shall provide with each source:

(a) A certification that the sealed source has been appropriately tested for leakage and contamination within 6 months of date of transfer.

(b) A certificate of assay for each source.

(c) Instructions for the safe handling and usage of the source.

H. Transfer Reports

1. Submission of transfer reports is not required for source(s) for which distribution is limited to specific licensees.

2. Each manufacturer, assembler, or distributor shall file an annual report in duplicate with the State specifying the total quantity of radioactive material transferred to persons generally licensed or exempt from regulations. The report shall identify the recipient by name and address, state the kinds and numbers of sources transferred, and specify the radionuclide and activity of each source. Each report shall cover the calendar year and shall be filed by January 31 of the following year. If no transfers of radioactive material have been made during the reporting period, the report shall so indicate. The State will forward one copy of the report to the Bureau of Radiological Health, Food and Drug Administration, Rockville, Md., 20857. The Bureau of Radiological Health will send copies of the report to all States.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIAL

NARM GUIDE 3

GAS AND AEROSOL DETECTORS FOR DISTRIBUTION TO PERSONS EXEMPT FROM REGULATION PURSUANT TO C.4(c)(3), SSRCR*

A. Scope

This Guide provides criteria for the evaluation of gas and aerosol detectors containing radioactive material which are to be distributed to persons exempt under C.4(c)(3) of the SSRCR. The gas and aerosol detectors covered by this Guide are only those designed to protect life or property from fires or airborne hazards.

B. Definitions

1. Device - Any piece of equipment designed to utilize sealed source(s).

2. Gas and aerosol detectors - Detectors, indicators, testers, and analyzers for gases, vapors, dusts, fumes, mists, and other airborne contaminants, products of combustion (both visible and invisible), and oxygen deficient atmospheres. As used in this Guide the term "detector" means the device with radioactive material incorporated into it.

C. General Criteria

The manufacturer, assembler, or distributor shall submit sufficient information regarding each type or model of detector for the evaluation of the detector. Such information shall include:

1. Identification

Identify the radioactive source(s) and detector, respectively, by model number or other specific model designation.

2. Proposed Use

Describe the proposed use of the detector and identify the environments and operating conditions expected during normal conditions of use. Include descriptions of the types of users, locations of use, possibilities of use in other products, and circumstances of normal use. In addition describe severe conditions, including accidents or fires, likely to occur in use and possible diversion from intended use.

3. Radioactive Material

Identify the radioactive material(s), activity per source(s), chemical and physical form of the radioactive material(s), and the details of the method of incorporation and binding of the radioactive material(s) in the source(s).

4. Construction

(a) Submit engineering drawings of the detector identifying all materials of construction, dimensions, methods of fabrication and means for incorporating the radioactive material in the detector.

(b) Include a detailed description of all special design features which protect the

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*Suggested State Regulations for Control of Radiation

radioactive material from abuse and minimize the radiation hazards. Describe in sufficient detail so that the nature, function, and method of operation are clearly defined.

5. Human Access

   Describe the degree of access of human beings to the detector during normal handling and use.

6. Estimated Distribution

   Submit an estimate of the total quantity of radioactive material to be distributed annually in this detector. This estimate will involve a market forecast for the detector.

7. Useful Life

   Indicate the expected useful life of the detector.

8. ANSI Classification

   State the American National Standards Institute (ANSI) classification designation.

9. Labeling

   Submit facsimiles of the labelling or marking to be placed on each detector and manual that will accompany the detector.

10. Additional Information

   Submit any additional information, including experimental studies and tests which will facilitate a determination of the safety of the detector.

D. Maximum Quantity

For detectors utilizing radium-226, the maximum quantity shall not exceed 0.1 microcurie.

E. Prototype Evaluation

1. A minimum of 2 prototype detectors shall be evaluated. Prototype detectors tested shall be of the same design and fabricated in a manner that can be duplicated in production units, especially as to material, tolerances and methods of construction. Any change in design or method of fabrication which could affect containment, shielding or the safe operation of the detector requires reevaluation of the new prototype incorporating such change. The appropriateness and reproducibility of the test conditions, accuracy of the observations, and interpretation of the results are among the points to be considered. In some cases, it may be desirable to have tests carried out by qualified independent laboratories.

2. The manufacturer, assembler, or distributor shall submit information including:

   (a) Maximum radiation levels at 5 and 25 centimeters from any external surface of the product averaged over an area not to exceed 10 square centimeters, and the method of measurement.

   (b) Results of tests performed on sources that establish the integrity of the source construction and seal under the most adverse conditions of use to which the source is likely to be subjected. These prototype tests should, insofar as possible, reflect the actual conditions of use and as a minimum shall meet the designated usage classification according to the current ANSI Standard entitled "Classification of Sealed Radioactive Sources."

(c) Procedures for prototype testing of the detectors to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the detector.

(d) Results of the prototype testing of the detectors, including any change in the form of the radioactive material contained in the detector, the extent to which the radioactive material may be released to the environment, any increase in external radiation levels, and any other changes in safety features.

(e) A safety analysis based on the evaluation of the ability of the detector to withstand the normal conditions of handling, use, storage and disposal and the effects on containment and shielding of abnormally severe conditions of use and disposal, as well as fires and accidents which are likely to be encountered by the detector when used for its designed purpose. Aging effects are of particular importance.

(f) The estimated external radiation doses and dose commitments relevant to the safety criteria in Appendix A and the basis for such estimates.

F. Quality Control

1. Each manufacturer, assembler, or distributor shall describe the quality control procedures to be followed in the fabrication and assembly of production lots of the detectors and the quality control standards for maintaining source design specifications.

2. Each manufacturer, assembler, or distributor shall describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

3. Each manufacturer, assembler, or distributor shall perform a leak test on each detector by (a), or each production lot by (b), as shown below:

   (a) Applying procedure(s) in the current ANSI Standard entitled "Classification of Sealed Radioactive Sources." Acceptability of source leakage shall be indicated by removal of less than 0.005 microcurie.

   (b) Performing an appropriate procedure given in (a) above in accordance with the Sampling Table in Appendix B. If any lot sampled in accordance with Appendix B includes a larger number of rejects than specified in Appendix B for a lot of that size, all detectors in that lot shall be sampled or the entire lot rejected.

G. Labeling and Instructions for Use of Detectors

The label or marking shall consist of the name, trademark, or symbol of the manufacturer, assembler or distributor, and the type and amount of radioactive material, the date of measurement, the standard radiation symbol, and the words "CAUTION - RADIOACTIVE MATERIAL". Disposal instructions shall be included on the label. The label or marking must be durable enough to remain legible for the useful life of the detector and be readily visible without disassembly of that part of the detector containing the radioactive material.

H. Transfer Reports

Each manufacturer, assembler, or distributor shall file an annual report in duplicate with the State specifying the total quantity of radioactive material transferred to persons exempt from regulations. The report shall state the kinds and numbers of detectors and sources transferred and specify the radionuclide and activity of each source. Each report shall cover the calendar year and shall be filed by January 31 of the following year. If no transfers of NARM have been made during the reporting period, the report shall so indicate. The State will forward one copy of the report to the Bureau of Radiological Health, Food and Drug Administration, Rockville, Maryland 20857. The Bureau of Radiological Health will send copies of the report to all States.

NARM GUIDE 3

Appendix A

SAFETY CRITERIA

The gas and aerosol detector shall be designed and manufactured so that:

1) In normal use and disposal of a single exempt unit, and in normal handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the detector, it is unlikely that the external radiation dose in any one year, or the dose commitment resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will exceed the dose to the appropriate organ specified in column I below:[1]

	Column I (rem)	Column II (rem)	Column III (rem)
Whole body: head and trunk: active blood-forming organs: gonads; or lens of eye	0.005	0.5	15
Hands and forearms feet and ankles; or localized areas of skin averaged over areas no larger than one square centimeter	0.075	7.5	200
Other organs	0.015	1.5	50

It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the detector from wear and abuse likely to occur in normal handling and use of the detector during its useful life.

In use and disposal of a single exempt unit and in handling and storage of the quantities of exempt units likely to accumulate in one location during marketing, distribution, installation, and servicing of the detector, the probability is low that the containment, shielding, or other safety features of the detector would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the preceding table and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the preceding table.[1]

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[1] It is the intent that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates which are to be made. The following values may be used in estimating compliance with the criteria:

Low- not more than one such failure per year for each 10,000 exempt units distributed.
Negligible-not more than one such failure per year for each one million exempt units distributed.

NARM GUIDE 3

Appendix B

SAMPLING TABLE

Lot size	Sample Size	Permissible number of rejects*
1-30	All	0
31-50	30	0
51-100	37	0
101-200	40	0
201-300	43	0
301-400	44	0
401-2000	45	0
2001-100,000	75	1

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* If any lot sampled in accordance with Appendix B includes a larger number of rejects than specified in Appendix B for a lot of that size, all detectors in that lot shall be sampled or the entire lot rejected.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

NARM GUIDE 4

MEASURING, GAUGING, OR CONTROLLING DEVICES

A. Scope

This Guide provides criteria for the evaluation of measuring, gauging, or controlling devices, commonly called gauges, containing radioactive material.

The Suggested State Regulations for Control of Radiation (SSRCR) provide for the distribution of measuring, gauging, or controlling devices containing radioactive material to persons generally licensed pursuant to C.22(d) and to specific licensees.

B. Definitions

1. Capsule - Protective envelope used for prevention of leakage of the radioactive material.
2. Gauge - A device designed to utilize sealed source(s) for determining or controlling thickness, density, level, interface location, radiation leakage, or qualitative or quantitative chemical composition.
3. Sealed source - Radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.
4. Source holder - A device used to support and retain the source.
5. Source housing - The enclosure containing or incorporating the source, source holder and means for attenuation of the radiation.

C. General Criteria

The manufacturer, assembler, or distributor, shall submit sufficient information regarding each type or model of gauge for the evaluation of the gauge. Such information shall include:

1. Identification

   Identify the radioactive source(s) and the gauge, respectively, by type, model number, or other specific model designation.

2. Proposed Use

   Describe the proposed use of the gauge and identify the environments and operating conditions expected during normal conditions of use. Include descriptions of the types of users, locations of use, possibilities of use as a component in other products, and circumstances of normal use. In addition, describe probable effects of severe conditions, including accidents and fires, and possible diversion from intended use.

3. Radioactive Material

   (a) Identify the radioactive material(s), maximum activity per source, chemical and physical form of the radioactive material(s), the details of the method of incorporation and binding of the radioactive material(s) into the source, activity per source, and the number of sources in the gauge.

(b) Submit the information required by NARM Guide 2 - "Evaluation of Sealed Sources."

4. Construction

(a) Submit engineering drawings of the source housing, identifying all materials of construction, dimensions, methods of fabrication and means for incorporating the radioactive material.

(b) Include a detailed description of all special design features which protect the radioactive material from abuse and minimize the radiation hazards. Describe in sufficient detail so that the nature, function, and method of operation are clearly defined.

5. Human Access

Describe the degree of access of human beings to the gauge during normal handling and use.

6. Useful Life

Indicate the expected useful lifetime of the gauge and of the source(s).

7. ANSI Classification Designation

State the American National Standards Institute (ANSI) classification designation of the gauge. Also state the ANSI classification designation for the source(s).

8. Labeling and Instructions for Use

Submit facsimiles of the labeling or marking to be placed on each gauge, and copies of the manual that will accompany the gauge.

9. Availability of Services

Submit information regarding the availability of the following services to the gauge user:

(a) Installation and relocation;

(b) Initial radiation survey;

(c) Leak testing;

(d) Repair, periodic maintenance, and shutter checks;

(e) Source exchange;

(f) Emergency procedures; and

(g) Disposal.

Note: If the gauge is to be distributed to person(s) generally licensed pursuant to C.22(d), the manufacturer shall provide assurance that the above services are available.

10. Additional Information

Submit any additional information, including results of experimental studies and tests, which will facilitate a determination of the safety of the gauge.

D. Maximum Quantity

Not applicable for this Guide.

E. Prototype Evaluation

1. At least one gauge shall be evaluated. The prototype gauge tested shall be of the same design and fabricated in a manner that can be duplicated in production units, especially as to materials, tolerances and methods of construction. Any change in design or method of fabrication which could affect containment, shielding, or the safe operation of the gauge requires reevaluation of the new prototype incorporating such change. The appropriateness and reproducibility of the test conditions, accuracy of the observations, and interpretation of the results, are among the points to be considered. In some cases, it may be desirable to have tests carried out by qualified independent laboratories.

2. The manufacturer, assembler, or distributor, shall submit information including:

   (a) Results of tests performed on sources that establish the integrity of the source construction and seal under the most adverse conditions of use to which the gauge is likely to be subjected. These prototype tests should, insofar as possible, reflect the actual conditions of use and as a minimum shall meet the designated usage classification according to the current ANSI Standard entitled "Classification of Sealed Radioactive Sources."

   (b) A safety analysis based on the evaluation of the ability of the final design to withstand the normal conditions of handling, use and storage including abrasion, corrosion, vibration, impact, puncture, compressive loads,and the probable effects on containment and shielding of abnormally severe conditions, such as explosion and fire. Aging effects are of particular importance. The results of testing which demonstrate that the gauge meets the designated performance classification according to the current ANSI Standard entitled "Classification of Industrial Radiation Gauging Devices" (currently in draft) shall also be submitted.

   (c) Submit radiation profiles (isodose curves e.g. 2 and 5 mR/h) of a prototype of the gauge with shutter(s) in the open and closed position(s). Radiation levels should be measured using the maximum activity of each kind of radioactive material expected to be used in the gauge. A description of the method used to measure the radiation levels should be included.

   (d) For gauges intended for distribution to persons generally licensed pursuant to C.22(d), sufficient information to provide reasonable assurance that:

      (i) the gauge can be safely operated by persons not having training in radiological protection:

      (ii) under ordinary conditions of handling, storage, and use of the gauge, the radioactive material contained in the gauge will not be released or inadvertently removed from the gauge, and it is unlikely that any person will receive in any period of one calendar year an external radiation dose or dose commitment in excess of the following organ doses:

Whole body: head and trunk; active
blood-forming organs; gonads; or
lens of eye . . . . 0.5 rem

Hands and forearms; feet and
ankles; localized areas of skin
averaged over areas no larger
than 1 square centimeter . . . . 7.5 rems

Other organs . . . . 3.0 rems

(iii) under accident conditions (such as fire and explosion) associated with handling, storage, and use of the gauge, it is unlikely that any individual would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active
blood-forming organs; gonads; or
lens of eye . . . . 15 rems

Hands and forearms; feet and ankles;
localized areas of skin averaged
over areas no larger than 1 square
centimeter . . . . 200 rems

Other organs . . . . 50 rems

F. Quality Control

1. Each manufacturer, assembler, or distributor shall describe the quality control procedures to be followed in the fabrication and assembly of the gauge and the quality control standards for maintaining source design specifications. Also, if available, describe the quality assurance aspects and provide certificate(s) of compliance related to the gauge.

2. Each manufacturer, assembler, or distributor shall describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

3. Each manufacturer, assembler, or distributor shall perform a leak test on each source by applying procedure(s) in the current ANSI Standard entitled "Classification of Sealed Radioactive Sources." Acceptability of source leakage shall be indicated by removal of less than 0.005 microcurie.

G. Labeling and Instructions for Use of Gauge

1. The label or marking shall consist of the name, trademark, or symbol of the manufacturer, assembler, or distributor, the type and amount of radioactive material, the date of measurement, the standard radiation symbol, and the words, "CAUTION - RADIOACTIVE MATERIAL." The label or marking must be durable enough to remain legible for the useful life of the gauge and be readily visible.

2. For gauges intended for distribution to persons generally licensed pursuant to C.22(d), the label shall indicate, in addition to the information in (1) above, the following statement in the same, or substantially similar form:

> The receipt, possession, use, and transfer of this device, Model ______, Serial No. ______, are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

3. Each distributor shall provide with each device:

   (a) A certification that the sealed source has been appropriately tested for leakage and contamination within six (6) months of date of transfer.

   (b) A certificate of assay for each source.

   (c) Instructions for the safe and efficacious usage of the source/device.

H. Transfer Reports

1. Submission of transfer reports is not required for gauge(s) distributed to specific licensees.

2. Each manufacturer, assembler, or distributor shall file a quarterly report, in duplicate, with the State, specifying the total quantity of radioactive material transferred to persons generally licensed. The report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the State and the general licensee, the type and model number of gauge transferred, and the type and quantity of radioactive material contained in the gauge. If one or more intermediate persons will temporarily possess the gauge at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed pursuant to C.22(d) SSRCR during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter. The State will forward one copy of the report to the Bureau of Radiological Health, Food and Drug Administration, Rockville, Maryland 20857. The Bureau of Radiological Health will send copies of the report to all States.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

NARM GUIDE 5

RADIOACTIVE MATERIAL FOR DISTRIBUTION TO PERSONS EXEMPT FROM REGULATION PURSUANT TO C.4(b), SSRCR*

A. Scope

This Guide provides criteria for the evaluation of exempt quantities of radioactive material for distribution to persons exempt from regulation pursuant to C.4(b) of the SSRCR.

B. Definitions

1. Exempt quantity - As used in this Guide, means that amount of radioactive material as listed in Schedule B, Part C, SSRCR (See Appendix A of the Guide). An exempt quantity may consist of one or more sources.
2. Source - As used in this Guide, means a processed chemical element, compound, or mixture, tissue sample, bioassay sample, counting standard, plated or encapsulated source, or similar substance.

C. General Criteria

The radioactive material can be considered for the exempt status providing:

1. The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being.
2. The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.

The manufacturer, assembler, or distributor shall submit sufficient information regarding each type or model of source for the evaluation of the source. Such information shall include:

1. Identification

   Identify the radioactive source by model number or other specific model designation.

2. Radioactive Material

   Identify the radioactive material, activity per source, chemical and physical form of the radioactive material, and the details of the method of incorporation and binding of the radioactive material in the source.

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*Suggested State Regulations for Control of Radiation

3. Construction

Submit engineering drawings of the source identifying all materials of construction, dimensions, and methods of sealing the source, if any.

4. Labels and Instructions for Use

Submit facsimiles of labeling or marking to be placed on each source and copies of instructions for use that will accompany the source.

5. Additional Information

Submit any additional information, including experimental studies and tests which will facilitate a determination of the safety of the source.

D. Maximum Quantity

1. The quantity of radioactive material per source shall not exceed that listed in Schedule B, Part C, of the SSRCR (See Appendix A of this Guide). These exempt quantities were determined by the method given in Appendix B.

2. No more than 10 exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

E. Prototype Testing

Not applicable to this Guide.

F. Quality Control

1. Each manufacturer, assembler, or distributor shall describe the quality control procedures to be followed in the fabrication of production lot(s) of the sources, as applicable, and the quality control standards for maintaining source design specification.

2. Each manufacturer, assembler, or distributor shall describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

G. Labeling and Instructions for Use

1. The immediate container for each exempt quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

   (a) identifies the radioactive material and the quantity of radioactivity, and

   (b) bears the words "Radioactive Material."

2. In addition, the label affixed to the immediate container, or an accompanying brochure, shall also:

   (a) state that the contents are exempt from Licensing State requirements;

(b) bear the words "Radioactive Material - Not for Human Use - Introduction Into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited - Exempt Quantities Should Not be Combined;" and

(c) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

H. Transfers and Transfer Reports

1. Each exempt quantity shall be separately and individually packaged. Not more than 10 such packaged exempt quantities shall be contained in any other package for transfer to persons exempt pursuant to C.4(b) SSRCR. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

2. Each manufacturer, assembler, or distributor, shall maintain records identifying, by name and address, each person to whom an exempt quantity is transferred. These records shall include the kinds and quantities of radioactive material transferred.

3. Each manufacturer, assembler, or distributor, shall file an annual summary report, in duplicate, with the State specifying the total quantity of each kind of radioactive material transferred. Each report shall cover the calendar year and shall be filed by January 31 of the following year. If no transfers of radioactive material have been made during the reporting period, the report shall so indicate. The State will forward one copy of the report to the Bureau of Radiological Health, Food and Drug Administration, Rockville, Maryland 20857. The Bureau of Radiological Health will send copies of the report to all States.

NARM GUIDE 5

Appendix A

EXEMPT QUANTITIES*

Radioactive Material	Microcuries	Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100	Gallium-72 (Ga 72)	10
Antimony-124 (Sb 124)	10	Germanium-71 (Ge 71)	100
Antimony-125 (Sb 125)	10	Gold-198 (Au 198)	100
Arsenic-73 (As 73)	100	Gold-199 (Au 199)	100
Arsenic-74 (As 74)	10	Hafnium-181 (Hf 181)	10
Arsenic-76 (As 76)	10	Holmium-166 (Ho 166)	100
Arsenic-77 (As 77)	100	Hydrogen-3 (H 3)	1,000
Barium-131 (Ba 131)	10	Indium-111 (In 111)	100
Barium-133 (Ba 133)	10	Indium-113m (In 113m)	100
Barium-140 (Ba 140)	10	Indium-114m (In 114m)	10
Bismuth-210 (Bi 210)	1	Indium-115m (In 115m)	100
Bromine-82 (Br 82)	10	Indium-115 (In 115)	10
Cadmium-109 (Cd 109)	10	Iodine-123 (I 123)	100
Cadmium-115m (Cd 115m)	10	Iodine-125 (I 125)	1
Cadmium-115 (Cd 115)	100	Iodine-126 (I 126)	1
Calcium-45 (Ca 45)	10	Iodine-129 (I 129)	0.1
Calcium-47 (Ca 47)	10	Iodine-131 (I 131)	1
Carbon-14 (C 14)	100	Iodine-132 (I 132)	10
Cerium-141 (Ce 141)	100	Iodine-133 (I 133)	1
Cerium-143 (Ce 143)	100	Iodine-134 (I 134)	10
Cerium-144 (Ce 144)	1	Iodine 135 (I 135)	10
Cesium-129 (Cs 129)	100	Iridium-192 (Ir 192)	10
Cesium-131 (Cs 131)	1,000	Iridium-194 (Ir 194)	100
Cesium-134m (Cs 134m)	100	Iron-52 (Fe 52)	10
Cesium-134 (Cs 134)	1	Iron-55 (Fe 55)	100
Cesium-135 (Cs 135)	10	Iron-59 (Fe 59)	10
Cesium-136 (Cs 136)	10	Krypton-85 (Kr 85)	100
Cesium-137 (Cs 137)	10	Krypton-87 (Kr 87)	10
Chlorine-36 (Cl 36)	10	Lanthanum-140 (La 140)	10
Chlorine-38 (Cl 38)	10	Lutetium-177 (Lu 177)	100
Chromium-51 (Cr 51)	1,000	Manganese-52 (Mn 52)	10
Cobalt-57 (Co 57)	100	Manganese-54 (Mn 54)	10
Cobalt-58m (Co 58m)	10	Manganese-56 (Mn 56)	10
Cobalt-58 (Co 58)	10	Mercury-197m (Hg 197m)	100
Cobalt-60 (Co 60)	1	Mercury-197 (Hg 197)	100
Copper-64 (Cu 64)	100	Mercury-203 (Hg 203)	10
Dysprosium-165 (Dy 165)	10	Molybdenum-99 (Mo 99)	100
Dysprosium-166 (Dy 166)	100	Neodymium-147 (Nd 147)	100
Erbium-169 (Er 169)	100	Neodymium-149 (Nd 149)	100
Erbium-171 (Er 171)	100	Nickel-59 (Ni 59)	100
Europium-152 (Eu 152) 9.2h	100	Nickel-63 (Ni 63)	10
Europium-152 (Eu152) 13 yr	1	Nickel-65 (Ni 65)	100
Europium-154 (Eu 154)	1	Niobium-93m (Nb 93m)	10
Europium-155 (Eu 155)	10	Niobium-95 (Nb 95)	10
Fluorine-18 (F 18)	1,000	Niobium-97 (Nb 97)	10
Gadolinium-153 (Gd 153)	10	Osmium-185 (Os 185)	10
Gadolinium-159 (Gd 159)	100	Osmium-191m (Os 191m)	100
Gallium-67 (Ga 67)	100	Osmium-191 (Os 191)	100

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*Includes NARM and byproduct material.

Radioactive Material	Microcuries
Osmium-193 (Os 193)	100
Palladium-103 (Pd 103)	100
Palladium-109 (Pd 109)	100
Phosphorus-32 (P 32)	10
Platinum-191 (Pt 191)	100
Platinum-193m (Pt 193m)	100
Platinum-193 (Pt 193)	100
Platinum-197m (Pt 197m)	100
Platinum-197 (Pt 197)	100
Polonium-210 (Po 210)	0.1
Potassium-42 (K 42)	10
Potassium-43 (K 43)	10
Praseodymium-142 (Pr 142)	100
Praseodymium-143 (Pr 143)	100
Promethium-147 (Pm 147)	10
Promethium-149 (Pm 149)	10
Rhenium-186 (Re 186)	100
Rhenium-188 (Re 188)	100
Rhodium-103m (Rh 103m)	100
Rhodium-105 (Rh 105)	100
Rubidium-81 (Rb 81)	10
Rubidium-86 (Rb 86)	10
Rubidium-87 (Rb 87)	10
Ruthenium-97 (Ru 97)	100
Ruthenium-103 (Ru 103)	10
Ruthenium-105 (Ru 105)	10
Ruthenium-106 (Ru 106)	1
Samarium-151 (Sm 151)	10
Samarium-153 (Sm 153)	100
Scandium-46 (Sc 46)	10
Scandium-47 (Sc 47)	100
Scandium-48 (Sc 48)	10
Selenium-75 (Se 75)	10
Silicon-31 (Si 31)	100
Silver-105 (Ag 105)	10
Silver-110m (Ag 110m)	1
Silver-111 (Ag 111)	100
Sodium-22 (Na 22)	10
Sodium-24 (Na 24)	10
Strontium-85 (Sr 85)	10
Strontium-89 (Sr 89)	1
Strontium-90 (Sr 90)	0.1
Strontium-91 (Sr 91)	10
Strontium-92 (Sr 92)	10
Sulphur-35 (S 35)	100
Tantalum-182 (Ta 182)	10
Technetium-96 (Tc 96)	10
Technetium-97m (Tc 97m)	100
Technetium-97 (Tc 97)	100
Technetium-99m (Tc 99m)	100
Technetium-99 (Tc 99)	10
Tellurium-125m (Te 125m)	10
Tellurium-127m (Te 127m)	10
Tellurium-127 (Te 127)	100
Tellurium-129m (Te 129m)	10
Tellurium-129 (Te 129)	100
Tellurium-131m (Te 131m)	10
Tellurium-132 (Te 132)	10
Terbium-160 (Tb 160)	10
Thallium-200 (Tl 200)	100
Thallium-201 (Tl 201)	100
Thallium-202 (Tl 202)	100
Thallium-204 (Tl 204)	10
Thulium-170 (Tm 170)	10
Thulium-171 (Tm 171)	10
Tin-113 (Sn 113)	10
Tin-125 (Sn 125)	10
Tungsten-181 (W 181)	10
Tungsten-185 (W 185)	10
Tungsten-187 (W 187)	100
Vanadium-48 (V 48)	10
Xenon-131m (Xe 131m)	1,000
Xenon-133 (Xe 133)	100
Xenon-135 (Xe 135)	100
Ytterbium-175 (Yb 175)	100
Yttrium-87 (Y 87)	10
Yttrium-90 (Y 90)	10
Yttrium-91 (Y 91)	10
Yttrium-92 (Y 92)	100
Yttrium-93 (Y 93)	100
Zinc-65 (Zn 65)	10
Zinc-69m (Zn 69m)	100
Zinc-69 (Zn 69)	1,000
Zirconium-93 (Zr 93)	10
Zirconium-95 (Zr 95)	10
Zirconium-97 (Zr 97)	10
Any radioactive material not listed above other than alpha emitting radioactive material	0.1

Appendix B

METHOD OF DETERMINING EXEMPT QUANTITIES OF RADIOACTIVE MATERIAL

Since inhalation is considered the most likely route of entry into the body, the quantity of radioactive material that would be inhaled by a standard man exposed for one year at the highest average concentration permitted in air for members of the general public in unrestricted areas is computed. Multiply the value given in the SSRCR, Part D, Appendix A, Table II, Column 1 concentration times 7.3×10^9 milliliters (ml/y). If the radionuclide emits gamma radiation, the quantity that, from a point source, would produce a radiation level of one milliroentgen per hour (mR/h) at a distance of ten centimeters is also computed. The smaller of these two quantities is then logarithmically rounded to the nearest decade, in microcuries. In the absence of published data on gamma emission, the following formula is used: $I = 0.156\ n\ E\ 10^5\ \mu_a$

Where I_γ = mR/hour at 1 meter per millicurie,
n = gamma quanta per disintegration,
E = energy of gamma quanta in MeV (million electron volts), and
u_a = energy absorption coefficient for gamma in air.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

NARM GUIDE 6

STATIC ELIMINATION AND ION-GENERATING DEVICES

A. Scope

This Guide provides criteria for the evaluation of static elimination devices and ion-generating tubes containing radioactive material. These products include lightning rods, brushes, precision balances, and other antistatic devices.

Since the Suggested State Regualtions for Control of Radiation, (SSRCR) do not provide for the exempt distribution or possession of static elimination devices and ion-generating tubes containing NARM, the distribution is limited to those persons generally licensed pursuant to C.22(d) or specific licensees.

B. Definitions

1. Device(s) - any piece of equipment which contains radioactive material designed for use as a static eliminator(s) or designed for the ionization of air.

C. General Criteria

The manufacturer, assembler, or distributor, shall submit sufficient information regarding each type or model of device for the evaluation of the device. Such information shall include:

1. Identification

Identify the radioactive source(s) and the device, respectively, by model number or other specific model designation.

2. Proposed Use

Describe the proposed use of the device and identify the environments and operating conditions expected during normal conditions of use. Include descriptions of the types of users, locations of use. In addition, describe severe conditions, including accidents or fires, likely to occur in use and possible diversion from intended use.

3. Radioactive Material

Identify the radioactive material, chemical and physical form of the radioactive material, the details of the method of incorporation and binding of the radioactive material into the source, activity per source, and the number of sources in the device.

4. Construction

(a) Submit engineering drawings of the device, identifying all materials of construction, dimensions, methods of fabrication and means for incorporating the radioactive material into the device.

(b) Include a detailed description of all special design features which protect the radioactive material from abuse and minimize the radiation hazards. Describe in sufficient detail so that the nature, function, and method of operation are clearly defined.

5. Human Access

Describe the degree of access of human beings to the device during normal handling and use.

6. Useful Life

Indicate the expected useful life of the device.

7. ANSI Classification Designation

State the American National Standards Institute (ANSI) classification designation for the source.

8. Labeling and Instructions for Use

Submit facsimiles of the labeling or marking to be placed on each device, and copies of the manual that will accompany the device.

9. Availability of Services

Submit information regarding the availability of the following services to the device user:

(a) Installation and relocation;

(b) Initial radiation survey;

(c) Leak testing;

(d) Repair, periodic maintenance, and shutter checks;

(e) Source exchange;

(f) Emergency procedures; and

(g) Disposal.

Note: If the device is to distributed to person(s) generally licensed pursuant to C.22(d), the manufacturer shall provide assurance that the above services are available.

10. Additional Information

Submit any additional information, including experimental studies and tests, which will facilitate a determination of the safety of the device.

D. Maximum Quantity

Not applicable for this Guide.

E. Prototype Evaluation

1. A minimum of 2 devices shall be evaluated. Prototype devices tested shall be of the same design and fabricated in a manner that can be duplicated in production units, especially as to materials, tolerances and methods of construction. Any change in design or method of fabrication which could affect containment, or shielding, or the safe operation of the device requires reevaluation of the new prototype incorporating such change. The appropriateness and reproducibility of the test conditions, accuracy of the observations, and interpretation of the

results, are among the points to be considered. In some cases, it may be desirable to have tests carried out by qualified independent laboratories.

2. The manufacturer, assembler, or distributor, shall submit information including:

   (a) Maximum radiation levels at 5 and 25 centimeters from any external surface of the device averaged over an area not to exceed 10 square centimeters, and the method of measurement.

   (b) Results of tests performed on sources that establish the integrity of the source construction and seal under the most adverse conditions of use to which the device is likely to be subjected. These prototype tests should, insofar as possible, reflect the actual conditions of use and as a minimum shall meet the designated usage classification according to the current ANSI Standard entitled "Classification of Sealed Radioactive Sources."

   (c) Procedures for prototype testing of the device to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage and use of the device.

   (d) Results of the prototype testing of the device, including any change in the form of the radioactive material contained in the device, the extent to which the radioactive material may be released to the environment, any increase in external radiation levels, and any other changes in safety features.

   (e) A safety analysis based on the evaluation of the ability of the final design to withstand the normal conditions of handling, use and storage, and the effects on containment and shielding of abnormally severe conditions of use, including fires and accidents. Aging effects are of particular importance.

   (f) For devices intended for distribution to persons generally licensed pursuant to C.22(d), sufficient information to provide reasonable assurance that:

      (i) the device can be safely operated by persons not having training in radiological protection;

      (ii) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar year an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.5 rem
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	7.5 rems
Other organs	3 rems

      (iii) under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15 rems
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	200 rems
Other organs	50 rems

F. Quality Control

1. Each manufacturer, assembler, or distributor, shall describe the quality control procedures to be followed in the fabrication and assembly of the devices and the quality control standards for maintaining source design specifications.

2. Each manufacturer, assembler, or distributor, shall describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

3. Each manufacturer, assembler, or distributor, shall perform a leak test on each source by applying procedure(s) in the current ANSI Standard entitled "Classification of Sealed Radioactive Sources". Acceptability of source leakage shall be indicated by removal of less than 0.005 microcurie.

G. Labeling and Instructions for Use of Device

1. The label or marking shall consist of the name, trademark, or symbol of the manufacturer, assembler, or distributor, the type and amount of radioactive material, the date of measurement, the standard radiation symbol, and the words, "CAUTION—RADIOACTIVE MATERIAL." The label or marking must be durable enough to remain legible for the useful like of the device and be readily visible.

2. For devices intended for distribution to persons generally licensed pursuant to C.22(d), the label shall indicate, in addition to the information in (1) above, the following statement in the same, or substantially similar form:

   > The receipt, possession, use, and transfer of this device, Model______, Serial No. ______, are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

3. The manual shall provide procedures to be followed during packaging and shipping of the device. As a minimum, the procedures shall assure compliance with the packaging and shipping requirements of the U.S. Department of Transportation.

4. Each distributor shall provide with each device:

   (a) A certification that the sealed source has been appropriately tested for leakage and contamination within 6 months of date of transfer.

   (b) A certificate of assay for each source.

   (c) Instructions for the safe handling and usage of the device.

H. Transfer Reports

1. Submission of transfer reports is not required for device(s) for which distribution is limited to specific licensees.

2. Each manufacturer, assembler, or distributor shall file a quarterly report, in duplicate, with the State, specifying the total quantity of radioactive material transferred to persons generally licensed. The report shall identify each general licensee by name and address, an individual by name and/or position who may constitute a point of contact between the State and the general licensee, the type and model number of device transferred, and the type and quantity of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under C.22(d), SSRCR, during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter. The State will forward one copy of the report to the Bureau of Radiological Health, Food and Drug Administration, Rockville, Maryland 20857. The Bureau of Radiological Health will send copies of the report to all States.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

NARM GUIDE 7

RADIOLUMINOUS PRODUCTS

A. Scope

This Guide provides criteria for the evaluation of radioluminous products containing radioactive material. These products include timepieces, instrument dials, luminous safety products, and other self-luminous light sources.

Since the Suggested State Regulations for Control of Radiation (SSRCR) do not provide for the exempt distribution is limited to those persons generally licensed pursuant to C.22(d) or specific licensees.

B. Definitions

1. Device - Any piece of equipment designed to utilize a radioluminous source.
2. Radioluminous source - A source consisting of a radioactive material firmly incorporated in solid and/or inactive material, or sealed in a protective envelope strong enough to prevent any leakage of the contained radioactive material to the environment under ordinary circumstances of use and incorporating a phosphor for the purpose of emitting light.

C. General Criteria

The manufacturer, assembler, or distributor shall submit sufficient information regarding each type or model of device for the evaluation of the device. Such information shall include:

1. Identification

   Identify the radioactive source(s) and the device(s), respectively, by model number or other specific model designation.

2. Proposed Use

   Describe the proposed use of the device and identify the environments and operating conditions expected during normal conditions of use. Include descriptions of the types of users, locations of use, possibilities of use in other products, and circumstances of normal use. In addition, describe severe conditions, including accidents or fires, likely to occur in use and possible diversion from intended use.

3. Radioactive Material

   Identify the radioactive material, chemical and physical form of the radioactive material, the details of the method of incorporation and binding of the radioactive material into the source, activity per source, and the number of sources in the device.

4. Construction

   (a) Submit engineering drawings of the device, identifying all material of construction, dimensions, methods of fabrication and means for incorporating the radioactive material into the device.

(b) Include a detailed description of all special design features which protect the radioactive material from abuse and minimize the radiation hazards. Describe in sufficient detail so that the nature, function and method of operation are clearly defined.

5. Human Access

Describe the degree of access of human beings to the device during normal handling and use.

6. Useful Life

Indicate the expected useful life of the device.

7. ANSI Classification Designation

State the American National Standards Institute (ANSI) classification designation of the source and the device if the device is classifiable by a current ANSI standard.

8. Labeling and Instructions for Use

Submit facsimiles of the labeling or marking to be placed on each device, and copies of the manual that will accompany the device.

9. Availability of Services

Submit information regarding the availability of the following services to the device user:

(a) Installation and relocation;

(b) Initial radiation survey;

(c) Leak testing;

(d) Repair, periodic maintenance and shutter checks;

(e) Source exchange;

(f) Emergency procedure; and

(g) Disposal.

Note: If the device is to be distributed to person(s) generally licensed pursuant to C.22(d), the manufacturer shall provide assurance that the above services are available.

10. Additional Information

Submit any additional information, including experimental studies and tests, which will facilitate a determination of the safety of the device.

D. Maximum Quantity

Not applicable for this Guide.

E. Prototype Evaluation

1. A minimum of 2 devices shall be evaluated. Prototype devices tested shall be of the same design and fabricated in a manner that can be duplicated in production units, especially as to materials, tolerances and methods of construction. Any change in design or method of fabrication which could affect containment, or shielding, or the safe operation of the device requires reevaluation of the new prototype incorporating such change. The appropriateness and reproducibility of the test conditions, accuracy of the observations, and interpretation of the results, are among the points to be considered. In some cases, it may be desirable to have tests carried out by qualified independent laboratories.

2. The manufacturer, assembler, or distributor shall submit information including:

   (a) Maximum radiation levels at 5 and 25 centimeters from any external surface of the device averaged over an area not to exceed 10 square centimeters, and the method of measurement.

   (b) Results of tests performed on sources that establish the integrity of the source construction and seal under the most adverse conditions of use to which the device is likely to be subjected. These prototype tests should, insofar as possible, reflect the actual conditions of use and as a minimum shall meet the designated usage classification according to the current ANSI Standard entitled "Classification of Sealed Radioactive Sources".

   (c) Results of tests performed on devices that establish the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the device and as a minimum shall meet the designated usage classification according to current ANSI Standard entitled "Classification of Radioactive Self-Luminous Light Sources," provided the means for assigning such a classification is described.

   (d) A safety analysis based on the evaluation of the ability of the final design to withstand the normal conditions of handling, use, storage and disposal, and the effects on containment and shielding of abnormally severe conditions of use and disposal, as well as fires and accidents which are likely to be encountered by the device when used for its designed purpose. Aging effects are of particular importance.

   (e) For devices intended for distribution to persons generally licensed pursuant to C.22(d), sufficient information to provide reasonable assurance that:

      (i) the device can be safely operated by persons not having training in radiological protection;

      (ii) under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar year an external radiation dose or dose commitment in excess of the following organ doses:

Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye.....	0.5 rems
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	7.5 rems
Other organs	3 rems

F. Quality Control

1. Each manufacturer, assembler, or distributor, shall describe the quality control procedures to be followed in the fabrication and assembly of the devices and the quality control standards for maintaining source design specifications.

2. Each manufacturer, assembler, or distributor, shall describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

3. Each manufacturer, assembler, or distributor, shall perform a leak test on each source by applying procedure(s) in the current ANSI Standard entitled "Classification of Sealed Radioactive Sources". Acceptability of source leakage shall be indicated by removal of less than 0.005 microcurie.

G. Labeling and Instructions for Use of Device

1. The label or marking shall consist of the name, trademark, or symbol of the manufacturer, assembler, or distributor, the type and amount or radioactive material, the date of measurement, the standard radiation symbol, and the words, "CAUTION - RADIOACTIVE MATERIAL. The label or marking must be durable enough to remain legible for the useful life of the device and be readily visible.

2. For devices intended for distribution to persons generally licensed pursuant to C.22(d), the label shall indicate, in addition to the information in (1) above, the following statement in the same, or substantially similar form:

   > The receipt, possession, use, and transfer of this device, Model _____, Serial No. _____, are subject to a general license or the equivalent, and the regulations of a Licensing State. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

3. Each distributor shall provide with each device:

   (a) A certification that the sealed source has been appropriately tested for leakage and contamination within 6 months of date of transfer.
   (b) A certificate of assay for each source.
   (c) Instructions for the safe handling and usage of the device.

H. Transfer Reports

1. Submission of transfer reports is not required for devices for which distribution is limited to specific licensees.

2. Each manufacturer, assembler, or distributor, shall file a quarterly report, in duplicate, with the State, specifying the total quantity of radioactive material transferred to persons generally licensed. The report shall identify each general licensee by name and address, and individual by name and/or position who may constitute a point of contact between the State and the general licensee, the type and model number of device transferred, and the type and quantity of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally licensed under C.22(d), SSRCR, during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter. The State will forward one copy of the report to the Bureau of Radiological Health, Food and Drug Administration, Rockville, Maryland 20857. The Bureau of Radiological Health will send copies of the report to all States.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

NARM GUIDE 8

ELECTRONIC AND ELECTRICAL DEVICES

A. Scope

This Guide provides criteria for the evaluation of electronic and electrical devices containing radioactive material. These devices include electron tubes, fluorescent lamp starters, gas discharge lamps, vacuum tubes, electric lamps, germicidal lamps, piezoelectric ceramics, and spark gap irradiators.

Since the Suggested State Regulations for Control of Radiation (SSRCR) do not provide for the distribution of electronic and electrical devices containing NARM to persons exempt from regulation or to general licensees, the distribution is limited to specific licensees.

B. Definitions

1. Electron tube(s) - includes spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwave tubes, indicator tubes, pickup tubes, radiation detection tubes, and any other completely sealed tube that is designed to conduct or control electrical currents.

2. Spark gap irradiator - a passive device, containing radioactive material attached near a spark gap to enhance reliability of ignition.

C. General Criteria

The manufacturer, assembler, or distributor shall submit sufficient information regarding each type or model of device for the evaluation of the device. Such information shall include:

1. Identification

   Identify the radioactive source(s) and the device, respectively, by model number or other specific model designation.

2. Proposed Use

   Describe the proposed use of the device and identify the environments and operating conditions expected during normal conditions of use. Include descriptions of the types of users, locations of use, possibilities of use in other products, and circumstances of normal use. In addition, describe probable effects of severe conditions, including accidents or fires, and possible diversion from intended use.

3. Radioactive Material

   Identify the radioactive material, chemical and physical form of the radioactive material, the details of the method of incorporation and binding of the radioactive material into the source, activity per source, and the number of sources in the device.

4. Construction

   (a) Submit engineering drawings of the device, identifying all materials of construction, dimensions, methods of fabrication and means for incorporating the radioactive material into the device.

(b) Include a detailed description of all special design features which protect the radioactive material from abuse and minimize the radiation hazards. Describe in sufficient detail so that the nature, function, and method of operation are clearly defined.

5. Human Access

Describe the degree of access of human beings to the device during normal handling and use.

6. Useful Life

Indicate the expected useful life of the device.

7. ANSI Classification Designation

State the American National Standard Institute (ANSI) Classification designation for the source or device if applicable.

8. Labeling and Instructions for Use

Submit facsimiles of the labeling or marking to be placed on each device, and copies of the manual that will accompany the device.

9. Additional Information

Submit any additional information, including experimental studies and tests, which will facilitate a determination of the safety of the device.

D. Maximum Quantity

Not applicable for this Guide.

E. Prototype Evaluation

1. A minimum of 2 devices shall be evaluated. Prototype devices tested shall be of the same design and fabricated in a manner that can be duplicated in production units, especially as to materials, tolerances, and methods of construction. Any change in design or method of fabrication which could affect containment, shielding, or the safe operation of the device requires reevaluation of the new prototype incorporating such change. The appropriateness and reproducibility of the test conditions, accuracy of the observations, and interpretation of the results, are among the points to be considered. In some cases, it may be desirable to have tests carried out by qualified independent laboratories.

2. The manufacturer, assembler, or distributor shall submit information including:

(a) Maximum radiation level at 1 centimeter from any external surface of the device averaged over an area not to exceed 10 square centimeters, and the method of measurement.

(b) Results of tests performed on sources that establish the integrity of the source construction and seal under the most adverse conditions of use to which the device is likely to be subjected. These prototype tests should, insofar as possible, reflect the actual conditions of use and as a minimum shall meet the designated classification according to the current ANSI Standard entitled "Classification of Sealed Radioactive Sources".

(c) Procedures for prototype testing of the device to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, and use of the device.

(d) Results of the prototype testing of the device, including any change in the form of the radioactive material contained in the device, the extent to which the radioactive material may be released to the environment, any increase in external radiation levels, and any other changes in safety features.

(e) A safety analysis based on the evaluation of the ability of the final design to withstand the normal conditions of handling, use and storage, and the effects on containment and shielding of abnormally severe conditions of use, including fires and accidents. Aging effects are of particular importance.

F. Quality Control

1. Each manufacturer, assembler, or distributor shall describe the quality control procedures to be followed in the fabrication and assembly of the devices and the quality control standards for maintaining source design specifications.

2. Each manufacturer, assembler, or distributor shall describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

3. Each manufacturer, assembler, or distributor shall perform a leak test on each source by applying procedure(s) in the current ANSI Standard entitled "Classification of Sealed Radioactive Sources". Acceptability of source leakage shall be indicated by removal of less than 0.005 microcurie.

G. Labeling and Instructions for Use of Device

1. The label or marking shall consist of the name, trademark, or symbol of the manufacturer, assembler, or distributor, the type and amount of radioactive material, the date of measurement, the standard radiation symbol, and the words, "CAUTION-RADIOACTIVE MATERIAL". The label or marking must be durable enough to remain legible for the useful life of the device and be readily visible.

2. Each distributor shall provide with each source/device:

   (a) A certification that the sealed source has been appropriately tested for leakage and contamination within 6 months of date of transfer.

   (b) A certificate of assay for each source.

   (c) Instructions for the safe handling and usage of the source/device.

H. Transfer Reports

Not applicable to this Guide.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

NARM GUIDE 9

LEAK TEST KITS AND SERVICES

A. Scope

This guide provides criteria for the evaluation of leak test kits and leak test services to be used for or in the assessment of leakage from sources of radioactive material.

B. Definitions

1. Leak test certificate – The written report of the analytical results of the leak test sample.
2. Leak test kit - Includes collection medium (filter paper, cotton swab, activated charcoal, etc.) and instruction for obtaining the test sample and for submitting it for analysis.
3. Leak test service - Includes the kit, analysis of test sample and reporting of results.

C. General Criteria

The leak test service company shall submit sufficient information to enable evaluation of each type of kit and service. Such information shall include:

1. Identification

   Identify the kit by type and identification number or other specific model designation.

2. Proposed Use

   Describe the proposed use of the kit and service.

3. Radioactive Material

   Identify the type of radioactive material(s) for which the kit is designed to be used. Identify the type of radioactive material(s) for which the service is designed.

4. Description of Kit and Service

   Identify the method of performing the leak test. Such tests shall meet or be equivalent to the tests specified in American National Standards Institute (ANSI) reports entitled "Classification of Sealed Radioactive Sources" and/or "Leak Testing Radioactive Brachytherapy Sources." The information to be submitted shall:

   a) Describe in detail all components of the kit. Submit drawings or facsimilies of the kit.

   b) Include copies of instruction for performing sample collection directly from the sources or elsewhere. In cases where the sample will not be taken directly from the source, drawings showing the proper site(s) for sample collection shall also be included. Instructions shall also be provided for returning the test sample to the leak test service company for analysis. These instructions shall include the performance of a radiation survey of the test sample for compliance with U.S. Department of Transportation or Postal Service Regulations.

c) Identify all instrumentation that will be used for analysis of the test samples. The identification shall include the manufacturer and model number of each instrument, the types and energies of detectable radiation, and the efficiency and minimum sensitivity of the instrument for each type of radioactive material to be tested and the frequency of calibration. As a minimum, the instrument must be capable of detecting 0.0005 microcurie of the radioactive material being tested or in the case of radium-226 brachytherapy sources, the leakage of radon–222 at the rate of 0.0001 microcurie per 24 hours.

d) Describe in detail the procedure for performing the analysis on the leak test samples.

e) Identify calibration standards to be used in the analysis of each material to be tested. Such standards shall be traceable to a National Standard.

f) Include sample calculations showing conversion from raw counting data to units of microcuries.

g) Include copies or facsimilies of leak test certificates. Such certificates shall identify (1) the name and address of the customer, (2) the date the sample was collected, (3) the individual collecting the sample, (4) the person performing the analysis, (5) the date the analysis was performed, (6) the unique identification of the source tested, (7) the radioactive material and mass number contained in the source, and (8) the result of the test expressed in microcuries. Actual test results shall be reported unless such results are less than 0.0005 microcurie or in the test for radon-222 leakage, 0.0001 microcurie per 24 hours.

5. Additional Information

Submit any additional information which will facilitate a determination of the adequacy of the kit and/or service.

D. Maximum Quantity

Not applicable to this Guide.

E. Prototype Evaluation

Not applicable to this Guide.

F. Quality Control

The leak test service company shall describe the quality control procedures to be followed in the evaluation of each leak test sample.

G. Instructions for Use

See Section C.4(b) of this Guide.

H. Records/Reports

A written report of the leak test results shall be furnished to the customer. In addition, immediate notification by telegraph or telephone shall be given to the customer for each leak test exceeding 0.005 microcurie; or in the case of radium-226 brachytherapy sources, those exceeding 0.001 microcurie of radon-222 per 24 hours.

The leak test service company shall maintain records of the results of each leak test analysis performed. These records shall include the information specified in C.4(g) of this Guide.

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

NARM GUIDE 12

IN VITRO TEST KITS

A. Scope

This Guide provides criteria for the evaluation of in vitro test kits containing radioactive material. The Suggested State Regulations for Control of Radiation (SSRCR) provide for the distribution of in vitro test kits containing radioactive material to persons exempt from regulation pursuant to C.4(b), to persons generally licensed pursuant to C.22(i), and to specific licensees.

B. Definitions

In vitro test kit (kit) - a package containing the necessary components, at least one of which is radioactive, to perform clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to humans or animals.

C. General Criteria

The manufacturer, assembler, or distributor shall submit sufficient information regarding each type or model of kit for the evaluation of the kit. Such information shall include:

1. Identification

Identify the kit by model number or other specific model designation.

2. Proposed Use

Describe the proposed use of the kit and identify the environments and application conditions expected during normal conditions of use. Include descriptions of the types of users, locations of use, possibilities of use in other products, and circumstances of normal use. In addition, describe the probable effects of severe conditions, including accidents and fires, and possible diversion from intended use.

3. Radioactive Material

Identify the radioactive material, chemical and physical form of the radioactive material, activity per vial or test unit, and the number of vials or test units per kit or package.

4. Construction

(a) Submit engineering drawings of the kit, identifying all materials of construction, dimensions, methods of fabrication and means for incorporating the radioactive material into the kit or package.

(b) Include a detailed description of all special design features which protect the radioactive material from abuse and minimize the radiation hazards. Describe in sufficient detail so that the nature, function, and method of application are clearly defined.

5. Human Access

Describe the degree of access of human beings to the radioactive material during normal handling and use.

6. Useful Life

Indicate the expected useful life of the kit.

7. ANSI Classification Designation

Not applicable to this Guide.

8. Labeling and Instructions for Use

Submit facsimiles of the labeling or marking to be placed on each vial or test unit and the kit package and copies of the instructions for use, storage, and disposal that will accompany the kit.

9. Additional Information

Submit any additional information, including results of experimental studies and tests, which will facilitate a determination of the safety of the kit.

D. Maximum Quantity

1. For kits intended for distribution to persons exempt from regulation pursuant to C.4(b) SSRCR, the quantity of radioactive material per kit shall not exceed that listed in schedule B, Part C, SSRCR. No more than 10 exempt quantities shall be sold or transferred in any single transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

2. For kits intended for distribution to persons generally licensed pursuant to C.22(i), SSRCR, the quantity of radioactive material per each separately prepackaged unit shall not exceed 10 microcuries of cobalt 57.

3. For kits intended for distribution only to persons specifically licensed, a maximum quantity per kit is not applicable.

E. Prototype Evaluation

1. A minimum of 2 kits shall be evaluated. Prototype kits tested shall be of the same design and fabricated in a manner that can be duplicated in production units, especially as to materials, tolerances and methods of construction. Any change in design or method of fabrication which could affect containment, shielding, or the safe use of the kit requires reevaluation of the new prototype incorporating such change. The appropriateness and reproducibility of the test conditions, accuracy of the observations, and interpretation of the results, are among the points to be considered. In some cases it may be desirable to have tests carried out by qualified independent laboratories.

2. The manufacturer, assembler, or distributor shall submit information including:

   (a) Maximum radiation level at any external surface of the package averaged over an area not to exceed 10 square centimeters, and the method of measurement.

   (b) Results of tests performed on kits that establish the integrity of the kit construction and seal under the most adverse conditions of use to which the device is likely to be subjected. These prototype tests should, insofar as possible, reflect the actual conditions of use.

   (c) A safety analysis based on the evaluation of the ability of the final design to withstand the normal conditions of handling, use and storage, and the effects on containment and shielding of abnormally severe conditions of use, including fires and accidents.

(d) For kits intended for distribution to persons exempt from regulation pursuant to C.4(b), or to persons generally licensed pursuant to C.22(i), sufficient information to provide reasonable assurance that the kit can be safely used by persons not having training in radiological protection.

F. Quality Control

1. Each manufacturer, assembler, or distributor shall describe the quality control procedures to be followed in the fabrication and assembly of the kits and the quality control standards for maintaining kit design specifications.

2. Each manufacturer, assembler, or distributor shall describe the assay method used to determine the radioactive content of the kit. The assay shall be traceable to a National Standard.

G. Labeling and Instructions for Use of Kit

1. The label shall consist of the name, trademark, or symbol of the manufacturer, assembler, or distributor, the type and amount of radioactive material, the date of measurement, the standard radiation symbol, and the words "CAUTION - RADIOACTIVE MATERIAL" and "NOT FOR INTERNAL OR EXTERNAL USE IN HUMANS OR ANIMALS". A readily visible label shall appear on each prepackaged unit and must be durable enough to remain legible for the useful life of the kit.

2. For kits intended for distribution to persons exempt for regulation pursuant to C.4(b), in addition to the labeling information required by (1) above, the label affixed to the prepackaged unit or an accompanying brochure, shall:

(a) state that the contents are exempt from Licensing State requirements;

(b) bear the words "Radioactive Material - Not for Human Use - Introduction into Foods, Beverages, Cosmetics, Drugs, or Medicinals, or into Products Manufactured for Commercial Distribution is Prohibited - Exempt Quantities Should Not Be Combined";

(c) set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

3. For kits intended for distribution to persons generally licensed pursuant to C.22(i), in addition to the labeling information required by (1) above, the label affixed to the prepackaged unit, or an accompanying brochure, shall contain the following statement or a substantially similar statement:

> This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of a Licensing State.
>
> ____________________
>
> Name of Manufacturer

4. In addition to the specific labeling required in 1, 2, and 3 above, the label or accompanying brochure shall contain adequate information as to the precautions to be observed in handling,storing, and disposing of the radioactive material.

H. Transfer Reports

1. Submission of transfer reports is not required for kits distributed to general or specific licensees.

2. For kits transferred to persons exempt from regulation pursuant to C.4(b);

   (a) Each kit shall be separately and individually packaged. Not more than 10 such packaged kits shall be contained in any outer package. The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem per hour.

   (b) Each manufacturer, assembler, or distributor shall maintain records identifying, by name and address, each person to whom a kit is transferred. These records shall include the kinds and quantities of radioactive material transferred.

   (c) Each manufacturer, assembler, or distributor shall file an annual summary report, in duplicate, with the State specifying the total quantity of radioactive material transferred. Each report shall cover the calendar year and shall be filed by January 31 of the following year. If no transfers of radioactive material have been made during the reporting period, the report shall so indicate. The State will forward one copy of the report to the Bureau of Radiological Health, Food and Drug Administration, Rockville, Maryland 20857. The Bureau of Radiological Health will send copies of the report to all States.

RATIONALE FOR NARM GUIDES

July 3, 1977

INTRODUCTORY NARM GUIDE

Products containing naturally occurring radioactive materials, primarily radium, have been used for consumer, industrial or medical applications since the early 1900's. Accelerator-produced radioactive materials have impacted on the marketplace within the past decade. Naturally occurring and accelerator-produced radioactive materials are collectively referred to as NARM. The population exposed to radiation from NARM products consists of millions of people. Most of these people are members of the general public who have consumer products that are radioactive and present a minimal degree of radiation exposure to the individual. Personnel working in medical and industrial facilities are also exposed to radiation from NARM sources and devices.

Since NARM is not comprehensively controlled by the Federal Government, the regulation of NARM has been left to the discretion of each State. To promote national uniformity, the Conference of Radiation Control Program Directors (CRCPD) established a Task Force in 1975 to develop uniform guidance for evaluation of NARM sources and products. The members of the Task Force included representatives of the CRCPD, Bureau of Radiological Health/FDA, Nuclear Regulatory Commission, and the Environmental Protection Agency. The Bureau of Radiological Health/FDA funded the Task Force activities. These Guides are compatible with existing guidance and procedures developed by the Nuclear Regulatory Commission (NRC) for other radioactive materials, e.g., byproduct and source materials. The Guides reflect recommendations and suggestions of the American National Standards Institute (ANSI) and the National Council on Radiation Protection and Measurements (NCRP). Also, the manufacturer is requested to describe the assay method used to determine the radioactive content of the source. The assay shall be traceable to a National Standard.

The NARM Guides classify NARM sources or products into 12 categories and provide criteria for evaluating a given NARM product regarding (1) manufacturer identification and model number, (2) results of radiation measurements, (3) labelling of name and amount of radioactive material, and (4) licensing recommendation for product control. The "Introductory NARM Guide" also presents a format on the "regulatory process" to appropriately control the manufacture, assembly, distribution, and use of a NARM product in conjunction with the Suggested State Regulations for Control of Radiation (SSRCR) and Radioactive Materials Reference Manual (RMRM).

NARM GUIDE NO. 1 - Calibration and Reference Sources Containing Radium-226 for Distribution to Persons Generally Licensed Pursuant to C.22(g), SSRCR

B. Definitions

The basis for the definitions of "Capsule," "Device" and "Source holder" is ANSI Report N5.10 - 1968. The definition of "Sealed source" is based on the definition given for this item in Title 10, Code of Federal Regulations, 10 CFR 34.2 (e). The definition for "Plated alpha source" is similar to the definition of "Sealed source" in the SSRCR; since a "Plated alpha source" is a matrix form designed to prevent the leakage and dispersal of radioactive material.

C. General Criteria

The request for information on the NARM product regarding its identification, use, construction, ANSI classification and labelling provide a reference basis for the radiological evaluation of the product. The description, function, and use of the source/device is to be clearly stated. From this information and its subsequent evaluation, the control agency can determine that the source/device may be used safely within regulations of the Agency or provisions of the SSRCR.

D. Maximum Quantity

The rationale for specifying five microcuries as the maximum quantity of a calibration or reference source incorporating radium-226 is that five microcuries is a usable quantity applied in the common practice of standardizing radiation survey instruments, and that use of this quantity over many years has attested to its acceptability. The maximum quantity allowed by C.22(g)(5)(i) SSRCR for americium-241 (10 CFR 31.8(c)(1)), plutonium (10 CFR 70.19 (c)(1)) and radium-226 is five microcuries in such sources.

E. Prototype Evaluation

The reason for performing items E.1(a) - (e) in that given order is because C.28(f) SSRCR requires the applicant to satisfy the general provisions of 10 CFR 70.39 which in turn requires that the five prototype tests be conducted in this sequence.

In item E.2, 0.005 microcurie of radioactivity has been specified as the leak test limit; since it has been a long standing practice by industry and regulatory agencies to accept this limit. It is cited extensively throughout NRC regulations and ANSI standards, e.g., 10 CFR 32.59 and N44.2 - 1973.

F. Quality Control

The rationale for specifying 0.0005 microcurie (item F.3) as the lower limit of instrumentation detection is that the concept of the instrumentation as being capable of detecting one order of magnitude less than the specified removable radioactivity contamination limit is recommended by ANSI N44.1 - 1973. Such instrumentation is readily available on the market.

NARM GUIDE NO. 2 - Sealed Sources

E. Prototype Evaluation

Measurements at the distances of 5 and 30 centimeters from any external surface of the source averaged over an area of 100 square centimeters for determination of maximum radiation levels are specified in item E.1. The distance of 5 centimeters satisfies the geometry limitations in the practical use of many radiation survey instruments. The distance of 30 centimeters approximates 12 inches cited in D.204(a) SSRCR (10 CFR 20.204(a)). ANSI N43-3.2 (draft 9/24/76) specifies 100 square centimeters as the maximum area for averaging radiation measurements. Radiation instruments meeting this criterion are commonly available; therefore, special instruments are not required.

F. Quality Control

The basis for the leakage rate of less than 0.001 microcurie of radon in 24 hours for radium-226 sources intended for brachytherapy (item F.3) is that paragraph 3.2.2 of ANSI N44.2 - 1973 specifies this leak test criterion of 1 nanocurie (0.001 microcurie) in 24 hours for radon.

H. Transfer Report

The rationale for not requiring transfer reports (item H.1) for sources distributed only to specific licensees is not a contradiction of A.4 SSRCR which requires that licensees (e.g., manufacturers) maintain records for the receipt, transfer and disposal of all radiation sources. In this case, persons who use the radiation source are specific licensees; hence, are known to, and routinely inspected by, the authorizing agency. There is no further need to identify specifically licensed source/device recipients.

NARM GUIDE NO. 3 - Gas and Aerosol Detectors for Distribution to Persons Exempt from Regulation Pursuant to C.4(c)(3) SSRCR

B. Definitions

The definition of "Gas and aerosol detector" (item B.2) is taken from AEC Licensing Guide - Exemption of Gas and Aerosol Detectors Containing Byproduct Material, dated October 10, 1969, which applies to the exemption of gas and aerosol detectors containing byproduct material.

C. General Criteria

The reason for requesting descriptions of the types of users, locations of use, possibilities of use in other products and circumstances of normal use (item C.2) is that these data are necessary for evaluation of the detector. Further, this language tends to promote uniformity with the NRC regulation and licensing guides for gas and aerosol detectors containing byproduct material.

An example of a special design feature (item C.4(b)) is a one-way screw or other access limiting tool which may be incorporated in the device.

The kinds of information requested in items C.6 and C.7 can be used to estimate the amount of radioactive material to ultimately be disposed to the environment and allow regulatory agencies to anticipate potential problems.

D. Maximum Quantity

The rationale for specifying a maximum quantity of 0.1 microcuries of radium in gas and aerosol detectors (item D) is that this amount is consistent with the Nuclear Energy Agency draft standard, April 1976, on ionization chamber smoke detectors intended for unrestricted distribution.

E. Prototype Evaluation

The basis for specifying a minimum of two prototype detectors (item E.1) for evaluation is given in the test specification procedures for evaluating brachytherapy sources in ANSI N44.1 - 1973. It may be advisable to have an independent evaluation performed by an outside laboratory under certain circumstances. These kinds of tests are also required of byproduct devices in AEC Licensing Guide - Exemption of Gas and Aerosol Detectors Containing Byproduct Material dated October 10, 1969 (See item B.2 of NARM Guide 3).

The distances of 5 and 25 centimeters from any external surface of the detector averaged over an area not to exceed 10 square centimeters for determination of the maximum radiation levels are specified in item E.2(a). These distances and this area are specified in 10 CFR 32.26(b)(6) by the NRC for similar detectors containing byproduct material. The rationale for requesting information on aging effects (item E.2(e)) is based on the requirement for gas and aerosol detectors containing byproduct material in the above referenced AEC licensing guide dated October 10, 1969.

APPENDICES

Appendix A for this Guide is based on NRC regulations regarding gas and aerosol detectors containing byproduct material in 10 CFR 32.27-28. Appendix B comes from 10 CFR 32.110 on "Acceptance sampling procedures under certain specific licenses."

NARM GUIDE NO. 4 - Measuring, Gauging or Controlling Devices

B. Definitions

The definition of "Gauge" (item B.2) is based on the provision given in C.22(d)(1) SSRCR and in 10 CFR 31.5(a).

C. General Criteria

The rationale for requesting information (item C.9) on the kinds of services available to the gauge user is in order for the agency to view the entire use range. Further, generally licensed gauges are transferred without prior agency evaluation of the recipients' training and experience. These kinds of services are required by C.22(d) of the SSRCR and 10 CFR 31.5.

E. Prototype Evaluation

The basis for requesting that at least one gauge be evaluated (item E.1) is that it is consistent with current practice as recommended in the ANSI N-538 - 1976 draft report on gauging devices.

The request for information (item E.2(d)(i)) that the gauge can be operated safely by persons not trained in radiation protection is consistent with the requirement C.28(d)(1)(ii)(a) of the SSRCR and 10 CFR 32.51 (a)(2)(i).

H. Transfer Reports

As some gauge systems are "turn key" operations there is a need to identify persons who only temporarily possess the gauge (item H.2). The identification of persons who possess the gauge temporarily, or otherwise, is consistent with the requirements of 10 CFR 32.52(a) and (b) as well as C.28(d)(4) of the SSRCR.

NARM GUIDE NO. 5 - Radioactive Material for Distribution to Persons Exempt from Regulation Pursuant to C.4(b) SSRCR

D. Maximum Quantity

The rationale for specifying a maximum limit of 10 exempt quantities (item D.2) is based on the requirement of C.28(b)(2) of the SSRCR (10 CFR 32.19 (a)).

H. Transfers and Transfer Reports

The reason for specifying the limit of 0.5 millirem per hour at the surface (item H.1) of a package containing radioactive material is based on the requirement of C.28(b)(2)(ii) of the SSRCR (10 CFR 32.19(b)) regarding this matter.

APPENDICES

The method of determining exempt quantities in Appendix B was given in an AEC memorandum from F. Western to E. Price dated February 6, 1968. The method later appeared in a statement of consideration for proposed rulemaking; Federal Register Vol. 33, page 11414, August 10, 1968.

NARM GUIDE NO. 6 - Static Elimination and Ion Generating Devices

B. Definitions

The definition of "Device" given in item B.1 of this Guide is different from the definition for "Device" cited in NARM Guides 1, 2 and 3; since the equipment addressed by Guide 6 may not contain a sealed source. Hence, the Guide 6 definition of "Device" is not applicable to NARM Guides 1, 2 or 3.

E. Prototype Evaluation

The rationale for requesting a minimum of two devices for evaluation is consistent with ANSI N44.1 - 1973.

NARM GUIDE NO. 7 - Radioluminous Products

B. Definitions

The definition of "Device" given in item B.1 of this Guide is different from the definition for "Device" cited in NARM Guides 1, 2, or 3; since the equipment addressed by Guide #7 may not contain a sealed source. Hence, the Guide #7 definition of "Device" is not applicable to NARM Guides 1, 2, or 3.

The definition, "Radioluminous product," (item B.2) is based on the definition for "self-luminous light source" given in the ANSI N540 - 1975 report entitled Classification of Radioactive Self-Luminous Light Sources.

E. Prototype Evaluation

The rationale for requesting a minimum of two samples of the radioluminous product for evaluation (item E.1) is consistent with paragraph 4.2 of ANSI N540 - 1975. The rationale for specifying maximum radiation levels of 5 and 25 centimeters from any external surface of the device averaged over an area not to exceed 10 square centimeters is cited from 10 CFR 32.22 (a)(2)(vi) for self-luminous products.

NARM GUIDE NO. 8 - Electronic and Electrical Devices

B. Definitions

The definition for "Electron tube" (item B.1) was taken from footnote 3 of C.4(c)(1)(vii) of the SSRCR and 10 CFR 30.15(a)(8). The definition of

"Spark gap irradiator" (item B.2) is based on the NRC definition of "Spark gap irradiator" given in the rulemaking proposal which appeared in 40 FR 49801, October 24, 1975.

E. Prototype Evaluation

The rationale for requiring a distance of 1 centimeter and a maximum rate of 1 millirad per hour measured through an absorber density of 7 milligrams per square centimeter is that these same factors are required by C.4(c)(1) SSRCR (10 CFR 30.15 (a)(8)).

The specification of the area of 10 square centimeters for averaging radiation level measurements is consistent with this same value cited previously for NARM Guides 3 and 7.

NARM GUIDE NO. 9 - Leak Test Kits and Services

B. Definitions

The definitions of "Leak test certificate," "Leak test kit," and "Leak test service" (items B.1, B.2, and B.3, respectively) were derived from Task Force consensus.

C. General Criteria

The rationale for specifying 0.0001 microcurie (item C.4(c)) as a minimum detection limit of the instrumentation used for measuring the radon-222 leakage from a radium-226 test sample is that this magnitude is recommended in paragraph 5.4 of ANSI N44.1 - 1973. Further, it is the consensus of the Task Force that instrumentation should be capable of detecting one order of magnitude less than the specified leakage rate limit for radon-222. Such instrumentation is readily available on the market. The rationale for specifying 0.0005 and 0.0001 microcurie (item C.4(g)) as the lower limits for the reporting of test results is that these values have been specified as the lower sensitivity limits of the instrumentation used for measuring radioactive contamination and leakage. Hence, any measured activity equal to or exceeding these values should be reported.

NARM GUIDE NO. 12 - *In Vitro* Test Kits

B. Definitions

The definition of "*In vitro* test kit" (item B) is based on C.22(i) of the SSRCR and 10 CFR 31.11(a).

D. Maximum Quantity

The basis for exempting a quantity composed of fractional parts provided that their sum does not exceed unity (item D.1) is C.28(b)(2) of the SSRCR. The reason for limiting the maximum amount of cobalt 57 to 10 microcuries per kit (item D.2) is that this limit is given for cobalt 57 in C.22(i)(1)(vi) of the 1976 Revision of the SSRCR.

H. Transfer Reports

The transfer limit (item H.2(a)) to persons exempt from regulation (pursuant to C.4(b) SSRCR) of no more than 10 kits contained in any outer package with a dose rate not exceeding 0.5 millirem per hour at the external surface of the package comes from C.28(b)(2)(ii) of the SSRCR (10 CFR 32.19(b)).

CHAPTER II

GENERAL AND BIOLOGICAL RISKS

CHAPTER II

General and Biological Risks

Although there are numerous texts, chapters, books, and reports dealing with general and biological risks of radiation and radioactivity, because of its pertinence to radioactivity in consumer products, the editors have included several papers dealing with this subject in the chapter. Owing to the nature of consumer products, only lower levels of radiation exposure generally need to be considered in the evaluation of biological risk. Therefore, low-level effects have been emphasized in this chapter.

The radioactive content of tobacco and its subsequent intake constitutes a unique route for exposure of the general public to radioactivity. This subject has been investigated by many authors and, for obvious reasons, has also been of interest to the general public. This chapter contains relevant information on the radioactivity content of tobacco and tobacco smoke as well as potential biological risks associated with intake of radioactive aerosols from smoke.

This chapter is not intended as a comprehensive review of the general and biological risks related to low doses of radiation. It is rather an introduction to the subject with the understanding that the interested reader can find appropriate texts from references included in this chapter.

BIOLOGICAL EFFECTS OF LOW LEVELS OF RADIATION EXPOSURE

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INTRODUCTION

Radiation Exposure from Consumer Products

The National Council on Radiation Protection and Measurements (NCRP, 1977a) has been studying radiation doses received from consumer products. The values given here are based on those studies.

This introductory information on dose provides some general perspective concerning the orders of radiation dose equivalent levels associated with exposure to ionizing radiations from consumer products rather than a comprehensive and precise cataloging of such doses. Considerations of the biological effects and risks of low levels of radiation exposure follow the introductory information.

Some consumer products emit low linear energy transfer (LET) radiations beyond their confines. These penetrating radiations can result virtually in whole-body irradiation, whereas in the case of other products the radiation to tissue consists mainly of the high-LET alpha particles that penetrate tissue only shallowly and close to the products.

Some radiation-emitting consumer products are in such widespread use in the United States that large numbers of people are irradiated by them. Some of these products, e.g., television receivers, timepieces with radium-containing dials, gas and aerosol detectors, and building and road construction materials, may irradiate 10^6 to 10^8 people to average annual whole-body or gonadal dose equivalents varying for different products over a range of 1 to 10 mrem. Approximately 10^4 people may be irradiated by vacuum high-voltage switches to 30 mrem or by electron microscopes to 300 mrem average annual whole-body or gonadal dose equivalent.

Smaller annual whole-body or gonadal dose equivalents, of less than 1 μrem to 1 mrem, may be received by many people (10^4 to 10^8) from cold cathode gas discharge tubes, X-ray airport inspection systems, timepieces with dials containing tritium or ^{147}Pm, radioisotopic check sources, static eliminators, and radioactive materials in transport in commercial passenger aircraft.

Small or unknown numbers of people receive annual whole-body or gonadal radiation dose equivalents of tens to hundreds of mrem from products such as personnel scanning systems and shoe-fitting fluoroscopes, or dose equivalents from a small fraction of a mrem to a few mrem from products such as radium-containing dials of old aircraft instruments and spark gap irradiators.

Certain other consumer products may locally irradiate certain tissues of many people (10^7 to 10^8) to relatively high annual dose equivalents of a few mrem to tens of mrem. Such sources include natural radioisotopes (^{210}Po and ^{210}Pb) in tobacco smoke and radioisotopes in fossil fuels, irradiating tissues of the respiratory tract; radioisotopes in dental prosthetics irradiating the oral mucous membrane; and radioisotopes in ophthalmic glass lenses irradiating the cornea and contiguous structures. There are also raw materials that are contaminated with radioisotopes, e.g., precious metals used to make jewelry, which may result in highly localized irradiation to relatively small numbers of people to dose equivalents up to thousands of rem.

It is conceivable that large numbers of people in the general public could accumulate, from combinations of the commonly used consumer product sources of radiation exposure, average annual whole-body or gonadal dose equivalents in the tens of mrem and additional, considerable doses to respiratory tract tissues, oral mucosa, and cornea.

For perspective, the average annual whole-body dose equivalent received by the population from natural background sources of radiation has been estimated to be about 100 mrem, and medically applied radiation adds approximately another 100 mrem annually.

Radiation Protection Criteria and Population Dose Equivalent Limits

The rem has been the dose equivalent unit in radiation protection. Numerically, the rem is equal to the absorbed radiation dose in rads (a rad being 100 erg/g) multiplied by the appropriate effectiveness modifying factors such as the radiation quality factor (Q), which is related to the linear energy transfer (LET), the dose distribution factor (D), and any other necessary modifying factors.

The current NCRP (1971) recommended annual whole-body dose equivalent limits for the general population are 500 mrem for individuals and 170 mrem average per capita for the population. The Federal Radiation Council (1960) recommended limit for the average annual per capita gonadal dose in the population as a whole was 5 rem in 30 years (a generation), which would amount to 170 mrem per year.

These recommended limits of the NCRP and the FRC were intended to apply to all sources of man-made ionizing radiation other than those directly associated with medical applications of radiation. Radiation exposures from medical applications were excluded on the assumption that such exposures to patients were justified by the health benefits.

The radiobiologic effects of greatest practical concern at radiation exposure levels and rates approaching or within those of the radiation protection guide limits are those for which no substantial dose threshold has been established by observation or theory such as genetic effects and cancerogenesis. Other low-dose somatic effects of concern in highly radiosensitive tissues are those effects that may have low dose thresholds such as some types of embryological (teratogenic) and developmental aberrations, cataract of the optic lens, and fertility impairment as a consequence of destruction of gametogenic (sperm- and ova-producing) cells.

Under radiation exposure conditions approaching those of the current NCRP radiation protection guide limits, no significant and unequivocal radiation injuries have been observed in man or experimental animals, except perhaps for some cytologic or cytogenetic effects with as yet unknown pathologic significance. On the other hand, the possibility that serious genetic and somatic effects, particularly cancer induction, could be caused in some incidence, however small, by such low levels of radiation dose cannot be dismissed on theoretical grounds.

Radiation protection policy during the past 20 years has been based partly on the possibility of no threshold doses for genetic and cancerogenic* effects. Owing to the

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*Cancerogenic refers to any malignancies of any kind or any origin.

lack of data on such effects at the low radiation levels of interest and in view of the practical improbability of ever obtaining reliable human data at such levels, the estimation of radiation risks at radiation levels within or approaching the radiation protection guide limits for the general population can be made only by extrapolation from observations of effects at much higher doses and higher dose rates. Such extrapolation necessarily involves assumptions concerning the nature of the effect, the dose-effect relationships below observational levels, the mechanisms of induction of the effect, the relative susceptibility of populations at risk and control populations, the influence of biological variables, and the influence of physical variables such as spatial and temporal distributions of dose, radiation quality, LET, and changing relative biological effectiveness of high-LET radiation with changes in dose size and dose rate. It is evident that such extrapolation should be aided by theoretical analysis that accounts adequately for the influence of the major variables.

The linear (proportional) nonthreshold dose-effect relationship, with its independence of dose size and dose rate and with relative neglect of other biological and physical variables, has often been chosen for extrapolation arbitrarily and pragmatically as a prudent, conservative approach to risk estimation for cancerogenic effects.*

Since it is not now possible to give assurance that low levels of radiation exposure are safe for everyone, the immediate task of setting radiation protection dose limits involves quantification of risks and assessment of risk justification to arrive at an acceptable level of risk.

This is a necessary and difficult task, made all the more difficult because the diseases of concern are nonspecific and cannot be distinguished from the same diseases occurring "naturally" or caused by other agents and because the effects of concern occur after long latent periods, e.g., many years for cancer and one or more generations for genetic effects. Such radiation effects at low radiation levels are detectable only statistically. The smaller the dose and dose rate, the more the potential effect is statistically confounded in the background "noise" and the less likely it is that the radiation in question was the sole and unaided cause of epidemiological effects statistically observed.

PERTINENT RADIOBIOLOGIC PRINCIPLES AND THEORIES

Dose Threshold And Dose-Effect Relationships

The radiation inductions of cataract of the lens, impairment of fertility, teratogenic effects (i.e., gross anomalies of embryologic formation), and significant deficiencies in development, all of which are associated with highly radiosensitive systems, depend on damage, reproductive sterilization, or destruction of substantial numbers of cells. Thus there are apparent dose thresholds for these effects above which the radiation effect or effectiveness per unit dose increases with the size of the acute dose in nonlinear (concave upward) fashion to a point of saturation of effect or plateau. With further increase in acute dose beyond the point of saturation of effect, the apparent effectiveness per unit dose declines because the larger doses are greater than required for the maximum degree of effect. For these types of radiation effect, extended fractionation or protraction of doses in the rising portion of the dose-effect curve tends to reduce the effect and effectiveness per unit dose, especially for low-LET radiations.

For radiation induction of genetic and cancerogenic effects, however, the possible absence of a significant dose threshold cannot be excluded on the basis of existing data or theory. The possibility remains that significant effects of these kinds may result from sublethal radiation injury in only one or a small number of cells.

The effectiveness of ionizing radiation for most types of biological effects, including embryological, genetic, and cancerogenic effects, has been observed to decrease with decreasing dose and dose rate, at least in the case of low-LET radiations such as X-rays and gamma rays.

Although the dose-effect relationships differ quantitatively among the various types of effects, it has been repeatedly observed experimentally that the relationships for induction of mutations, chromosomal aberrations, reproductive sterilization of cells, cell destruction, teratogenic effects, cancerogenic effects, and lifespan shortening, all depend on the dose size, dose rate, and LET of the radiation (NCRP, 1977b). In general, the slopes of the dose-effect curves for low-LET radiation increase with increasing magnitude of dose and dose rate in concave upward fashion to a maximum or plateau, then with further increase in dose bend down (owing to excessive cell killing or sterilization) for genetic cancerogenic effects. At low doses and low dose rates, the dose-effect curve for many radiobiological effects is nearly linear and with a lower slope than at higher dose and higher dose rates.

The dose-effect curves for high-LET radiations, e.g., neutrons or alpha particles, tend to rise more rapidly at lower dose levels than those for the low-LET radiations, are closer to straight lines in their rising parts, and the effectiveness is less dependent on the dose size or dose rate in those regions.

In general, the experimentally observed shapes of the dose-effect relationships for low-LET radiations and their dependence on dose size and dose rate support the conclusions (UNSCEAR, 1972; NCRP, 1975) that simple linear extrapolation or interpolation on dose from effects observed at intermediate to high doses and high dose rates, i.e., on the rising portions of the observed curves, without accounting for the influence of dose size, dose rate, and other influencing variables, tends to systematically overestimate the overall risks at low doses and low dose rates.

The influence of dose rate on the effectiveness of radiation has long been known clinically for somatic effects and experimentally for both genetic and somatic effects. On the basis of results of experiments with mice showing that lowering of the dose rate reduces the numbers of mutations produced, the NAS-BEIR Committee (1972) and the UNSCEAR Committee (1972) employed a conservative effect-reducing factor of three in extrapolating to low dose rates from high radiation exposure levels in their estimation of risks at low doses and low dose rate levels. In its studies of the evidence that the effectiveness per rad of low-LET radiations for lifespan shortening and cancer induction is lower at low doses and low dose rates than at high doses and high dose rates, the NCRP (1977b) found that the reduction with dose rate appears to vary from about 0.05 to about 0.8, depending on the effect in question and the dose level involved, with most of the reduction factors being in the range of 0.1 to 0.2 for doses of 100 to 300 rads. It was also found that the overall effectiveness per rad of low-LET radiation is generally reduced with decrease in dose size as well as decrease in dose rate, so that it is possible that the effectiveness of very low doses at very low dose rates may be very much smaller than that of high doses at high dose rates. However, as the degree of reduction has not yet been estimated with confidence, only conservative effectiveness-reducing factors for these variables have been proposed so far.

The difficulty in formulating complete and precise dose-effect relationship models for estimation of radiation risks to human beings or to experimental animals resides not only in the paucity and fragmentary nature of the available data on dose and effects, but importantly also in the incompleteness of knowledge of the details of the mechanisms of radiation induction of the effects. Theoretically, for an effect that can be produced by the action of a single radiation track or "hit" in relation to the pertinent biological target, the dose-effect relationship should be linear (proportional) over a certain range of dose levels, other conditions being unchanged during irradiation. For effects requiring two radiation tracks or target hits, the yield of the effect would theoretically be related to the square of the dose. Available data indicate that the biochemical and biological amplification of the radom radiation-induced initial molecular changes into manifest cellular and tissue damage and lesions is influenced by balance and interactions between the production of injury and the repair of injury. These interacting processes, as well as the probability that a single hit can cause a given effect, apparently depend on the type of effect, the radiation quality (LET), the spatial and temporal distribution of dose, and the physiological condition or phase of the relevant cells being irradiated.

LET, RBE, Q, and Dose-Effect Relationships

Substantial differences in the LET of radiations are reflected in differences in dose-effect relationships, as already indicated. The relative biological effectiveness (RBE) of radiations of different qualities or types is related at least in part to their LET. The RBE is essentially the quotient of the absorbed dose (rads) of a reference radiation (for radiation protection usually 200-150 kV X-rays) divided by the absorbed dose of the radiation of different LET, in each case being the dose required to cause a specified type and degree of effect, all other conditions being equal.

A few decades ago, for purposes of radiation protection, it was often assumed that the RBE values, determined largely at high doses and high dose rates for certain effects, pertained to all effects and all dose levels. On this basis, the "dose equivalent," i.e., the product of the absorbed dose and the RBE, was assumed to be related to biological effect and additive for multiple types of radiation at all dose levels. The subsequent experimental demonstrations that the RBE varies with dose size led to the replacement of RBE with the "quality factor" (QF or Q) for purposes of radiation protection.

Rossi and Kellerer (Rossi, 1970; Kellerer and Rossi, 1971 and 1972), on the basis of their observations that the RBE of neutrons for different biological effects varies inversely as the square root of the dose over a wide range of doses, have theorized that this represents a general radiobiological relationship. They postulated that the biological effect is the result of changes or impairments at two sites within a single target in the cell nucleus, and that the yield of such changes for a given LET is proportional to the mean square of the specific energy (absorbed energy at a site ÷ mass of site) and thereby proportional to a quadratic function of the absorbed dose. In other words, the yield (Y) of impairments is a function of a proportional dose (D) term plus a dose squared relationship term, as in

$$Y = aD + bD^2$$

Where the coefficient a is a function of the size of the site and the radiation quality (LET), and the value of the coefficient b varies from zero to one, depending on the probability of interaction between sites of radiation impairment and therefore on dose rate and time available for repair. For high-LET radiations, the linear term greatly predominates and the dose square term is of little importance over the practical range of doses. For low-LET radiations, the dose squared term is important at high dose levels, and the linear term becomes important only at low dose levels. Spreading out the primary impairments produced by an intermediate or high dose of low-LET radiation by reducing the dose rate reduces the probability of interactions between impairments because of repair.

As the effect of high LET radiation is proportional to dose (linear) and independent of dose rate, the RBE of that radiation increases as the dose and/or dose rate decrease, not because the effectiveness of the high-LET radiation changes but because the effectiveness of the low-LET reference radiation decreases with reduction of dose and/or dose rate. In regard to any requirement for a minimum amount of radiation energy deposited within a small volume to initiate a biological effect, the probability of low-LET radiation producing the effect with a single track or hit is small, and the probability increases with increasing LET to a point above which the efficiency in terms of energy per unit mass may decrease with increase of energy deposition that is superfluous or "wasted" in terms of production of the specified effect. Thus, the RBE may increase with increasing LET to a peak at an intermediate LET, often observed to be from about 100 to 300 keV per micrometer, and then may decrease as LET rises further, without dependence on the size of dose and dose rate.

In view of the dependence of RBE on dose size and dose rate, it is important to translate such information into quality factors appropriate for the low radiation exposure levels of concern in radiation protection.

CONSIDERATIONS OF RISKS AT LOW RADIATION LEVELS

Nontumorigenic Somatic Effects

Nontumorigenic somatic effects of concern in highly radiosensitive tissues such as teratogenic aberrations, developmental deficiencies, cataract of optic lens, and fertility impairment as a consequence of destruction of gametogenic cells have apparent dose thresholds, presumably because their induction to degrees of concern depends on the damage, reproductive sterilization, and/or destruction of large numbers of cells. The apparent acute dose thresholds for these effects are well above the current radiation protection dose equivalent limit for members of the general population (500 mrem per year), and the risks of induction of these effects appear to be negligible, if not zero, at the doses and dose rates to the relevant tissues from the consumer products discussed at the outset of this paper.

Spermatogenesis

Although occasional small-scale epidemiological studies have suggested deleterious effects of occupational radiation exposure on human spermatogenesis, no studies of long-extended low-level irradiation in the range of radiation protection limits for the public or of natural background levels on spermatogenesis in man have been adequate to qualify as definitive in regard to epidemiologic, biomedical, radiobiologic, dosimetric, and quantitative aspects. However, such studies do point up the possibility of some degree of effect in the occupational radiation exposure range. The whole-body or gonadal doses from consumer products discussed at the outset of this paper seem unlikely to impair spermatogenesis significantly.

In the 20-year experiment with male Beagle dogs (Casarett and Eddy, 1968) involving brief daily whole-body X-irradiation from sexual maturity to death, with daily exposures of 0, 60, 120 or 600 milliroentgens (mR), only the 600 mR per day level caused marked depression of spermatogenesis, and the 120 mR per day level may have caused a slight depression but this was statistically equivocal. Spermatogenesis in the dog is about as radiosensitive as that in man. Survival and causes of death were similar in all groups, with possible slight, but equivocal, lifespan shortening at the 600 mR per day level and possible slight, but equivocal, lifespan lengthening at the 60 mR per day level.

Ovogenesis

In the ovary there is a limited supply of germ cells shortly after birth, and this supply declines with increasing age. Radiation destruction of oocytes causes a lasting reduction in the total lifetime reproductive potential which, if severe, may result in a practical realization of impaired fertility at some time when the remaining oocytes decrease to low levels.

No definitive studies have been done to determine the effect of long-extended low-level irradiation on the ovaries or fertility of women or large experimental animals. Most of the experimental work of this kind has been done with mice, a species with much higher ovarian radiosensitivity than other mammalian species studied, including the human species, in terms of magnitude of sterilizing doses and susceptibility to induction of ovarian tumors.

Exposure to 1 R per day of gamma radiation has considerable effect on the mouse ovary but little or no detectable effect on ovaries of other species studied. Experiments with mice have shown that 1 rad per day to the embryos and fetuses over a large part of the gestation period is the lowest level to cause deficient development of gonads (NCRP, 1977c).

It seems highly improbable that extended exposure of human females with protracted doses as low as a few rads per year, or the lower doses to gonads from the consumer products discussed earlier, would cause appreciable or detectable effects on fertility on the basis of destruction of gametogenic cells and gametes (ova).

Lens of Eye (Cataractogenesis)

The human dose threshold for low-LET radiation induction of progressive cataracts severe enough to impair vision seems to vary between 200 and 500 rads (depending on age) for a single brief exposure and 1000 rads or more for exposures fractionated over a period of months. The fragmentary data for fission neutrons suggest a dose threshold for such cataracts in the range of 75-100 rads, with less influence by dose protraction or fractionation. Stationary small cataracts or plaques that do not impair vision can be produced by smaller doses.

Minute, microscopically detectable lens changes in the highly radiosensitive lens of the mouse have been caused by brief 14-MeV neutron doses as low as 12 rads (Darden, 1971). For larger doses and effects, the mouse lens has been regarded as about 16 times more sensitive than the human lens.

The consumer products discussed at the outset of this paper are not likely to irradiate the lens of the eye to dose equivalent levels causing significant changes.

Development after Embryonic-Fetal Irradiation

With brief, single, low-LET radiation exposures in experimental animals (mice or rats), the lowest doses observed to cause effects on development, growth, function, or behavior range from a few rads to 50 rads, depending on the stage of development at the time of irradiation and the biologic endpoint. The incidence or severity of effects at these low doses are usually very small (NCRP, 1977c).

A few rads kill occasional germ cells at certain stages in development, with no detectable functional effects. Brief irradiation of the mouse zygote in the early preimplantation stage, with subsequent examination 16 days later for relative embryo survival, has shown a detectable effect on survival by less than 5 rads of neutrons, with an exponential survival curve at higher doses (up to 20 rads). The RBE for neutrons for this effect was about 4 compared with X-rays over this dose range.

Subtle but permanent morphologic changes and deletions of cells of the nervous system, with some permanent disorganization of the tissues they compose, are caused by brief doses of 10-20 rads at some stages of development, but no obvious changes in behavior have been detected unequivocally below about 25 rads given at sensitive prenatal stages.

There have been some reports of subtle behavioral changes detected by complex test systems after one or a few rads, but these reports still need confirmation.

In animal experiments, 1 rad per day over a large part of the gestation period has been shown to be the lowest level of extended irradiation to cause detectable effects, namely, some life shortening and deficient development of gonads and some other organs (NAS-BEIR, 1972).

Similar data for man at low radiation levels are not available, but observations on developmental effects of *in utero* irradiation of Japanese A-bomb survivors would indicate that the minimal doses for detectable effects on head size and mental retardation may be between 25 and 50 rads. However, these data are complicated by the neutron component of the radiation in Hiroshima which, if assigned an adequate value for RBE, would probably increase the gamma radiation dose required for these effects. On the other hand, the methods available for measuring these effects were not very sensitive.

Although the embryo-fetus is sensitive to radiation induction of teratogenic aberrations and developmental effects in some stages of organ development, most of these sensitive stages are very short. Therefore, the parts of the total dose received by the embryo-fetus from consumer products at the times of these sensitive stages would be small. The annual dose equivalents that the embryo-fetus could receive from combined consumer products affecting large numbers of people in the general population are far below the lowest dose shown to be capable of causing a significant incidence of considerable developmental effect in experimental animals. Any possible teratogenic or developmental effect of such low doses and/or low dose rates would not be detectable. Most of the available data suggest an apparent threshold of about 10 rads of acute irradiation and a sigmoid dose-response relationship for induction of lethal effects and developmental abnormalities (NAS-BEIR, 1972). However, this value could actually be too high in view of the limited observations and lack of application of sensitive methods for detection of small defects.

Genetic Effects

Despite extensive investigation of genetic effects, including chromosomal effects, neither the amount of change that will be caused by very low levels or irradiation nor the degree of associated detriment is known. This is owing to the great difficulty in detecting the relevant rare events at low radiation levels against a high noise background involving mutations from other causes and variable influences which are not yet adequately understood.

In the NAS-BEIR report (1972), the Genetics Subcommittee assumed that the experimental mouse data at the lower doses and lower dose rates were more appropriate than the data at the higher doses and higher dose rates for the kinds of radiation exposure that most of the human population would experience, and the subcommittee based their risk estimates on the lower-dose, lower-dose-rate mouse data. They indicated that the calculations of genetic risks for low doses should be made on the assumption that the relationship between the lowest accurate measurements of effect and zero-induced effect at zero dose is linear. This had the effect of giving a lower slope to their assumed linear relationship than would have been the case had they used the data for larger, more intense exposures.

The mutation doubling dose for low-dose, low-dose-rate irradiation was taken to be between 20 and 200 rem, based almost entirely on the experimental mouse data, with some support from experimental data on Drosophila and observations of offspring of Japanese A-bomb survivors.

The Genetics Subcommittee assessed the genetic risk from irradiation on four bases (in decreasing order of confidence), going from a firm basis to little more than an informed guess, as follows:

1. In terms of risk relative to natural background radiation. Exposure to man-made radiation at levels below the level of background radiation would produce additional genetic effects that are less in quantity and no different in kind than those that man has experienced and tolerated throughout his history.

2. In terms of risk estimates for specific genetic conditions. The effect of 170 mrem per year (i.e., 5 rem per 30-year reproductive generation) was calculated to cause between 100 and 1800 cases of serious dominant or X-linked diseases and defects per year in the U.S. in the first generation of descendants, assuming 3.6 million births annually. This is an incidence of 0.003% to 0.05%. At equilibrium, after several generations, the number of cases would be about 5 times greater, or 0.015 to 0.25%. In addition, a smaller number of cases would be caused by chromosomal defects and recessive diseases.

3. In terms of risk relative to current prevalence of serious disabilities. In addition to the specific genetic conditions just mentioned, which are caused by single gene defects and chromosomal aberrations, there are the congenital abnormalities and the constitutional diseases that are partly genetic. The Genetics Subcommittee estimated that the *total* incidence from all these, including the specific genetic conditions mentioned above, would be between 1100 and 27,000 per year at equilibrium in the U.S. (again, based on 3.6 million births annually). This would be an incidence of 0.03% to 0.75% at equilibrium and 0.02% to 0.1% in the first generation.

4. In terms of risk relative to overall ill health. This is probably the most tangible measure of total genetic damage, and it includes, but is not limited to, the previous categories of genetic conditions mentioned above. The Genetics Subcommittee thought that between 5% and 50% of ill health is proportional to the mutation rate.

Assuming a value of 20% of ill health as being proportional to the mutation rate and assuming a doubling dose of 20 rem, they calculated that 5 rem per generation would lead eventually to an increase of 5% in the ill health of the population. Assumption of a doubling dose of 200 rem would give 0.5% increase in ill health.

Recently, another committee (NAS, 1977) estimated the genetic effect of 5 rem per generation by modifying the estimates of the NAS-BEIR Committee (1972) to account for new data and approaches. According to these modified risk estimates, it can be calculated that 1 mrem per year gonadal dose equivalent to the U.S. population could lead to about .04 additional cases of genetic disease per million live births (0.9 at the very unlikely upper limit) against a background of an estimated 94,000 "natural" cases per million live births, or 0.14 additional cases of genetic disease in the U.S. population per year. There are 3.6 million live births per year in the U.S. population. At the unlikely extreme upper limit of possible genetic effects of radiation, it can be estimated that there would be about 3 additional cases to the 94,000 x 3.6 = 340,000 live births with genetic defects per year in the United States.

Cancerogenic Effects

At the low doses or low dose rates with which we are here concerned, there is no unequivocal information on cancerogenic effects in man or experimental animals. The effects are inferred on the basis of data at higher doses and higher dose rates and on the basis of theory and assumptions concerning dose-incidence relationships and mechanisms.

The NAS-BEIR Committee (1972), in estimating risks for radiation induction of cancers at the low doses and low dose rates to which populations are exposed, chose to base the estimates exclusively on available human data at high dose and/or high dose rate, but with acknowledgment of the data and principles and theories derived from experiments on animals.

The Committee assumed a linear (proportional) nonthreshold dose-incidence relationship for extrapolating from the observed data at high dose and/or high dose rate, fitting the relationship to the observed data, and interpolating it to pass through the control incidence at the intercept or zero dose and effect. Data on A-bomb survivors in Japan, certain groups of patients irradiated for medical reasons, and certain groups occupationally exposed were used.

These risk estimates involved extrapolations by factors greater than 1,000 in dose and from 100 million to a billion in dose rate.

The body of the BEIR report indicated the factors that might invalidate this linear extrapolation but justified the approach on pragmatic grounds.

The Committee cited the cogent radiobiological reasons, both theoretical and factual, for doubting that the dose-incidence relationship remains constant despite changes in dose, dose rate, and population at risk.

The Committee recognized that, at least for low-LET radiation, the cancerogenic effectiveness probably decreases with decreasing dose and dose rate, that there may be a linear component at low dose and/or low dose rate, and that the slope of that linear component would probably be lower than the overall linear slope employed for extrapolation from high-dose, high-dose-rate data.

The Committee also recognized in their report that their treatment of the neutron component in the data from the Hiroshima A-bomb studies, which are a major basis for the Committee's risk estimates, might seriously underestimate the neutron RBE and overestimate the gamma radiation cancer induction risk at low doses and low dose rates but stated that firm data enabling other approaches were lacking.

The Committee concluded that it was impractical at the time to use other than the linear hypothesis for estimating risks in support of public policy on radiation protection. The linear hypothesis permits the grouping and averaging of various individual doses, the integration of partial organ doses over the whole organ, and the neglect of dose rate. It should be noted, however, that such practices may tend to impose linearity on the data to some extent in the process of preparing them for analysis.

The Committee recognized that estimates of risks at low doses and low dose rates based on linear extrapolation from observed effects at high doses and high dose rates in the range of rapidly rising incidence, i.e., before the curve reaches the very high doses at which there is a decline in cancerogenic effectiveness attributable to excessive cell killing, may well be overestimates of risks for low-LET radiation. The Committee stated that, therefore, these estimates should be considered as upper limits of risk for low-LET radiation at low levels of exposure, where the lower limit could be considerably smaller (zero not excluded by the data).

The Committee's overall risk estimates for various specific malignancies, in terms of cancer deaths (or cases for thyroid cancer) per 10^6 persons exposed, per year, per rem, were approximately as follows:

1-2 for leukemia.
2.5-9.3 cases for thyroid cancers in irradiated children with lesser risk in irradiated adults.
1 for lung cancer.
3 for breast cancer in women.
0.2 for cancer of the skeleton.
1 for cancer of the gastrointestinal tract.
Possibly 1 for cancers at other sites combined.

These rates were based on the periods of time after irradiation during which an excess of the incidence of the neoplasms has been evident.

The BEIR Committee estimated that the overall excess mortality from cancer, including leukemia, in irradiated populations can be largely accounted for by the specific types of neoplasms for which risk estimates were given. In the Japanese atomic bomb survivors, this excess mortality at high doses and high dose rates approximates 2.5 deaths per 10^6 exposed persons per year per rem, averaged over the period in which the excess has been observed.

Some studies of diagnostic *in utero* irradiation effects have suggested that prenatal irradiation might increase the overall juvenile cancer mortality at the rate of 50 cases per 10^6 persons per year per rem, averaged over the first 10 years of life. The Committee has pointed out, however, that a possibility still exists that the excess incidence observed in these studies may be dependent on factors other than radiation.

The BEIR Committee has also pointed out that to estimate the actual risk of cancer attributable to a particular increase in the level of exposure of the general population to radiation would require systematic information on the effects of lifelong, low-dose irradiation that is not available.

However, the Committee made an approximate calculation at the level of mortality on the basis of the data from the 25-year followup studies on A-bomb survivors and on patients treated with intensive spinal irradiation for ankylosing spondylitis. The rates of radiation-induced excess mortality from all forms of malignancy were extrapolated linearly to low-dose and low-dose-rate levels. Exposure of the U.S. population of about 200 million persons to, for example, 100 mrem during 1 year could be expected to cause 1350-3300 deaths from cancer during the 25 years after irradiation or about 50-130 deaths per year in the U.S. Continued exposure of the population to an additional 100 mrem per year could be expected ultimately to cause 1350-3300 deaths annually, provided the effect of a given increment of dose did not persis beyond 25 years after exposure. The rate per million persons on this basis would be about 7-17 at 100 mrem per year.

An estimation of the complete cumulative experience of an entire population requires more specific attention to age at exposure, duration of latency, size and duration of effect, age and sex distribution in the population, age specific mortality from the various malignancies, and other factors influencing the effect. Because of these influential factors, the BEIR Committee considered it advisable to illustrate the great uncertainty that necessarily characterizes its estimates of the effect of a particular level of low-dose and low-dose-rate radiation exposure on the entire population. The Committee chose a range of values for each parameter entering into such estimates. The estimates based on these ranges of selected values for each parameter, for the annual number of cancer deaths associated with an increase in radiation exposure of the whole U.S. population by 100 mrem per year, ranges from about 2,000 to 9,000. Much weight was given to these estimates by the high risk estimates for juvenile cancer mortality from prenatal irradiation, based on the suggested risk from epidemiological studies of prenatal diagnostic irradiation. These studies are still questionable regarding the contribution of radiation to the effect which has not been confirmed in studies of the Japanese A-bomb populations.

The Committee considered that the most likely estimate from this approach (still using the linear extrapolation) is about 3,000-4,000 cancer deaths or roughly about 1% of the annual cancer death rate in the U.S. population.

Recently, dose-effectiveness reduction factors have been used by certain groups (NRC, 1975; NCRP, 1977b) to adjust the estimates of cancer risk at low radiation doses and low dose rates obtained by linear extrapolation as in the case of the NAS-BEIR Committee (1972) estimates, for the reduced effectiveness of low-LET radiation at low doses and low dose rates. These proposed reduction factors are still conservative in the interest of prudent radiation protection because possible larger factors cannot yet be determined with confidence. The reduction factors proposed so far were intended for use in estimating the overall cancerogenic risk from low levels of low-LET radiation for all malignancies combined, rather than risk for individual types of cancer for which reliable reduction factors have not yet been determined. The proposed reduction factors for overall cancerogenic risk range in size from 0.2 for doses less than 10 rads or for larger doses at dose rates less than 1 mrad per minute to 1.0 for doses of 200 rads or more at dose rates greater than 1 mrad per minute.

In the NRC study (1975), the upper limit of risk estimates was derived from absolute risk estimates of the NAS-BEIR Committee (1972), the central estimates were derived by the application of the effectiveness reduction factors for low doses and low dose rates of low-LET radiation, and the lower limit estimates were based on the assumption that the risk was zero below a threshold dose of 10 or 25 rem.

NCRP's (1977b) dose-effectiveness factors are similar in range and direction to those of the NRC study but differ in size at low doses, especially between 10 and 100 rads, so that risk estimates derived with them are intermediate between those derived in the NRC study and those reported by the NAS-BEIR Committee.

Taking together all the risk estimates derived in these three studies (BEIR, NRC, NCRP) for the number of cancers or cancer deaths attributed to continuous irradiation of the U.S. population at a rate of 100 mrem per year, the values range from 0 to about 9,000 per year, depending on the risk model and the method used in deriving the risk estimates. The value of 9,000 is close to 3% of the annual cancer death rate in the United States (NAS-BEIR, 1972).

On the basis of the NAS-BEIR (1972) risk estimate, it can be calculated that 100 mrem per year to the population could cause from about 7 to 45 cancer deaths per million exposed persons per year, depending on the risk model used, with zero risk at such radiation levels and rates not excluded by the data. The application of the dose-effectiveness reduction factors of the NRC (1975) and NCRP (1977b) studies resulted in estimates ranging from about 3 to 22 cancer deaths per million persons exposed per year, depending on the risk model and reduction factors used.

The estimation of the possible cancer induction risks from the dose equivalents of whole-body irradiation received from consumer products are subject to the problems and uncertainties of extrapolation and risk estimation discussed above.

In addition to these risks from whole-body irradiation, the possibility of cancerogenic risks from localized alpha and other irradiation to skin, oral mucosa, eye tissues, and respiratory tract are also to be considered. The NAS-BEIR Committee (1972) risk estimates for radiation induction of lung cancer (deaths) is 1 per 10^6 exposed persons per year per rem. Although radiation induction of cancers of the skin and other epidermoid tissues has been documented, the data on dose in relation to effect are not yet adequate to establish dose-effect relationships that can be used to yield risk estimates such as those described above. At the present time, the risk per rad for radiation reduction of skin cancer is regarded as being either low relative to that for leukemia or certain other cancers or as possibly higher than now appreciated owing to a combination of long latency, insufficient followup, and inadequate study to date (Casarett, 1973). If one accepts the linearly extrapolated risk estimates of the NAS-BEIR report (1972) for other tissues, a possible risk of the general order of 1 excess case of cancer of epidermoid tissue (epidermis, oral mucosa, superficial eye tissues) per million exposed persons per year per rem to the germinal cells of these tissues may not be grossly out of the question.

Dose calculations by Tobias and Chatterjee (1974) indicate that the annual alpha-particle dose to the germinal cell layer of the cornea (50-μm depth) from eyeglasses containing 0.05 percent thorium-232 by weight, in equilibrium with its daughters and worn for 16 hours per day, is 0.2 rad and that the beta-particle dose is about the same. Using these data and applying a quality factor of 20 for alpha radiation, Casarett et al. (1974) estimated that the dose-equivalent rate to the germinal cells of the cornea would be approximately 4 rem per year at 50-μm tissue depth and 1 rem per year at 60-μm depth and that the dose-equivalent rate for beta radiation would be a small fraction of this. Such doses are above the NCRP (1971) recommended annual dose-equivalent rate limit of 0.5 rem for individuals in the general population.

It would be prudent radiation safety practice to assume that dose equivalent rates of tens of mrem per year or greater to the whole body or to germinal layers of epidermoid tissues from consumer products might entail some cancerogenic risk, however small, and to promote a benefit-risk-cost approach to reducing unnecessary and unjustified exposure.

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POLONIUM-210 IN TOBACCO

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INTRODUCTION

Perhaps the first to point out the possible hazard of inhaled ^{210}Po were Marsden *et al.* (1963), who presented their case merely as a question worthy of further examination. Radford *et al.* (1964) were the first to measure the ^{210}Po content of cigarettes and mainstream smoke and to indicate the general level of ^{210}Po to be found in the bronchial epithelium of a smoker. Since these initial measurements, many published studies have tried to assess the possible role that ^{210}Po may play in the etiology of lung cancer in smokers. The measured data indicate that in the region of the tracheobronchial tree where lung tumors appear there is a total of about 2 pCi of ^{210}Po in smokers and 0.5 pCi in nonsmokers. The question is: Can this small a quantity of radioactivity be significant?

The purpose of this paper is to present the measurements that have been made on tobacco and tobacco products and to indicate the studies that show the amount transferred to mainstream smoke and inhaled. The amounts reported to be in the lung are summarized. We have attempted to show what average values might be expected in the lung due to normal deposition and clearance of the smoke aerosol and to compare these values with the measurements. Finally, the average dose to cells in the bronchial epithelium is estimated for the activities reported to be on the bronchial surface, and a comparison of this dose with a known tumorigenic alpha dose is attempted.

POLONIUM-210 IN TOBACCO LEAF, CIGARETTES, AND CIGARETTE SMOKE

The measurement of the ^{210}Po content of cigarettes was first made by Radford *et al.* (1964). Rapidly, measurements of the ^{210}Po content of cigarettes, both in the U.S. and in other countries, as well as of tobacco leaf and other tobacco products appeared in the literature. These are summarized in Tables 1-5. From the data of Table 1, the calculated average ^{210}Po content of U.S. cigarettes is 0.44 pCi per cigarette and ranges from 0.30 to 0.65 pCi for different brands. From Table 2, it can be seen that the average ^{210}Po content of cigarettes from other countries ranges from 0.09 pCi/g for Indian cigarettes to 0.67 pCi/g for Central and South American cigarettes. Table 3 indicates the ^{210}Po content of a few tobacco products other than cigarettes. Some measurements have been made of the variation of ^{210}Po content with tobacco quality. There is no clear correlation, but there may be a possible trend

TABLE 1
^{210}Po IN U.S. CIGARETTES AND TOBACCO

pCi/Cigarette	pCi/g	Range*	Number of Types or Brands	References
0.43	–	0.39–0.48	4	Radford (1964)
0.45	–	–	1	Yavin (1965)
0.38	0.43	0.32–0.48	6	Ferri (1966)
0.39	–	0.30–0.49	6	Ferri (1967)
0.54	0.52	0.39–0.60	8	Black (1968)
–	0.51	0.39–0.65	–	Hill (1965)
–	0.33	0.32–0.34	2	Rajewsky (1966)

*Range is for the value in pCi/cigarette when both are given

to higher ^{210}Po content in higher grade tobacco, as indicated by Yermolayeva-Makovskaya *et al.* (1965) and Abel *et al.* (1974).

The ^{210}Po content of tobacco leaf for a variety of growing and curing conditions is shown in Table 4. The ^{210}Po is in equilibrium with ^{210}Pb in cigarettes and cigarette tobacco. There is no equilibrium with ^{226}Ra (Tso *et al.*, 1964 and Ferri *et al.*, 1966a). Francis *et al.* (1967) have shown that most of the ^{210}Po grows in from ^{210}Pb incorporated into the plant during the growing season.

Polonium-210 and ^{210}Pb are not reported in equilibrium in pipe tobacco, presumably because it is not aged (Ferri *et al.*, 1966b). Some of the variation reported among investigators in the content of tobacco products may be due to shelf storage time either before or after purchase of the product.

The ^{210}Po concentration values for tobacco leaf in other countries is given in Table 5. The low and high values in New Zealand and Rhodesia are reflected in the values seen in cigarettes from these countries where presumably a larger portion of local tobacco is used in cigarette manufacture. Blending different tobacco types and parts for cigarettes results in less variation in cigarette tobacco than in tobacco leaf.

The large variation in ^{210}Po in tobacco leaf from different countries provides a unique opportunity to study the origin of ^{210}Pb and ^{210}Po. So far there are no data to indicate whether large differences in the airborne ^{210}Pb concentration exist in areas where tobacco is grown. Perhaps the ^{210}Pb concentration in rainfall is also responsible for differences. Tobacco that is lower in ^{210}Po is highly desirable if any of the health effects of smoking can be attributed to its presence.

To evaluate the biological significance of ^{210}Po, the amount of ^{210}Po transferred first to mainstream smoke and then to the lungs must be determined.

Table 6 summarizes the available data on the amount of ^{210}Po transferred to mainstream and sidestream smoke. The differences among studies are not related to the size of the cigarettes tested or to the presence or absence of a filter.

The average transfer of ^{210}Po from the cigarette to the total smoke is 50% as shown by Radford *et al.* (1964), Hill (1965), Ferri *et al.* (1966a), and Rajewsky *et al.* (1966). The fraction in the mainstream smoke depends on the smoking pattern. This accounts for some of the variation in reported values.

TABLE 2
^{210}Po IN CIGARETTES FROM OTHER COUNTRIES

Country	pCi/Cigarette	pCi/g	Range*	Number of Types or Brands	Reference
Australia	–	0.64	0.61–0.66	–	Hill (1965)
Canada	0.21	0.26	0.21–0.22	2	Black (1968)
Central and South America	–	0.67	0.29–1.36	–	Hill (1965)
Egypt	0.38	–	–	1	Black (1968)
England	0.47	0.46	0.23–0.62	7	Black (1968)
France	0.63	0.56	–	1	Black (1968)
Finland	0.29	0.63	0.27–0.32	2	Black (1968)
Germany	0.48	0.45	0.41–0.60	3	Rajewsky (1966)
Germany	0.52	0.56	–	1	Black (1968)
India	–	0.09	0.07–0.15	–	Singh (1976)
India and Pakistan	–	0.41	0.25–0.57	–	Hill (1965)
Indonesia	–	0.23	–	–	Hill (1965)
Italy	–	0.45	0.37–0.53	–	Carfi (1966)
Japan	0.60	0.60	0.45–0.89	4	Black (1968)
Japan	0.51	0.54	0.33–0.75	12	Okabayashi (1975)
New Zealand	–	0.36	0.23–0.46	5	Gregory (1965)
New Zealand	0.31	–	0.24–0.45	8	Gregory (1965)
Norway	0.23	–	–	–	Black (1968)
Philippines	0.29	0.18	–	1	Black (1968)
Rhodesia	–	0.65	0.60–0.70	–	Hill (1965)
Slovakia (cigarette tobacco)	–	0.49	0.17–1.05	7	Abel (1974)
Slovakia (Cigarettes)	0.43	0.64	0.11–0.68	8	Abel (1974)
Turkey and Greece	–	0.24	0.21–0.28	–	Hill (1965)
USSR	0.40	0.43	0.32–0.56	12	Yermolayeva-Makovskaya (1965)
USSR	0.38	0.60	–	1	Black (1968)
Unspecified	0.96	1.00	0.50–1.78	9	Yermolayeva-Makovskaya (1965)
Yugoslavia (cigarette tobacco)	–	0.40	0.36–0.76	5	Kilibarda (1966)
Yugoslavia (cigarettes)	–	0.38	0.20–0.60	4	Kilibarda (1966)

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*Range is for the value in pCi/cigarette when both are given.

TABLE 3
^{210}Po IN TOBACCO PRODUCTS OTHER THAN CIGARETTES

U.S.

Type	^{210}Po pCi/g	Range	Number of Types or Brands	Reference
Cigar filler type 41	0.17	–	1	Tso (1964)
Cigar wrapper type 61	0.27	0.25–29	1	Tso (1966)
Cigar wrapper type 62	0.32	0.18–0.46	1	Tso (1966)
Cigars	0.48	0.23–0.81	10	Black (1968)
Cigars	0.46	–	2	Ferri (1966)
Pipe tobacco	0.40	0.24–0.54	25	Black (1968)
Pipe tobacco	0.20	–	2	Ferri (1966)
Other Countries				
New Zealand roll your own blends	0.17	0.11–0.22	3	Gregory (1968)
New Zealand pipe tobacco	0.18	0.12–0.23	3	Gregory (1965)
Slovakia pipe tobacco	1.11	0.63–1.24	7	Abel (1974)
India cigars	0.039	0.025–0.052	2	Singh (1976)
Cheroot	0.065		–	Singh (1976)
Beedi filling	0.081		–	Singh (1976)

A correlation of ^{210}Po content with puff size has been shown by Black *et al.* (1968). In those cases where a standard smoking procedure (a 35-ml draw of 2-second duration, once each minute) was adhered to, just under 7 percent of the ^{210}Po or 0.04 pCi per average unfiltered U.S. cigarette is transferred to the mainstream smoke. This value can increase considerably with larger puffs or more frequent draws.

In general, no correlation in these studies could be made with the mainstream smoke content of filter or nonfilter cigarettes because the amount of ^{210}Po in the cigarette tobacco varies. Two investigations, Hill (1965) and Black *et al.* (1968), have reported the smoke content of the same cigarette with and without filters. The results in these studies indicate a 33 to 58 percent reduction in ^{210}Po content of the mainstream smoke from cigarettes with filters.

A correlation between the particulate matter and ^{210}Po content of mainstream smoke was indicated by Kelly (1965). Values of ^{210}Po per mg of total particulates are shown in Table 7 to be fairly constant regardless of the presence of a filter.

TABLE 4
^{210}Po IN U.S. LEAF TOBACCO OF VARIOUS TYPES

Type	pCi/g	Range	Reference
Maryland Type 32	0.15	–	Tso (1964)
Burley Type 31	0.47	0.45–51	Tso (1966)
Bright Type 14	0.38	0.30–0.48	Tso (1964)
Bright Type 12	0.36	0.25–0.48	Tso (1964)
Mixed varieties (10 types)	0.95	0.17–1.54	Berger (1965)
Wisconsin*	2.0	1.3 –2.8	Francis (1967)
Mixed varieties (5 types–18 samples)	0.49	0.35–0.70	Gregory (1965)

*12 months after harvest.

TABLE 5
^{210}Po ACTIVITY IN LEAF TOBACCO FROM VARIOUS COUNTRIES

Country	pCi/g	Range	Number of Types	Reference
Bulgaria	0.43	0.21–0.58	6	Nikolova (1972)
New Zealand	0.15	0.08–0.22	18	Gregory (1965)
Rhodesia	0.75	0.67–0.84	3	Gregory (1965)
Russia	1.13	0.60–1.60	6	Yermolayeva-Makovskaya (1965)
South Africa	0.41	0.34–0.53	3	Gregory (1965)

About 30 percent of the ^{210}Po content of a cigarette is transferred to a sidestream smoke or about 2.6 pCi for an average pack of U.S. cigarettes. The smoking of one pack of cigarettes in an average-sized room with poor ventilation could increase the air concentration of this alpha emitter by one or two orders of magnitude over the normal level.

VARIATIONS OF ^{210}Po CONTENT IN LEAF TOBACCO

In examining the variation of radioelement content in plant material, one needs to consider the differences in geographical locality, year (rainfall and other environmental changes), plant species or variety, soil fertilizer, plant parts, culture, and postharvest handling practices.

Plant species differ in their ability to absorb radioelements. For example, Brazil nuts can accumulate radium in seed twice the amount of its level in the soil, up to 30

TABLE 6
^{210}Po IN CIGARETTE SMOKE

Mainstream		Sidestream			
pCi*	% of Cigarette Content	pCi	% of Cigarette Content	Filter	Reference
0.079	20	0.10	25	Yes	Radford (1964)
0.11	24	0.12	25	No	Radford (1964)
0.035	–	–	–	Yes	Kelly (1965)**
0.033	–	–	–	No	Kelly (1965)**
0.070	19	0.12	35	Yes	Ferri (1966)
0.082	22	0.091	24	No	Ferri (1966)
0.021	–	–	–	–	Holtzman (1966)**
0.027	6.8	0.223	47	–	Black (1968)
–	30	–	–	–	Kilibarda (1966)
In the following samples, the same cigarette type was smoked with and without filter:					
0.055	11	0.15	30	No	Hill (1965)**
0.032	6.5	0.15	30	Yes	Hill (1965)**
0.030	–	–	–	No	Black (1968)**
0.015	–	–	–	Yes–Cellulose	Black (1968)**
0.027	–	–	–	No	Black (1968)**
0.017	–	–	–	Yes–Charcoal & Cellulose	Black (1968)**

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*For one cigarette.

**Standard smoking pattern used.

pCi/g (Russell, 1963). Tobacco seed, however, has a very low concentration of radioelements (Tso *et al.*, 1968b).

In many scientific publications dealing with radioelements in tobacco, especially those not conducted by tobacco scientists, no specifications were mentioned relating to varieties, culture, source, or year of the material. Data of such a nature should be evaluated with those reservations in mind, especially when they are used for comparison purposes.

Leaf Tobacco from Different Countries

Table 4 lists the ^{210}Po content of leaf tobacco from the U.S. and Table 5, the leaf tobacco content from various countries. Generally, Russian and Rhodesian leaves

TABLE 7
^{210}Po PER MILLIGRAM OF TOTAL PARTICULATES IN MAINSTREAM SMOKE

fCi ^{210}Po /mg	Filter	Reference
3.4	Yes	Ferri (1966)*
3.0	No	Ferri (1967)*
2	–	Hill (1965)
2.6	Yes	Kelly (1965)
2.7	No	Kelly (1965)
(0.8–1.5)**	–	Martell (1974)

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*Calculated from data presented.

**Value for ^{210}Pb.

were higher in ^{210}Po content than others. No data are available to indicate the reasons for this.

Manufactured Tobacco Products from Different Countries

Manufactured products generally consist of tobacco material of mixed or nonspecified nature. Many of the individual materials originate in different countries. For example, cigarettes made in the United States are blended types consisting of Bright, Burley, Maryland, and Oriental leaves in various proportions according to brand. English cigarettes are made of straight Bright tobacco. The year and source of each leaf type are purposely mixed to achieve a "balanced" taste which characterizes the specific brand and also avoids any drastic changes in the manufactured products from year to year. So far as U.S. products are concerned, the average ^{210}Po content in cigarettes and cigars, on a per unit weight of leaf tobacco basis, does not differ widely. Pipe tobacco appears to have a slightly lower ^{210}Po activity. It is well known that a relatively high amount of additives, especially sugar, is mixed with pipe tobacco.

The use of reconstituted sheets in tobacco manufacture is a common practice in most countries. The amount of sheet usage may vary from 5 to 20%. Most reconstituted sheets are made of stems, "fines," "wastes," or low-grade tobaccos. There are no published data available reporting the ^{210}Po content in sheet material in comparison with natural tobacco. Sheets made of straight stems may have a lower radioelement content since it is known that stems (midrib) usually have a much lower ^{210}Po level than lamina (Athalye *et al.*, 1972 and Tso, 1977). On the other hand, sheets made of other materials may not differ significantly from mature tobacco. The effect of ^{210}Po levels in cigarettes containing such sheets may therefore not differ significantly.

TABLE 8
^{210}Po (pCi/g) IN SOIL AND FERTILIZER USED FOR U.S. TOBACCO PRODUCTION
(Black *et al.*, 1968)

Samples & Source	Activity
Soil	
Beltsville, Md.	0.35–0.37
Oxford, N.C.	0.26–0.33
Florence, S.C.	0.55
Tifton, Ga.	0.33–0.40
Greenville, Tenn.	0.36–1.01
Quincy, Fla.	0.46
Fertilizer	
Calcium phosphate (C.P.)	0.07
Super phosphate	6.72–7.90
Commercial mix	
4-8-12	13.76
3-9-9	12.67
5-10-5	10.53
Ammonium nitrate	0.03
Sulfate of potash	0.52

Factors Affecting ^{210}Po Content in Tobacco Production

The primary source of radioelement accumulation in leaf tobacco is through root absorption from soil and fertilizer (Tso, 1972). The greatest accumulation of ^{210}Pb and ^{210}Po in the tobacco plant is found in the roots (Athalye, 1972).

Extensive studies relating to soil, fertilizer, tobacco types, and year were made on the levels of ^{210}Po in U.S. tobacco. Table 8 lists the ^{210}Po levels in soils and fertilizers used for U.S. tobacco production. Fertilizer, particularly phosphate, was considered the main source of ^{210}Po in leaf tobacco (Tso *et al.*, 1968a).

Various stages of plant growth also showed different levels of radioelement accumulation. Young tobacco seedlings accumulated ^{210}Pb and ^{210}Po to a concentration much higher than that found in the soil; the levels decreased as plants grew older (Tso *et al.*, 1968b). Among tobacco types, a variation also existed as shown in Table 4. The variation of ^{210}Po content from year to year is generally not significant.

Among different varieties within the same tobacco type, some differences in radioelement levels were also observed. These differences in levels may be due to variation in the development of root systems. In one study, a higher level was found in cv. (cultivated variety or cultivar) Virginia Gold in comparison with cv. Delcrest (Athalye *et al.*, 1972); in another study, only minor differences were observed between cv. Coker 319 and cv. Virginia Bright (Tso *et al.*, 1968a). Two methods of flue-curing, a closed system with wood and an open system with kerosene, did not

TABLE 9
DISTRIBUTION OF ^{210}Po (pCi/g) IN A TOBACCO PLANT
(Athalye *et al.*, 1972)

Plant Part	Varieties	
	Delcrest	Va. Gold
Stalk	38.8	56.3
Leaves		
1st (oldest) pair	455	1157
2	265	267
3	192	340
4	74	192
5	42	125
6	10	187
7	9.5	169
8	9.2	159
9	8.2	86
10	6.3	177
11	3.8	Not detected
Inflorescence	8.5	Not detected

produce any differences in levels of radioelement accumulation on leaf tobacco (Tso *et al.*, 1968a).

The distribution of ^{210}Po in a tobacco plant was carefully examined in a tracer experiment using two Bright tobacco varieties (Athalye *et al.*, 1972), as shown in Table 9. Generally, the lowest leaf of a plant had the highest ^{210}Po content; the level of activity in leaves decreases gradually toward the top of a plant, with the lowest concentration at the uppermost leaf. It has been suggested that this portion of the plant be used in the manufacture of cigarette tobacco to produce a product that is lower in ^{210}Po content.

TRANSFER OF ^{210}Po TO THE BRONCHIAL EPITHELIUM, ALPHA DOSE, AND POSSIBLE HEALTH EFFECTS

Model

In recent years, sufficient data have become available on the mechanism of deposition and clearance in the lung to justify calculated estimates of the overall alpha activity in the lung. First of all, in this section, the normal background alpha activities present in the lung are considered, and then the additional alpha activity added by cigarette smoking is estimated. The background activities consist of the short-lived daughters of radon-222, ^{218}Po (RaA) and ^{214}Po (RaC′), as well as the long-lived daughters, ^{210}Pb and ^{210}Po. All the radon daughters except for a few percent of the ^{218}Po (RaA), which exists in a near atomic state, are attached to naturally occurring aerosols. The deposition in the lower lung and on the upper bronchial airways is governed exclusively by the characteristic particle size of the carrier aerosol. The alpha activity median diameter (AMD) of the aerosols for short-lived radon daughters has been shown by George (1975) to be about 0.2 μm. There is no reason to believe that the AMD for the long-lived daughters would be significantly different.

A steady-state or equilibrium value of alpha activity is established in the lower lung and on the bronchial tree because aerosol deposition during the breathing cycle, radioactive buildup or decay whole in the lung, clearance of material from the pulmonary region to the tree, and clearance of particles from the lung.

In the case of cigarette smoke, an AMD of 0.45 μm is used. Carter *et al.* (1975) have shown this to be the median particle diameter with a range from 0.1 to 1.0 μm, and it is assumed that there is no appreciable fractionation of the alpha activity with particle size. Fractionation for other constituents of cigarette smoke has been discussed by Berner *et al.* (1967).

In this calculation, values for ^{210}Pb as well as for ^{210}Po are estimated for completeness and also because a small amount of ^{210}Po, equal to 7% of the ^{210}Pb parent activity, builds up from its parent in the lower lung.

The values of activity in the lower lung are also necessary for estimating the steady-state activity on the bronchial tree because a fraction of the material on the lower lung is cleared rapidly to the bronchial tree.

For this calculation a hybrid model is used. The parameters for the lower lung are taken from the International Commission on Radiological Protection (ICRP) Task Group Model (1972). For the bronchial tree, the Weibel dichotomous model A is used, and the fractional deposition is determined from a modification of the Gormley-Kennedy (1949) diffusion equations. It is assumed that diffusion is the dominant mode of deposition in this size range. The modification considers the effect of the turbulent flow profile in the upper airways (Weibel generations 0-6). The diffusion in this case, where Poiseuille flow has not been established, has been termed convective diffusion (Levich, 1962; Friedlander, 1967; Bell, 1974; and Cheng *et al.*, 1976). Turbulence produces a somewhat greater particle deposition than would be observed for laminar flow. Martin and Jacobi (1972) have developed a set of empirical factors that were used to correct the Gormley-Kennedy equations for this effect.

The results of this hybrid model showing the steady state values of ^{210}Pb and ^{210}Po are shown in Table 10. The basic assumptions of the model are:

1. The percentage deposited in the lower lung for 0.2-μm and 0.45-μm particles is 40% and 30%, respectively.

2. All aerosols are considered to be in ICRP class W intermediate solubility. For this solubility, 15% of the particles are cleared to the blood with 10-day half-life; 40% of the particles are cleared to the tracheobronchial tree with a 1-day half-life; 40% of the particles are cleared to the tracheobronchial tree with a 10-day half-life; and 5% of the particles are cleared to the lymph nodes with a 10-day half-life. Some evidence of the intermediate class solubility for ^{210}Po has been shown by Little *et al.* (1968), Holtzman *et al.* (1974), Kilibarda *et al.* (1966), and Okabayashi *et al.* (1975).

TABLE 10
CALCULATED STEADY-STATE ACTIVITIES IN THE LOWER LUNG AND ON THE BRONCHIAL TREE FOR ^{210}Pb AND ^{210}Po INHALED NATURALLY AND IN CIGARETTE SMOKE. RADON DAUGHTER ACTIVITY SHOWN FOR COMPARISON

	Air		Cigarettes*		Air
	^{210}Pb	^{210}Po	^{210}Pb	^{210}Po	Radon Daughters
	fCi/kg				
Lower lung	1000	270	2600	4800	30000
	^{210}Pb	^{210}Po	^{210}Pb	^{210}Po	Radon Daughters
	fCi/cm^2				
TB tree	0.04	0.01	0.1	0.2	1.3

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*Activities due to 40 cigarettes per day only. Contribution from inhalation of ^{210}Pb and ^{210}Po in air not included.

3. Direct deposition on the tracheobronchial tree is calculated according to Gormley-Kennedy with the modification for convective diffusion already discussed.
4. Tracheobronchial activities are reported for Weibel generation 4 or at about the level of the segmental bronchioles. This region yields the highest surface activities.
5. Normal average atmospheric concentrations of ^{210}Pb and ^{210}Po are 15 fCi/m^3 and 3 fCi/m^3, respectively. The daily amounts inhaled are 300 fCi and 60 fCi, respectively.
6. The average atmospheric concentration of ^{222}Rn, RaA, RaB, RaC is 100/90/70/70 pCi/m^3 with 8.5% unattached RaA (Fisenne *et al.*, 1974).
7. The average amounts of ^{210}Pb and ^{210}Po inhaled from one cigarette are 25 fCi and 50 fCi, respectively. The ratio of 2/1 for $^{210}Po/^{210}Pb$ in mainstream smoke has been measured by Holtzman *et al.* (1966), Radford *et al.* (1975), and Ferri *et al.* (1967).

Measured Values

The measured values of ^{210}Pb and ^{210}Po in the lower lung and in the tracheobronchial tree are summarized in Tables 11 and 12 for nonsmokers and smokers, respectively.

TABLE 11
MEASURED ^{210}Pb AND ^{210}Po IN NONSMOKERS LUNGS

	^{210}Pb	^{210}Po	
	fCi/kg		
Lower lung	7400 ± 4000	3200 ± 1800	Blanchard (1967)
	–	3100 ± 500	Ferri (1966)
	–	3400(1200–7700)	Hill (1965)
	1500(600–2400)		Holtzman (1966)
	–	1900(1000–2000)	Little (1965)
	4000(3800–4600)	3000(500–4000)	Radford (1975)*
	–	2500	Rajewsky (1966)

	^{210}Pb	^{210}Po		
	fCi/cm^2			
TB tree	–	1(0–4)	Airways	Little (1965)
		7(0–27)	Bifurcations	
	2(0.6–3.2)	0	Airways	Radford (1975)*
	7(3.6–16)	0.8(0.2–1.2)	Bifurcations	

---

*Calculated from pCi/mg dry weight assuming that 1 g dry = 5 g wet and that the thickness of the epithelial tissue is 40 μm.

If the modeled values are compared with the measurements, it is obvious that a large discrepancy exists. Measured values of ^{210}Pb and ^{210}Po are factors of about 4 and 10 times higher in the lower lung and 10 to 100 times higher for ^{210}Pb and ^{210}Po measured in the tracheobronchial tree. The discrepancy in the lower lung is undoubtedly due to the incorporation of dietary ^{210}Pb and ^{210}Po into lung tissue (Bogen *et al.*, 1976; Holtzman *et al.*, 1974; and Parfenov, 1974). In areas where dietary ^{210}Pb and ^{210}Po are high compared to inhalation intake, it is well known that lung tissue will be elevated in these elements (Blanchard *et al.*, 1970 and Kauranen *et al.*, 1969). Holtzman (1974) has suggested that much of the ^{210}Po measured in tissue is supported by its grandparent ^{210}Pb and that the short halftime of ^{210}Po in the tissues would not allow a significant fraction of the ^{210}Po to be due to diet alone. In all probability, however, a fraction in the lung is particulate and on the surface.

The discrepancy of as much as a factor of 100 between measured ^{210}Pb and ^{210}Po in the bronchial tree with that predicted cannot be explained as readily. The activity/cm^2 in the bronchial epithelium due to contamination by diet should be about 0.01 fCi/cm^2 for both ^{210}Pb and ^{210}Po. This is based on the levels observed in the lower lung. If the tracheobronchial clearance times in the model are incorrect and actually are larger, it would tend to put the modeled values in better agreement.

TABLE 12
MEASURED ^{210}Pb AND ^{210}Po IN SMOKERS LUNGS

	^{210}Pb	^{210}Po	
	fCi/kg		
Lower lung	–	10000 ± 2000	Blanchard (1967)
	–	6500 ± 1200	Ferri (1966)
	–	9900(6600–15600)	Hill (1965)
	6000(4300–10000)	–	Holtzman (1966)
	6000(3000–11000)	7300(480–13000)	Radford (1975)*

	^{210}Pb	^{210}Po		
	fCi/cm^2			
TB tree	–	< 10		Hill (1965)
	–	1(0–10)	Airways	Little (1965)
		18(0–56)	Bifurcations	
	–	3	Airways	Radford (1964)
		33	Bifurcations	
	11(1–32)	3(0.2–6)	Airways	Radford (1975)*
	14(2–17)	3(0.1–11)	Bifurcations	
		0.8(0.1–2)	Bifurcations	Rajewsky (1966)

---

*Calculated from pCi/mg dry weight assuming that 1 g dry = 5 g wet and that the thickness of the bronchial epithelium is 40 μm.

Also, local variations in the deposition pattern in the tracheobronchial tree can occur, and these are unaccounted for in the model. These are most noticeable at bifurcations where deposition as high as a factor of 5 over airway values has been reported (Cheng *et al.*, 1976). On the other hand, a consideration of the measurements indicates that the small number of samples of epithelium and the very low activities involved do not allow accurate average values in nonsmokers to be determined at this time. The spread in the observed values of Table 11 of from 0-27 fCi/cm^2 for ^{210}Po may actually represent the normal inhomogeneitles of activity found on the bronchial tree.

The measured values of ^{210}Pb and ^{210}Po in smokers are somewhat higher than those predicted for the lower lung. This can now be explained by the fact that, in addition to the amount predicted from cigarettes, there is a baseline value present due to diet and the inhalation of environmental ^{210}Pb and ^{210}Po. Also, the particulates ^{210}Pb and ^{210}Po cleared to the tracheobronchial tree are ultimately swallowed and become an additional dietary source. Thus the ^{210}Po value for smokers should equal the baseline value observed in nonsmokers of about 3000 fCi/kg plus the particulate contribution of about 5000 fCi/kg for 2 packs per day or a total of 8000 fCi/kg. This is in good agreement with the measurements. Variations in the smoking pattern can affect the amount of ^{210}Pb and ^{210}Po deposited. Peeckmans (1965) has suggested that differences in smoking patterns may cause variations of a factor of 2 in lower lung deposition.

The measured values for the bronchial epithelium in smokers are about 100 and 50 times higher for ^{210}Pb and ^{210}Po, respectively. Again, this may be due to incorrect values for clearance halftimes and high local values of deposition unaccounted for in the model. As in nonsmokers, more measurements of the bronchial epithelium are required to obtain truly reliable averages.

Dose

The pertinent alpha dose is to basal cells in the bronchial epithelium which are supposedly critical in tumor formation. This dose is given by

$$\bar{D}_{22} = (5.8\times10^{-3})(A) \text{ rad/year} \tag{1}$$

where

$\bar{D}$ = absorbed dose at 22 μm below the surface of the bronchial epithelium, the accepted location of shallow basal cell nuclei, and

A = activity of ^{210}Po on the bronchial epithelium in fCi/cm^2. The activity must be uniformly distributed within the unit area.

This expression gives the dose from ^{210}Po homogeneously distributed in a 15-μm-thick mucus layer on the surface of the epithelium.

Depending on the distribution of the activity within a unit area on the bronchial surface, the numerical value of the dose can vary significantly. If ^{210}Po were located at one point rather than evenly distributed per cm^2, the above expression would not apply. The dose to a few cells would be considerably larger. It is well known that certain components of cigarette smoke are cilia-toxic and that areas in the bronchial epithelium of smokers are damaged and even denuded of cilia. It would be anticipated that these areas have little or no clearance and may contain higher activity levels. Although the activity levels in some areas may be many times the average and high doses can be calculated, the dose affects relatively few cells.

Martell (1974) has suggested that tobacco trichomes each contain about 3x10^{-3} fCi of ^{210}Pb and that these insoluble particles in small areas on the bronchial tree for periods of up to 3 to 5 months (Radford *et al.*, 1975) gives rise to ^{210}Po on the bronchial tree and yields the significant tunorigenic dose.

It is not known at this time if the majority of the measured ^{210}Po in the bronchial epithelium is the result of buildup from ^{210}Pb incorporated into particles or is an equilibrium activity established because of the deposition and clearance of ^{210}Po-tagged smoke particles. Perhaps it is the combination of both effects. Neither is it known whether the major fraction of the measured ^{210}Po activity (Table 12) is due to ^{210}Po within particles on the bronchial tree or whether it is incorporated into epithelial tissue. More work remains to be done to answer these particular questions.

For the present, it is possible to estimate the dose to basal cells in the bronchial epithelium from the data of Tables 11 and 12 if the assumption is made that the reported activity is uniformly distributed over the unit area.

TABLE 13
AVERAGE ANNUAL ALPHA DOSE ESTIMATED FOR BASAL CELLS IN BRONCHIAL EPITHELIUM ESTIMATES FOR ^{210}Po DOSE BASED ON REPORTED VALUES OF ^{210}Po IN BRONCHIAL EPITHELIUM FROM TABLES 11 AND 12

		Nonsmokers	Smokers
		rad/yr*	rad/yr*
^{210}Po		0.01(0–0.2)	0.05(0–0.3)
Radon daughters		0.02	0.02
	Total	0.03(0.02–0.22)	0.07(0.02–0.32)

---

*Average (range).

The estimated annual absorbed alpha dose from ^{210}Po for the mean value of 9 fCi/cm^2 and the range (0-56 fCi/cm^2) is shown in Table 13. The annual alpha dose is also estimated for nonsmokers using the average value of 2 fCi/cm^2 and the range (0-27 fCi/cm^2). The annual absorbed dose of 0.02 rads from the inhalation of the short-lived daughters of radon is shown for comparison (Harley *et al.*, 1972). It is not known if there is any significant local increase in the alpha dose from short-lived radon daughters due to impaired clearance in the bronchial tree in smokers. Presumably there is, but the effect cannot be evaluated at the present time.

Health Effects

It is known that the ratio of the annual mortality from lung cancer in smokers to that in nonsmokers is 10/1 (USDHEW, 1975). It is of interest to see if this ratio can be accounted for by considering the relative alpha doses. Snihs (1973) has reported excess lung cancer incidence in Swedish metal miners due to exposure to short-lived radon daughters. To increase the normal Swedish annual mortality by a factor of ten required an exposure of about 400 working level months (WLM) in this group of miners. This corresponds to a dose of about 130-200 rads to basal cells in the bronchial epithelium. This group of miners was exposed to short-lived radon daughters for at least 10 years, so the final value of dose to observe a tenfold increase may be somewhat less than that indicated here if more lung tumors arise after a longer followup. The maximum dose to smokers from Table 13 is 0.3 rad/yr or 6 rads in 20 years. This would not seem to account for the increased lung cancer incidence in smokers on a dosimetric basis.

High doses can be obtained from the measurements in Table 12 if the activities are assumed to be distributed nonuniformly. In the case of the metal miners, the dose of 130-200 rads applies to the majority of the basal cells in the bronchial epithelium. If hot spots are considered in smokers' lungs, a comparable dose can be delivered, but fewer cells are affected. Whether these two types of exposures may be compared directly remains a question. What is needed now are answers to these unresolved questions.

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RADIATION DOSE TO THE RESPIRATORY TRACT DUE TO INHALATION OF CIGARETTE TOBACCO SMOKE*

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INTRODUCTION

The naturally occurring radioisotopes ^{210}Pb and ^{210}Po have been implicated as potential initiators of lung cancer in smokers (Radford and Hunt, 1964; Little et al., 1965; Marsden, 1965). The levels of both are greater in the lungs of smokers than in nonsmokers (Little et al., 1965; Holtzman and Ilcewicz, 1966; Hill, 1965; Rajewsky and Stahlhofen, 1966). The ^{210}Po in tobacco is volatilized at the burning tip of cigarettes and is inhaled by smokers apparently after attachment to smoke particles. The ^{210}Pb apparently is associated with an insoluble particulate fraction (Martell, 1974 and 1975) in the smoke and after deposition in the lung decays to ^{210}Bi which in turn decays to ^{210}Po. The significant lung dose is thus delivered by the 5.3-MeV alpha particles from the decay of ^{210}Po. Since measurements of ^{210}Po and ^{210}Pb in lung tissue of smokers are available, factors affecting environmental levels, uptake in tobacco plants, levels in smoke, and intake and clearance by man are not included in dose calculations. However, intake and clearance will be discussed in connection with comparisons between intake of polonium isotopes from smoking and from background radon daughters.

The dose from ^{210}Po alpha particles due to smoking may be compared to doses from the inhalation of ^{218}Po and ^{214}Po alpha particles due to background levels of radon daughters and to doses associated with lung cancer in uranium miners also due to radon daughters. The scheme for radon, as given by Holtzman (1970) follows with the decay energy in MeV.

$$^{222}\text{Rn}\xrightarrow[3.823\ \text{day}]{5.49\ \alpha} \qquad ^{218}\text{Po(RaA)}\xrightarrow[3.05\ \text{min}]{6.00\ \alpha} \qquad ^{214}\text{Pb(RaB)}\xrightarrow[26.8\ \text{min}]{0.7\ \beta}$$

$$^{214}\text{Bi(RaC)}\xrightarrow[19.7\ \text{min}]{3.3\ \beta}> \qquad ^{214}\text{Po(RaC}')\xrightarrow[164\ \mu\text{sec}]{7.687\ \alpha} \qquad ^{210}\text{Pb(RaD)}\xrightarrow[21\ \text{yr}]{0.02\ \beta}$$

$$^{210}\text{Bi(RaE)}\xrightarrow[5.01\ \text{day}]{1.16\ \beta} \qquad ^{210}\text{Po(RaF)}\xrightarrow[138.4\ \text{day}]{5.30\ \alpha} \qquad ^{206}\text{Pb(RaG–Stable)}$$

In all three cases, smoking, background radon daughters, and radon daughters in uranium mines, the significant radiation dose is from alpha-emitting polonium isotopes. Therefore, differences in effects, if effects are due to alpha radiation, will primarily be due to differences in dose or dose distribution.

Other potential chemical initiators of cancer are present in cigarette smoke (Wynder and Hoffman, 1967). However, the comparison of smokers with uranium miners, who were also heavy cigarette smokers, assures that the same chemical carcinogens would be present in each case. In addition, uranium miners were exposed to other agents in mine atmospheres which could potentially influence cancer incidence (Archer et al., 1971; BEIR, 1972). However, the epidemiological studies of uranium miners clearly demonstrate a strong correlation between cumulative exposure to radon daughters and lung cancer incidence (Lundin et al., 1971; Archer et al., 1971). Thus it appears valid to assess the significance of radiation dose due to smoking by using a comparison with uranium mining and background exposures to radon daughters.

INTAKE AND CLEARANCE OF ^{210}Pb AND ^{210}Po

Doses to the respiratory tract due to smoking will be based on available measurements of ^{210}Pb and ^{210}Po in the lungs of smokers. However, the relative magnitude and nature of intake from smoking and from background radon daughters brings out some important questions that merit discussion.

A major question is whether ^{210}Pb and ^{210}Po measured in the lungs of smokers are due to their presence in tobacco smoke or result from reduced clearance of normal intake of radon daughters in smokers. Based on levels of ^{210}Pb and ^{210}Po in cigarettes, the maximum intake of these radioisotopes for a two-pack-per-day smoker would be about 2-4 pCi/day (Rajewsky and Stahlhofen, 1966; Martell, 1974). Based on background levels of radon daughters (Hamrick and Walsh, 1974; Harley, 1973), the intake for continuous exposure would be in the range of 200-2000 pCi/day. It would appear that a slightly reduced clearance could easily account for an excess of radioactivity in smokers' lungs. One would expect ^{210}Pb levels to be a good indication of short-lived radon daughter intake since its half-life ($\sim$22 years) is very long compared to the preceding radon daughters (half-life of about 30 minutes for ^{218}Po–^{214}Po). Under normal conditions, one would expect the radon daughters, including ^{210}Pb, to be cleared rather rapidly before significant ingrowth of ^{210}Po. If clearance is reduced or clearance patterns altered, as probably occurs in cigarette smoking, then higher levels of ^{210}Pb with potential ingrowth of 210Po would result. The radio of ^{210}Po to ^{210}Pb would yield an indication of the residence time of ^{210}Pb in the lung (Radford and Martell, 1975). However, the determination of residence times in smokers is complicated because of the presence of ^{210}Pb and ^{210}Po in smoke as well as normal room and outdoor air.

From the above discussion, it would appear that the levels of ^{210}Pb in smokers could be accounted for by a slightly reduced clearance or altered clearance pattern of short-lived radon daughters. However, this possibility has apparently never been seriously entertained. Instead, the higher levels of ^{210}Pb and ^{210}Po in smokers' lungs are assumed to be due to their presence in tobacco. Because it is volatile at temperatures occurring at cigarette tips, ^{210}Po was thought to represent a significant radiation hazard. It became apparent, however, that the volatile compounds of ^{210}Po should be deposited rather uniformly and should be cleared rapidly (Holtzman, 1967). There remained the problem of explaining the higher local tissue concentrations of ^{210}Po reported by Little et al. (1965). Martell (1974) introduced the possibility of accumulation of insoluble ^{210}Pb particles at bronchial bifurcations as an explanation. According to Martell (1974), these insoluble ^{210}Pb particles are formed during curing and pyrolysis of tobacco trichomes. They are apparently present in mainstream smoke and their residence time in the lung may be long enough to allow ingrowth of ^{210}Po. After ^{210}Po is formed, it is assumed to remain in the insoluble particles that have accumulated at bifurcations, so that it would not be cleared before radioactive decay (Radford and Martell, 1975). Under these conditions there is a potential for relatively high doses from ^{210}Po alpha particles to small tissue volumes (Martell, 1974; Radford and Martell, 1975). The critical test of Martell's hypothesis is, of course, whether the insoluble component of ^{210}Pb is significantly greater in smokers than in nonsmokers. If the insoluble component is not greater in smokers, the higher levels of ^{210}Pb and perhaps ^{210}Po in smokers are more likely due, as discussed above, to reduced clearance of short-lived radon daughters.

DOSE CALCULATIONS

The dose due to alpha emitters at a particular location in tissue is

$$D \sim 1.6 \times 10^{-8} \, \phi \frac{dE}{\rho dx} \text{ (rads/year)} \qquad (1)$$

where ϕ is the flux of alphas (alphas/cm^2-yr) at the location of interest and dE/ρdx is the stopping power of tissue (MeV-cm^2/g) for alpha particles of a given energy at that location. The flux depends critically on the local geometric configuration and the physical characteristics of the source.

The question regarding exposure to ^{210}Po alpha particles in cigarette smoke is whether one should consider uniform exposure patterns, in which case the dose would be insignificant, or whether one should consider local "hot spot" concentrations of alpha activity. The extreme for hot spots would be when the alpha activity is concentrated in one particle. In this case, localized fluxes would be enhanced by at least a factor of 10^3. However, in the case of ^{210}Po attached to cigarette smoke particles, the radioactivity must be spread out over a number of particles, and the flux at a particular location would arise from a "surface activity." Such surface activities can be compared directly with estimated surface activities due to inhalation of short-lived radon daughters.

The possible accumulation of insoluble ^{210}Pb particles at bifurcations suggested by Martell (Martell, 1974; Radford and Martell, 1975) appears to represent a hot spot situation. However, measurements of ^{210}Po in lungs of smokers reflect both the direct inhalation of ^{210}Po as well as a possible inhalation of insoluable ^{210}Pb that decays to ^{210}Po in the lung. Further work that would help to elucidate the role of insoluable ^{210}Pb particles is duscussed later.

Measurements of ^{210}Po in the lungs of smokers have been reported in several papers. Rajewsky and Stahlhofen (1966) report surface activity values ranging from 1 to 18 x 10^{-4} pCi/cm^2 in the lungs of cigarette smokers. They noted that the highest value reported by Little and Radford (1967) was about 0.03 pCi/cm^2 at a bronchial bifurcation. Holtzman (1967) notes that the autoradiographic measurements by Hill (1965) on specimens of vacuum-dried epithelium, from bronchial bifurcations taken from smokers, showed an upper limit of alpha activity of 0.01 pCi/cm^2. Levels in the bronchial epithelium of the trachea and lobar bronchi reported by Little and Radford (1967) were about 0.001 pCi/cm^2 and lower. Levels in other parts of the lung were one to two orders of magnitude lower than in the trachea or lobar bronchi. Differences and uncertainties in the measurements have been discussed by Little and Radford (1967) and by Holtzman (1967). Whether the highest levels reported for bifurcations (0.01–0.03 pCi/cm^2) represent hot spots can be decided by a comparison with surface activities expected from exposures to short-lived radon daughters. In this paper, the highest reported levels at bifurcations where about 0.1 g of tissue would be involved will be compared with levels expected from short-lived radon daughters both from background and from uranium mining exposures where the entire tracheobronchial epithelium will be involved (∿50 g).

Exposures to short-lived radon daughters for uranium miners and often for background exposures are given in working level months (WLM). The relationship between exposure in WLM and dose to the respiratory tract as well as the association between cancer incidence and WLM exposure have been discussed extensively (BEIR, 1972; Archer et al., 1971; Lundin et al., 1971; Walsh, 1970; Parker, 1969; Nelson et al., 1970; Jacobi, 1964 and 1973; Holiday et al., 1957; Harley and Pasternak, 1972; Haque and Collinson, 1967; Federal Radiation Council, 1968; Altshuler et al., 1964). A detailed discussion will not be given here. A WLM is defined as exposure to a 1 working level concentration for 170 hours. The working level is defined as any combination of radon daughters in one liter of air that will result in the emission of 1.3 x 10^5 MeV of alpha energy in the complete decay through RaC′ (^{214}Po) (Holiday et al., 1957). Here the surface activities to be expected from exposures to radon daughters in WLM will be compared to the measured activities given above for cigarette smokers.

The major factors of potential importance when comparing uranium mining atmospheres with normal room or atmospheric air are particle size distribution, equilibrium conditions, and fraction of free or uncombined radon daughters. Other factors such as relative breathing rates, continuous versus 8 hr/day exposures, exposures to other agents, and age distribution of the exposed populations are important, but there is as yet no methodology for quantifying their significance. However, an overriding consideration is that regardless of cigarette smoking or exposure to other potential carcinogenic agents, the major etiologic agent for lung cancer in uranium miners is exposure to alpha-emitting radon daughters (Archer et al., 1971; BEIR, 1972). The effects are apparently dose-rate independent and directly proportional to cumulative exposure. Therefore, although many factors of potential importance can be suggested, none except cigarette smoking appear to influence dose response relationships in mining groups to a detectable degree. Cigarette smoking appears to be a promoter of lung cancer but not a synergist with radiation. As stated before, it would appear to be valid to assess the significance of the alpha dose from cigarette smoking by comparisons with the alpha dose from radon daughters.

Table 1 gives surface activities for WLM exposures to radon daughters for three different equilibrium conditions and for uncombined ^{218}Po fractions varying from 0 to 0.5. The data given in Table 1 are based on deposition by diffusion (Gormley and Kennedy, 1949) in the Weibel (1963) respiratory tract model. The fractional deposition of attached radon daughters in the tracheobronchial region of the model was 0.1 while the deposition of unattached RaA was 0.9. These fractional depositions may be high for uranium mine atmospheres and the fraction of 0.9 may be high for the uncombined fraction in any case (Harley and Pasternak, 1972). However, the values used are thought to be representative for both uranium mine and room air and are probably not high by more than a factor of 2. An uncombined fraction of RaB and RaC of 0.01 would increase the surface activity values about 10-20%, and an uncombined fraction of RaB and RaC of 0.1 would approximately double the surface activity values. Most calculations and measurements show that

TABLE 1
ALPHA SURFACE ACTIVITIES FOR VARIOUS EQUILIBRIUM CONDITIONS AND "FREE" ^{218}Po FRACTIONS

	pCi/l					
^{218}Po	^{214}Pb	^{214}Bi	Fraction of "Free" ^{218}Po	Surface Activity ^{218}Po Alpha (dis/cm^2 WLM)	Surface Activity ^{214}Po Alpha (dis/cm^2 WLM)	Total Surface Activity (dis/cm^2 WLM)
100	100	100[a]	0	3.45×10^{3}	5.58×10^{4}	5.92×10^{4}
			0.1	6.20×10^{3}	5.85×10^{4}	6.47×10^{4}
			0.2	9.00×10^{3}	6.13×10^{4}	7.03×10^{4}
			0.3	1.14×10^{4}	6.37×10^{4}	7.47×10^{4}
			0.5	1.72×10^{4}	6.95×10^{4}	8.67×10^{4}
975	0	0[b]	0	3.36×10^{4}	3.36×10^{4}	6.72×10^{4}
			0.1	6.10×10^{4}	6.10×10^{4}	1.22×10^{5}
			0.2	8.75×10^{4}	8.75×10^{4}	1.75×10^{5}
			0.3	1.11×10^{5}	1.11×10^{5}	2.22×10^{5}
			0.5	1.68×10^{5}	1.68×10^{5}	3.36×10^{5}
200	100	77[c]	0	6.90×10^{3}	5.41×10^{4}	6.10×10^{4}
			0.1	1.08×10^{4}	5.80×10^{4}	6.88×10^{4}
			0.2	1.79×10^{4}	6.51×10^{4}	8.20×10^{4}
			0.5	3.45×10^{4}	8.17×10^{4}	1.16×10^{5}

[a] Represents equilibrium among short-lived radon daughters.

[b] Represents extreme disequilibrium among short-lived radon daughters.

[c] Represents an intermediate equilibrium condition more typical of actual conditions.

deposition of the combined radon daughters is 5-7% (Holleman et al., 1968; Martz, 1968; Walsh, 1970; Nelson et al., 1970). For a 10% compliment of uncombined RaA and a 1% compliment of RaB and RaC, a total deposition of about 10% for the tracheobronchial tree appears representative of both uranium mine and room air atmospheres. For purposes of comparison with surface activities produced by cigarette smoking, which are subject to large uncertainties, it is not necessary to be more precise.

DISCUSSION

The calculated surface activity values given in Table 1 may be compared to the maximum surface activities measured for bifurcations in smokers' lungs. The surface activity values given in Table 1 range from about 5×10^4 to 1×10^5 dis/cm^2-WLM or about 6×10^5 to 1.2×10^6 dis/cm^2-yr for exposure to a 1 WL concentration for a year. The maximum measured activities in smokers' lungs range from 0.01-0.03 pCi/cm^2 or 5×10^3 to 1.5×10^4 dis/cm^2-yr. Thus the highest measured surface activities in cigarette smokers are about two orders of magnitude (10^{-2}) lower than for inhalation of radon daughters at a 1 WL concentration. Uniform deposition over the entire tracheobronchial tree was assumed for radon daughters. It is possible that much higher surface activities for radon daughters could be produced at bifurcations. Therefore, comparing the highest levels measured at bifurcations in smokers with the average for the entire tracheobronchial epithelium for uranium miners would overestimate the potential cancer risk in smokers. This is especially true since the majority of uranium miners were also heavy cigarette smokers. The radiation dose due to cigarette smoking is usually ignored when estimating the radon daughter dose to the respiratory tract of uranium miners.

Dose conversion factors based on epidemiological studies of underground mining groups are about 5-6 rem/WLM (Walsh, 1976; BEIR, 1972). Such conversion factors are essentially in agreement with theoretical dose estimates using quality factors based on animal toxicological studies (Walsh, 1976; Archer et al., 1971). Therefore, the surface activities given in Table 1 for uranium miners would be equivalent to 60-72 rem/yr, and the highest local doses associated with cigarette smoking would be 0.6-0.7 rem/yr.

Exposures in WLM associated with an approximate doubling in lung cancer risk for uranium miners are 100-120 WLM (Archer et al., 1971; BEIR, 1972; Lundin et al., 1971; Sevc et al., 1976). Such exposures correspond to doses of about 500-600 rem. Thus the highest doses associated with cigarette smoking (about 30-35 rem for 50 years of smoking) can only account for a fraction (< 10%) of the excess lung cancer associated with cigarette smoking.

The highest measured surface activities associated with cigarette smoking are equivalent to continuous exposure to radon daughters at a concentration of about 0.0025 WL. The general population is exposed to radon daughter levels that vary from less than 0.001 to 0.01 WL depending on geographical location and dwelling construction materials (Hamrick and Walsh, 1974). Thus the highest doses to bifurcations due to cigarette smoking are comparable to the average doses to the entire tracheobronchial epithelium from background radon daughters. Further, the possibility exists, as was the case for uranium mining exposures, that the doses to bifurcations could be substantially higher than average bronchial epithelium doses. Based on average bronchial epithelium doses, background radon and radon daughters could account for up to 20% of the lung cancer risk in nonsmokers over a 50-year period.

UNCERTAINTIES AND RESEARCH NEEDS

Comparison of dose due to polonium alpha particles among smokers, uranium miners, and general populations are based on many assumptions. The major assumptions are that dose-response relationships for alpha particles are linear and exhibit no threshold. These assumptions may be acceptable when dose is from high linear energy transfer (LET) radiation. However, we state them simply as assumptions here. In addition, there are uncertainties associated with the above analysis in particular which merit discussion. Many uncertainties are involved in dose estimates, measurements of ^{210}Pb and ^{210}Po in lung samples, and risk estimates. Rather than attempt to give a detailed discussion here, some uncertainties related particularly to analysis of the significance of ^{210}Pb and ^{210}Po in cigarette smokers will be discussed briefly.

Perhaps the major question, as mentioned before, is whether the greater quantities of ^{210}Pb and ^{210}Po in the lungs of smokers as compared to nonsmokers are due to ^{210}Pb and ^{210}Po in cigarette smoke or due to reduced clearance of ^{210}Pb from the decay of inhaled radon daughters. The comparison given above was between the highest measured activities in smokers and calculated average activities for uranium miners and general population. These calculated activities for the general population from exposure to background radon daughters should correspond to measured activities in nonsmokers. However, in most cases, the measurements were made in lung samples collected several hours and sometimes days after death, and this results in uncertainty in comparison of measured and calculated values. There is still greater uncertainty in comparison of measurements in smokers and calculations for nonsmokers. Smokers may have stopped smoking several days before death. These uncertainties could be reduced substantially by comparison of measurements for smoking and nonsmoking accident victims.

Comparisons between smoking and nonsmoking groups would also be enhanced by a careful study of cigarette smoke to determine the particle size distribution with which ^{210}Pb and ^{210}Po are associated. Knowledge of ^{210}Pb-^{210}Po activity size distribution would facilitate deposition calculations as well as more quantitative assessment of the relative importance of clearance. The insoluble ^{210}Pb particles are described by Martell (1974) as constituting a unique hazard from cigarette smoking because of their relatively high specific activity (3×10^{-6} pCi/particle). However, as discussed by Hamrick and Walsh (1974), radon daughters attached to existing dust particles can result in activities of 10^{-5} pCi/particle for radon daughter concentrations of about 0.3 WL. Such activities are generally through to be relatively low (by comparison with plutonium particles, for example). Thus the insoluble ^{210}Pb particles described by Martell (1974) are not unique in terms of activity per particle. However, a careful study of smoke particles may indicate whether they differ from radon daughters in activity/particle.

The question may be raised as to whether the quality factors (Q) for ^{218}Po and ^{214}Po alphas are the same as for the ^{210}Po alpha. The mean LET is about 110 keV/μm for the 7.68-MeV ^{214}Po alpha, about 127 keV/μm for the 6.0-MeV ^{218}Po alpha, and about 132 keV/μm for the 5.3-MeV ^{210}Po alpha. The Q for lung cancer induction by natural alpha particles is uncertain. However, no significant differences in Q over the range of LET of 110-132 keV/μm are expected.

CONCLUSIONS

1. The higher levels of ^{210}Pb and ^{210}Po in the lungs of cigarette smokers compared to nonsmokers may be due to reduced clearance (due to smoking) of ^{210}Pb resulting from decay of inhaled short-lived radon daughters rather than from ^{210}Pb and ^{210}Po present in cigarette smoke.
2. Insoluble ^{210}Pb particles described by Martell do not represent a unique situation as regards activity/particle when compared to radon daughters. Thus the dose/particle due to radon daughters is comparable to dose/particle for Martell's insoluble ^{210}Pb particles.
3. The highest levels of ^{210}Po measured at bifurcations in lung samples of smokers do not represent hot spots relative to levels produced by the inhalation of radon daughters.

4. The highest doses to bifurcations in smokers' lungs are comparable to the average doses to the entire tracheobronchial epithelium due to background levels of radon daughters.

5. The highest doses to bifurcations in smokers' lungs over a 50-year period are about an order of magnitude lower than doses associated with an approximate doubling in lung cancer incidence for underground miners. This includes uranium miners who were heavy smokers as well as exposed to elevated radon daughter concentrations.

6. Measurements of ^{210}Pb and ^{210}Po in lung samples from smoking and nonsmoking accident victims would make possible more accurate assessments of the importance of clearance in comparisons of smokers and nonsmokers.

7. Measurements of ^{210}Pb and ^{210}Po in cigarette smoke as a function of particle size would make possible more detailed comparisons among amokers, underground miners, and the general population.

8. Based on risk estimates derived from studies of underground mining groups, exposure of the general population to background levels of radon daughters for 50 years could account for up to 20% of the lung cancer risk in nonsmokers.

9. Factors other than ^{210}Pb and ^{210}Po in cigarette smoke must play a major role in initiation of lung cancer in cigarette smokers. However, radioactivity may interact with other potential carcinogens in cigarette smoke to influence cancer induction.

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NATURALLY OCCURRING RADIOACTIVITY IN OPHTHALMIC GLASS

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INTRODUCTION

The manufacture of ophthalmic glass frequently utilizes mixtures of rare earths and zirconium oxides, which contain low levels of alpha-emitting decay products of natural thorium and uranium. Because of a concern about the possible effects of alpha irradiation of the cornea of the eye, the US Atomic Energy Commission in 1974 conducted a survey to determine the nature and quantity of radioactivity that might be present in ophthalmic glass in the United States and reviewed the pertinent dosimetry and radiobiologic significance related to the use of such glass. This report summarizes the salient features of the dosimetry used, briefly discusses the pertinent radiobiology, presents the results of analyses of 441 glass samples, and describes the industry ophthalmic glass radiological standard, issued voluntarily by the industry on November 1, 1975.

Radioactivity found in some ophthalmic glass is a natural consequence of the glass manufacturing processes and should not be confused with intentionally thoriated lenses used in special instruments (not in eyepieces). The optical properties and contents of such lenses differ markedly from those of conventional spectacles and are beyond the scope of this report. Also, source materials (uranium or thorium or any combination of the two) up to 0.05% by weight in any chemical mixture, are exempt from Federal regulations or licensing regarding their use. Therefore, an additional interest concerned the possibility that ophthalmic glasses might conceivably contain more than 0.05% of thorium as an unintentional natural contaminant.

DOSIMETRY

Because thorium and uranium are distributed widely in the earth's crust and are present at very low levels in practically all sands and other raw materials used in opthalmic glass manufacture, some background activity can be expected in all samples. Primary ^{232}Th or ^{238}U are the sources of decay products of varying radiation qualities, energies, and half-lives, and the degree of equilibrium among the parent radionuclides and their daughter products poses additional problems in dosimetry of ophthalmic glass. The uranium, thorium, and actinium decay schemes are shown in Tables 1, 2, 3. These radionuclides and their daughter products emit alpha particles with energies ranging between about 4 MeV and about 8.8 MeV.

TABLE 1
THORIUM SERIES - ABBREVIATED TABLE OF CONSTANTS[1]

	Radiation	Half-life	Decay Energy[2] (MeV)	Beta Energy[1] (MeV)	Gamma Energies[1,3] (MeV)
Th-232	α γ	1.41 x 10^{10} y	4.08	--	-
Ra-228	β γ	5.77 y	0.055	0.024	0.01
				0.048	0.026
Ac-228	β γ	6.13 h	2.14	0.45	0.057
				2.10	0.338
Th-228	α γ	1.913 y	5.52	--	0.084
					0.234
Ra-224	α γ	3.64 d	5.79	-	0.240
					0.650
Rn-220	α γ	55 s	6.41	-	0.542
Po-216	α	0.16 s	6.91	--	-
Pb-212	β γ	10.6 h	0.58	0.17	0.115
					0.415
Bi-212	α β γ	60.6 m	β 2.25	0.08	0.039
			α 6.21	2.27	1.809
Po-212	α	3.04 x 10^{-7} s	8.78	-	-
Ti-208	β γ	3.1 m	4.99	2.38	-
Pb-208	stable	stable	--	--	-

[1] From Lederer *et al.* (1967), CRC (1973).

[2] Alpha-particle energies are somewhat below the decay energy.

[3] Among several energy levels, the lowest and highest are shown.

Furthermore, the decay schemes indicate the presence of beta and gamma emissions for many of the daughter products. Each decay scheme produces a radioactive lead isotope with gamma ray emission of sufficient energy to be useful in nondestructive sample analyses. The range of alpha particles in glass is an important parameter in determining potential alpha-particle exposures. Tobias and Chatterjee (1974) performed calculations on alpha energy-range relationships assuming that the radionuclides were uniformly distributed in glass whose density was 4.5 g/cm^3. Using the energy-range relationships developed by Hill *et al.* (1965), they calculated a range of about 5 x 10^{-3} g/cm^2 for the 4.08-MeV alpha particle up to 14.5 x 10^{-3} g/cm^2 for 8.78-MeV alpha particles.

In addition to the variation in energy of the alpha particles generated within glass, a geometric relationship of the distance the alpha particle may traverse and the angle of traversal is required. Potential corneal exposure from alpha particles in glass is primarily concerned with those originating on or very near the surface of the lens facing the eye. Figure 1 schematically identifies some of the many angles, energies, and potential depths of penetration considered in the dosimetric model. For

TABLE 2
ACTINIUM SERIES - ABBREVIATED TABLE OF CONSTANTS

	Radiation	Half-Life	Alpha Decay Energy (MeV)	Beta Decay Energy[1,2] (MeV)	Gamma Decay Energies[1,2] (MeV)
U-235	α γ	7.1×10^8 y	4.681	—	0.110 0.204
Th-231	β- γ	25.5 h	0.381	0.299 0.090	0.017 0.267
Pa-231	α γ	3.25×10^4 y	5.15	—	0.019 0.517
Ra-227	β- γ	21.6 y	0.043	—	0.009 0.190
Th-227	α γ	18.5 d	6.15	—	0.029 0.304
Ra-223	α γ	11.4 d	5.98	—	0.031 0.58
Rn-219	α	4.0 s	6.95	—	—
Po-215	α	1.8×10^{-3} s	7.5	—	—
Pb-211	β- γ	36 m	1.37	0.10 1.36	0.065 0.265
Bi-211	α 99.72% β γ 2.28%	2.15 m	6.75	0.060	0.350
Po-211	α γ	0.52 m	7.6	—	0.880
Ti-207	β- γ	4.8 m	1.44	0.53 1.44	0.897
Pb-207	Stable	Stable	-	—	—

[1] From Lederer *et al.* (1967), CRC (1973).

[2] Among several energy levels, the lowest and highest are shown.

expedient calculation of depth of penetration of alpha particles, the tissue thickness and the air layer were converted to the equivalent glass thicknesses by using the mass relative stopping powers, calculated to be 1.26 for air/glass and 1.47 for tissue/glass.

A useful index of potential injury would require estimation of the dose absorbed by the cornea's germinal layer estimated to be at a tissue depth of about 50 μm. The dosimetric model also included a lacrimal layer of about 7–10 μm overlying the corneal surface; the critical cell layer of germinal cells would lie between 50 and 60 μm below the exposed surface of the lacrimal layer (Maximow and Bloom, 1948). The dosimetric model employed an assumption that the distance between the surface of the eye and the glass was 1.5 cm. An individual wearing ordinary ophthalmic glasses for 16 hours a day would accumulate about 6,000 hours of use per year.

Because of the stopping power represented by the air gap and the outer layers of the cornea, only the most energetic alpha particles (i.e., those over 6.5 MeV) emitted

TABLE 3
URANIUM SERIES – ABBREVIATED TABLE OF CONSTANTS

	Radiation	Half-Life	Alpha Decay Energy (MeV)	Beta Decay Energy[1,2] (MeV)	Gamma Decay Energy[1,2] (MeV)
U238	α	4.51 x 10^9 γ	4.268	—	0.048
Th-234	β	24.1 d	0.263	0.191 0.100	0.029 0.093
Pa-234	β^- IT.	1.17 m 6.75 h	2.23	0.23 1.02	0.043 0.153
U-234	α	2.5 x 10^5 y	4.856	—	0.053 0.580
Th-230	α	8 x 10^4y	4.77	—	0.068 0.206
Ra-226	α	1600 y	4.97	—	0.186 0.610
Rn-222	α	3.82 d	5.59	—	0.510
Po-218	α β	3.05 m	α 6.111 β 0.28	—	—
Pb-214	β^-	27 m	1.04	0.59 1.04	0.053 0.777
Bi-214	α β	19.7 m	α 5.62 β 3.28	0.082	0.063 0.806
Po-214	α	1.64 x 10^{-4} s	7.84	—	0.800
Ti-210	β^-	1.3 m	5.5	1.3 2.3	0.097 2.4
Pb-216	α β^-	21 y	α 3.72 β 0.061	0.015	0.046
Bi-210	β^- α	5 d 3 x 10^6 y	β 1.16 α 5.04	—	—
Pb-206	Stable	Stable	—	—	—

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[1] From Lederer *et al.* (1967), C.R.C. (1973).

[2] Among several energy levels, the lowest and highest are shown.

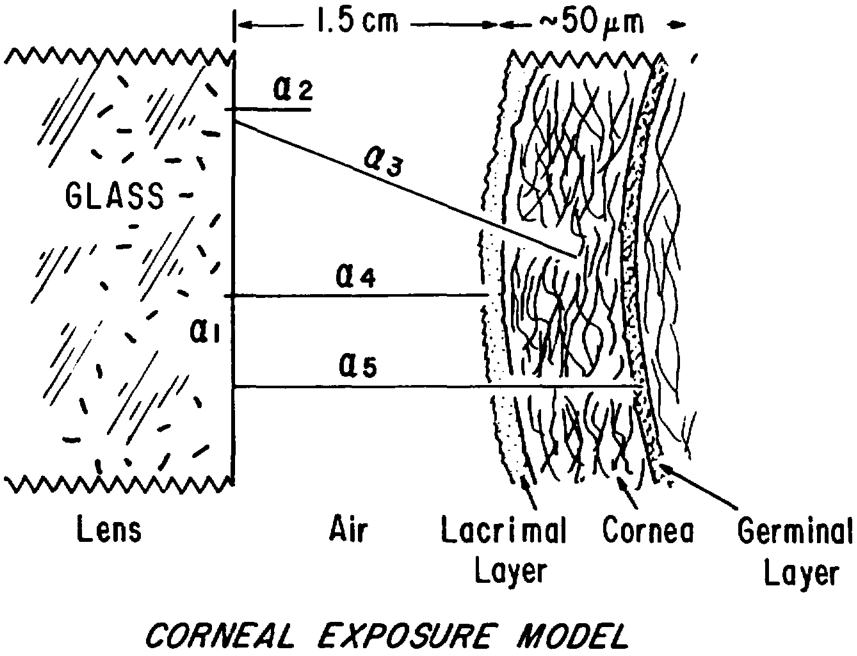

Figure 1. Corneal exposure model indicates that alpha particles originating in glass (α_1, α_2, α_4) or from its surface (α_3, α_5) must traverse 1.5 cm of air and 50 μm of tissue before reaching the critical corneal germinal cell layer. Alpha energies above 6.5 MeV are required (e.g., α_5).

from the surface of glass can penetrate to the germinal layer depth. If one corrects for the distribution of alpha-particle energies available, it is apparent that ^{212}Po would be the main contributor to the critical dose because of the 8.78-MeV energy of its alpha particle. The potential exposure, primarily from the ^{212}Po and ^{216}Po, in a hypothetic glass containing 0.05% thorium by weight in equilibrium with its daughter products, would yield a calculated dose to the critical depth of 50 μm of about 0.2 rads per year, whereas at 60-μm tissue depth, the annual dose would be about 0.1 rad. Application of a quality factor (Q) of 20 for alpha irradiation would yield corresponding doses of 4 rem and 2 rem annually to the 50- and 60-μm tissue depths, respectively.

Although alpha irradiation is the major concern for these contaminants in ophthalmic glass, the additional radiation dose from beta and gamma rays also was considered in this model. Beta radiation doses were of the same order of magnitude as those from alpha irradiation. In glass containing 0.05% thorium, an annual exposure of 6,000 hours would result in an estimated annual dose of between 0.24 and 0.58 rads. Since the quality factor for beta irradiation is considered to be unity, the rem dose from beta radiation would be much less than that from alpha rays. The dose from gamma radiation was calculated to be smaller than that from the beta particles.

RADIOBIOLOGIC EFFECTS

No information is available on the potential of low rates of protracted alpha irradiation from external sources on eye tissues in either humans or experimental animals. The possible radiopathological effects of alpha radiation on ocular tissue might include considerations of (1) damage to the superficial epithelium of eye tissues, (2) oncogenesis in these structures, and/or (3) effects on the crystalline lens. At sufficiently high doses, alpha irradiation might contribute to the first two effects, while low linear energy transfer (LET), more penetrating radiation could contribute to all three.

If degenerative changes were induced by these low levels of radiation, the high regenerative power of corneal tissue would probably mask these alterations. There are no known reports of such changes associated with the use of spectacles.

A major concern might be the possible neoplastic induction in irradiated tissues. Again, no epidemiologic clues to the relationship between such neoplasia and spectable use are available. Furthermore, corneal tumors are generally quite rare, and radiation-induced corneal tumors are expected to be even more rare. Carcinomas of the corneal limbus and conjunctiva (e.g., Bowen's disease) and basal cell carcinomas of the lower lid (the most common site for this tumor) are more common but are rarely metastatic (Saphir, 1959). The possible contribution of low doses and rates of alpha irradiation to cancer risk in these tissues cannot be ruled out.

Theoretically, the magnitude of radiation risk might be appraised by a linear extrapolation of the NAS BEIR (1972) estimate of one additional case of cancer of the ocular epithelium in each million exposed persons per year for each rem. A more definitive analysis of the potential risk is hampered by lack of specific information on the response of any target tissue to such radiation. Radiobiologic considerations would suggest that the most logical target might be the germinal layer of the cornea. As discussed above, only alpha particles with energies in excess of about 6.5 MeV and emitted from an optical surface would be of concern. Therefore, ^{212}Po and ^{216}Po in the thorium series, and ^{214}Po in the uranium series apparently are the only radionuclides that can contribute to the germinal layer dose.

SURVEY OF NATURALLY OCCURRING RADIOACTIVITY IN OPHTHALMIC GLASS

Glass samples, obtained from four US manufacturers (American Optical Corp., Bausch and Lomb Co., Corning Glass Works, and Shott Optical Glass, Inc.), were grouped according to chemical composition and by manufacturer. One hundred forty different types of glasses were divided into 28 different groups, each containing about 10–20 samples, and were examined; 441 samples were analyzed. All radioactivity calibrations and sample measurements were performed by the ERDA Health Services Laboratory (Analytical Chemistry Branch), Idaho Falls, Idaho.

Alpha spectrometry of the thorium fraction of certain ophthalmic glass samples showed the ratios of ^{232}Th and ^{228}Th to be about 1:20. Apparently, thorium had been removed from the glass additives, while ^{228}Ra (daughter of ^{232}Th) had remained. To estimate the quantity of ^{228}Ra in the glass and determine the potential alpha activity from the thorium daughters, gamma rays from the ^{228}Ac (a short–lived daughter of the ^{228}Ra) were measured. In a few samples, the ^{228}Ac activity was greater than that for ^{212}Pb, but the small number of samples precluded quantitative conclusions.

An estimate of the uranium daughters derived from the decay of ^{226}Ra was accomplished by measurement of the 325-KeV peak from ^{214}Pb. Each glass sample was ground into sand and a measured volume of sand was placed in a standard counting vial and weighed. Each sample was counted on a Ge-Li detector for 30 minutes, and the resulting gamma ray spectra were evaluated for ^{212}Pb and ^{226}Ra (and all other daughters). Because some of the radon gas from uranium and thorium may have escaped during the grinding process, several samples were recounted later to determine whether their activity had increased; no increase was found.

The accuracy of the procedure for thorium analysis was verified by careful radiochemical separation and alpha spectrometry of ^{228}Th. The ^{212}Pb contents of these same samples were measured later in the manner previously described. These comparisons, summarized in Table 4, indicate that the assumption of equilibrium between ^{212}Pb and ^{228}Th was valid. In addition, three samples that were known to be in equilibrium (data from New Brunswick Laboratory) and that had been analyzed by fluorometry and alpha spectrometry by the Health Services Laboratory were used to verify the procedures of thorium determination using ^{212}Pb and ^{228}Ac gamma emissions. These results are summarized in Table 5. Both calibration checks verify the validity of lead photon counting as an accurate indicator of potential exposure.

Calibration for uranium series determinations used a sample of pitchblende with a known specific activity of ^{238}U in equilibrium with all its daughters. To simulate the specific activity in glass and the geometry used in the measurement on glass samples, the pitchblende was diluted with SiO_2, and the ^{214}Pb content was measured in the same way as in glass samples. These results, summarized in Table 6, again confirm the accuracy of the procedure used.

The data derived from the measurement of all 441 ophthalmic glass samples for ^{212}Pb and ^{214}Pb activity are shown in Table 7, which provides a frequency distribution of the observed count rates. All but seven samples exhibited count rates below 50 dpm/g; the seven higher ^{212}Pb activities were actually 50.1, 55.9, 71.6, 125, 164, 197, and 359 dpm/g. The corresponding ^{214}Pb activity of these samples was 0.1, 16.5, 26, 58.9, 31.7, 50.9, and 86.9 dpm/g.

In these seven samples the ^{228}Ac activity was equal to that for ^{212}Pb. All the samples were from the same manufacturer and contained significant amounts of rare earth oxides. In a glass sample containing 0.05% by weight of thorium in equilibrium with all its daughters, the ^{212}Pb activity would be approximately 120 dpm/g. For a sample containing 0.05% by weight of uranium in equilibrium with its daughters, the ^{214}Pb activity is calculated to be about 370 dpm/g.

The ubiquity of thorium and uranium in practically all sands and raw materials used in ophthalmic glass manufacture would predict some low-level background activity in any glass sample. For lack of a background standard for uncontaminated ophthalmic glass, we used an empirical approach to a background definition. As most of the samples exhibited count rates for ^{212}Pb and ^{214}Pb below 10 dmp/g and another large group of samples contained at least one whose count rate was above 20 dpm/g, we arbitrarily decided to consider a sample to be uncontaminated when the square root of the sum of squares of ^{214}Pb disintegration rates was below 20

TABLE 4

Verification of Accuracy of Procedure for Thorium Analysis

	Thorium Series		
	^{228}Th as Calculated[1] Alpha Spectrometry in dpm/g	^{212}Pb as Calculated[1] Gamma Spectrometry (directly on crystal) in dpm/g	^{212}Pb as Calculated[1] Gamma Spectrometry (sample changer) in dpm/g
	1000-5000 min count time	1000 min count time	60 min count time
Sample A	27.8 ± 0.5	26.4 ± 0.3	25.2 ± 1.4
Sample B	13.1 ± 0.4	14.5 ± 0.2	13.0 ± 1.1
Sample C	16.6 ± 0.6	15.3 ± 0.2	18.0 ± 1.2

[1] Deviation shows only counting uncertainty.

TABLE 5

Verification Accuracy of Procedure of Thorium Analysis

	Thorium Series			
	New Brunswick Laboratory	Health Services Laboratory (Fluorometric and Alpha Spectrometry)	% Thorium Calculated[1] as ^{212}Pb Using Gamma	% Thorium Calculated as ^{223}Ac Using Gamma
	% Thorium			
Sample I	1.01 ± 0.01	1.01 ± 0.01	1.02 ± 0.02	1.08 ± 0.01
Sample II	0.101 ± 0.002	0.101 ± 0.003	0.103 ± 0.001	0.105 ± 0.002
Sample III	0.0102 ± 0.0001	0.0102 ± 0.0002	0.0104 ± 0.0001	0.0106 ± 0.003

[1] Deviation shows only counting uncertainty.

TABLE 6

Verification Accuracy of Procedure for Uranium Analysis

	Uranium Series	
	Specific Activity ^{238}U Series	^{214}Pb as Calculated[1] from Gamma Spectrometry (sample changer)
		30 minute count time
Undiluted pitchblende	6050 ± 40 dpm/g	6100 ± 40 dpm/g
Pitchblende diluted with SiO_2	642 ± 5 dpm/g	630 ± 10 dpm/g

[1] Deviation shows only counting uncertainty.

dpm/g. We used the mean of their count rates as the "ophthalmic glass background" and found that 351 glass samples of 441 measured met this count rate criterion. For the 351 uncontaminated (or background) samples, the count rate per gram for ^{214}Pb was >3.9 dpm (i.e., 1.6 ± 3.9) and, for ^{214}Pb, it was >4.8 (3.3 ± 4.8).

By using the ophthalmic glass background, we then estimated the percentage of contaminated samples in each of the 28 groups. These groups are described in Table 8 and include the mean count rates for the two lead isotopes measured. The group distribution of contaminated lens pressings with the upper 80% confidence limits is given in Table 9.

Ninety samples (20%) of the 441 measured exhibited activity in excess of 20 dpm/g, and seven of these (1.6%) manifested activity in excess of 50 dpm/g. Nine of the 28 groups contained samples with activity in excess of 20 dpm/g. Several of these groups consisted of several types of glass, and in some cases all the contaminated pressings came from a few glass types. As a notable example, group 18 contained ten types of glass, four of which are contaminated. The contaminated samples had an average count rate of 56.28 dpm/g of ^{212}Pb whereas the others in the group averaged 3.6 dpm/g.

Count rate variability was quite large within some types of glass. In group 19, for example, one glass type showed count rates of 7.78, 125, 197, and 359 dpm/g in four pressings.

Although this survey was limited, the following observations seem particularly important. The widely varying ratios of ^{232}Th to ^{228}Th and the nonequilibrium conditions observed in the samples measured clearly indicate that data on source materials (in one instance the ratio of $^{232}Th/^{228}Th$ was 1:20), when expressed in terms of weight percentage, cannot adequately specify the radiation emitted from ophthalmic glass by radionuclides. It is important to note that the thorium and uranium decay schemes are so patterned that, under nonequilibrium conditions, it is quite possible for a sample to manifest a declining count rate for some years and, as

TABLE 7
FREQUENCY DISTRIBUTION OF THE OBSERVED COUNT RATES

	Ophthalmic Glass Samples			
	^{212}Pb		^{214}Pb	
Interval (dpm/g)	Frequency	Cumulative Proportion	Frequency	Cumulative Proportion
0.0-0.5	45	0.102	49	0.111
0.5-1.0	33	0.177	18	0.152
1.0-1.5	35	0.256	18	0.193
1.5-2.0	52	0.374	18	0.234
2.0-2.5	31	0.444	19	0.277
2.5-3.0	40	0.535	24	0.331
3.0-3.5	26	0.594	23	0.383
3.5-4.0	20	0.639	18	0.424
4.0-4.5	23	0.692	20	0.469
4.5-5.0	8	0.710	20	0.515
5.0-5.5	10	0.732	16	0.551
5.5-6.0	8	0.751	8	0.569
6.0-6.5	8	0.769	12	0.596
6.5-7.0	8	0.787	10	0.619
7.0-7.5	4	0.796	8	0.637
7.5-8.0	13	0.825	14	0.669
8.0-8.5	4	0.834	14	0.701
8.5-9.0	5	0.846	8	0.719
9.0-9.5	2	0.850	11	0.744
9.5-10.0	4	0.589	4	0.753
10.0-11.0	9	0.880	9	0.773
11.0-12.0	4	0.889	11	0.798
12.0-13.0	4	0.898	5	0.810
13.0-14.0	5	0.909	4	0.819
14.0-15.0	3	0.916	3	0.825
15.0-16.0	3	0.923	3	0.832
16.0-17.0	0	0.923	5	0.844
17.0-18.0	1	0.925	5	0.855
18.0-19.0	2	0.930	3	0.862
19.0-20.0	4	0.939	1	0.864
20.0-21.0	2	0.943	5	0.875
21.0-22.0	2	0.948	4	0.884
22.0-23.0	1	0.950	3	0.891
23.0-24.0	2	0.955	7	0.907
24.0-25.0	2	0.959	4	0.916
25.0-26.0	0	0.959	5	0.927
26.0-27.0	1	0.961	6	0.941
27.0-28.0	1	0.964	9	0.961
28.0-29.0	1	0.966	3	0.968
29.0-30.0	2	0.971	3	0.975
30.0-35.0	3	0.977	6	0.989
35.0-40.0	1	0.980	2	0.993
40.0-45.0	1	0.982	0	0.993
45.0-50.0	1	0.984	0	0.993
50.0→	7	1.000	3	1.000

TABLE 8
RESULTS OF GAMMA MEASUREMENTS – OPHTHALMIC GLASS SAMPLES

Group No.	Lead-212 Distintegration per minute per gram		Lead-214 Distintegration per minute per gram		Glass Description
	Mean[1]	Standard Deviation[2]	Mean[1]	Standard Deviation[2]	
1	1.84	1.28	3.71	2.00	Clear crown
2	3.27	3.27	13.15	2.28	High index segments for fused bifocals, contains 3-6% ZrO_2
3	2.55	0.97	5.46	1.62	High index segments for fused bifocals, contains $\sim$ 1% ZrO_2
4	3.12	1.57	2.87	1.92	Crown glasses – different tints
5	7.37	1.66	24.15	2.78	Barium segment – 5-7% ZrO_2
6	2.16	1.19	5.13	1.84	Flint segments; high lead content – 0-2% ZrO_2
7	2.19	1.24	4.40	1.85	Clear crown
8	15.39	3.11	6.34	2.27	Pink crowns – 2-3% rare earth oxides
9	18.82	2.35	9.90	2.42	Crookes crown – $\sim$6% rare earth oxides
10	2.11	1.31	1.78	1.89	Green crown – no rare earth oxides
11	1.93	1.26	2.45	1.83	Neutral crown
12	2.18	1.28	3.01	1.89	Tan crown
13	1.73	1.34	3.40	2.08	Blue crown
14	2.24	1.25	3.75	1.96	Yellow crown
15	2.08	1.28	2.81	2.00	Special glass for strengthening
16	10.00	1.80	27.48	2.80	Barium segments $\sim$7% ZrO_2
17	1.62	1.32	2.52	1.95	Clear crown
18	23.17	10.81	6.70	2.88	Tinted glasses – 1 to 10% rare earth oxides
19	64.56	23.38	16.37	7.14	Crooks glasses < 10% rare earth oxides
20	1.65	0.88	3.02	1.30	Tinted glasses – no rare earth oxides
21	1.93	0.99	2.73	1.46	Tinted glasses – no rare earth oxides
22	2.60	1.15	4.14	1.91	Tinted glasses – no rare earth oxides
23	4.55	1.51	8.69	2.37	Photocromic glass – 1-10% ZrO_2
24	2.35	1.48	3.26	1.97	Welding and industrial glasses
25	2.72	0.89	8.28	1.67	Flint segments – 1-10% ZrO_2
26	1.29	0.73	2.09	1.15	Flint segments no ZrO_2
27	5.79	1.27	18.60	3.01	Clear barium segments – 1-10% ZrO_2
28	7.04	1.16	22.44	2.61	Tinted barium segments – 10% ZrO_2

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[1] Background included.
The background pooled from 6 individual determinations is: for ^{212}Pb – 1.32 ± 1.30 dpm/g
for ^{214}Pb – 1.45 ± 1.85 dpm/g

[2] Standard Deviation includes both measurement error and the within-group variability.

TABLE 9

Number of Contaminated Lens Pressings in Each Glass Group

Group No.	Total Lenses in Group	Contaminated Lenses[1] Percentage	Contaminated Lenses[1] Upper 80% Confidence Limits
1	15	0.00	1.18
2	22	13.64	20.35
3	16	0.00	1.10
4	10	0.00	1.76
5	20	90.00	94.91
6	16	0.00	1.10
7	15	0.00	1.18
8	16	37.50	47.89
9	16	68.75	78.02
10	16	0.00	1.10
11	18	0.00	0.98
12	16	0.00	1.18
13	18	0.00	1.47
14	15	0.00	1.18
15	12	0.00	1.47
16	15	100.00	100.00
17	16	0.00	1.10
18	16	25.00	34.60
19	16	75.00	83.50
20	15	0.00	1.18
21	15	0.00	1.18
22	11	0.00	1.60
23	15	0.00	1.18
24	16	0.00	1.18
25	16	0.00	1.10
26	15	0.00	1.18
27	16	50.00	60.45
28	18	72.22	80.61

[1] *See text for definition.*

the longer-lived daughters build up, for the sample to then exhibit increasing emission rates; the maximum would be about a factor of two above the minimum rate. Standards that directly refer to radiation emissions from ophthalmic glass seem to be more suitable. A practical approach might be to specify maximum allowable contamination by ^{228}Ra and ^{228}Th for the thorium series and by ^{226}Ra for the uranium series. The ^{228}Ra can be identified by measuring the gamma emissions from the ^{228}Ac; the gammas from ^{212}Pb decay can indicate the ^{228}Th; and the ^{214}Pb can provide an index for ^{226}Ra content. Photon counting of thorium and uranium daughters apparently provides a practical approach to reasonably accurate assays.

Only certain batches of rare earth and zirconium oxides probably are the sources of the radioactivity found in these glass samples, and their impact could be minimized by a proper quality control. Although some dosimetric estimates have been performed, their radiobiologic significance at this time is uncertain.

RADIOLOGIC STANDARD FOR OPHTHALMIC GLASS

The Optical Manufacturers Association issued a voluntary performance standard (OMA, 1975) to establish a uniform maximum limit for radioactive emissions for ophthalmic glass. In essence, the standard limits alpha emissions to less than 0.45 alpha particles/cm^2 per minute from ophthalmic glass lens surfaces. The standard further recommends the use of photon counting to estimate potential alpha particle content. The standard states that manufactured ophthalmic glass not exceed the following limits:

1. ^{228}Ac activity: 30 dpm/g
2. ^{212}Pb activity: 30 dpm/g
3. ^{214}Pb (or ^{214}Bi) activity: 30 dpm/g

In addition, the standard specifies that the sum of the thorium and uranium indicators not exceed 30 dpm/g. Under the assumptions used in our model, these limits could produce a maximal annual dose of about 500 mrem to the corneal germinal layer.

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ASSESSMENT OF RADIATION DOSES FROM RADIOACTIVE MATERIALS IN CONSUMER PRODUCTS – METHODS, PROBLEMS, AND RESULTS

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INTRODUCTION

Many aspects of technology, including the use of radionuclides in consumer products, are being scrutinized by an environmentally concerned public and by responsible Federal agencies. One consequence of this scrutiny is a requirement that potential radiation doses to man from radionuclide-containing products be identified and quantified to the fullest reasonable extent. This requirement does not reject the historic or "pre-NEPA" approach to dose assessment; it asks that assessments be expanded to consider all exposure pathways, not only the obvious ones, and a representative sample of all potentially exposed persons, not only the maximally exposed ones. Further, it asks that estimates be made of potential radiation doses not only to individuals but also to the entire population.

Recognizing the desirability of thoroughly assessing potential radiation doses to the general public from radionuclide-containing consumer products, the U.S. Nuclear Regulatory Commission established two related assessment projects at the Oak Ridge National Laboratory during 1973. One project involves both the development of a general methodology for thorough assessment of potential radiation doses to individuals and to the population during distribution, use, and disposal of radionuclide-containing products and the application of the methodology to assessments of products that are currently exempt from licensing requirements (10 CFR Parts 30 and 40). The second project involves the preparation of Environmental Statements on proposed products. Radiation dose assessments are integral parts of these Statements.

This paper presents some accomplishments of these projects and discusses some potentially important assessment problems. After a brief description and discussion of the assessment methodology, assessments of four products are summarized. The product assessments illustrate the versatility and utility of the methodology and provide examples of typical assessment difficulties.

ASSESSMENT METHODOLOGY

A general assessment methodology called CONDOS has been developed for the systematic assessment of potential radiation doses to man during distribution, use, and disposal of radionuclide-containing products (O'Donnell et al., 1975; Killough et al., 1976). Basically, the methodology consists of two parts: (1) an outline and checklist for modeling the lifespan of a consumer product and (2) the CONDOS II computer code which uses input (exposure) data from the model to calculate individual and population radiation doses.

As shown in the scrap metal assessment, the methodology can be used to assess radiation doses during the manufacture of products, but such assessments are not generally within the scope of our projects. Applications of the methodology to assessments of manufacturing facilities would be useful for verification of the methodology. Manufacture is the stage of a product's lifespan that can be modeled with reasonable confidence and that can be monitored completely at a reasonable cost. Thus, predicted doses can be compared with actual doses for verification.

Application of the methodology requires collection of all available data and testimony on a product and its distribution, use, and disposal. Of particular importance are product descriptions, identities and habits of potentially exposed persons, and experimental data on nuclide behavior and exposure pathways [e.g., deposition in the body of tritium evolved from wristwatches (Moghissi et al., 1975) and, measurements of airborne contaminants from welding processes (Breslin et al., 1952; Johnson, 1959)].

This information is used to construct a model of a product's lifespan, which identifies and describes all likely exposure events (situations during which individuals or groups of persons may be exposed to the product). Each event description identifies relevant exposure pathways, specifies exposure conditions, and quantifies the number of persons so exposed. Exposure conditions are input to the computer code which uses them in the dose calculations and outputs the results.

Output consists of the potential dose commitments to total body or to specific body organs of an individual who may be involved in one or more exposure events. The contribution of each exposure pathway (direct irradiation, immersion in and inhalation of contaminated air, and ingestion of radionuclides) to an individual's dose commitment is clearly identified for each exposure event. Addition of doses to each individual involved in an exposure event gives an estimate of the population dose associated with the event. Population dose commitments are also given for selected groups of exposed individuals and for the entire exposed population.

All doses are interpreted as 50-year dose commitments resulting from exposure to a product during a selected time period. For example, if a person is exposed to a product for 1 year, both external (direct irradiation and immersion in contaminated air) and internal (inhalation and ingestion of radionuclides) exposure could occur. Total doses to the individuals are expressed as millirems per year of exposure and are the sum of doses from external exposures delivered during the year and from internal exposures delivered during the year and the succeeding 49 years.

Advantages of the CONDOS methodology include its general applicability and its versatility as an assessment tool. Applicability is demonstrated by the diversity of the products assessed. Versatility as an assessment tool is twofold: (1) assessments can be made at a level compatible with available data (e.g., partial or complete, selective or thorough) and (2) because of the output format, potentially important exposure events and pathways and maximally exposed individuals and groups of persons can be identified rapidly. This second feature facilitates concentration of effort toward better definition of the more important exposure conditions.

A disadvantage of the methodology is the quantity of input data required for the complete assessment of a product. This disadvantage is due largely to the multiplicity of exposure events that may occur during distribution, use, and disposal of a consumer product. Steps have been and are being taken to minimize this disadvantage. Sponsors of new radionuclide-containing products are now required to develop and supply much of the needed data (NRC, 1976a). Procedures and practices commonly used in transporting and distributing consumer products are being modeled (Etnier, 1976) for inclusion in the data base of the computer code. Parts of this model are used in the following assessments. A similar model is planned for the disposal of products as municipal solid waste. Completion of these efforts will reduce significantly the input data requirements for complete assessments.

ASSESSMENTS

A variety of radionuclide-containing consumer products has been or is being assessed. Four of these assessments are summarized to indicate the versatility and utility of the methodology and to illustrate some typical assessment problems. Details of product lifespan models can be found in the references.

In all the assessments, the lifespan models are based on typical exposure scenarios. Dose assessments are based on conservative exposure conditions selected from the range possible for the scenarios.

Spark-gap irradiators containing cobalt-60 were assessed during the preparation of an Environmental Statement concerning a proposal to exempt their distribution, use, and disposal from licensing requirements (NRC, 1977). Irradiators are small devices intended to improve ignition reliability and performance in medium-sized spark-ignited fuel-oil burners. An irradiator consists of a circular 1.6-cm diameter springsteel clip with a flattened end onto which is electrodeposited no more than 1μCi of Co-60. The total plated area is approximately 0.15 cm^2.

An annual demand for 6000 irradiators is predicted. The expected life of an irradiator is limited by the life of the oil burner in which it is installed, typically 15 years. Thus, at equilibrium, about 90,000 irradiators could be in use.

Approximately 95 percent of the irradiators would be packaged and distributed with oil-burner units; the remaining 5 percent would be mailed directly to users or installers. At the burner installation site (a commercial or small industrial facility), an installer would unpackage an irradiator, snap it in place on the nozzle of the oil burner, and install the burner in the heating unit. Except for routine maintenance or service work, the irradiator would remain inaccessible inside the heating unit. After 15 years of service, the irradiator would be discarded with the burner to which it is attached.

Using the above scheme, information obtained from commercial carriers and several U.S. Postal Service facilities, and typical installation, service, and operating procedures, the lifespan of a typical irradiator was modeled. A large number of potentially exposed persons was identified, especially during distribution of the devices. This model was used to assess potential radiation dose commitments from using 6000 irradiators for 15 years.

Table 1 summarizes the results of the assessment. As expected, persons using the irradiators are likely to receive the largest doses, but, unexpectedly, a few distribution workers could receive comparable doses. The maximum dose, to an installer, could be as high as 12 mrem per year, if the installer carries each of the 50 irradiators he installs in a pocket for 8 hours. Less extreme but still conservative exposure conditions are responsible for all upper limit dose estimates. The population dose commitment from 15 years of irradiator use could be 15 man-rems.

This assessment presented few difficulties because of the nature of the product. No likely pathway for internal deposition of Co-60 could be identified. The device has only one intended use and is not particularly suited for other uses. Also, once

Table 1. Summary of Potential Dose Commitments from 6000 Spark-Gap Irradiators, Each Containing 1 μCi of Co-60

Exposed Group	Number of Persons in Group	Range of Individual Dose Commitments (mrem)	Population Dose Commitments (man-rem)
Commercial carriers	40	1×10^{-2} to 2	2×10^{-2}
Postal employees	625	6×10^{-4} to 1	3×10^{-2}
Airline employees	201	2×10^{-4} to 7×10^{-2}	8×10^{-4}
Airplane passengers	4,900	4×10^{-4} to 4×10^{-1}	2×10^{-2}
Installers	288	3×10^{-1} to 12	2
Service men	120	1×10^{-2} to 6	1
Furnace operators	6,000	6×10^{-3} to 2	11
Public – nearby	60,000	0 to 2×10^{-1}	1
– distant	90×10^{6}	0 to 2×10^{-5}	5×10^{-3}
Waste collectors	1,800	0 to 1×10^{-3}	2×10^{-3}
Landfill operators	600	0 to 4×10^{-3}	3×10^{-3}
All		0 to 12	

installed, access to the device is strictly limited and the device is immobile. Thus, the only problem was the usual one of collecting information to characterize exposures of various types for distribution workers and persons directly involved with the irradiators.

Personnel neutron dosimeters containing natural thorium were also assessed in conjunction with the preparation of an Environmental Statement (NRC, 1976b). A typical dosimeter consists of a 0.6-cm-thick aluminum case that contains a radiator foil (thorium fluoride) and a detector foil (polycarbonate film). The radiator contains approximately 50 mg of thorium.

At equilibrium, an annual demand for 300,000 dosimeters is predicted for use by persons employed in or visiting facilities in which they may be exposed to fast neutrons. These persons would wear the dosimeters and could remove them from the facility.

New dosimeters would be airmailed from suppliers to users as needed. Defective dosimeters would be returned the same way. The useful life of a dosimeter is expected to be 4 years. Normally, obsolete radiator foils would be discarded by suppliers as radioactive waste. A few could be lost or discarded as solid waste.

In modeling the lifespan of the dosimeters, various postal and airline employees, members of the general public, workers who distribute dosimeters at use sites, and users and their families were considered. This model was used to assess potential annual radiation dose commitments associated with the use of 300,000 dosimeters.

Table 2 summarizes the results of the assessment. Wearers are predicted to be the most exposed population group by a large margin. Except for persons who might receive 1 mrem by wearing dosimeters for an entire workyear and by carrying them home, no person should receive an annual dose commitment in excess of 0.2 mrem. An annual population dose commitment of 200 man-rems, virtually all to wearers, could result from an annual intensive use of 300,000 dosimeters.

Table 2. Summary of Potential Annual Dose Commitments from 300,000 Personnel Neutron Dosimeters, Each Containing 50 mg of Thorium

Exposed Group	Number of Persons in Group	Range of Individual Dose Commitments (mrem)	Population Dose Commitments (man-rem)
Postal employees	2.3×10^3	2×10^{-4} to 2×10^{-1}	1×10^{-3}
Airline employees	6.4×10^3	5×10^{-5} to 8×10^{-2}	1×10^{-3}
Airplane passengers	1.1×10^5	2×10^{-7} to 5×10^{-3}	3×10^{-3}
Distributors	1.5×10^3	8×10^{-4} to 2×10^{-1}	1×10^{-2}
Wearers	1.5×10^5	1×10^{-1} to 1	2×10^2
Wearers' families	6.0×10^5	0 to 8×10^{-4}	5×10^{-1}
Wearers' associates	1.5×10^6	0 to 2×10^{-4}	3×10^{-1}
Public	3.9×10^6	0 to 2×10^{-8}	2×10^{-6}
Disposal workers	2	2×10^{-7} to 2×10^{-4}	2×10^{-7}
All		0 to 1	2×10^2

This assessment was complicated by the possibility that the dosimeters can be carried into a great variety of environments. Very conservative exposure conditions were assumed for exposures of the public and persons near the wearers. These assumptions were not refined because the small resultant dose estimates did not justify further consideration. A further complication arises because of the complex decay chain of natural thorium. Depending on the time assumed to have elapsed since chemical purification of thorium, dose estimates may vary significantly. This topic is discussed in the gas mantle assessment but was not pursued in the dosimeter assessment because the conservative assumption that 20 years had elapsed since purification of the thorium did not result in prediction of high individual dose commitments.

Slightly *contaminated scrap iron*, about 30,000 tons, could become available during the next few years. An alternative that arises from considerations of the disposition of this material is that it be recycled for unrestricted commercial use. During recycling, the contaminated iron would be processed as ordinary scrap iron (i.e., it would be recycled into new products). To determine the suitability of this alternative, an assessment was made to determine potential radiation doses to man if this alternative is selected (ERDA, 1976). Several metals were considered in the assessment, but only iron is selected for discussion.

Scrap iron is smelted into ingots containing five parts per million of both uranium and technetium-99. The uranium is composed of enriched uranium (1.5 weight percent uranium-235) and, possibly, a minute quantity (3.8×10^{-13} weightpercent) of uranium-232. The smelter is government-owned and is not considered in the assessment.

The assessment considered transport of the ingots either to a sheet-metal (26,000 tons) or to a frying-pan (4,000 tons) fabricator. Fabricator of the products was assessed for the case in which only the recycled metal is used. Distribution and use of finished products were then considered.

For this assessment, bulk transportation, ironmaking and fabrication processes (including slag handling and use), product distribution, and product use were modeled. Fortunately, a good description of ironmaking and fabrication procedures was available (Boback, 1975; Mautz, 1975). The resulting model is quite comprehensive (ERDA, 1976).

Table 3 summarizes the results of the assessment. Even assuming that only contaminated metal was used in all processes and products, annual individual dose commitments are not expected to exceed 0.6 mrem. The highest doses, those to product manfuacturers, are due to inhalation of uranium that might be released into the plant atmosphere during manufacturing processes. An air concentration of 5 mg of iron per cm^3 of air was postulated (the occupational Threshold Limit Value). Under the conservative assumptions used, the potential annual population dose commitment from recycling 30,000 tons of scrap iron could be approximately 1 man-rem.

This assessment was the most ambitious application of the CONDOS methodology. Product manufacture was considered in addition to the distribution and use of the products. Model construction required accumulating large quantities of exposure data.

An interesting point that arose in this assessment was the contribution of an apparently insignificant quantity of a possible contaminative radionuclide. A minute quantity of uranium-232 contributed between 45 and 80 percent of the doses from

Table 3. Summary of Potential Annual Dose Commitments from Recycle of 30,000 Tons of Uranium-Contaminated Scrap Iron

Exposed Group	Number of Persons in Group	Range of Individual Dose Commitments (mrem)	Population Dose Commitments (man-rem)
Bulk-transport workers	4.3×10^3	7×10^{-5} to 3×10^{-3}	2×10^{-4}
Product manufacturers:			
Sheet metal	1.0×10^2	2×10^{-4} to 6×10^{-1}	8×10^{-4}
Frying pans	2.0×10^2	2×10^{-6} to 2×10^{-1}	4×10^{-3}
Slag	1	0 to 1×10^{-2}	1×10^{-5}
Product distributors			
Sheet metal	8.6×10^3	7×10^{-5} to 3×10^{-3}	4×10^{-4}
Frying pans	3.3×10^5	3×10^{-7} to 1×10^{-2}	4×10^{-2}
Product users			
Construction	2.1×10^4	1×10^{-3} to 1×10^{-2}	3×10^{-1}
Sheet metal	3.2×10^4	1×10^{-3} to 1×10^{-2}	3×10^{-1}
Frying pans	2.0×10^6	0 to 4×10^{-4}	3×10^{-1}
Slag	1.0×10^3	0 to 2×10^{-2}	2×10^{-2}
General public	1.0×10^8	0 to 4×10^{-5}	7×10^{-3}
All		0 to 6×10^{-1}	1

external exposure, depending on the source geometry. In addition, this nuclide and its daughters contributed about 20 percent of the doses via inhalation. This example points out the need for well-defined source terms.

Incandescent mantles containing natural thorium have been in use for many years. An assessment of the mantles is in progress, but preliminary work indicates a need for experimental verification of some potential exposure pathways.

Approximately 20.5 million mantles are used annually by campers and an additional 4.5 million by homeowners. Each mantle contains between 250 and 400 mg of thorium as the oxide. Consideration has been given both to distribution of the mantles and to use by campers and homeowners. A comprehensive distribution model has been developed but needs some refinement. The use model requires both additional information and refinement.

An initial assessment of incandescent mantles is complete. The following set of simple (base case) assumptions about the state and behavior of thorium in mantles was used: (1) each mantle contains 350 mg of insoluble thorium, (2) the thorium has aged 20 years since chemical purification, and (3) radon-220 does not emanate from the mantles. Average dose commitments to the total body were conservatively estimated by assuming that the average dose to the total body from inhaled and ingested thorium is equal to the sum of the average doses to the lung from inhalation and to the gastrointestinal (GI) tract from ingestion.

Table 4 summarizes the results of the initial assessment. A few transportation and distribution workers (warehousemen) could receive the highest annual individual doses, as much as 15 mrem. However, very conservative exposure conditions were assumed; more realistic conditions should reduce the predicted doses by a factor of two. Of more concern are the potential doses to campers and their families and to outdoor lamp installers.

Table 4. Summary of Potential Annual Dose Commitments from 25 Million Incandescent Mantles Containing Natural Thorium (Base Case)

Exposed Group	Number of Persons in Group	Range of Individual Dose Commitments (mrem)	Population Dose Commitments (man-rem)
Transportation workers	1.6×10^{6}	5×10^{-5} to 1	5
Distribution workers	1.1×10^{5}	7×10^{-4} to 15	90
Campers	1.7×10^{6}	7×10^{-2} to 4×10^{-1}	700
Campers' families	5.1×10^{6}	1×10^{-2} to 8×10^{-2}	400
Indoor lamps – users	4.0×10^{5}	2×10^{-2} to 1×10^{-1}	20
Outdoor lamps – users	5.0×10^{6}	0 to 1×10^{-3}	14
– installers	1.8×10^{3}	3×10^{-3} to 3	50
General public	1.0×10^{8}	0 to 2×10^{-4}	3
All		0 to 15	1282

Campers and outdoor lamp installers may ingest or inhale thorium as a result of mantle replacement. Data are needed to verify the assumptions that a mantle changer may ingest thorium that adheres to the hands and fingers while removing a broken mantle and that thorium may become airborne and subsequently be inhalted during mantle changes and initial burn of new mantles. These pathways of exposure account for approximately 80 percent of the predicted annual dose commitments to campers (0.4 mrem) and outdoor lamp installers (3 mrem). All persons may be exposed externally via direct irradiation. External exposures are estimated under assumptions of maximum reasonable exposure duration and minimal attenuation of photons by intervening structures.

A difference between this assessment and the preceding ones is the prediction of a surprisingly high population dose commitment, almost 1300 manrems. In this case, a more detailed assessment is justified and is in progress. This assessment will require: (1) refinement, verification, and completion of the model; (2) modification of the very conservative total-body dose calculations based on a more detailed treatment; and (3) consideration of potential effects from variations of the assumptions about the state and behavior of thorium in mantles.

Table 5 summarizes potential dose commitments to the total body, lungs, and GI tract of a maximally exposed camper under the base case exposure conditions for four sets of assumptions about the state of thorium in mantles. The base case (the one used in the initial assessment) assumes 20-year-old thorium with no radon-220 (thoron) escape from the mantles. The second case assumes complete escape of thoron from the mantles with retention in the plastic packaging limiting airborne thoron to material emanating from unpackaged mantles. The third and fourth cases parallel the first two, but assume thorium that has aged only 1 year since purification.

Doses to the total body are dominated by direct irradiation from mantles. These doses are relatively insensitive to the assumed states of thorium, varying by no more than a factor of three (between 0.03 and 0.08 mrem). Slightly lower doses would be expected for 5 year-old thorium which contains approximately half as much thorium-228 and its daughters as does 1 year-old thorium.

Doses to the lungs are dominated by the inhalation pathway and are highly dependent on the fate of radon-220. If thoron does not emanate from unpackaged mantles (cases 1 and 3), direct irradiation and inhalation of thorium during mantle changes can result in 50-year dose commitments to the lung of about 0.2 mrem. If thoron emanates from unpackaged mantles (cases 2 and 4), inhalation of radon-220 and its daughters can result in 50-year dose commitments of about 30 mrem. (Five-year-old thorium releases radon-220 at about one-half the rate of 1 year-old thorium, therefore doses would be lower by approximately a factor of two.)

In assessing doses due to radon-220 emanation (cases 2 and 4), the following assumptions were made: (1) Radon-220 emanates from unpackaged mantles at a rate equal to its formation rate (4×10^{-10} Ci/sec); (2) radon diffuses instantaneously throughout a 3.4×10^{8} cm^{3} volume (a home); (3) the ventilation rate is one air change per hour (Handley et al., 1973); and (4) radon-220 and its daughters are present in dynamic, not secular equilibrium. Modification of these assumptions, especially of the first two, may be required.

Doses to the GI tract are slightly dependent on the age of thorium but not on the fate of radon-220. Variations between 0.13 and 0.21 mrem are predicted. Verification of the ingestion pathway is needed.

Table 5. Comparison of Effects of the State of Thorium in Mantles on Potential Dose Commitments to a Maximally Exposed Camper

Organ	Case[a]	50-Year Dose Commitment (mrem) Via			
		Direct Irradiation	Inhalation	Ingestion	Total
Total	1	0.08	N[b]	N	0.08
	2	0.05	N	N	0.05
	3	0.05	N	N	0.05
	4	0.03	N	N	0.03
Lungs	1	0.07	0.20	N	0.27
	2	0.05	34	N	34
	3	0.04	0.17	N	0.21
	4	0.02	29	N	29
GI tract	1	0.07	N	0.14	0.21
	2	0.05	N	0.14	0.19
	3	0.04	N	0.11	0.15
	4	0.02	N	0.11	0.13

[a] 1 = 20-year-old thorium, no radon-220 emanation.
2 = 20-year-old thorium, radon-220 emanation.
3 = 1-year-old thorium, no radon-220 emanation.
4 = 1-year-old thorium, radon-220 emanation.

[b] N = Dose commitment not calculated for this exposure pathway but is estimated to be low.

Based on these preliminary findings, inhalation of radon-220 emanating from mantles appears to be the critical exposure pathway. Persons who use incandescent mantles (e.g., campers and their families, indoor light users, and mantle installers) are susceptible to exposure via this pathway. Inhalation and ingestion of thorium during or after mantle changes are potentially important, but unverified, exposure pathways.

SUMMARY

Four product assessments are summarized. Assessment techniques and methodology are described briefly and some assessment problems discussed. Specific topics of concern in assessments of radiation doses to man from consumer products include an accurate and complete definition of the source term; knowledge of the state of the radionuclides present (i.e., abundance and physical and chemical behavior); and accurate definition of potentially important exposure pathways, preferably based on empirical data.

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CHAPTER III
RADIOLUMINOUS MATERIALS

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Historically, radioluminous materials constituted the first application of radioactive materials in a consumer product. These materials also yielded the first radiation injuries and provided data for the first correlation between exposure and effects. Because of the long history and interest regarding radioluminous materials, the information in this chapter is more comprehensive than in other chapters of the book. This chapter contains information relevant to production technology and occupational exposure as well as population and environmental exposure resulting from application of radioluminous materials.

Originally, radium was the radionuclide of choice as an activator in radioluminous materials. Gradually other radionuclides have replaced radium; however, that element is still being used in significant quantities for this purpose. Although the total quantities of radionuclides applied and the degree of population exposure are relatively modest, this subject continues to be treated in national and international regulations and guides. Radioluminous materials are still a major source of radioactivity in consumer products.

EVALUATION OF PUBLIC HEALTH IMPLICATIONS OF RADIOLUMINOUS MATERIALS

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INTRODUCTION

In a recent study, Moghissi and Carter (1975) evaluated the public health significance of radioluminous materials. Since the publication of that report, some new information has become available. In particular, data on occupational exposure in radium dial painting plants have modified the conclusion of their findings.

Although early warnings on the radiation effects of radium in humans were expressed by co-workers of Roetgen and Curie, it was the tragic cases of dial painters that showed the deleterious effect of radium. Castle et al. (1925) were among the first to recognize these dangers. However, it was Martland et al. (1929) who clearly demonstrated the devastating radiation effects caused by radioluminous dial painting as a result of tipping the brush on the lips.

In more recent times, the availability of many potentially useful radionuclides, notably tritium and promethium-147, made it possible to replace radium with these radionuclides.

This paper compares the radiological significance of radium-226, promethium-147, and tritium. It includes occupational exposure incurred during the painting process; in the assembly plant where objects painted with radioluminous materials are assembled; in the storage, retail and repair facilities; and the exposure to the users of the products. As a matter of convenience, each radionuclide is discussed separately.

RADIUM

Occupational aspects of radium have been of considerable interest to numerous investigators and have been summarized (Moghissi, 1975). These investigations have led to improvements in health and safety conditions of dial painting operations, although these operations lag behind the normal radiochemical laboratories. Another group that pioneered in this field was led by Evans (1937) who, for many years, studied occupational exposures, working conditions, and many other factors related to dial painting operations and suggested many improvements in the dial painting process. The radiological monitoring of the workers was made possible by radon in breath measurements and whole-body counting.

At present, as in the past, an estimation of radiation exposure to the workers is difficult because many dial painting operations do not keep adequate records and, in some instances, are not obligated to monitor the workers. However, many studies have been carried out by investigators for short periods of time.

Duggan and Godfrey (1967) recorded extensive data from the United Kingdom. Moghissi and Carter (1975), who reevaluated their data, concluded that the risk associated with the processing of radium-226 can be described in three categories: (1) radiation dose to the bone as a result of deposition of radium in bone, (2) external radiation, and (3) radiation dose as a result of inhalation of radon and its daughters.

Based on Duggan and Godfrey's values, Moghissi and Carter calculated an average radium body burden of 2.0 nCi/mCi processed. According to the International Commission on Radiological Protection (ICRP, 1968), an uptake of 1 Ci of radium by the blood corresponds to 100 rem dose commitment to the bone. Using the value of 2.0 nCi, a dose commitment to the bone of 200 person-rem for each Ci processed is calculated.

Table 1 contains relevant data on external radiation exposure. These recently available data originate from a U.S. plant that processes about 1.5 Ci of radium per year using a work force of 35 workers. Table 1 also indicates an average risk of 36.5 person-rem/Ci, which is considerably lower than the value of 600 person-rem calculated by Moghissi and Carter (1975) using certain assumptions. The column person-rem/Ci indicates an increase of risk in recent years which seems to run contrary to a more conservative radiation protection philosophy in recent years.

Another source of exposure is radon. Measurements of this radionuclide in radium dial painting operations are scarce. Based on Duggan and Godfrey's (1967) limited measurements, which were confirmed by calculations, Moghissi and Carter (1975) suggest an average radon concentration of 10 pCi/l of air in dial painting plants. The dosimetry was based on the work by Harley and Pasternack (1972). According to their model, a continuous exposure of 168 h/week to a concentration of 1 pCi/l of radon corresponds to 1520 mrem/yr to the basal cell nucleus of segmental bronchioles or 250 mrem for the duration of exposure of 1440 hours in the plant as described above. The individual exposure would be 250 x 10 = 2.5 rem, whereas the total dose is about 125 person-rem/Ci of radium.

In addition to the exposure during dial painting, the exposure in various other operations must be considered. The worker's exposure in the assembly plant may be significant and in terms of person-rem comparable to the exposure during the painting operation. However, radon release from the painted materials will be substantially lower than from the dry paint because of the sealing ability of many materials such as those used in paints.

Moghissi and Carter (1975) assumed that in the assembly plants the radiation dose from external radiation for each Ci processed was equal to the external radiation dose during painting.

An estimation of the radiation dose during the storage of timepieces in warehouses, retail stores, and other areas has not been made because of the uncertainties involved in making any realistic assumptions of the conditions of exposure during the storage.

The exposure to the user of objects painted with radium is significant and requires considerable attention. One of the major disadvantages of radium is its inherent

TABLE 1

External radiation exposure in a plant located in the U.S. as measured with film badges for a 12-year period

Year	No. of Workers	Person-rem	Activity processed (Ci)	Person-rem/Ci
1964	31	34.21	1.06	32.3
1965	31	35.10	1.09	32.2
1966	31	73.35	2.28	32.2
1967	31	82.58	2.57	32.1
1968	29	23.25	0.77	30.2
1969	31	59.78	1.86	32.1
1970	37	57.05	1.62	35.2
1971	34	57.99	1.65	35.1
1972	31	37.14	1.15	32.3
1973	46	79.91	1.68	47.6
1974	55	95.28	1.67	57.0
1975	38	25.20	0.64	39.4
Average	35	55.10	1.50	36.5

emission of a great deal of radiation that is not useful for producing light and yet exposes the users of objects painted with radium.

Radon emissions from watches and clocks have seldom been measured. In the past, it was assumed that, because of the containment properties of components of paint, little radon should escape from the timepiece. In addition, because more expensive watches usually are luminous, it was expected that many of them were water resistant, and thus they would tend to retain the radon should it be released from the paint.

The fallacy of these assumptions becomes evident if one considers that these same assumptions have been presumed valid for tritium. In the case of tritium, many of the watches are water resistant. Presumably, all but a few percent of tritium should be contained in the paint, the fraction released being that which has become solubilized and is uniformly mixed in the lacquer and thus exposed to air. This fraction is, however, too small to account for the continuous release of tritium several years after the painting operation.

One would expect, therefore, that certain radiation-chemical mechanisms are involved which decompose the lacquer and crack its surface enabling the underlying surfaces to be exposed. These mechanisms that cause tritium release could conceivably lead to radon release from watches. Radon exposure is important because of the comparatively significant biological effects of alpha radiation.

However, in the following calculation, the contribution of radon is neglected because of the difficulties associated with the exposure estimates and because the whole-body exposure by gamma radiation is large enough to make a comparative evaluation possible. Joyet (1960) and Joyet and Miller (1960), who made comprehensive measurements and dose estimates from radium-containing timepieces, suggest a genetically significant annual dose of 65-70 mrem/μCi of radium. Several other studies deal with this subject, as summarized by Moghissi and Carter (1975), including those by Haybittle (1958) who measured a dose rate of 0.275 mrem/μCi-h at the back of a watch. If the watch is worn 24 h/day, an annual dose of 2.4 rem/μCi to the surface of the wrist can be calculated from his data.

Paul (1963), who made a survey of New York storage and import houses, pointed out the importance of pocket watches as a source of increased genetically significant dose to the male population. He made the observation that pocket watches are worn in closer proximity to the gonads than wristwatches and, accordingly, the dose would be higher. Moghissi and Carter (1975) calculated the radiation dose by assuming the pocket watch is worn 16 h/day at a distance of 25 cm from the gonads with an exposure rate of 0.84 mrad/h-mCi-m. The annual dose can be calculated to be 78 mrem/μCi.

This value compares with a gonadal dose of 65-70 mrem/μCi as measured by Joyet (1960) for wristwatches. The reason for the agreement between these two values is the difference in the exposure time. Joyet assumes 24 h/day exposure, whereas pocket watches are not usually worn 24 h/day. This reduction in exposure time is counter balanced by the smaller distance of the pocket watch from the gonads as compared to wristwatches.

Similarly, the annual dose to the user of an alarm clock was calculated for an 8 h/day exposure at 2-m distance to be 0.6 mrem/μCi.

Another possibility for exposure to radium is at repair facilities where large numbers of devices, painted with radium-activated radioluminous paint, are stored prior and subsequent to repair. Moghissi and Carter (1975) have summarized several reports on aircraft instrument shops which indicate that air and surface contamination is significant and external radiation is substantial. It is difficult to make a risk-benefit evaluation because of the lack of availability of the quantity of radium processed by these operations.

The exposure to members of certain aircraft crews must have been considerable as a result of the past widespread use of radioluminous instrument dials. The complexity and design of more recent aircraft have made the application of radioluminous materials unnecessary except for exit signs, which are advantageously prepared with promethium or tritium gas.

TRITIUM

Metabolism of tritiated luminous compounds has been the subject of many investigations as summarized by Wawerna (1973). From his evaluation, it can be seen that biological behavior of tritiated luminous compounds varies considerably. One interesting finding is related to the percutaneous absorption of tritiated compounds. This kind of exposure may result in a delayed excretion of tritium from its exposure site to the body water.

Another significant finding was the presence of organic compounds in the urine of rats fed with tritiated compounds, and this caused significant loss of tritium subsequent to the distillation of urine. This finding led to the recommendation that, in operations where tritiated compounds are used, radiobioassay should be performed using undistilled urine.

Because of the uncertainty associated with the fraction of tritium which ends up in the organic fraction of the tissue, Moghissi et al. (1970) suggest a uniform distribution of tritium in all hydrogen-containing materials of the body. This assumption is probably conservative soon after exposure but, under occupational exposure, conditions become more realistic at a later date. After prolonged continuous exposure of varied concentrations, the uncertainties of the concentration of tritium in body tissue exceed those in body water. This consideration is disputed by Lambert and Vennart (1972), who suggest that little or no tritium is introduced into the organic fraction of the tissue under occupational conditions, and thus dosimetry based on body water alone is sufficient.

Another important consideration relates to the quality factor of tritium. Originally, this factor was 1.7 (ICRP, 1967). In 1969, the ICRP reduced the quality factor of tritium to 1 (ICRP, 1969) and this value was also adopted by the National Council on Radiation Protection and Measurements (NCRP, 1971). This value is in contradiction with a recent review by Johnson (1973) and new experiments by Moskalev et al. (1973), who suggest a quality factor of 2 for tritium. Although the evidence appears to be in favor of a quality factor of 2, a quality factor of 1 is used in this paper, in conformity with current practices of the ICRP and NCRP.

An interesting study by Colvin and Everts (1973) indicates the necessity of care in evaluating hazards of radioluminous materials. These authors observed chromosomal aberrations in kidney and also in lung tissues subsequent to cutaneous absorption of tritiated luminous compounds. Although these aberrations were not excessive for the quantity of tritium used, the lung tissue aberrations were particularly important because the lung is generally not expected to be the site for the concentration of absorbed tritiated compounds.

The tragic history of dial painting with radium seems to have been partially repeated as a result of tritium exposure (Seelentag, 1973). Although the subject was exposed to radium and strontium-90, as well as to tritium, the predominent exposure was tritium which, according to Seelentag, was the cause of death. Seelentag suggests that overexposure was caused by lack of appropriate regulations and controls in Switzerland where the exposure occurred. Present Swiss regulations, according to Krejci (1972a), are in conformity with international guidelines, and thus the occurrence of future overexposures of the magnitude that led to the fatal case is unlikely.

The common application of tritium in radioluminescent materials is in a polymer form. Potentially, all polymers containing hydrogen are available for this application. In practice, one is limited to reactions which permit easy hydrogenation during the process. Krejci (1972a and 1972b), who reviewed various proposed polymers, concluded that polystyrene was probably the most suitable polymer. He based his recommendation on its ease of preparation, solubility properties, and radiation resistance because of its predominant aromatic character. Aside from polystyrene, the only other compound with commercial applicability is a silicon polymer prepared by Evans and Maynard (1966).

Again, occupational and environmental exposures need to be distinguished. Vennard (1967) reports that when tritium was introduced in the dial painting industry, it was anticipated no tritium would be released from the tritiated paint. This expectation is somewhat unjustified since radiation decomposition of organic materials was well known and, at the specific activities in which these materials were used, self-decomposition could have been estimated (Evans, 1965).

Lambert and Vennart (1972) point out the inaccuracies associated with the radiobioassay of tritium. They suggest that, because of the short biological half-life of tritium of 10 days, even if weekly samples are taken, the dose may be underestimated by 60-70% if the exposure occurred precisely subsequent to the previous sampling.

However, one should take into account the peculiarities of exposure of the workers. Although single large intakes occasionally occur in a dial painting operation, the contamination of air and surfaces is continuous, and thus the workers usually are subjected almost to continous exposure. In addition, if the dose is underestimated by sampling too long after a significant intake, this underestimation is probably offset by the overestimation of the dose if a measurement is done shortly after a significant intake. This is particularly true for operations with many employees who are randomly subjected to exposure. There is, however, no question that a more precise dose measurement of the workers would be desirable, and thus a radiobioassay program with sampling more frequent than monthly may be advisable.

Table 2 contains occupational exposure as measured by Moghissi et al. (1970) and Krejci (1972a and 1972b). The values reported by Krejci are revealing because they indicate differences exceeding one order of magnitude. Both Moghissi et al. and Krejci include the average specific activity of the paint in their data. Although it seems that higher specific activities are associated with higher doses, this relationship is weak and inconsistent.

Moghissi and Carter (1975) estimated the exposure of the workers in assembly plants where watch hands and faces and mechanical parts are assembled. According to these authors, the average radiation dose to workers is 4.5 mrem/Ci of tritium.

Bradley et al. (1971) evaluated several storage facilities where tritiated watches were kept. They measured tritium concentrations as high as 28.8μCi/l of urine. The average air concentration divided by the total quantity of tritium on hand was 0.02 nCi/l-Ci. They indicated one or two employees at each storage facility. Using the ICRP model, a quality factor of one for tritium radiation, and an occupancy of one worker per storage facility, a value of 12 person-mrem/Ci can be calculated.

Measurements in the repair shops are sketchy and limited. Bradley et al. (1971) report average body burdens of 50 nCi/l corresponding to 5 mrem/yr. They indicate 12-18 workers handling 10.5 Ci of tritium annually. If the average number of workers is assumed to be 15, an average of 7 person-mrem/Ci-yr can be estimated. It should be noted that this dose is not delivered for every Ci of tritium processed in the dial painting of new watches because only a small fraction of watches is repaired.

Again, environmental exposure (user's exposure) should be given considerable attention. Fitzsimmons et al. (1972) reported tritium concentrations in body water ranging from 0.5 to 11 nCi/l above background, corresponding to a radiation dose of <0.1 to 1.1 mrem/yr with an average of 3.2 nCi/l corresponding to 0.3 mrem/yr. Schell and Payne (1971) report an average tritium concentration of 2.6 nCi/l above

TABLE 2

Average Occupational Exposure to Tritium

Location of plant	Average paint activity (mCi/g)	Processed T (Ci/person-yr)	Average urine conc. (μCi/1)	Radiation-risk (person-mrem/Ci)	Reference
U.S.A.	150	104.3	20.4	19.1	Moghissi (1970)
Switzerland	150	193.4	2.57	1.3	Krejci (1973)
Switzerland	227	64.9	3.43	5.3	Krejci (1972)
Switzerland	102	140.8	7.64	5.4	Krejci (1972)
Switzerland	164	222.2	13.1	5.9	Krejci (1972)
Switzerland	262	67.6	4.86	7.2	Krejci (1972)
Switzerland	354	79.6	9.57	12.0	Krejci (1972)
Switzerland	453	65.3	1.2	21.7	Krejci (1972)
Average				9.1	

background in the urine of people who are using pocket watches and wristwatches for an average of 18 h/day.

Moghissi et al. (1976) studied human exposure to tritium for radioluminous watches under controlled conditions. The average annual dose per mCi of tritium paint was 0.03 mrem. The range of the values was 0.012 to 0.044 mrem/mCi. Considering differences in the chemical composition of the paint, variations in the manufacture of watches, and differences in the tritium turnover rate in the subjects, the relatively small range of these values seems to be remarkable.

Bradley et al. (1971), who had access to a large number of watches, suggest values ranging from 1-5.6 mCi/watch. In a recent study, O'Donnell (1976) suggests a reduction in the tritium content of timepieces in recent years. His data for 1974 indicate an average of 1.3 mCi (0.4-4.1) tritium per timepiece. However, it is somewhat difficult to estimate tritium content of watches in previous years, particularly for imported timepieces. Krejci and Zeller (1977) in a careful study established the average tritium content of watches to be 1 mCi and that of clocks to be 1.6 mCi. Moghissi and Carter (1975) suggested a value of 5 mCi for both. However, their value was based on estimations made from a very limited number of watches. The records from the Nuclear Regulatory Commission (NRC) suggest an average of 0.7 mCi for watches and 0.4 mCi for clocks. In the following calculations, a value of 1 mCi is used as an average for watches and clocks. Because the number of clocks activated with tritium is relatively small, this value is essentially that reported by Krejci and Zeller (1977) and exceeds those obtained from NRC. An overestimation of the activity is justified by the underestimation of imported and unreported timepieces.

A second method of application of tritium consists of light sources produced using capillary tubes coated internally with zinc sulfide and filled with elemental tritium at various pressures. Application of tritium in elemental form is potentially desirable and safe provided certain requirements are met. Since the biological absorption of elemental tritium is less by a factor of 10,000 than that of tritiated water, it is imperative to maintain a low water level in the container. During the production process, separation of water from elemental hydrogen does not pose any significant problem. However, subsequent to the introduction of tritium into the tube, residual moisture as well as dissolved oxygen or oxygen-containing materials in the crystal and the glass wall lead to production of tritiated water either by oxidation or by hydrogen exchange. Because carrier-free tritium is used in these tubes, minute quantities of oxygen or water may lead to significant quantities of tritiated water.

The actual measurements in regard to water content of gas-filled tubes are scarce and contradictory. Knaptan and Comer (1971) report values for T_2O in T_2 of up to 50%. These values are disputed by Guthrie and Coats (1972), who suggest 1-2% T_2O in T_2 under proper manufacturing conditions. McNelis et al. (1972), who exposed experimental animals to ruptured tritium gas-filled tubes, found T_2O levels corresponding to 2-3% of the total activity. Also, Niemeyer (1969) reports T_2O values of 2-3% in T_2. These contradictions may be based on inaccurate measurements or reflect differences in production methods.

The occupational exposure during production of these tubes could be significant if tritium is not properly contained. This is particularly important because elemental tritium is usually absorbed on titanium, zirconium, or uranium, and the biological implications of inhalation of these tritides are unknown.

Coats (1970) evaluated public health implications of gas-filled tubes. Also, Doda (1973) evaluated public health implications of the manufacture of these sources. It is generally accepted that the major route of exposure would occur during the breakage of the tube. Because of the lack of available information on the occupational exposures and release rates from these tubes, it is presently not possible to estimate a dose associated with the application of these light sources.

If properly manufactured, tritium release from gas-filled tubes should correspond to the diffusion rate of hydrogen through a glass wall as confirmed by Niemeyer (1969). However, values that exceed those produced by the diffusion rate have been measured indicating imperfections in the production process. Here again, the chemical form would be of significance because of the differences in biological absorption of the two chemical forms.

Although several relevant studies have been reported (Haff et al., 1967, and Nellis et al., 1967), the entire field of gas-filled tubes requires a careful study because of the apparent interest of the industry in this area and the potential attractiveness and use of these tubes. Because of the substantially larger quantities of radioactivity in these tubes, it is necessary that sufficient information be available before they enter the market on a large scale.

PROMETHIUM

Since promethium-147 is produced abundantly in the fission process, it is available at a reasonable cost. Promethium-147 decays with a half-life of 2.62 years to samarium-147 by beta emission with a maximum energy of 224 keV. Samarium-147 is an alpha emitter with a half-life of 1.05×10^{11} years. In evaluating radiation hazard, the presence of Sm-147 can be neglected because a decay of approximately 1 Ci of Pm-147 would result in an activity of about 25 pCi of Sm-147.

Various aspects of Pm-147 have been discussed in several publications and summarized by Moghissi and Carter (1975). The uptake of Pm-147 through the GI tract is small and about 0.001%. This extremely low absorption is an added advantage for the application of Pm-147 in radioluminous materials. In a study conducted by the present authors, certain relevant data were obtained and the findings are summarized below.

Luminous compounds activated with promethium-147, obtained from five manufacturers, and carrier free soluble promethium-147 ($PmCl_3$) were fed to cats. Ten cats were used in each group. Feces and urine were separately collected for the first 40 hours post injection and combined excreta for the rest of the duration of the study of about 20 days. Subsequently, the animals were sacrificed and the promethium content of the carcass determined. The GI tract absorption was calculated by assuming the feces excretion of the first 40 hours to be unabsorbed but urine excretion during the same period, total excretion thereafter, and the carcass to be absorbed. The GI tract absorption for various compounds ranged from 0.005-0.08% as compared to 0.09% for the soluble promethium. The lowest absorption was observed for promethium deposited on microspheres. Interesting was a comparison among other compounds which were all presumably prepared by precipitating promethium on zinc sulfide and heating the final product. The values ranged from 0.009 to 0.08% indicating the radiological significance of the production procedures.

Injected promethium quickly disappears from blood and is deposited in the liver and the bone. The biological half-life of promethium in humans is about 1,000 days (Osborn and Smith, 1956) and agrees with measurements in large animals such as dogs and pigs. Experiments by Palmer et al. (1970) in humans indicated a fraction of 0.4 to 0.5 going from blood to liver which is in disagreement with the ICRP (1959) value of 0.06, calculated from rat data. Promethium excretion in humans is complex in that, in the first few days subsequent to intake, the excretion is predominately through urine, whereas at a later date fecal excretion dominates (Palmer et al., 1970). The situation here is somewhat analogous to radium in that a dynamic and complex relationship exists between intake and excretion.

The major route of intake of Pm-147 under occupational conditions is probably by inhalation which would amount to an uptake of 25% vs. 0.001% through the GI tract. No experiments are known on the possible cutaneous absorption of Pm-147, although this route may be as significant as inhalation because of the specific habits of dial painters.

From the above, it is evident that excretion data cannot be used to estimate the body burden of dial painters. Whole-body counting is not possible because of the nature of the Pm-147 emission, which is a beta particle of relatively low energy. Attempts to use the bremsstrahlung of Pm-147 for whole-body counting have failed because of the presence of natural radiation in the body which produces significant bremsstrahlung.

Promethium-147 is often accompanied by Pm-146 at levels ranging from 0.5 to 3 ppm. Promethium-146 decays with a half-life of 4 years, 35% by a beta decay with a maximum energy of 0.78 MeV and 65% by electron capture with cascading gamma emissions of 0.453 and 0.75 MeV, respectively. Because these two gamma photons are in coincidence, they are ideally suited for whole-body counting. The reasonable similarity between the half-lives of Pm-146 and Pm-147 (4 vs. 2.6 years) and their identical chemical properties are added advantages. It may, therefore, be desirable to use a small trace of Pm-146 in Pm-147 to permit whole-body counting of workers. The level of Pm-146 in Pm-147 should be carefully considered to avoid a significant increase in external radiation, both at occupational and environmental levels.

In the United States, there is only one plant that used Pm-147 on a scale comparable to that used by other dial painting operations. This plant manufactures special devices and, because of its specific market conditions, is capable of maintaining occupational control conditions more comparable to radiochemical laboratories than to dial painting plants. Although certain occupational exposure data are available from this plant, their validity for other plants is questionable. In addition, they cannot be easily related to radiation doses of the workers.

Moghissi and Carter (1975) evaluated the available literature on the radiation dose received by the users of wristwatches containing Pm-147. They suggest a genetically significant dose of 5 mrem/mCi of Pm-147. The computation of population dose requires knowledge of the average promethium content of timepieces. O'Donnell (1976) suggests a value of 41 mCi (range 29-63) per timepiece. These data were obtained through a search of the records of the Nuclear Regulatory Commission.

EVALUATION OF TOTAL RISK

Table 3 summarizes risks from processing one Ci of radium, promethium-147, and tritium. Internal exposure to radium is appropriately expressed as dose commitment, whereas other exposures are expressed in terms of annual dose.

Occupational skin exposure is not included in this evaluation. Evaluation of skin exposure to various radionuclides has been the subject of several studies, including investigations relative to radium dermatitis. Moghissi and Carter (1975), who summarized these data, indicate extreme difficulties in estimating, even roughly, the skin exposure in dial painting operations which presumably would be the area where the major exposure would occur. This exclusion, although regrettable, would not change the conclusions of this paper because it is acknowledged that although skin is as radiosensitive as most other body tissues in terms of carcinogenesis, skin cancers respond favorably to treatment and with proper care are unlikely to be fatal.

The evaluation of the total risk should be based on the benefits of the application of radioluminous materials. Although economic gain is certainly a consideration in evaluating the benefit, it cannot be used as the sole criterion. Unquestionably, the main benefit from the production of radioluminous materials is the light available on a continuous basis. Because the light production has a finite half-life, the usefulness of the paint must take this decay into account. For example, if exit signs are prepared from radioluminous materials, they are of no benefit in terms of risk-benefit analysis as soon as they decay below the user's visibility level.

In actuality, the subject is more complicated because a dark adapted eye is capable of detecting lower levels of luminosity than an eye which is not dark adapted. In addition, the optimum wave length of light shifts to shorter wave lengths

TABLE 3

Total Risk in Person-mrem from Various Radionuclides Per Ci Processed

Occupational Dial Painting	Radium	Tritium	Promethium-147
Bone	200,000	NA	Unknown
Whole Body	36,000	9.1	5*
Lung	125,000	NA	Unknown
Assembly			
Whole Body	36,500	4.5*	Unknown
Storage			
Whole Body	Unknown	12*	Unknown
Environmental (user's dose from wristwatches)			
Whole Body	(65-70) 10^6	30	5000*

*Estimated values with limited usefulness.

as a result of dark adaptation of the eye. All these facts must be taken into account if various radionuclides with different half-lives are being compared.

It is generally accepted that zinc sulfide is damaged by the action of ionizing radiation, the very radiation that produces light. Wallhausen (1956) suggested a half-life of 10 years for ZnS, a value which is also accepted by the IAEA (1967) expert group. This decay must be considered in evaluating the useful luminosity of the radioluminous materials.

Due to the long physical half-life of radium,' the effective half-life of radium-activated paint will be about 10 years. The effective half-life of Pm-147 activated paint is calculated by combining the physical half-life of Pm-147 of 2.62 years with the 10-year half-life of ZnS resulting in an effective half-life of 2.1 years. Using the same procedure, the effective half-life for tritium gas in tubes can be calculated to be 5.5 years. The actual value is rarely that long because of tritium release from the tubes. A calculation of effective half-life for tritiated paint is somewhat more difficult because of differencs in the decomposition rate of various tritiated polymers. The IAEA (1967) report assumes no tritium release and thus obtains the 5.5-year value calculated for tritium gas. This assumption is obviously invalid in view of many recent measurements both with paint and with users of luminous paints.

It is well known that tritium release is elevated during the first few weeks subsequent to application. Chollet (1968) suggests an annual tritium release of 10-20%. Lorenzer and Born (1968) report 16% release per year, whereas, Guenther

(1974) suggests a 25% release rate. Coenen (1963) reports tritium release rates of 0.08-0.35 μCi/mCi-d with an average of 0.1 μCi/mCi-d. If the highest value is disregarded, this average corresponds to 3.6% per year, whereas his highest value relates to about 13%. From these data, an average tritium release half-life of 4 years can be estimated. The effective luminosity half-life can thus be calculated from the physical half-life of tritium of 12.3 years, the stability half-life of ZnS of 10 years, and the tritium release half-life of 4 years to be 2.3 years.

To properly compare these radionuclides, it is assumed that in every case sufficient activity is used so that at the end of the useful life of the object the minimum luminosity is above the level of effective visibility. In addition, the increased luminosity at the beginning is given credit by comparing the midpoint of the useful life of the object. Figure 1 shows that this approach results in values equivalent to the integral of light during the useful life of the object. Table 4 contains tritium and promethium-147 activities corresponding to 1 Ci of radium. The conversion factors are taken from IAEA (1967) and are 5.0×10^3 Ci for tritium and 1.7×10^2 Ci for Pm-147. These quantities produce a luminosity corresponding to that produced by 1 Ci of radium.

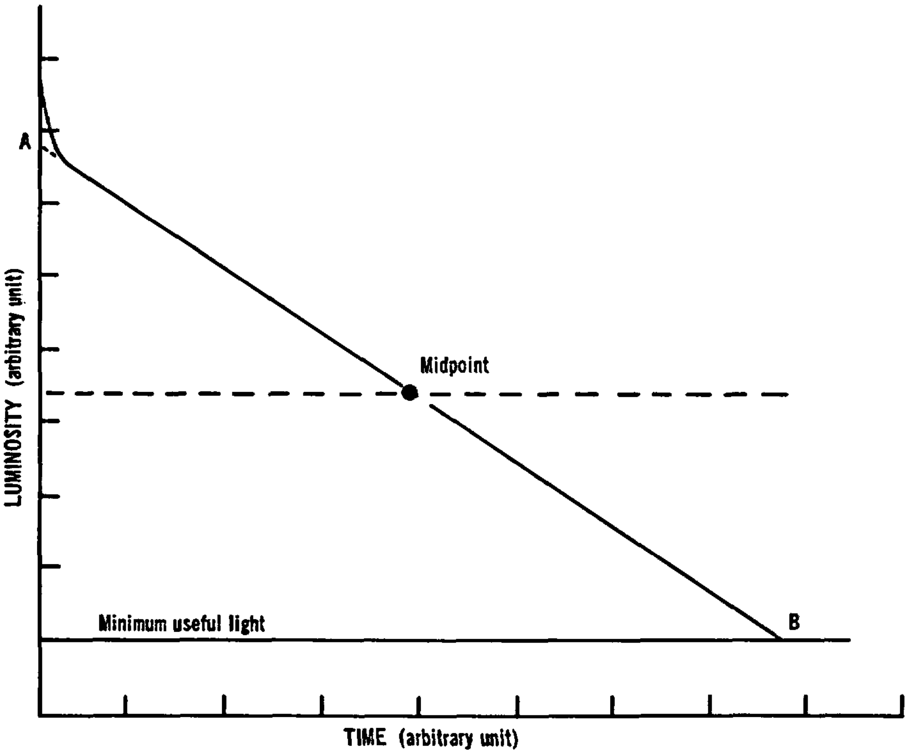

FIGURE 1. Decrease of luminosity with time. The average from A to B is expressed by the horizontal line passing through the midpoint.

TABLE 4

Required quantities of tritium and promethium-147 in Ci to produce an average luminosity equal to the average luminosity of 1Ci of radium for objects having useful lives of 3, 5, and 10 years, respectively.

Useful life, years	Tritium	Promethium-147
0	5,000	170
3	8,000	280
5	11,000	390
10	23,000	880

The IAEA (1967) suggests a useful life of 10 years for timepieces. Increasing repair costs have undoubtedly reduced this value. In addition, the 10-year value was suggested by a panel consisting largely of representatives from countries where repair costs are smaller than those in the United States. In the following evaluation, values have been calculated for useful lives of 3, 5, and 10 years.

The evaluation of the total risk on a comparative basis is somewhat complicated by the differences in organs of reference. It is difficult to compare bone exposure with whole-body exposure. In addition, many of the necessary data, particularly for promethium, are unknown. A close look at Table 3 indicates that, for tritium, an occupational exposure of about 25 person-mrem would be about the same as that for environmental exposure of 30 person-mrem. For radium, the user's dose of 65-70 x 10^6 person-mrem is clearly dominant. To facilitate the comparative evaluation of these three radionuclides, occupational and environmental (user's) exposures are discussed separately.

Table 5 contains radiation dose values to various organs as a result of processing 1 Ci of radium and equivalent quantities of tritium and promethium-147. The values for tritium and promethium-147 have been calculated from data in Table 2 using coefficients of Table 3 for useful lives of 3, 5, and 10 years.

Table 5 shows that although the whole-body dose from tritium exceeds that for radium, this difference is more than offset by the bone dose and, to a certain extent, by the lung dose. As mentioned previously, it is somewhat difficult to compare bone dose with whole-body dose. The comparison between bone dose from tritium may be approximately if one considers that tritium is uniformly distributed in the entire body hydrogen. Therefore, every organ is subjected to a dose proportional to the hydrogen content of that organ provided the T/H ratio is constant in the entire body. In addition, because hydrogen concentration of the bone is about one-half of that of the total body, radiation dose from tritium to the bone is only one-half of that shown in Table 5 for the whole body. Therefore, the highest bone dose from tritium is about 105 person-rem as compared to 200 person-rem from radium to which 36.5 person-rem external dose must be added. Obviously, gamma radiation exposes all organs.

From the above, it can be seen that the occupational exposure from radium is at least as high at that from tritium and probably higher.

TABLE 5

Occupational dose in person-rem as a result of applications of 1 Ci of radium and equivalent quantities of tritium and promethium-147. The values have been normalized for objects with useful lives of 3, 5, and 10 years, respectively.

Organ	Useful life, years	Radium person-rem	Tritium person-rem	Promethium-147 person-rem
Dial Painting				
Bone	3	200	NA	Unknown
Bone	5	200	NA	Unknown
Bone	10	200	NA	Unknown
Whole body	3	36.5	73	1.4*
Whole Body	5	36.5	100	2.0*
Whole Body	10	36.5	209	4.4*
Lung	3	125	NA	Unknown
Lung	5	125	NA	Unknown
Lung	10	125	NA	Unknown
Assembly				
Whole Body	3	36.5	36*	Unknown
Whole Body	5	36.5	50*	Unknown
Whole Body	10	36.5	105*	Unknown
Storage				
Whole Body	3	Unknown	96*	Unknown
Whole Body	5	Unknown	144*	Unknown
Whole Body	10	Unknown	276*	Unknown

*Estimated values with limited usefulness.

Due to similarities in the chemical properties of radium and promethium, it can be expected that a major fraction of radiation from promethium decay would be delivered to the bone. Unfortunately, no data for promethium are available and none can be expected to become available because of the extreme difficulties in measuring the body burden of the workers.

Table 6 compares relative environmental risk (user's risk) for tritium and promethium-147 as compared to radium. This table is based on values taken from Table 3 using coefficients of Table 4. It is evident that radium exposes users of the objects by many orders of magnitude more than tritium or promethium although the values for promethium could be inaccurate by as much as one order of magnitude.

TABLE 6

Relative radiation risk to the user of a wristwatch painted with radioluminous material containing tritium or promethium as compared to radium. The values have been calculated for indicated useful life of the watch.

Useful life, years	Tritium	Promethium-147*
3	3×10^{-3}	2×10^{-2}
5	5×10^{-3}	3×10^{-2}
10	10×10^{-3}	6×10^{-2}

*Numbers for promethium are of limited usefulness.

It should be mentioned that these estimates are for wristwatches. Pocket watches would result in similar doses for radium as indicated previously. The annual gonadal dose would be, in this case, about 78 mrem/μCi. Pocket watches containing tritium would probably result in smaller exposure than wristwatches because of the absorption possibility of tritiated water by fibers of the clothing. The estimates for promethium are missing.

The risk for alarm clocks would be smaller than for wristwatches for all three radionuclides. For radium, the user's exposure would be reduced by two orders of magnitude as described previously. However, at least a proportional reduction in tritium and promethium should be observed and thus values in Table 6 would not change in favor of radium. The comparison between promethium and tritium is, at present, not possible because of the lack of available data.

Tritium gas-filled tubes are potentially the least hazardous of all radioluminous materials. However, poor quality in manufacturing could lead to "leakage" that would significantly affect population exposure more than any other radioluminous consumer product. Unfortunately, pertinent data are unavailable at this time.

POPULATION DOSE

Radioluminous materials are being used in many applications. It has been impossible to obtain sufficient information to make a reasonable estimate relative to the types, numbers, and activity contents of the objects or the exposure data. However, this information is fundamental in estimating the population dose and person-rem data. It is known that radioluminous materials are being used in exit signs, compasses, gun sights, and many other objects. The description of types and numbers of these objects is in many cases guarded by manufacturers and, occasionally, users of these objects.

Because of the limited information available, only timepieces are considered for estimation of person-rem data. It is realized that this estimate represents a minimum of the actual exposure.

Moghissi and Carter (1985) estimated quantities of various timepieces activated with tritium, promethium, and radium. Table 7 contains an updated version of their data. These new values are in many cases higher than those published previously.

TABLE 7

Quantity of Luminous Timepieces (x10^6) Distributed in the United States

	1971	1972	1973	1974	1975	1976
Wristwatches						
a) Tritium activated						
U.S. made	6.10	4.23	3.79	3.84	2.70	3.91
Imported	12.40	13.20	6.60	6.08	5.93	4.54
b) Promethium activated						
U.S. made	Negligible	Negligible	0.07	0.08	0.03	0.06
Imported	0.53	0.85	0.93	0.04	Negligible	Negligible
c) Radium-226 activated	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible
Clocks						
a) Tritium activated						
U.S. made	0.02	0.01	0.07	0.07	Negligible	Negligible
Imported	0.51	0.19	0.26	0.29	(0.31)*	(0.31)*
b) Promethium-147 activated						
U.S. made	Negligible	Negligible	Negligible	Negligible	Negligible	Negligible
Imported	1.47	0.98	1.37	0.35	(1.0)*	(1.0)*
c) Radium-226 activated						
U.S. made	1.0	1.0	1.0	1.2	1.8	2.2
Imported	1.8	1.8	1.8	1.6	1.0	0.6

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*Data unavailable, average of the data from previous years.

However, due to the conservative estimate of the radioactivity content of timepieces, the population dose calculated from the new data does not significantly deviate from the previous dose estimates. It is of interest to compare the distribution of radioluminous watches in the U.S. with that in Switzerland as determined in a recent survey (Krejci, 1977). Whereas in Switzerland about 60% of timepieces are activated with tritium, in the U.S. this value is about 75%. This difference can be accounted for by the lack of popularity of promethium-147 in the U.S.

Table 8 contains data relevant to the quantities of timepieces, radioactivity, and the population dose.

TABLE 8

Evaluation of Population Dose in the U.S. to Radioluminous Timepieces

	Tritium	^{147}Pm	Radium
No. of timepieces	28 x 10^6	2.6 x 10^6	8.4 x 10^6
Average activity of timepiece	1mCi	41 μCi	0.5 μCi
Total activity	28,000 Ci	107 Ci	4.2 Ci
Population dose, 10^3 person-rem/yr	0.8	0.5	2.5

These data assume a useful life of 3 years for the timepieces and are calculated for the period ending with January 1, 1977.

The data for tritium and promethium-147 assume that the exposure in every case is from wristwatches. This calculated overestimation is probably offset by unreported imported watches and other objects such as compasses painted with radioluminous materials. The reason for the comparatively small dose from radium is that its use is limited to alarm clocks. The same quantity of radium in wristwatches would have resulted in substantially higher values.

If, for the useful life of timepieces, a value larger than 3 years is used, the population dose would increase accordingly. However, for a value higher than 5 years, this increase would be considerable because, prior to this period, radium was used to produce wristwatches.

The recordkeeping requirements in the U.S. for tritium and promethium-147 do not necessarily apply to radium. As a naturally occurring radionuclide, radium is not covered by rules and regulations promulgated by the Nuclear Regulatory Commission. Although certain State rules and regulations include radium, the lack of uniform rules and regulations has led to certain inaccuracies in estimating radium exposure.

The data indicate that although tritium and promethium constitute a large fraction of the total inventory of timepieces, they constitute a minor fraction of the dose. The calculated doses for promethium are certainly overestimates, possibly by one order of magnitude because the dose was based on wristwatches whereas the timepieces were clocks.

It is of interest to compare these data to those reported by Butler (1975). This author surveyed 48 households in east Tennessee and found 35 luminous clocks of which 17 emitted penetrating radiation. He concluded that the latter clocks contained radium. The decrease in radiation intensity did not follow the inverse square law. Therefore, it is somewhat difficult to relate his measurements to the radium content of the clock. However, if his average values at 0.5 inch are accepted as valid, a radium content of slightly less than 0.2 Ci per clock can be calculated.

Extrapolating Butler's data to the U.S., there would be a total of about 24 x 10^6 clocks containing radium in the country. This is based on a total of 68.3 x 10^6 households (U.S. Bureau of Census, 1973). This value is higher by a factor of 2.8 than our estimate for the same period, which is based on production data. However, this apparent disagreement does not significantly affect the dosimetry because the total inventory of radium on clocks calculated from Butler's data is about 4.5 Ci, which is in agreement with the 4.2 Ci calculated from our data and has been the basis for population dose computations.

CONCLUSIONS

Radiation exposure to the United States population as a result of application of radioactive luminous compounds, although relatively small, is significant. Radiation dose estimates indicate about 800 person-rem from tritium, 500 person-rem from promethium, and 2500 person-rem from radium to the population of the United States during the calendar year of 1973. If one accepts 3800 person-rem as a reasonable estimate from all these radionuclides, an average exposure of 0.02 mrem/yr for the entire population of the United States of 2.15 x 10^6 people can be calculated. The dose would have been significantly higher if radium had been used to produce wristwatches rather than clocks. If the occupational exposure is taken into account, these estimates would be higher by a factor of two.

The occupational exposure in the U.S. for producing radioluminous devices is comparable for tritium and radium. No assessment of occupational aspects of promethium is possible at this time because of the lack of relevant information.

Like tritium, promethium-147 emits soft beta radiation, which makes it suitable as an activator for radioluminous materials. External radiation from these radionuclides is small and, in the case of tritium, almost nonexistent. Unlike tritium, promethium-147 is not evenly distributed in the body and follows a dynamic excretion pattern. It is, therefore, very difficult, if not impossible, to estimate body burden of dial painters by any known methods. Before a large-scale application of promethium-147, methods must be developed to protect the workers from possible overexposure. One possibility consists of increasing the Pm-146 content of Pm-147. However, this increase must be carefully studied to avoid an unnecessary increase in population exposure to gamma radiation from Pm-146.

In the case of tritium, exposure during assembly and, to some extent, during storage are insufficiently known. Further studies in this area are needed. Radioluminous tubes filled with tritium gas are potentially useful. However, the chemical compositon of tritium in these tubes and the mechanism of tritium release must be carefully studied prior to their widescale application.

Population dose from radium is higher by several orders of magnitude as compared to tritium and promethium-147 for producing the same quantity of light for objects with useful lives of 3, 5, or 10 years. Radium offers no advantage as compared to tritium and should not be used in radioluminous materials.

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PURIFICATION METHODS AND PACKAGING OF TRITIUM AT OAK RIDGE NATIONAL LABORATORY FOR DISTRIBUTION TO COMMERCIAL USERS

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Nearly all of the tritium used in consumer products is converted into final use form by commercial organizations equipped to handle relatively large quantities ($<$1000 Ci) of tritium gas procured from the Department of Energy through the Oak Ridge National Laboratory (ORNL) Isotopes Sales Office. Although small amounts of tritium are used in a large number of consumer products and in industrial and scientific applications, large quantities are maintained by only a few processors where inspection and regulation can be easily administered. Purchase of tritium from ORNL is limited to licensed users, and the declaration of a valid state or NRC license number is required prior to shipment from ORNL.

The principal end use for tritium involves light sources in which tritium is sealed into small glass tubes containing fluorescent powder that emits light when activated by the soft (0.018 MeV) beta radiation produced when tritium decays to stable ^{3}He. Other important tritium uses are in the manufacture of targets for neutron generators and in tagging organic compounds for tracer studies in medicine and basic chemical research. Important oil field tracer applications using tritiated water are routine in the management of water flooding in secondary recovery from oil wells.

Tritium shipped from ORNL is purified (Case 1964) just before shipment to minimize the amount of the ^{3}He decay product and atmospheric gas impurities. This purification step also helps to ensure that accurate measurement is made of the tritium loaded into the shipping cylinders since the quantity shipped is determined by a volume/pressure measurement.

The tritium purification process involves conversion of elemental tritium to uranium tritide and is accomplished by reacting tritium gas with activated uranium metal powder in a closed system from which atmospheric gases have been removed. The activated uranium trap is prepared by placing 10 to 20 grams of nitric acid–washed uranium chips into a stainless steel chamber. Although uranium "U" tube traps and dead end traps have been used at ORNL, our current preference is a dead end trap. With the uranium chips in the trap, the cap is welded in place and a sintered metal filter is attached to the trap inlet tube. This filter controls loss of small particles from the trap during processing.

To activate the uranium trap, it is heated to 600°C under vacuum for 4 to 6 hours, after which hydrogen is admitted to the trap and it is allowed to cool to room temperature. Uranium hydride is formed on the surface of the uranium.

The uranium hydride is decomposed by heating the trap and pumping off the released hydrogen, and the process of cooling the trap in the presence of hydrogen followed by heating to decompose the hydride is repeated several times. This procedure provides an active uranium structure that (1) will absorb 10,000 to 15,000 curies of tritium and (2) may be used for several years of continuous operation.

Tritium to be purified may contain traces of water and atmospheric gases in addition to the ^{3}He decay product. The ^{3}He does not react with the uranium and is pumped out of the reaction chamber after the tritium/uranium reaction is complete. Other gases such as oxygen, nitrogen, or water vapor either do not react with the uranium or are not desorbed during decomposition of the uranium tritide to produce a final product.

Since some unreacted tritium is always present in the residual gas remaining in the system after the tritium/uranium reaction, this gas is pumped through a copper oxide reaction chamber heated to 600°C where tritium is converted to water and is collected on a molecular sieve in a liquid nitrogen cooled trap. The exhaust gas from the cold trap is essentially free of tritium and is discharged to the plant off-gas system. This exhaust gas recovery system is operated until 100,000 to 150,000 Ci of tritium are processed through the uranium purification step, after which the molecular sieve trap is heated and purged with steam to recover tritium by distillation into a glass cold trap cooled to liquid nitrogen temperature. Approximately 2,000 to 3,000 Ci of tritium are recovered from the exhaust gas for each 100,000 to 150,000 Ci purified. The glass trap containing tritiated water is incorporated into concrete and disposed of by burial. (Figure 1).

A typical analysis of ORNL tritium product is shown in Table 1.

TABLE 1

ORNL Tritium Product Analysis (mol %)

T_2	98.4
DT	1.04
HT	0.05
T_2O	0.04
N_2	0.02
H_2O	0.01
D_2	0.01
Others'*	<0.01
Total T	99.2

*H_2. ^{3}He, HD, ^{4}He, HDO, D_2O, CT_4, O_2, Ar, and CO_2

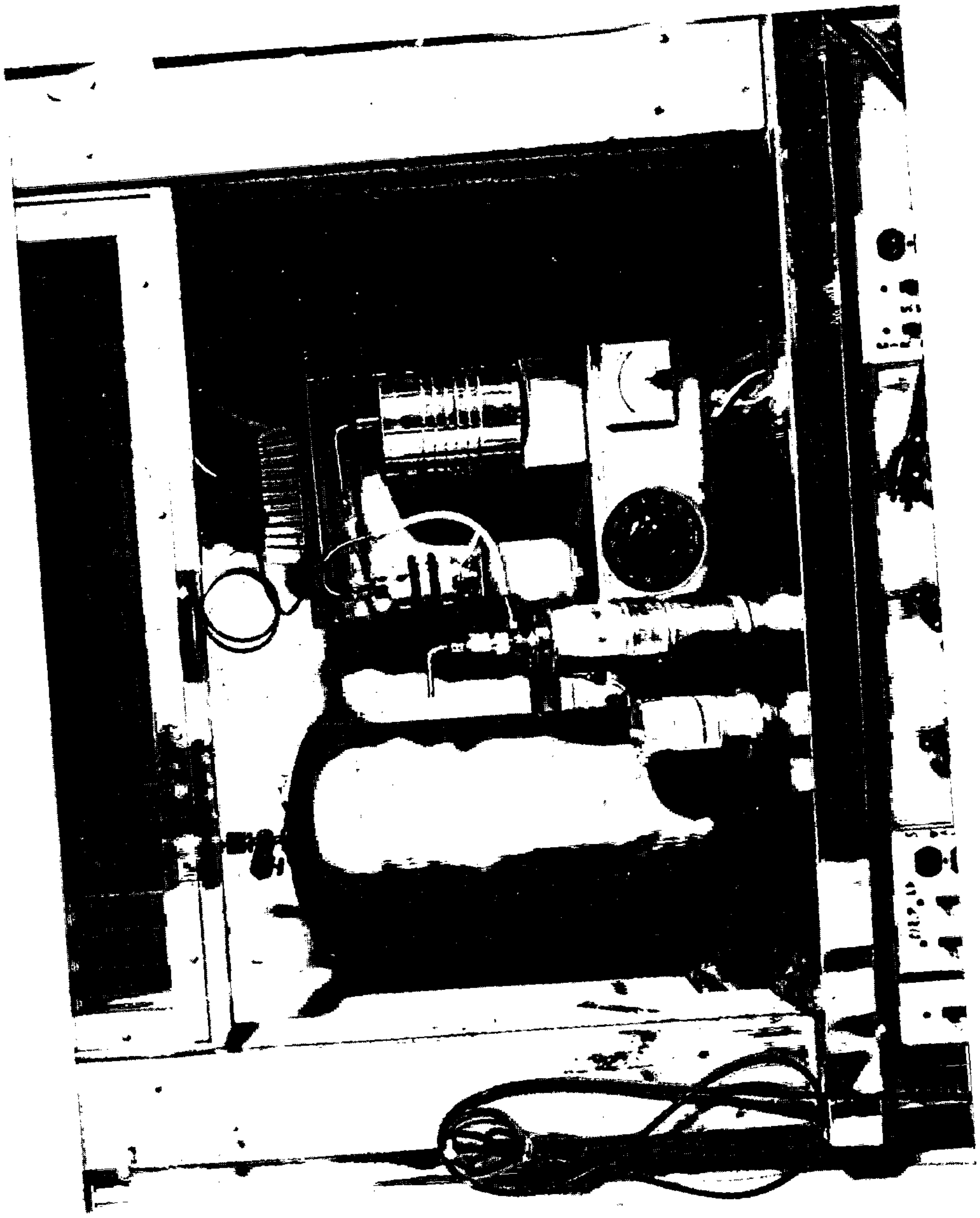

Figure 1. Copper Oxide Converter and Cold Trap for Recovery of Tritium from Exhaust Gas Streams

Analysis of the tritium product is difficult primarily because of the difficulty in obtaining an uncontaminated sample. Special precautions must be observed in the treatment of the sample ampule to exclude water. This requires that the ampule be flamed while it is connected to the purification system vacuum, and tubing connections must be pumped for overnight time periods in order to minimize contamination by atmospheric gases and water vapor. The same precautions must be observed when the sample is introduced into a mass spectrograph.

Shipments of tritium gas made by Oak Ridge National Laboratory are packaged in returnable stainless steel cylinders having a double wall and fitted with a diaphragm sealed valve. During shipment the valve assembly is covered with a cap that is threaded to the top of the cylinder and sealed with an O-ring compression seal. (Figure 2).

Prior to loading, the cylinder is evacuated to <25 torr by pumping with a mechanical and an oil diffusion pump. The gases pumped from the cylinder, which may contain residual tritium from a previous shipment, are discharged through the off-gas copper oxide converter described earlier. After the pumping operation the valve on the evacuated cylinder is closed and the cylinder is shelf tested for 12 hours to observe for an increase in pressure that would indicate a leak.

Cylinders that are determined to be leak free are connected to the purification system and tritium is loaded into them by heating the uranium tritide to approximately 500°C, at which temperature the tritium is released. The desired quantity is obtained by controlling the pressure of gas in the cylinder as measured with a mercury manometer. The size of the cylinder is selected to provide adequate volume for the desired quantity to be loaded without exceeding atmospheric pressure. Excess tritium in the purification system is recovered by cooling the trap to room temperature where the tritium reacts with the activated uranium to form uranium tritide.

The purification system is then isolated from the shipping cylinder, and the cylinder valve port is capped to contain tritium contamination present in the valve. A wax seal is placed on this cap for use as an indication of tampering during transport to the user. A second wax seal is placed on the valve tension nut since this nut controls the tension on the valve seal and can cause valve leakage if it is loosened. In addition a wire/lead seal is placed on the valve handle to provide an indicator of unauthorized valve opening. (Figure 3).

The valve cover is placed on the cylinder after the loading and sealing operations are completed, and the cylinder is again shelf tested for at least 4 hours. At the end of the shelf test an evacuated ionization chamber is connected to the valve cover. Air from inside the cover is drawn into the ionization chamber to determine whether tritium has leaked from the cylinder valve after loading. A tritium concentration of 5×10^{-6} μCi/ml is set as the upper limit for release of the shipment to common carrier transport. (Figure 4). Following the leak test the cylinder is checked for removable contamination by randomly smearing approximately 10% of the external surface with a foamed polyethylene swab. This swab is dissolved in scintillation liquid for determination of the tritium contamination removed from the cylinder. The surface contamination must be less than 1 nCi as determined by the above method for release of the cylinder for shipment.

Up to 1000 Ci of tritium is shipped in a Type A package meeting Department of Transportation (DOT) and International Atomic Energy Agency (IAEA) test

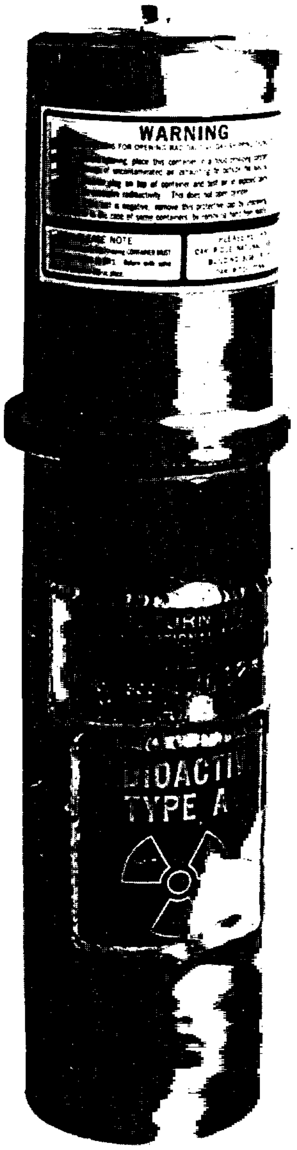

Figure 2. Tritium Shipping Cylinder with Valve Cover and Sample Port

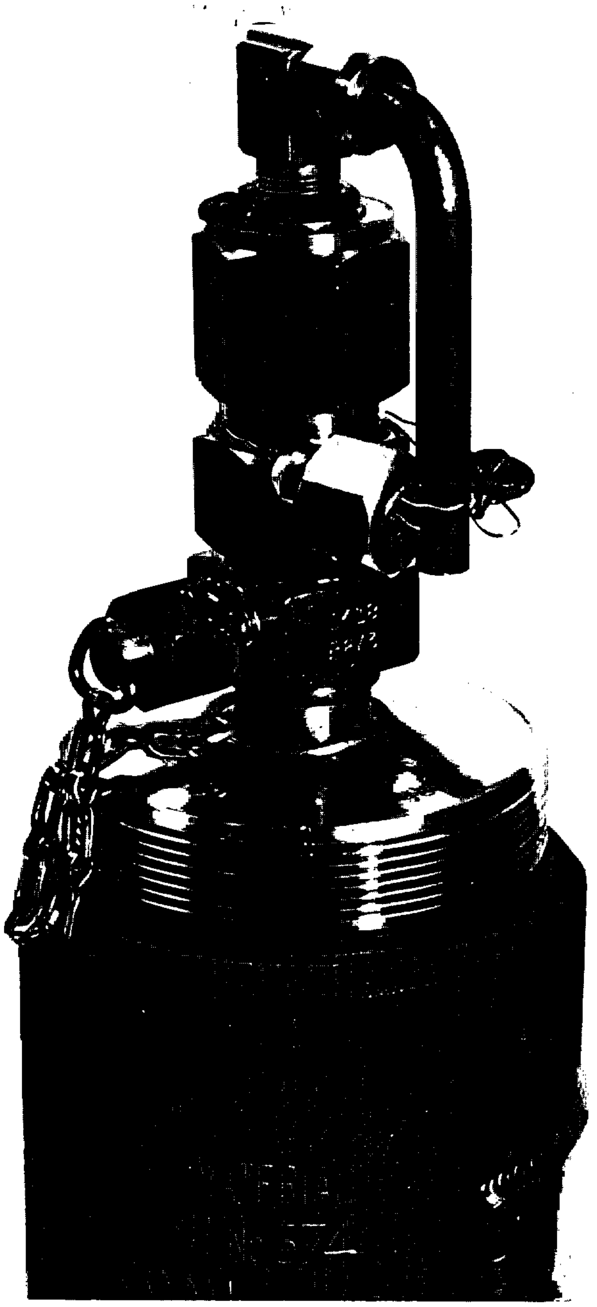

Figure 3. Tritium Shipping Cylinder Showing Wax Seals and Wire Seal on Valve Handle

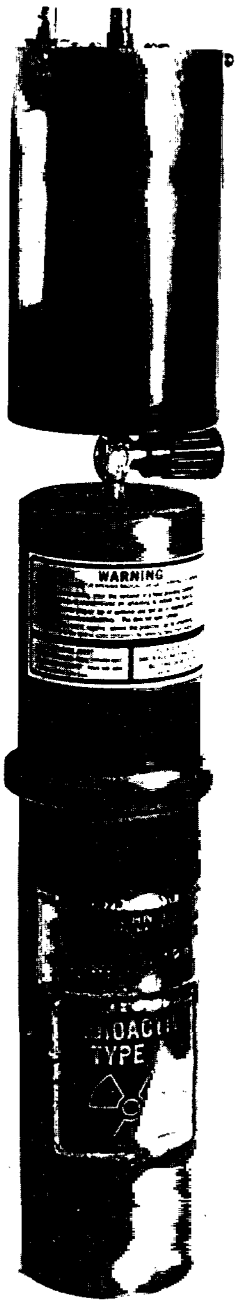

Figure 4. Tritium Shipping Cylinder with Ion Chamber Sampler Attached

specifications. Shipments greater than 1000 Ci are made in a fire shield overpack to meet Type B DOT and AEA specifications.

A non-returnable Type A cylinder for use in shipping up to 1000 Ci of tritium is under development. DOT and IAEA specified tests are met by this one-time use cylinder, and its use will eliminate the transport of internally contaminated returnable containers and save transportation and decontamination costs now associated with returnable containers.

Tritium is shipped as uranium tritide in sealed traps in Europe to reduce package size and provide a convenient storage form for the user.

Oak Ridge National Laboratory is operated by Union Carbide Corporation for the Department of Energy.

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PUBLIC HEALTH ASPECTS OF PRODUCTION AND APPLICATION OF RADIOLUMINOUS MATERIALS ACTIVATED WITH TRITIUM AND CARBON-14

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New developments in the watch industry in recent years have considerably influenced the production of radioactive luminous compounds. Because of new technical solutions for illumination of Light Emitting Diode (LED) and Liquid Crystal Display (LCD) wrist-watches, the production and use of radioactive luminous materials have dropped in industrialized countries. The total amount of tritium activity used worldwide on wristwatches and alarm clocks has not changed much.

The production of tritium luminous compounds requires some 60-80 KCi annually. A substantial portion, some 60%, is manufactured in Switzerland.

The technology of manufacture and application is well advanced. The common form of luminous compounds,is a copolymer with tritiated polystyrene, obtained by ordinary hydrogenation of phenylacetylene (Krejčí, 1972a). The addition of various copolymers improves the end product relative to its stability and insolubility in adhesive solvents. These copolymers are being used for coating zinc sulphide or other phosphor crystals. Silicone polymers, as reported by Evans and Maynard (1966), are also currently used.

The excellent hygienic radiation parameters of tritium (halflife 12,3 years, maximum beta energy 18 keV, average beta energy 5.7 keV, decay product ^{3}He, simple dosimetry by tritium measurement in urine) have gradually encouraged the use of tritium as the radioactive product for the watch industry. The absence of external radiation is an important factor that distinguishes this kind of luninous compound from other products previously used in the watch industry. About 98% of all luminous material currently used in Switzerland is activated with tritium.

The only disadvantage of tritium luminous materials for the user is the risk of internal contamination due to the release of tritium from watches containing tritium paint. Our study describes the environmental impact of the production and application of tritium luminous compounds, the occupational exposure, and other relevant factors.

CONSUMER PRODUCT

According to Recommendation No. 23 of the European Nuclear Energy Agency and the International Atomic Energy Agency "Radiation Protection Standards for Radioluminous Timepieces," the following amounts of tritium are permitted on timepieces:

wristwatches	maximum 7.5 mCi	average 5 mCi
pocket watches	maximum 7.5 mCi	average 5 mCi
clocks	maximum 10 mCi	average 7.5 mCi
special timepieces	maximum 25 mCi	

Measurements made for more than 8 years by the authors show that the practical amounts, with the exception of special timepieces, vary from a small activity necessary to achieve a fair brightness to 50% of permissible activity. Only in special cases can one find total activities close to the maximum. These findings disagree with those by other authors (Moghissi, 1975; Bradley, 1971), who have found an average activity on wristwatches of about 5 mCi. Results, based on destructive and nondestructive methods of luminous intensity measurements of watches, show for yearly series of about 2000 pieces the following values:

	tritium activity mCi			
horary instrument	0.2 – 0.3	0.3 – 1.5	1.5 – 3	>3
wristwatches	62%	26%	10%	2%
pocket watches	no data available			
clocks	8%	80%	10%	2%
special timepieces				100%

An average content of 1 mCi for wristwatches and 1.6 mCi for clocks has been determined. Factors that influence the amount of tritium applied to timepieces include the size and shape of dial and hands, color of dial surface, layer of paint, color and specific activity of luminous compound, and stability and solubility of tritiated polymer. Direct proportions exist between the amount of tritium applied and the release of activity from watches. Also, the specific activity of applied luminous paint has a slight influence on the percentage of release as the following measured values indicate:

specific activity:		release:	
	100 mCi/g		4.6% per year
	250 mCi/g		5.0%
	420 mCi/g		5.4%
	650 mCi/g		8.2%

According to sales statistics, about 70% of the luminous watches made in Switzerland are coated with tritium material having a specific activity in the range of 200 to 400 mCi/g. This corresponds to a release of 5.2% tritium per year and gives the following amounts of released activity:

	maximum release of tritium activity	
activity of watches	day	year
0.2 – 0.3 mCi	44 nCi	16 μCi
0.3 – 1.5 mCi	214 nCi	78 μCi
1.5 – 3 mCi	427 nCi	156 μCi
5 mCi	712 nCi	260 μCi
25 mCi	3560 nCi	1300 μCi

The resulting dose for the user, according to Moghissi (1975), who reported 0.3 mrem/mCi of tritium paint, reaches an average of 0.03 mrem/yr for wristwaches and 0.05 mrem/yr for clocks.

According to a study to determine the number of tritium luminous watches and luminous clocks used by 1032 Swiss city and country people in 1976, the following results have been found:

number of consumers	^{3}H watches	^{147}Pm and ^{226}Ra watches	Nonluminous watches	Digital watches	without watches
1032	470 (45.5%)	127 (12.3%)	348 (33.7%)	30 (2.9%)	57 (5.5%)

number of consumers	^{3}H clocks	clocks painted with ^{147}Pm or ^{226}Ra or phosphorescent material	electric clocks	without clocks
1032	240 (23.3%)	358 (34.7%)	185 (17.9%)	249 (24.1%)

A closer analysis of the number of luminous timepieces by different consumer groups shows the following figures:

	luminous watches		luminous clocks
	tritium	others	
Consumer	% 2 S.D.	% 2 S.D.	% 2 S.D.
men	47.8 ± 4.9%	18.7 ± 3.8%	52.0 ± 4.0%
women	32.2 ± 4.6%	10.5 ± 3.1%	64.8 ± 4.4%
children (7 - 16)	65.8 ± 6.4%	3.7 ± 2.5%	56.6 ± 5.7%
total	45.5 ± 3.1%	12.3 ± 2.0%	58.0 ± 2.6%

(values with 2 standard deviations)

As stated above, we have calculated an average activity of 1 mCi of tritium for wristwatches and 1.6 mCi of tritium for clocks. We estimate that about 40% of luminous clocks are tritium treated, 45% promethium-147 treated, and a small number are painted with radium-226 or phosphorescent pigment only.

These estimates result in the following number of tritium luminous timepieces and evaluated annual dose for the Swiss population:

	number of	number of	dose (person-rem/yr)
consumer	^{3}H wristwatches	^{3}H clocks	2 S.D.
men	1,103,200	481,700	57.2 ± 1.9
women	804,800	648,300	56.6 ± 1.8
children (7 - 16)	733,300	254,400	34.7 ± 1.1

This study did not evaluate population doses from promethium-147 and radium-226 pointed watches and clocks. In previous statistics based on a smaller number of persons, we found that out of 201 luminous watches only 4 pieces (2%) were painted with radium-226 and out of 164 luminous clocks 18 pieces (11%) were painted with radium-226 liminous compound.

If these results are applied to our new study, with extrapolation to the Swiss population, a total of 68,450 wristwatches and a total of 377,800 clocks are assumed to have been coated with radium-226 material.

OCCUPATIONAL EXPOSURE

The release of tritium from luminous paint is the main course of public exposure. Otherwise, considering the amount of processed activities in different regions of Switzerland and the large number of persons handling luminous compounds in the watch industry, the occupational exposure is of far more interest. The tables below give values for radiation exposure of individuals connected with the production and use of tritium luminous compounds and provide data on environmental releases. The figures are based on measurements of tritium bioassay and production statistics from the last 10 years.

Measurements for determining tritium concentration in urine are made directly without any preparation of urine such as distillation or discoloration with charcoal in order to eliminate the risk of loss of activity during preparation. As described in a previous paper (Krejčí, 1972), we use 10 ml Unisolve-1 Cocktail from Koch-Light with 1 ml urine. The method of internal standard (HTO from LMRI-Saclay) is used for calculation of tritium activities. Moghissi (1975) suggests evaluating the dose according to the following equation:

$$H = 0.1\ C$$

where H is the annual radiation dose in mrem and C is the concentration of tritium in body water in nCi/l. Thorough analysis of a group of plants for painting luminous dials and hands shows great differences among the plants. These differences are not only due to the amount or specific activity of processed tritium luminous compound but also here to radiation protection installations such as ventilation and to room dimensions and working discipline.

Table: average data from different luminizing plants over 4 years

plant	average activity in paint mCi/g	processed tritium Ci/person-yr	average urine activity μCi/l	risk-person mrem/Ci
A	140	144	7.0	4.86
B	320	85	12.0	14.11
C	260	116	7.8	6.72
D	420	56	7.7	13.75
E	170	210	12.7	6.05
F	240	107	5.1	4.77
G	200	238	8.0	3.36
Average		137	8.6	6.28

Table: average data from 7 luminizing plants

year	processed tritium Ci/person-year	average urine activity μCi/l	risk-person mrem/Ci
1972	119	7.9	6.64
1973	154	8.0	5.19
1974	150	9.8	6.53
1975	112	6.3	5.63

Similar statistics from luminous compound manufacturers show accordingly the influence of the technical equipment available and improvements of laboratory methods:

year	manufactured Ci/person	average ^3H concentration in urine $\mu Ci/l$	risk person-mrem/Ci
1968	16,700	18.8	0.113
1969	26,000	29.6	0.114
1970	32,000	36.5	0.114
1971	23,000	13.3	0.058
1972	18,500	12.1	0.065
1973	18,500	11.6	0.063
1974	15,500	10.0	0.065
1975	14,000	9.2	0.066
1976	20,000	10.7	0.054
Average	20,467	16.9	0.083

IMPROVEMENT POSSIBILITIES

There is a general tendency to reduce tritium activities on watches while maintaining a good legibility. Special lacquers have been developed that permit improving by a factor of 2 the previously published relationship of 10 mCi to get 1 μCd. For example, recently developed trititum luminous compounds mixed with special lacquers result in a luninosity of 2 μCd per 10 mCi. The stability of the polymer has been increased by a different purification method introduced for monomer styrene. Gas chromatographical control is necessary to check the efficiency of the tritiation and purification.

One should recommend the use of a luminous compound of natural green color only since this material provides best luminosity efficiency. To achieve similar luminosity with colored paint, it is necessary to apply the following amounts of tritium:

color	relative amount	color	relative amount
natural green	1	deep green	1.9
white	1.5	red	6.6
yellow-green	1.2	orange	5
grass green	1.7		

The design of dials should provide specific activities of the middle range and good legible marks. In a previously published paper (Krejčí, 1972b) describing our calculation disc, we have given a short and simple calculation method for designing illuminated timepieces.

Eliminating the direct contact of people with radioactive material in luminizing plants is connected with reducing radiation dose. The use of semi-automatic equipment like the "Stylograph" pen and "Luxomat" printing machine is a convenient solution.

ENVIRONMENTAL RELEASES FROM LUMINOUS COMPOUND PRODUCTION AND APPLICATION

In the production chain an important amount of radioactive wastes occurs. There are different kinds of tritium wastes to be treated or transferred to the environment after appropriate dilution. The estimated tritium waste is as follows:

Production	gaseous trititum, HTO, organic vapor (intermediate products), wastes of luminous powder, contaiminated glass, and other laboratory material Amount: 0.04 Ci per processed Ci
Luminizing plants	gaseous tritium, HTO, vapor from lacquer solutions, wastes of luminous powder, contaminated laboratory material, rejects Amount: 0.1 Ci per processed Ci
Consumer	released tritium Amount: 0.05 Ci per applied Ci in 1 year

The tritium release from consumer products does not have any environmental significance because this release is highly diluted and spread over long periods of time. However, for the production and luminizing plants, the possibility of accumulating air and surface water tritium does exist in some regions.

Tritium has been measured in waste water in Switzerland since 1972. Different reports (Bezzegh, 1975; Kaufmann, 1975; Kuer 1973-1976) reveal the following concentrations of tritium:

	Tritium Concentrations (nCi/e)				
	1972	1973	1974	1975	1976
Manufacturer A	880	470	250	860	330
Manufacturer B	–	100	–	–	–
Area La Chx-de-F.	4.5	58	160	100	–
Area Bienne	–	1.9	–	–	–

According to measurements effected by SUVA (Swiss National Accident Insurance Fund) (Galliker, 1976), EAWAG (Bezzegh, 1975), and ourselves of the environment of a luminous compound factory and luminizing plants, the following tritium concentrations have been found:

Luminizing plants:

1. waste water: 7.10^{-2} µCi/ml ± 50%
   drained in canalization after dilution: 7.10^{-3} – 7.10^{-4} µCi/ml
2. surface contamination: average 0.7 µCi/cm^2
   range 0.1 to 1.1 µCi/cm^2

Luminous compound producer:

1. waste water: 2.6×10^{-3} µCi/ml ± 30%
   drained in canalization after dilution: 1.3×10^{-5} to 2.1×10^{-5} µCi/ml
   after passing municipal water purification plant system: 3.7×10^{-6} to 4.3×10^{-6} µCi/ml
   rain water in factory area: 0.85×10^{-4} to 3.8×10^{-4} µCi/ml
   snow in factory area: 3.5×10^{-4} µCi/ml

2. surface contamination: 0.1 μCi/cm^2 to 4 μCi/cm^2
3. concentration of air in laboratory rooms: 2 μCi/m^3 to 30 μCi/m^3

According to ICRP Publication No. 10, the maximum permissible concentration in drinking water for radiation workers for a 40-hour week is 0.1 μCi/ml, and the maximum permissible concentration in inhaled air for radiation workers for a 40-hour week is 5 μCi/m^3.

A new filtration system has been developed in collaboration with SUVA for partial elimination of waste water contamination. This system consists of two separate chambers and a filter with the necessary pumping and sampling equipment. Using this sytem, it is possible to reduce the waste water contamination by a factor of 5 to 10, depending on the amount of filtered luminous particles, their specific and total activity, and the length of time of filter use.

The occupational hazard resulting from tritium luminous compound production and application has reached the following values for persons employed in these activities during the last years (Kaufmann, 1976):

year	number of persons employed	collective doese (man-rem)
1969	334	618
1970	313	478
1971	226	476
1972	217	268
1973	219	231
1974	290	316
1975	235	239

CARBON-14 LUMINOUS PRODUCTS

In the past carbon-14 luminous compounds have only been used for special purposes such as testing thermoluminescent dosimeter readers (McCall, 1969), calibrating night airglow photometers (Kulkarni, 1969), calibrating photocells and photomultiplier tubes, or as secondary standards of luminosity. Reduction in the price of carbon-14 raw materials over the last 3 years has also allowed the use of this kind of luminous compound for labelling special objects such as rifle sights, instrument dials, or special timepieces.

For over 4 years, we have been producing luminous standards containing carbon-14 activated phosphor, hermetically sealed in a cerium stabilized optical glass envelope. An external black eloxated aluminium housing is used to provide a unit with extreme shock resistance. Carbon-14 luminous compounds in comparison with tritium luminous compounds have a better efficiency calculated per activity unit. The long half-life of 5570 years, an average beta radiation of 0.054 MeV, a maximum beta radiation of 0.158 MeV, body fat, a maximum permissible body burden of 400 μCi, and an effective half-life of 10 days are parameters of carbon-14 that seem to be most favourable for luminizing of specially controlled objects. The published luminous efficiency (Mehl, 1965) of 0.19 mCi/g to produce 1 μL luminosity is higher than the efficiency determined by us. For an especially radiation-resistant, fine-grained zinc sulphide phosphor of 10 mCi/g specific activity, we obtained about 16 μL powder brightness or 4 μL applied brightness for 50 mg/cm^2. This corresponds to 0.4 mCi/μCd and, when compared with tritium luminous compound having a factor of 6 mCi/μCd, it shows the possibilities and limits of this kind of luminous material.

A wide choice of special phosphors available in different colors and also combinations of different phosphors with very definite peaks in the whole range of the visible spectrum help to solve specific problems. The typical phosphors with their corresponding characteristics are listed in the following table. Luminous standards also require other phosphors having a very narrow peak and phosphors of great temperature stability.

phosphor	emission color	peak nm	relative luminance %
5000	green	520	100
4000	yellow	555	73
8000	white	580	45
3000	orange	622	40
9014	green	545	31
6000	blue	440	14

The total activity of luminous standards varies from 0.05 mCi to 100 mCi per piece depending on size, color and required luminosity. The specific activity of carbon-14 luminous compounds varies from 0.01 mCi/g to 45 mCi/g.

The sources are tested for leakage, surface contamination, and surface radiation dose.

Delivered with each lot is a calibration certificate of light standard sources and all specific data and test results. Except for sources containing small quantities of byproduct material, a specific license is required to obtain or possess light standard sources. The exempt amount of radioactive material in the United States is 100 μCi carbon-14 per source.

The yearly total activity of carbon-14 light standard sources manufactured over the last 3 years amounts to approximately 270 mCi.

The production of carbon-14 luminous compounds and the completion of sources are carried out in ventilated glove boxes and give the producer a body contamination below the limits of detection. According to ICRP Publication No. 10, one calculates that 10 nCi/l of urine 4 days after the event (corresponding to 14 nCi/day) permit the detection of an intake of 4.7 mCi of carbon 14 (carbonate) to the total body.

Long-term brightness inspections of carbon-14 luminous compounds applied to special timepieces show an excellent stability of luninosity and good legibility. The amount of radioactivity for different dials and hands varies from 16 μCi to 100 μCi per piece. A specially protected carbon-14 tracer is used, and the immersion test on paint shows readings in the range of 0.045 to 0.100%. The high price of carbon-14 is probably the main factor in the lack of increase in demand for C-14 luminous material.

CONCLUSION

The radiation exposure for the Swiss population resulting from the use of tritium luminous compounds on timepieces is relatively small and reaches 148.5 person-rem/yr., or an average of 0.023 mrem/person-yr. In comparison with previously published data by Joyet (1960) who reported an average dose of 3.7 mrem/yr of radiation exposure to the Swiss population from radium-226 luminous watches, the use of tritium represents a great improvement toward decreasing the population dose.

In view of the large number of luminizing plants and the important amount of processed tritium activity in Switzerland, the occupational hazard of 239 person-rem/yr is more significant.

The production and the use of tritium luminous material influence slightly the concentration of tritium in the environment, but this concentration does not reach the permissible values.

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EXPERIENCE IN THE SAFETY OF RADIOLUMINOUS LIGHT SOURCES TESTED AT THE U.S. ARMY ENVIRONMENTAL HYGIENE AGENCY*

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The military possesses and uses large quantities of materials containing radioluminescent light sources. These devices range from such simple items as wrist watches and compasses to complicated artillery fire control equipment. Army regulations now require that such devices be tested for radiological safety by the U.S. Army Environmental Hygiene Agency (AEHA) located at Aberdeen Proving Grounds, Maryland, prior to procurement. For the past 15 years, AEHA has tested many different radioluminescent light sources.

The most commonly used phosphor activator is tritium, although promethium-147 is also used. In the past, radium, strontium-90, and carbon-14 were used. Army regulations now forbid the procurement of items with radium-activated phosphors.

This paper describes the testing procedures for items containing radium, tritium, and promethium-147 and the results of these tests on various types of equipment.

RADIUM

For many years, radium was the only phosphor activator in use, and the military procured many items containing this element. During the 1960's, the items containing radium that were tested included toggle switch markers, azimuth indicator scales, and survival and wrist compasses. Usually the main test procedures were: (1) a wipe test of the item using a moistened wipe with alpha counting in a low-background proportional counter, (2) measurement of the gamma emission by use of a G-M detector, and (3) alpha counting with a gas proportional counter, PAC-3G. On occasion, the rate of radon leakage from the device was determined by packaging the item in a plastic bag for a period of time, then separating the radon from the air in the bag and counting the alpha emissions by scintillation counting.

Of the devices in this category that were tested, only two will be discussed. These are azimuth indicator scales and wrist compasses. The azimuth indicator scale was a curved scale 70 cm long, 2.5 cm wide and having a radius of curvature of 43 cm

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*The opinion or assertions contained herein are the private views of the authors and are not to be construed as reflecting the views of the Department of the Army or the Department of Defense.

mounted in the turret of an armored vehicle. (Figure 1). The scale markings were 0.013 cm in width and 0.04 cm in depth. To these markings was applied a white base coat that was then covered with the luminous paint. Following this, the entire face of the scale was covered with an acrylic material.

FIGURE 1 AZIMUTH INDICATOR SCALE CONTAINING A RADIUM-ACTIVATED PHOSPHOR

One of these scales was removed from a vehicle and tested in the laboratory. Examination of the indicator at time of receipt showed that the acrylic coat was peeling away from the metal, exposing the luminous paint at various points. It was also noted that the lower portion of the scale had been scraped, which also removed the acrylic material. Because the acrylic coating was broken, a wipe test of the surface was not performed.

The beta-gamma dose rate at one foot from the center of the scale was 6 mrem/hr, while on contact with the scale, the dose rate was 100 mrem/hr. An alpha probe placed against the face of the scale showed 0.55 nCi/cm^2. After one week of collection, 13.6 nCi of radon were found to have leaked from the scale.

This scale was replaced in the vehicle and it was found that the scale pointer on the traversing mechanism was movable and in certain positions could scrape the scale, loosening and stripping off the acrylic coat. At various sites in the compartment, the beta-gamma dose rate was measured and it was found that the average dose rate was 2 mrem/h and the dose rate at the position of the gunner, approximately one foot from the scale was 7 mrem/h.

Seventeen vehicles were randomly selected from among those in storage at a depot. These vehicles were surveyed immediately after opening for beta-gamma and alpha contamination. This was found in only one vehicle, where the level was approximiatley 4 pCi/cm^2 beta-gamma and 5 pCi/cm^2 alpha contamination.

During this survey it was found that a preservative grease had been applied to the hatch traversing mechanism and also covered the scale. Wipes of the scale, which removed some of the grease, showed beta-gamma activity as high as 37.8 nCi and 29.2 nCi of alpha activity. Apparently the grease trapped the radon, preventing contamination of the inside of the vehicle with radon daughters. Subsequent to these tests, the scales were removed from the vehicles and replaced with a type that contained a nonradioluminescent phosphor.

In the military it is possible to order a specific item of equipment when need is high but receive this item at a later date when the need is low. This was the situation that occurred with 38,000 wrist compasses that were purchased in 1953, placed in a warehouse, and subsequently examined for radiation safety in 1966. The compasses were packaged for overseas shipment 300 to a wooden crate. Inside the crate there were three cardboard cartons sealed in a "tar paper" type wrapping. Each of these cartons, which were coated with a wax compound, contained 100 individually boxed compasses wrapped in tissue paper.

Air was drawn from one of the cartons by use of a hypodermic needle attached to a vacuum flask. The radon gas was separated and counted by alpha scintillation; 267 nCi of radon gas were measured.

Measurements of the surface contamination were made on the packing material as the compasses were unpacked. The results of these measurements are shown in Table 1. Twenty-four compasses were selected at random from one box. The measurement of alpha contamination was made with a PAC-3G survey meter on the compass body, front and back, and the web strap, front and back. The compass bodies were then wiped with a dry cloth wipe followed by a repeat wipe test with a cloth wipe that was moistened with alcohol. The residual alpha contamination measurements were then repeated with the alpha survey instrument. The results of the wet and dry tests are shown in Table 2 and the results of the alpha measurements with the PAC-3G are shown in Table 3, as well as beta-gamma measurements using a Geiger-Mueller counter. In addition, a one-inch section of strap was cut from five compasses and counted in a gas flow proportional counter. The results of this test showed an average of 418 (range 159 – 546) pCi of beta activity and an average of 149 (range 46 to 213) pCi alpha activity in these one-inch sections of strap.

Because of the levels of radon gas within the packages and the resultant surface contamination of the webbing of the straps, it was recommended that these compasses be removed from the warehouse and disposed of as radioactive waste.

TRITIUM

During the 1960's tritium replaced radium as the principal phosphor exciter for radioluminescent devices. Among the items containing tritium that were tested by AEHA were lensatic compasses, survival compasses, rifle sights, wristwatches, and other such devices. Usually the testing procedures were: (1) a wipe test of the item using a moistened membrane filter and counting by liquid scintillation and (2) submerging the item in water for a 24-hour period and then counting an aliquot of the water by liquid scintillation. Occasionally the rate of tritium leakage was determined by submergence of the item in water. The limits of detection for the wipe test are 3.8 μCi.

In this section we will only discuss three of the devices that were tested. These are the lensatic compass, prototypes of a rifle sight, and fire control components. The lensatic compass (Figure 2) generally contained 75 mCi of tritium, although several of these items contained 120 mCi of tritium. The tritium is located in three different areas: (1) the actual compass face, (2) the bezel of the compass, and (3) the sight wire screws.

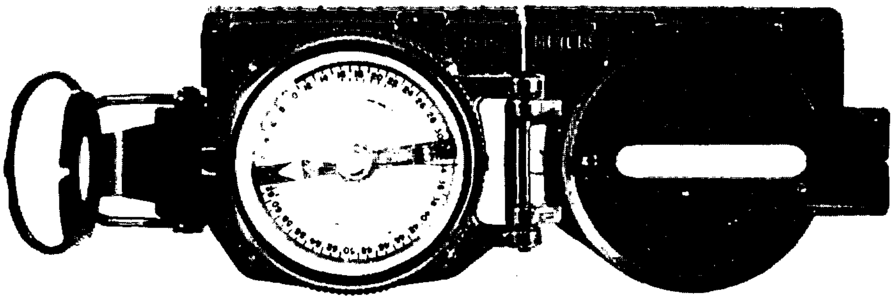

FIGURE 2 LENSATIC COMPASS CONTAINING A TRITIUM-ACTIVATED PHOSPHORESCENT PAINT

In 1965, 40 compasses that were manufactured in 1964 were tested in the following manner: a submergence test followed by a 24-hour wash in running water and a repeat submergence test. In the first submergence test, an average of 1.9 μCi of tritium was detected while in the second test 1.7 μCi was measured.

Eighteen of the remaining twenty compasses were tested with a wipe test and two submergence tests as above. The wipe tests exhibited 16 nCi of activity while the submergence tests were essentially the same as for the first 20 compasses.

TABLE 1

Survey of Packing Material
Wrist Compasses Containing Radium

Location	Measurement
Surface of wooden crate	5 mr/h – beta-gamma
Surface of "tar paper" sealed package	8 mr/h – beta-gamma
Interior surfaces of sealed wrapper	4.5 nCi
Outer surfaces of waxed waterproof wrapper	2.2 nCi
Outer surface inner carton	4.5 nCi
Inside surface of carton	13.5 nCi
Surface of individual compass boxes	4 nCi
Wrapping of individual compass	4.5 nCi

TABLE 2

Wipe Tests of Wrist Compasses Containing Radium

Compass	Dry Wipes		Wet Wipes	
No.	Beta (pCi)	Alpha (pCi)	Beta (pCi)	Alpha (pCi)
1	25	17	150	48
2	35	25	128	26
3	45	23	89	37
4	36	28	119	30
5	27	14	102	26
6	60	35	154	34
7	46	25	150	40
8	27	19	99	24
9	46	27	107	24
10	52	28	113	24
11	36	18	128	33
12	45	28	132	37
13	72	57	156	49
14	51	29	163	47
15	46	35	93	21
16	46	25	119	25
17	47	26	172	68
18	64	43	95	18
19	43	26	133	39
20	51	35	134	34
21	25	21	143	36
22	45	32	269	136
23	34	25	63	20
24	33	10	149	90
Average:	43 ± 12	28 ± 9	132 ± 40	40 ± 26

TABLE 3

Results of Beta-Gamma and Alpha Surveys
Wrist Compasses Containing Radium
Compasses 1 thru 24

	Beta-Gamma Dose Rate mR/h			Alpha pCi Before Wet Wipe Test				Alpha pCi After Wet Wipe Test	
Compass No.	Face on Contact	Back on Contact	Face at 6 Inches	Strap Underside	Strap Topside	Compass Face	Compass Back	Compass Face	Compass Back
1	13	1.2	0.5	720	450	180	90	225	180
2	15	1.2	0.6	540	946	180	135	293	225
3	12	1;1	0.5	810	856	225	90	248	315
4	15	1.0	0.5	1036	946	225	90	180	180
5	14	1.1	0.6	720	1216	225	68	135	225
6	14	1.2	0.6	1081	585	225	180	225	360
7	13	1.2	0.6	1036	435	225	113	135	135
8	15	1.0	0.6	946	540	225	135	270	270
9	12	1.0	0.5	810	1216	225	135	203	315
10	13	1.1	0.6	99 0	495	135	113	203	315
11	12	1.1	0.5	946	1036	225	360	225	157
12	13	1.1	0.6	1036	675	315	315	180	90
13	13	1.4	0.6	1351	585	225	315	157	225
14	14	1.0	0.6	680	990	315	225	90	135
15	16	1.2	0.7	675	1396	270	360	90	135
16	12	1.1	0.5	1081	690	270	225	270	225
17	13	1.1	0.8	540	1306	360	225	225	360
18	13	1.1	0.6	450	360	315	180	225	203
19	13	1.2	0.7	675	945	225	225	225	270
20	13	1.2	0.5	810	450	225	225	135	135
21	10	0.9	0.5	1081	630	228	270	157	157
22	11	0.9	0.6	720	1261	360	450	225	203
23	14	1.2	0.5	1081	630	180	315	157	293
24	16	1.1	0.6	450	1261	270	360	225	225
Average:	13.3 ± 1.5	1.1 ± 0.1	0.6 ± 0.1	842 ± 236 840 ± 240	829 ± 325 830 ± 330		216 ± 106 210 ± 110	195 ± 54	222 ± 76

In addition, the carrying cases of these compasses were placed in distilled water and allowed to stand at room temperature for 72 hours. The results of this test showed approximately 100 μCi of tritium in the water.

After completion of the two submergence tests and a 24-hour washing of the 38 compasses so tested, 8 compasses showed water leakage into the compass well and 22 compasses showed water leakage under the bezel. When the compasses had dried on the outside upon completion of the above tests, a white powder formed at the junction of the bezel ring and the metal of the case. A small unweighed amount of this powder from one compass was added to the scintillator and counted. Approximately 0.2 μCi of tritium was detected.

As a result of these results, compasses stored at other locations and manufactured at other items were tested. A total of 150 separate compasses were tested during the course of this study; 144 compasses were marked as containing a nominal 75 mCi of tritium and 6 compasses 120 mCi. The oldest compass was manufactured in 1962 and the newest in 1965. The results of these tests are shown in Table 4. It can be seen that there is no significant difference in the leakage from compasses containing different amounts of tritium nor were there any significant differences between compasses made at different times or by different manufacturers.

As part of this study, the compass storage environment was surveyed in three locations representing semi-arid, and moderate- and high-humidity regions. Compasses were found to be stored in a semi-open shed, a well-ventilated brick warehouse, a humidity-controlled warehouse, a quonset hut, and a sealed warehouse section. The environment was not contaminated with tritium gas except inside the sealed warehouse where the activity noted was in the order of 1.5×10^{-5} μCi/ml.

Even though the most general warehouse areas were uncontaminated with tritium gas, gas concentrations could be measured in the vicinity of filled compass cartons. Air taken from between cartons of compasses measured 1.3×10^{-5} μCi/ml. In addition, the gas concentration within the storage cartons was measured and found to be 3.7×10^{-5} μCi/ml. Wipe tests of storage cartons, shelving, and areas surrounding the cartons showed no significant removable contamination. It was found, however, that inner surfaces of cartons did show some levels of tritium contamination.

From the results of these tests, it is obvious that the tritium is not confined to the compasses. In fact, the average daily leak rate from compasses was measured to be between 9.7 and 12 μCi/day. This is especially true in a moist atmosphere. In a separate test at another agency, it was found that storage of the compasses at 35°C and 95 percent humidity caused the complete leakage of tritium from the compass. It was recommended that the compass be redesigned with emphasis placed on tritium containment.

Also tested by AEHA were prototype rifle sights that contain various amounts of tritiated gas sealed into capillary tubes. These sources were manufactured in both England and the United States. This study covered the examination of the capillary sources and of finished rifle sights.

Fifteen sights manufactured in England contained a nominal 10 millicuries of tritium gas. With the exception of one sight, these sights were found to have surface contamination and leakage of tritium less than the amount listed in paragraph 32.101 (f), Title 10, Code of Federal Regulations. The one sight that did exhibit contamination had an average daily leak rate of 0.22 μCi/day.

TABLE 4

Tritium Detected as a Function of Activity of Tritium in Lensatic Compass

Test	No. of Compasses	Tritium Activity in Compasses (mCi)	Tritium Measured (μCi)
Smear – Compass Face and Slip Ring	119	120 and 75	0.009
	113	75	0.008
	6	120	0.002
Smear – Sight Wire Screws	102	120 and 75	1.01
First Submersion	91	120 and 75	1.97
	85	75	1.95
	6	120	2.21
Second Submersion	91	120 and 75	1.86
	85	75	1.89
	6	120	1.44
Submersion of Carrying Cases	71	120 and 75	4.75
	65	75	4.75
	6	120	4.68

Four of the above sights were subjected to a temperature of 45°C and a vacuum of 2 mm of mercury. At the completion of these tests, the sights were reevaluated, and it was found that the integrity of these capillary tubes had not been violated.

Of the sources manufactured in this country, 80 capillaries and two sights of five different configurations of rear sights and front sights were tested. Wipe tests of the 80 capillaries showed that a small number of the capillaries had surface contamination greater than 1 nCi. However, the submergence tests of these capillary tubes revealed signficant leakage from only two of the capillaries. One week after the submerging test, the capillaries were wiped again and at that time it was found that only those two capillaries that previously showed high leakage in the submergence tests exhibited surface contamination greater than 0.001 μCi.

The prototype rifle sights, a typical example of which is shown in Figure 3, were subjected to a wipe test followed by a submergence test; both tests were repeated a week later. Of the 20 rifle sights so tested, only 2 exhibited high leakage rates of tritium gas. These rates were in the order of 3.5 and 7 μCi/day.

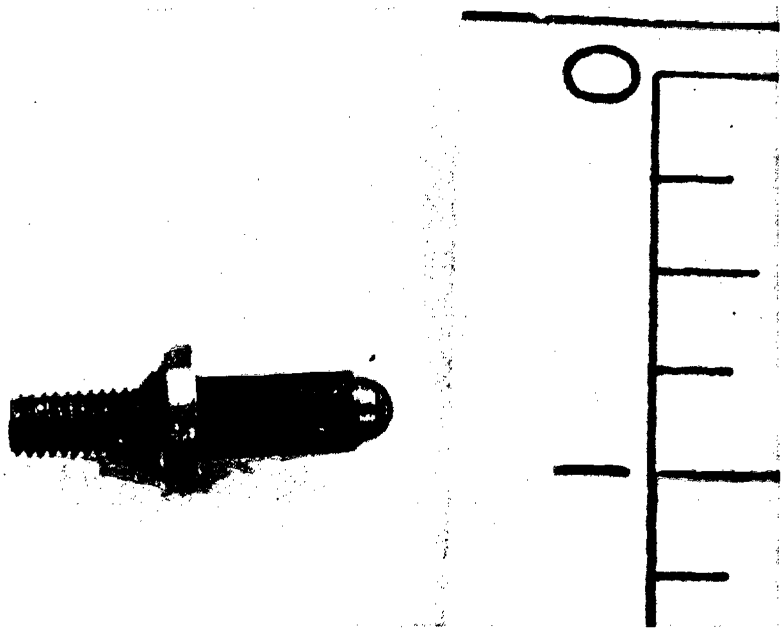

FIGURE 3 PROTOTYPE OF A FRONT SIGHT CONTAINING A TRITIUM-GAS-ACTIVATED PHOSPHOR

The last tritium-containing items that will be discussed are components of an artillery fire control set. Each set is composed of 7 components containing 26 self-luminous sources that contain a total of 17,450 mCi of tritium gas encapsulated in heat-tempered borosilicate glass. Table 5 lists the components and sources in each set.

During this study, five sets of components were tested in the laboratory after field testing of the units. The fire control components were wipe-tested as the self-luminous sources were removed from the components. The results of all these wipe tests were below the detection limits for this test. 117 self-luminous tritium gas sources were removed. Each source was wipe tested. Results showed that 110 sources exhibited surface contamination less than the detection limits for this test. Of the seven sources that showed surface contamination greater than this limit, the range of measured activity was between 4.0×10^{-6} and 2.2×10^{-5} μCi/wipe-test sample.

TABLE 5

Self-Luminous Tritium Gas Sources in a Typical Set of Fire Control Components

Component	Number of Self-Luminous Sources	Activity (mCi)	Total Activity (mCi)
Fire Control Quadrant	4	450	1800
Fire Control Quadrant	4	450	1800
Panoramic Telescope	4	400	1600
	6	450	2700
Elbow Telescope	2	1400	2800
	2	600	1200
Telescope Mount	2	75	150
Bore Sight	1	3000	3000
Aiming Light Post	1	2400	2400
			17450

Sources were subjected to a submergence test. After the second submergence test, if the test results indicated leakage, repeated soak tests were performed to measure the severity of the leakage. The submergence tests showed that 4 of the 117 sources were leaking tritium. Table 6 shows the daily leak rate from the worst of the four leaking sources during a 1.5 month period.

PROMETHIUM-147

Of the ^{147}Pm devices tested at AEHA, only one will be discussed. This was a launcher sight containing three mCi of ^{147}Pm encapsulated in plastic. Exposure rate measurements were made with a Geiger-Mueller counter having an end window probe (Window thickness: 1.4 mg/cm^2). Exposure rates were measured through a 50 mg/cm^2 absorber at 10 centimeters from the sight containing the ^{147}Pm. Exposure rate results of the sights range from 0.02 to 0.11 mR/hr.

Submergence tests were performed on these sights. The results of these tests on 132 sights showed leakage less than the detection limit of this test, 30 pCi per sample. The three sights that exhibited leakage greater than this amount ranged between 32 and 93 pCi/day.

Experience has shown that devices containing radium and tritiated paints as the phosphor exciter leak significant amounts of radioactivity. This leakage results in reduced brightness life and also could be a potential health hazard. Although such an item of equipment may not present a radiological hazard to the user personnel, it is also apparent that storage of large numbers of these items can result in the buildup of a sizable airborne level of radiation in the storage environment. In addition, in

TABLE 6

Repeated Soak Test Results for Self-Luminous Tritium Gas Source No. 185

Soak Test Number	Date of Soak Test	Activity (μCi/d)
1	–	1.5×10^{-3}
2	–	4.9×10^{-4}
3	19 – 20 Jun 74	1.4×10^{-4}
4	1 – 2 Jul 74	2.6×10^{-5}
5	9 – 10 Jul 74	1.5×10^{-5}
6	22 – 23 Jul 74	2.3×10^{-4}
7	29 – 30 Jul 74	4.8×10^{-3}
8	30 – 31 Jul 74	5.0×10^{-3}
9	31 Jul – 1 Aug 74	6.9×10^{-3}
10	1 – 2 Aug 74	1.6×10^{-2}

storage of radium-containing items, one also has a large gamma source than can further expose warehouse personnel.

The use of tritium gas encapsulated in glass reduces the problem of tritium leakage. Even with such a system, a small percentage of the sources still exhibit leakage of tritium. As an example of this, the highest leakage measurement in the fire control sources was 1.6×10^{-2} μCi/day. Since the components containing tritium gas are used outdoors, it is highly unlikely that any tritium will enter the bodies of user personnel. If this amount of tritium did enter the body daily during a period of one year, it would result in a dose of less than 250 mrem per year to the whole body, (ICRP, 1968).

Based on the small experience that we have on ^{147}Pm light sources, they do not show significant leakage of radioactivity. In addition, the external radiation exposure is low at the levels used in these devices.

In part, because of the results of testing at the Army Environmental Hygiene Agency, radium can no longer be used as a phosphor exciter in light sources for military application. In addition, testing at the agency has made both manufacturers and procurement personnel acutely aware of problems with certain items of equipment containing radioactive materials as designed. This had led to redesign of a number of items to lessen the problems of radioactive leakage from radioluminescent light sources.

REFERENCE

International Commission on Radiological Protection (1968), "Report of Committee IV on Evaluation of Radiation Doses to Body Tissues from Internal Contamination due to Occupational Exposure." Pergamon Press, Oxford, England.

TRITIUM-BASED LUMINOUS DIALS AS A FACTOR OF RADIATION HAZARD TO TELEPHONE USERS

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Luminous telephone dials generally contain a circular sealed glass tube filled with tritium gas in which beta particles emitted by tritium excite the phosphor material deposited on the walls, thus causing the emission of light. Such devices are currently being produced by some manufacturers, and it is possible that their use will become rather widespread in the foreseeable future. Under normal conditions they do not present any radiation hazard; however, in view of the fact that the tritium activities involved are rather high - they are on the order of 1 Ci per item - the rupture of a tritium-filled glass tube would result in considerable air contamination in the room affected. This calls for a thorough analysis of the radiation hazard for persons staying in a room where the release of tritium gas occurs.

This paper presents a quantitative analysis of the radiation dose that would be received by an individual in such a situation. The possible radiation hazard due to such a tritium release depends on a number of factors; to enable it to be assessed for any set of input parameters, the problem has been treated in a general way.

ASSUMPTIONS AND PRELIMINARY CONSIDERATIONS

Although the principles for calculating doses due to tritium are known (ICRP, 1968; Bennet, 1972; and Croach, 1973), the problem of calculating the effects of a single release of gaseous tritium (HT) requires detailed analysis in view of the interaction of the following factors:

- HT activity released
- volume of the room considered
- time of exposure to contaminated air
- room ventilation (aeration)
- buildup of HTO in room air as well as the pathways of exposure to tritium:
- inhalation of HTO
- absorption of HTO through skin
- dose to skin and respiratory tract epithelium due to HT.

To simplify the problem or because of lack of data, the following factors that also influence the radiation hazard will deliberately not be considered:

- influence of air humidity and pressure on HTO formation
- propagation of HT and HTO in room air by diffusion (uniform distribution of these two species in room air at any time is assumed)
- contribution of tritium bremsstrahlung to the total dose (the corresponding dose is smaller than the beta dose by 4 to 5 orders of magniture).

Let A(t) be the total activity of tritium in the room air at any moment. It is composed of tritium gas activity and freshly formed oxidized tritium (HTO) activity:

$$A(t) = A_{HT}(t) + A_{HTO}(t) \qquad (1)$$

At the release moment of t = 0:

$$A = A_o = A_{oHT}$$

The corresponding concentrations are:

$$a, a_{HT}, a_{HTO}$$

Using these notations, the above enumerated factors influencing the dose considered can be discussed.

First is the ventilation rate of the room, a factor mainly determining the temporal variations of the radiation hazard. Its quantitative measure is the air change rate k, by which the ventilation effect can be described as follows:

$$\frac{dA}{dt} = -kA$$

$$\therefore\ A = A_o e^{-kt};\ a = a_o e^{-kt}$$

The value of k may vary from 0 (complete lack of air change in a fully sealed room) to about 10 (open windows in summer, slight draughts). According to Johnson (1973), the practical range of values for dwellings is 0.25 - 5.

As to HTO buildup, it is assumed that the formation of HTO from HT proceeds mainly by the autocatalysis mechanism. This term is defined as the oxydation of HT molecules stimulated by tritium beta particles. Isotope exchange also contributes to some extent to the generation of tritiated water vapor.

The ingrowth of HTO (in the absence of ventilation) can be described as:

$$\frac{dA_{HTO}}{dt} = \ell A_{HT}$$

where ℓ is the HTO buildup factor, a constant parameter.

Hence,

$$A_{HTO} = A_o(1 - e^{-\ell t})$$

According to the data reported by Geisler (1971), the numerical value of ℓ may be assumed as:

$$\ell = \frac{10^{13}\text{HTO molecules}}{1\ \text{Ci HT} . 1\ \text{s}} = 0.0018\,\frac{\text{Ci HTO}}{\text{Ci HT.S}}$$

This coefficient describes HTO generation by autocatalysis only. There are no data available on the HTO formation rate in air by exchange; however, since this process is slow as compared to the mean hazard time considered, its contribution need not be taken into account.

The radiation dose received by persons staying in an HT/HTO atmosphere was calculated as follows.

Tritiated Water

According to ICRP (1968) the intake of 1 μCi HTO - in this case as water vapor existing in air - is equivalent to a dose to the total body of 1.67×10^{-4} rem. Hence the dose factor DF_1 is:

$$DF_1 = 167 \text{ rem/Ci HTO}$$

Since the intake of tritiated water by absorption through the skin can be assumed to be equal to the intake due to inhalation of HTO-contaminated air (ICRP, 1968), a factor of $2DF_1$ will be used to account for the total hazard due to the presence of HTO in the room atmosphere.

The breath air intake of HTO at a given concentration depends on the air demand of a man. Using standard man data (ICRP, 1959), one obtains the breath air consumption rate:

$$B = \frac{20 \text{ m}^3}{24 \text{ h}} = 0.833 \text{ m}^3/\text{h}$$

Elemental Tritium

No direct data are available on the dose produced by HT gas, although its action on living organisms is fairly well known (Butler, 1964; Pinson, 1957).

It was therefore decided to base the calculations on ICRP Publication 2 (ICRP, 1959), where maximum permissible concentration in air (MPC_a) values for HT are given. Assuming that the MPC_a for continuous submersion in an HT atmosphere (critical organ: skin) and professional exposure is based on the yearly dose of 5 rem, the dose factor DF_2 for HT submersion was calculated as:

$$DF_2 = 1.43 \frac{\text{rem} \cdot \text{m}^3}{\text{h} \cdot \text{Ci}}$$

The maximum permissible yearly cloud dosage based on time integral of gas concentration:

$$CD = \int a \, dt \; (\text{Ci.m}^{-3}.\text{h})$$

for HT is

$$MPC_a \times t = 4 \times 10^{-4} \; \mu\text{Ci/cm}^3 \times 8.76 \times 10^3 \text{ h} = 3.504 \text{ Ci.h.m}^{-3}$$

Other parameters influencing the dose, HT radioactivity released, volume of the room, and time of exposure do not require any comment.

CALCULATION OF THE DOSE

To calculate the dose due to HT and HTO, temporal variation functions of their concentrations must be known and then integrated in time.

First, let us consider the HTO dose. The decrease of tritium gas activity (or its concentration) due to both ventilation and HTO formation is:

$$\frac{dA_{HT}}{dt} = -kA_{HT} - lA_{HT}$$

$$\therefore A_{HT} = A_{oHT}e^{-(k+\ell)} = A_o e^{-(k+\ell)t}$$

or

$$a_{HT} = a_o e^{-(k+\ell)t}$$

Based on eq. (1), formation of HTO can be expressed as:

$$A_{HTO} = A - A_{HT}$$

or

$$A_{HTO} = A_o \left[e^{-kt} - e^{-(k+\ell)t}\right]$$

$$a_{HTO} = a_o\, e^{-kt}(1 - e^{-\ell t}) \tag{4}$$

This relationship is illustrated in Fig. 1. As can be seen, as a result of ventilation a_{HTO} attains its maximum after a definite time t_{max} and then decreases to zero. This time is

$$t_{max} = (1/\ell)\, \ell n \frac{k+\ell}{k}$$

Fig. 2 presents a_{HTO} for different values of ventilation rate k. As can be seen, with improving ventilation a_{HTOmax} decreases rapidly and t_{max} shifts toward smaller values.

The dose due to HTO in exposure time t_e is:

$$D_{HTO} = K\int_o^{t_e} a_{HTO}\, dt$$

where, by assumptions made, constant K equals:

$$K = 2\, DF_1 \cdot B$$

$$D_{HTO} = Ka\left[\int_o^{t_e} e^{-kt}\, dt - \int_o^{t_e} e^{-(k+\ell)t}\, dt\right]$$

$$\therefore D_{HTO} = \frac{2\, A\, DF_1\, B}{V}\left[\frac{\ell}{k(k+\ell)} - e^{-kt_e} \cdot \left(\frac{1}{K} - \frac{1}{k+\ell}e^{-\ell t}\right)\right] \tag{5}$$

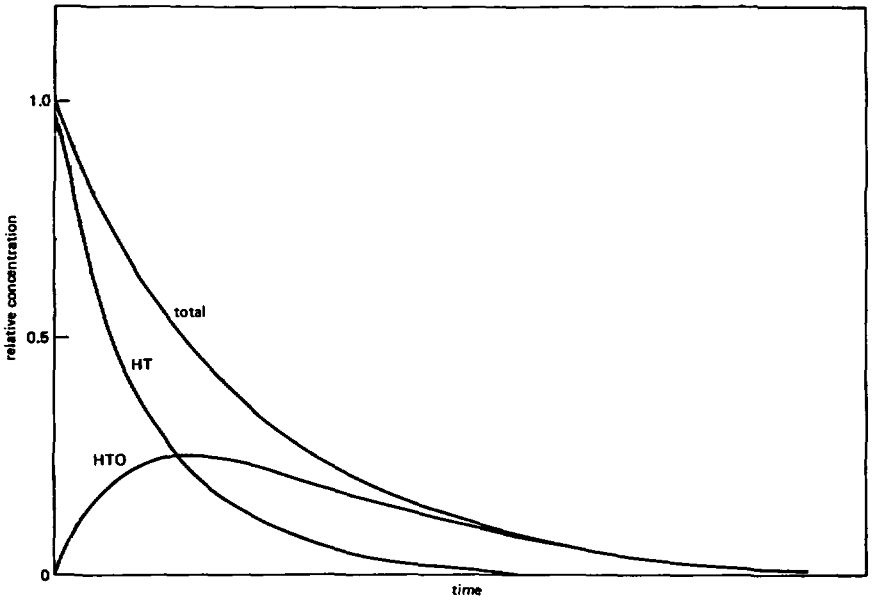

Figure 1. Effect of Ventilation on Concentrations of HT and HTO in Air

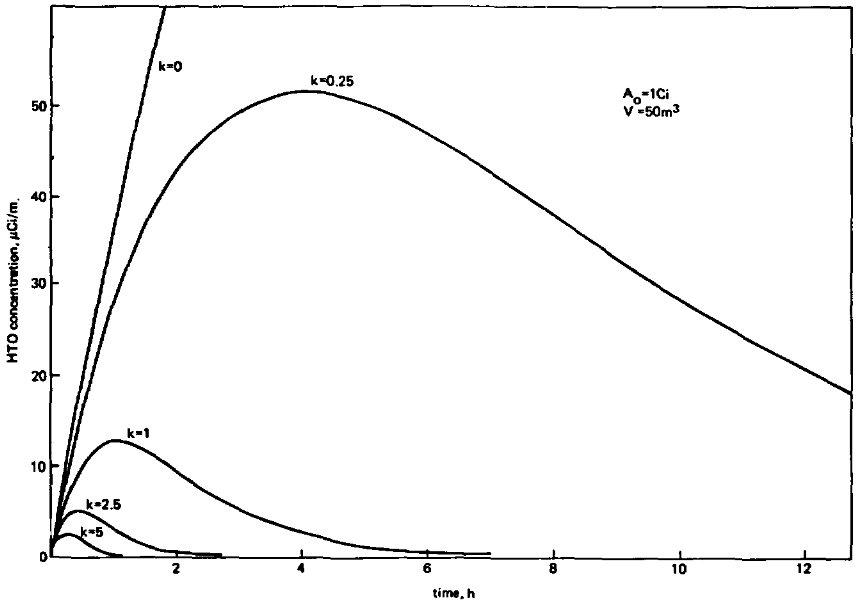

Figure 2. HTO Concentrations as a Function of Time for Different Air Change Rates K

This is a function growing monotonically in time, beginning with zero and attaining, asymptotically, the saturation value of:

$$D_{HTOs} = \frac{2A\ DF\ .\ B\ l}{V k (k+\ell)}$$

for a sufficiently long time t_e. The dependence of D_{HTO} on time, at different ventilation rates k, can be seen in Fig. 3. The doses thus calculated are underestimated by 10 to 15 percent as a result of not taking into account the generation of HTO by isotopic exchange.

Dose due to the coexistence of tritium gas with HTO can be calculated by simply integrating the HT concentration function (3) for exposure time t_e and multiplying the result by the dose factor DF_2. Thus we obtain:

$$D_{HT} = \frac{A\ DF_2}{V (k+\ell)} \left[1 - e^{-(k+\ell)t_e}\right] \qquad (6)$$

The dependence of D_{HT} on exposure time is shown in Fig. 4.

The total dose to an individual is the sum of the two components: D_{HTO} and D_{HT}. It can be calculated for different imput data from the above equations (5) and (6). The graph of the total dose and its components for typical conditions (released radioactivity A_o = 1 Ci, room volume V = 50 m^3, ventilation rate k = 0.25 changes per hour) as a function of exposure time is shown in Fig. 5. As can be seen, during the first 8 hours the dose due to HT prevails, and only after 8 hours does the dose due to HTO predominate.

In general, however, these two components of the total dose are more or less equal, which is contrary to the currently accepted opinion that, as far as simultaneous risk to HT and HTO is concerned the former is by far dominated by the latter. For infinite exposure time this ratio is

$$\frac{D_{HTO}}{D_{HT}} = \frac{0.159}{0.113} \cong 1.4$$

Another interesting feature can be inferred from the diagram in Fig. 6: during the first 2 hours the total dose rate is nearly constant as a result of the compensation of the HT dose decrease by an increasing HTO dose. At about 3 hours these dose rates are equal, and from then on HTO dose rate prevails. Although the shapes of both dose and dose rate curves vary for different values of k, their general picture is similar, except for k = 0, when all HT gradually converts into HTO.

DISCUSSION

As can be seen from the above calculations, for an exposure time of 12 h, typical for staying overnight in a room, as well as for typical conditions of exposure assumed above, the following doses would be obtained:

D_{HT} = 108 mrem
D_{HTO} = 128 mrem
D_{tot} = 236 mrem

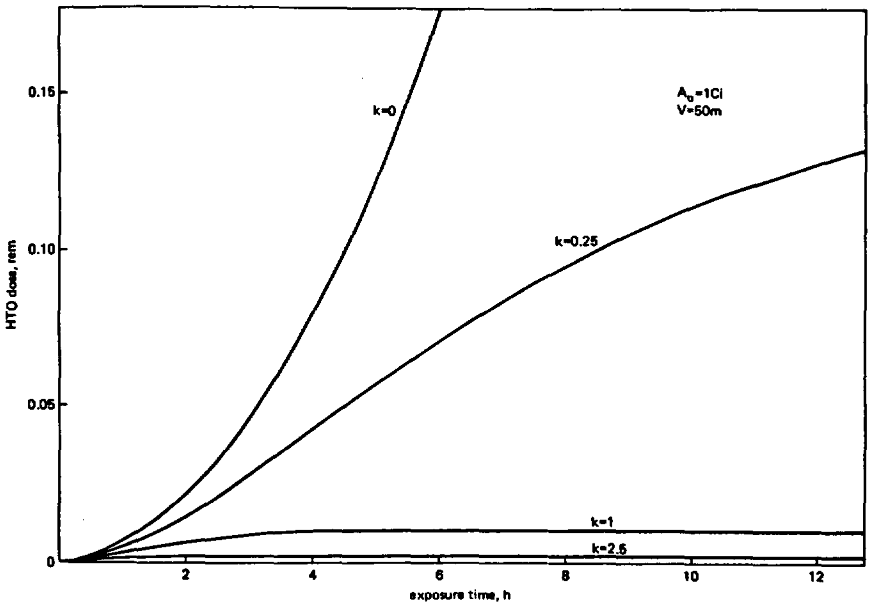

FIG. 3. DOSE DUE TO HTO, FOR DIFFERENT K

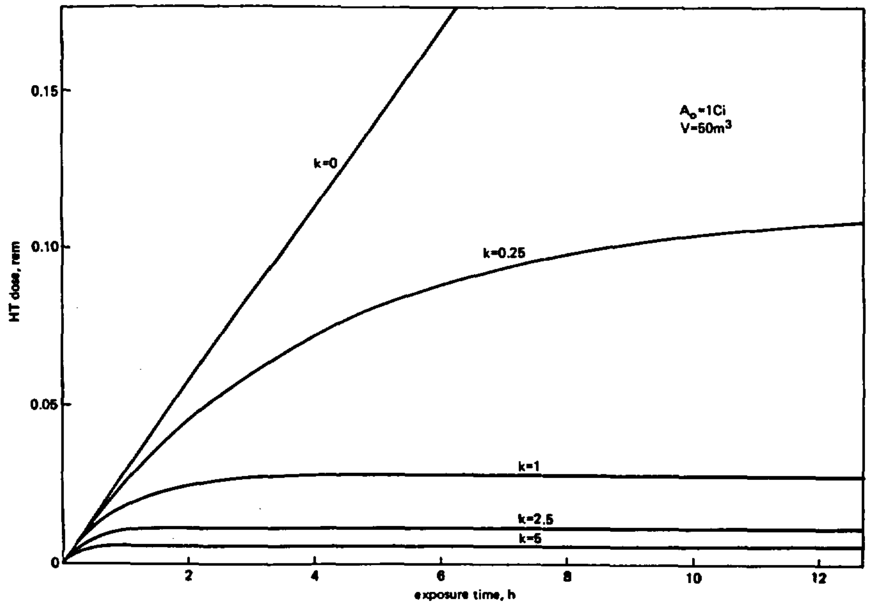

FIG. 4. DOSE DUE TO HT, FOR DIFFERENT K

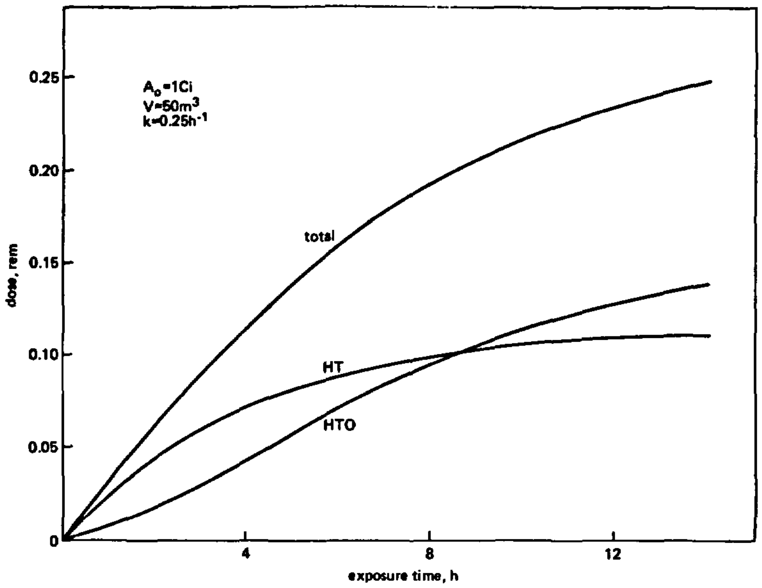

FIG. 5. TOTAL DOSE AND HTO AND HT DOSES FOR TYPICAL CONDITIONS FOR A = 1 Ci, V = 50 m^3, k = 2.5

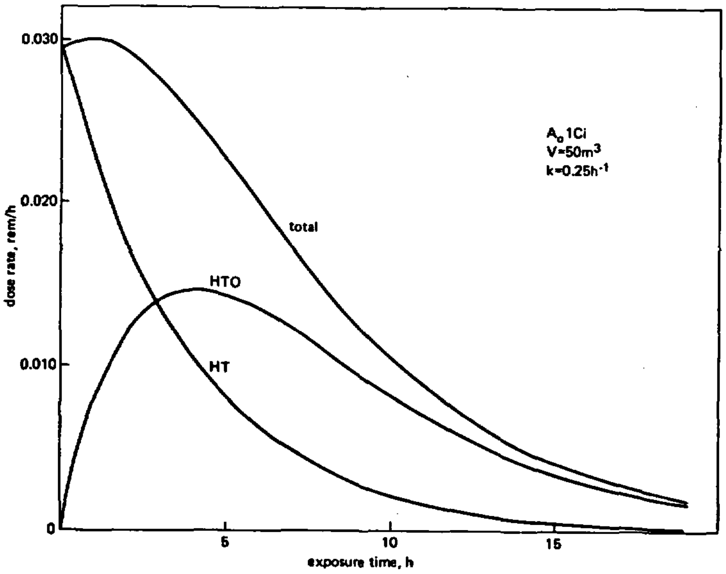

FIG. 6. TOTAL DOSE RATE AND HTO AND HT DOSES FOR TYPICAL CONDITIONS FOR A = 1 Ci, V = 50 m^3, K = 2.5

Since cases of breaking a glass tube containing HT gas occur infrequently, such dose may be compared to the maximum permissible yearly dose for adult individuals of the public (ICRP, 1966) of 0.5 rem. Such comparison gives a radiation hazard factor of:

$$236 : 500 \cong 0.47 = 47\%$$

In the case of children and pregnant women, for whom the maximum permissible yearly dose should be lower than the above-mentioned value, this radiation hazard can attain or exceed the safe level.

Although some of the assumptions made for this assessment are conservative (low ventilation rate, rather long exposure time), the conclusion may doubtless be drawn that a single release of HT at a level on the order of 1 Ci, in a room, might well cause doses to individuals on the order of the maximum permissible dose.

It should be remembered, however, that the above considerations indicate an extremely strong influence of the ventilation rate on the radiation hazard involved. As emerges from the calculations, the increase of ventilation intensity from 0.25 to 1 change per hour - under the conditions assumed above - reduces the pertinent radiation hazard by a factor of 60. This shows that luminescent devices containing tritium can be used safely in well-aerated rooms of dwellings or places of professional activity. The existence of mechanical ventilation or air conditioning would doubtless be a factor of essential improvement for radiation safety in the rooms considered.

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TRITIUM RELEASE FROM TRITIUM–PAINTED WATCHES UNDER SIMULATED STORAGE CONDITIONS

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INTRODUCTION

Tritium paint on consumer items slowly releases tritium and therefore is a source of potential exposure to users of such items. As a rule, the quantity of tritium released from a single tritium-painted item does not contribute significantly to exposures (McMillan et al., 1971). However, persons engaged in the manufacture and distribution of these commodities will be exposed to several thousand items that are continuously releasing tritium.

The exposure of manufacturing personnel has been studied extensively. (see references). The need for data to evaluate exposures in areas where these items are stored has been recognized, but estimates of potential exposures have been based largely on data developed for quality assurance testing. Often a very conservative approach is used. The quality control rejection criteria for tritium release is taken as the average tritium release. Using this larger release value, the tritium concentration is then calculated for a storage area based on the number of items stored, the volume of the storage area, and the air exchange rate. An acceptable tritium concentration in the air may be obtained by limiting the number of items in the storage area or by increasing the air exchange.

In an effort to establish storage criteria more realistically, the work discussed in this paper investigated the tritium concentration in the air of a simulated storage area. The primary advantages of the simulated area were that only 100 watches were used for the test, the air exchange could be controlled in the small laboratory test chamber, and the tritium concentration in the air could be monitored easily.

The following discussion describes the samples used for the test, their normal packing configuration, and the results of the original quality assurance tests. A description of the simulated storage arrangement, test procedures, and results is also given. Finally the results are discussed, and an attempt is made to understand some of the discordant findings.

SAMPLES

The test items were one hundred general-purpose wristwatches manufactured to meet the requirements of MIL-W-46374B(MU). This specification permitted up to 25 mCi of tritium in tritiated paint to be applied to the hands and dials. However, each watch had only 3.5 mCi of tritium.

Each watch was wrapped with paper and then surrounded with a porous packing material and placed in a box measuring 5.4 cm x 5.4 cm x 4 cm. The individual boxes were packed in groups of 10 into an intermediate carton (5 cm x 11.8 cm x 29.8 cm). For shipping and storing, larger boxes were used, with groupings of 100 or 200 watches.

QUALITY ASSURANCE TESTING

Samples of the painted hands and dials were tested before the final assembly of the watches to ensure compliance with the specification. Each dial and each hand was placed in 10 ml or 5 ml of water for 24 hours. The tritium content in the water was then determined. Results are shown in Table 1; they are applicable for the manufacturing lot from which the sample watches for this report were taken.

STORAGE SIMULATION

Figure 1 shows the arrangement of a simulated storage room. The sample chamber is a stainless steel box with an inside volume of 0.18 m^3. The tritium concentration was measured with a Triton, model 955B (Johnston Laboratories, Inc.,), which has a volume of 0.01 m^3. By appropriately opening or closing different valves, the system may be operated as a closed system, as an open system, or with traps (liquid nitrogen, water bubblers, etc).

TESTS

The first test was conducted before the shipping box with 100 watches was opened. The box was placed in the test chamber, and the system was operated in a closed cycle with 24.5 ml of water in a bubbler. The bubbler served two purposes: (1) the water saturated the air, which should have made the tritium removal faster, and (2) the water served as a trap for the tritium. At the end of 18.5 hours the tritium concentration was 3.1 $\mu Ci/m^3$ in the air and 0.139μCi/ml in the water. Since the density of saturated water vapor at 24°C is 21.7 g/m^3, the calculated tritium concentration in air from water vapor was 3 $\mu Ci/m^3$ (21.7 x 0.139). The total tritium trapped during the 18.5 hour test was 24.5 ml x 0.139 μCi/ml, or 3.40 μCi. If we assume that the rate of release was constant, then the rate of release was 4.4 μCi/d for the 100 watches.

The shipping container was opened after this test. The shipping box was designed for 200 watches, but contained only 100. The vacant space was filled with 100g of a low-density expanded plastic filler.

TABLE 1

Quality Testing for Tritium Released (nCi/d) in Water from Painted Watch Parts

	Mean	Standard Deviation
Dials	390	330
Hands		
Hour	368	440
Minute	656	440
Second	508	200
Total	1922	730

One of the intermediate packages was opened, and samples of all the packing materials were analyzed for tritium. The results of these tests are given in Table 2. The total tritium in the packing material of a single watch was 0.49 μCi. The total trapped tritium in the packing material of 10 watches and the intermediate carton was 6.26 μCi.

In the next two tests the watches were placed in the sample chamber, with air flowing through the chamber at 0.01 m^3/minute. The 100 watches were in the intermediate packing cartons. The cartons were placed close together in the first test, so that only a small surface was exposed to the air. The packages were separated in the second test, thus increasing the surface exposed to the air.

The tritium concentration in the air for the close-packed test was 1.2 μCi/m^3, for the open-packed test, it was 2.0 μCi/m^3. When these results were converted to tritium released per day, we obtained 17.3 and 28.8 μCi/day, respectively.

Another test used 90 watches in the storage chamber in a closed system. A beaker with 3000 ml of water was placed in the air stream. The air flowed over the water rather than bubbling through it. The tritium concentration in the water was measured at 0.1, 0.2, 0.3, and 4.0 days. The rate of tritium removal from the air was almost constant. The results were 32, 34, 35 and 34.5 μCi/day, respectively. The release rate of 383 nCi/day for each watch was higher than that for any other test. Over the four days, 500 ml of H_2O evaporated from the beaker. This water was absorbed by the packages.

The results of the above tests are summarized in Table 3.

INDIVIDUAL WATCH TESTS

Five watches were subjected to a water soak test. Each watch was submersed in 60 ml of water for 24 hours. One milliliter of the water was used to determine the tritium concentration, and the total tritium released was then calculated. The average release was 172 nCi/day, the range was from 133 to 209 nCi/day.

Two watches were placed in a closed loop system that had a volume of 0.011 m^3 and included a 25 ml water bubbler. After 16-1/3 hours, the concentration of tritium in the water was 18 nCi/ml, which converts to a release rate of 660 nCi/day or 330 nCi/day for each watch.

DISCUSSION

The results from these tests indicate that the tritium distribution in the storage environment is complex and that the evaluation of potential exposure should not be limited to the tritium concentration in the air. The wide variation in measured tritium release rates was influenced by changing the test environment. The following discussion examines the factors affecting the release rate.

The tritium released from the watch must pass through several layers of packing material before it will be released to the atmosphere. As shown in Table 2, the tritium concentration decreases as the material is moved farther from the watch. However, the larger boxes will have a larger mass and a higher activity than the individual internal boxes. Furthermore, as the tritium concentration in the surrounding air fluctuates, the total activity in the packing material changes. In addition to the packing material surrounding the watches absorbing tritium, any material in the warehouse may also become an absorber of tritium and thus reduce the expected tritium concentration in air.

TABLE 2

Packing Material Tritium Concentration

	Total Mass (g)	Tritium Concentration (nCi/g)	Total Tritium (μCi)
Intermediate package[1]	100	13.6	1.36
Individual box[2]	14	10.7	0.15
Packing material[3]	4	55.4	0.22
Wrapping paper[4]	1.5	78	0.12

[1] Corrugated cardboard box

[2] Heavy paper

[3] Many layers of thin paper

[4] Thin tissue paper

TABLE 3

Summary of Tritium Release Rates

Test	Number of Watches	Release Rate (μCi/day)	Release Rate/ Watch (nCi/day)
Shipping carton bubbler	100	4.4	44
Intermediate packages Close packing	100	17.28	173
Open packing	100	28.8	288
Open packing (water)	90	34.5	383

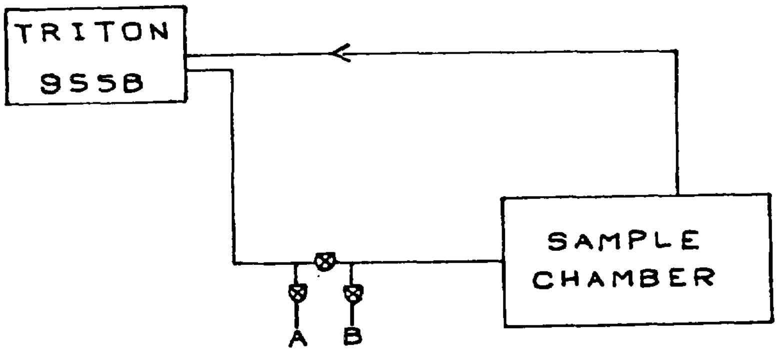

Figure 1. Arrangement for connecting sample chamber to TRITON MONITOR. Inlets A and B may be used to connect water bubbler or gas dryer.

The experiments in the simulated storage environment further illustrate the problem. The measured release rate changed with the packing arrangement and with the amount of packing material. The low value for the release rate in the initial experiment was probably caused by absorption on the expanded plastic filler, which has a large surface area.

The difference between the two packing arrangements probably represents non-equilibrium condition; However, tests conducted for the month seem to confirm the open-packing value, while the close-packing value agrees well with the water submersion test.

The almost constant release rate of 383 nCi/day in the four-day test is puzzling. It would be expected that the release of tritium trapped in the packing material would produce an initial high rate, but that the rate found for the water submersion test would ultimately become more important.

The establishment of storage criteria cannot be established on specification requirements alone. For these watches, specification permits up to 25 mCi of tritium, but only 3.5 mCi is used on each watch. The rejection criteria for quality control on the hands and dials would permit 600 μCi/day to be released in the water submersion tests. Less than 2 μCi/day was actually observed in the tests for this particular lot. The completed watch released only 172 nCi/day, and the simulated storage experiments gave a maximum of 383 nCi/day. Storage criteria based on the quality assurance test rejection criteria of the specification will result in overdesigning storage specifications by a factor of over 1000. The use of actual quality control test data will produce an overdesign by a factor of 4. Neither of these considers the effects of surface absorption in the storage area.

Further health physics evaluations of storage areas are needed to consider the release of the product and the materials in the storage environment. Contamination of these materials by absorption will alter the tritium air concentration, and the contamination can be carried to other areas without the original product moving to these areas.

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THE USE OF TRITIUM LUMINOUS SOURCES FOR LIGHTING DIGITAL WRISTWATCHES

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The backlighting of liquid crystal digital watches with sealed tritium luminous sources represents a major applications advance in digital display technology. This paper presents one manufacturer's views on the development of this new radioluminous consumer product from its conception, through the engineering design stages, and into the ultimate manufacturing and distribution of the product.

Electronic digital watches started out as a gimmick consumer item more than 5 years ago. The technology has since evolved into a viable consumer product offering many advantages over the traditional mechanical timepieces. The two technologies currently comprising virtually all of the digital electronic watch market are LED's (for light emitting diodes) and LCD's (for liquid crystal display). These two competing technologies offer a completely different approach to the age-old art of time-keeping. The LED offers a readout on demand, whereas the LCD offers a continuous readout. The LED display is activated by the push of a button, requiring the use of both hands. Those who have worn classical analog watches for years can list many situations when pushing a button would be inconvenient or even dangerous.

The reason behind the LED time-on-demand approach relates to the high power dissipation inherent in the operation on the LED display. The battery life expectancy is anywhere from 3 to 9 months for the LED and 18 to 24 months for the LCD. The LED is clearly visible at night but suffers from "wash out" under bright sunlight. The LCD is visible under all normal ambient lighting conditions, but becomes marginal at twilight and is not visible in the dark. Unlike the LED, the LCD is a passive display. That is, the display does not emit light but instead attenuates existing light. The LCD uses a thin film of specifically oriented liquid crystal material whose interaction with polarized light and an electric field is the basis for the display operation. The main single advantage of the LCD is that it requires very little power to operate. The usefulness of the LCD is nonetheless limited by its lack of visibility under low-level lighting conditions.

Until recently the only solution for use of the LCD under low-level light conditions was the addition of a backlighting scheme that used a miniature incandesent light bulb placed behind the display. The light is activated by a pushbutton much like the LED. This approach of supplemental lighting on demand compromises much of the advantage of the LCD. The user must push a button to read the watch under low-level lighting conditions, requiring the use of both hands. A second and somewhat more costly compromise results from a marked decrease in battery life expectancy. The battery life becomes dependent on how many times the back light is activated.

Recently, the first digital watch using sealed tritium luminous sources appeared in the market place. Up to this point in time these sources were used strictly for military applications. The LCE/tritium luminous source display results in a truly legible display under all lighting conditions at just a glance. The tritium luminous sources, or "beta lights" as they are sometimes called, consist of a hollow glass tube whose inside walls are coated with an inorganic phosphor. The tube is evacuated, back-filled with tritium gas, and laser sealed. The principle is quite simple. The radioactive decay of the tritium gas releases a low-energy beta, which in turn transfers its energy to the phosphor. The phosphor releases this energy in the form of light. When these tubes are placed behind a liquid crystal display, the result is a self-contained lighting system completely independent of external power. For watch applications, oval or flattened tubes generally are between 0.76 mm (0.030") and 1.27 mm (0.050") thick between 2.1 mm (0.080") and 3.2 mm (0.125") in width and 5 to 10 mm (0.2 to 0.4") long with a total tritium content of 200 mCi or less per watch. The tubes are purchased as sealed units mounted in metal pans.

The time between conception and manufacturing was dedicated to engineering design efforts along with stringent prototype testing. The main goals were to design a product that would do more than pass the standards set by the Nuclear Regulatory Commission (NRC). The standard shock, vibration, and environmental tests were performed. The basic design incorporated subassemblies that made not only tritium tube breakage unlikely but also prevented the ever-curious consumer from reaching the tubes themselves. Radiation risk to the consumer as well as the risk resulting from catastrophic accidents during storage, shipment, and distribution, were all carefully considered. The tubes themselves have a diffusion rate of less than 0.1 μCi per 24 hours; and testing has shown that, in general, the watches exhibit a diffusion rate of less than 0.01 μCi per 24 hours. If this is compared to more familiar terms, the allowable diffusion rate for a mechanical timepiece using a luminous painted dial containing tritium is 25 μCi per 24 hours or some 250 to 2500 times greater than for the digital watches using sealed tritium sources.

Having successfully fulfilled the NRC requirements and simultaneously having designed a product that would withstand normal consumer abuse, State and local regulations governing manufacturing and storage had to be addressed. Both 100% air monitoring and routine urinalysis were put into effect in the manufacturing assembly area. Local fire codes required significant modification of both manufacturing and storage areas. The success of the engineering design efforts can be measured by the company's manufacturing safety record. Out of 70,000 sets of tubes that were handled in 1976 a total of 33 tubes were broken; or less than 0.03% of the tubes handled were broken during manufacturing. Assembly workers' urinalysis showed an average tritium activity of 0.0451 μCi per liter over the year with the high being 0.180 μCi per liter. This compares to an allowable tritium activity of 28.87 μCi per liter.

The quality control standards incorporated into the manufacture of this product start with the manufacturer of the tritium luminous sources. Each individual source is 100% diffusion tested. The sources undergo a 10% lot tolerance per cent defective LTPD level diffusion test after they are mounted in their metal pans. At this point the sources are accepted for assembly into timepieces. During the assembly operations, the manufacturing area undergoes continuous air monitoring for tritium concentration. After assembly of the timepieces, units are drop tested three times each from 3 feet and vibrated for 30 minutes at a 10% LTPD level. The tested units then undergo diffusion testing. No manufacturing lot is released for shipment until all test results are received. The average diffusion rate for the more than 55,000 timepieces manufactured and tested at 10% LTPD level was less than 0.01 μCi per 24 hours.

The performance of the time piece in the hands of the consumer reflects the rigid quality control standards placed on this product. A total of approximately 40,000 timepieces were distributed during 1976. Of this total, only two watches have been returned for tritium tube breakage. Both of these returned units appeared to have undergone abnormal abuse. This breakage corresponds to a 0.005% rate in the field.

Customer acceptance has been excellent. The ability to read a digital watch under any lighting condition, at first glance, coupled with the increased reliability and accuracy has resulted in a unanimously positive response from the consumer.

THE USE OF RADIOLUMINESCENT MATERIALS AND RADIOLOGICAL CONSEQUENCES FOR USERS

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Radioluminescence is the luminous emission produced by the return to a stable state of a body excited by ionizing radiation. This phenomenon, which has been known since the turn of the century, was initially considered as a laboratory curiosity, but soon found commercial applications such as in the radioluminescent paints used mainly by the clock and watch industry since about 1930.

The first paints of this type were radium based and reached a peak usage around 1950. Since 1962, however, the substantial irradiation delivered by radium and its daughters, together with their toxicity, led to its gradual abandonment in favor of pure beta-emitters.

Some attempts were made to use strontium-90 and promethium-147. At present, however, the main material employed is tritium, either in the form of a tritiated organic compound in radioluminescent paints or in gaseous form in autoluminescent tubes.

This discussion seeks to draw a parallel between the older and current products and the conditions in which they are used.

RADIUM

Product Characteristics

The isotope 226 of radium was employed in the form of the sulfate, mixed with the luminescent product, generally consisting of zinc sulfide. By adding a binder, a paint was obtained with a mean radium content of 50 to 60 μCi/g, and a maximum of 100 μCi/g. The powder mixing phase required for preparation of the paint involved a considerable risk of contamination. Moreover, since radium and its derivatives are gamma-emitters, the product delivered substantial external irradiation.

In effect, if all the daughter products are trapped in the mix and if selfshielding is considered negligible, the absorbed dose rate delivered at 10 cm by 10 grams of paint is about 4 mrad . h^{-1}.

Use of the Paints and Consequences for Workers

The paints were mainly employed in the watch and clock industry for dials and hands of watches and alarm clocks, and also on sign panels. In France, the watch and clock industry alone consumed about 2 curies of radium annually.

During the prewar and immediate postwar periods, the harmful effects caused by radiation became generally known, but safety techniques had barely been recognized and were practically ignored by users. The prevailing legislation was directed at hazardous, unhealthy, and unsanitary establishments and was not adapted to the specific problems of radioisotopes.

The paint was applied to the dials and hands with a brush, on simple workbenches, without any protection to prevent dispersion of the product. Cases have been mentioned in which rags used to clean the brushes were stored away in the same drawer as the lunch sandwich.

Smudges and overflows on sign panels were scraped off after drying, thus leading to dispersion of the powder produced.

Surface contamination, and very probably atmospheric contamination, inevitably caused internal contamination of the personnel. Figures on internal exposures are unavailable owing to the inadequacy of techniques of medical observation at the time.

However, it is easier to estimate the external irradiation. Measurements taken at work stations provide an estimate of the mean absorbed dose rate at about 25 mrad . h^{-1}, with peaks of 300 to 500 mrad . h^{-1}. Hence for continuous work for 2000 hours per year, the dose equivalent resulting from external irradiation alone could reach an average of 50 rems, or ten times the annual average presently authorized for a worker directly assigned to radiation work.

To this external irradiation should be added the internal irradiation due to contamination, which was far from negligible as stated above.

In France, it is estimated that about 250 persons were employed simultaneously in this work and thus were subject to these risks.

However, this figure applies only to those persons working directly with the paint. One must also account for the fact that, at the time, these operations were semi-crafts, implying that many applications were made at home, mainly by women. In view of the working conditions and ignorance of the risks involved, it is probable that the contamination also extended to families and acquaintances. Hence it may be estimated that, during the period of the use of radium, 1000 to 1500 persons in France incurred the risks deriving from its manipulation, which nevertheless represents a minute fraction of the overall population.

The Use of Manufactured Articles and Consequences for the Public

The hazards related to sign panels in use are relatively insignificant. They are employed in passageways, and hence do not generate consequences caused by prolonged residence in the vicinity.

It is interesting to examine the risks incurred by the wearing of luminous watches. The problem of contamination may be ignored, as the radon emanating from the paint and its daughter products are almost totally trapped within the watch. As for irradiation, measurements taken on two wristwatches gave the following figures:

- contact with the glass: 0.3 and 0.8 mrad . h^{-1}
- contact with the watch case: 0.1 and 0.3 mrad . h^{-1}

This means that the continuous wearing of a wristwatch leads to a dose equivalent at the wrist of about 1.7 rem per year, or more than one-fourth of the standard set by French legislation, which is 6 rems per year for the hands and forearms of members of the public.

TRITIUM

Product Characteristics

Tritium emits very-low-energy beta radiation (a few keV) and decays to helium. The luminescent product is generally zinc sulfide, but tritium may be used in two different forms, depending on whether the final article is a luminous tube or paint. In the tubes, tritium is enclosed in sealed tubes whose inner walls are coated with zinc sulfide. The activity is about 80 to 200 mCi per tube. In paint, the tritium replaces hydrogen in the preparation of a resin occurring in the form of a powder. This powder is taken up by an organic solvent and mixed with the sulfide by hot evaporation. The paint is then prepared by the addition of a binder. It contains an average of 4 to 500 mCi of tritium per gram.

Preparation and application methods

The methods described here are employed in France by the Laboratoire Lumina, exclusive distributor of tritium, manufacturer of tubes and paints, and also users of the latter.

The tubes are produced in a ventilated enclosure under negative pressure (10 cm H_2O). The tritium gas is distributed through pipes to which the tubes are attached. When filled, the tubes are cut and sealed by laser.

The resin for the paint is also produced in ventilated enclosures. The tritiated product is mixed with the sulfide in a glove box featuring filtered and ventilated atmosphere with a negative pressure of 10 cm H_2O.

During the evaporation operation, significant degasification of tritium and diffusion through the gloves of the box were observed. To remedy this, the handlers installed a hood in front of the box, with ventilation of the intermediate space thus created. The minimum recommended airflow speed is 150 cm . s^{-1}.

The powder is then conveyed in small containers to the application room and mixed, as required, with a binder in a sealed enclosure provided with entrance and exit locks. The paint is applied in a ventilated fume hood. Workers wear gloves, and the product, held in a tank, is applied by means of air injectors, which are cleaned after work by soaking in a solvent. Hence no contaminated dust is produced. It is also interesting to note a precaution observed by this laboratory: the trays in which painted articles are placed rest in the fume chamber on sharp-angled supports, and not directly on the bottom. This prevents any contamination of the tray bottoms by traces of paint possibly occurring on the floor of the fume hoods.

Consequences for Personnel

In view of the energy of the beta radiation emitted and the absence of gamma radiation, risks incurred by the personnel are exclusively internal contamination risks.

Tests performed monthly on the eight persons working at this laboratory show that urine contamination is 0.8 to 20 μCi/1, or a few μCi/1 on the average. However, urine contamination was far higher before the installation of double ventilation: in general 50 to 90 μCi/1, and as high as 120 μCi/1.

It may be estimated (Sutra-Fourcade, 1967), that for 10 μCi/1, the dose equivalent rate delivered to the entire organism is 0.2 mrem . h^{-1}. If this concentration is considered as an average always present in the urine of any given worker, the dose equivalent received in the course of a year would be 1.7 rem or about one-third of the allowable dose for a worker assigned to radiation work.

In this company, most of the employees are assigned at random, according to need, to the production of tubes and paint and to the application of the latter. Hence it is difficult to determine which of these operations gives rise to internal contamination. The decline in urine contamination observed after the improvement of the paint production conditions seems to indicate that the latter predominates.

Use of the Products

The annual consumption of tritium in France for radioluminescent products is about 17,000 to 18,000 curies, including 2000 to 3000 for tubes and the remainder for paints.

Tubes are mainly employed to mark special equipment such as marine compasses, safety devices on aircraft instrument panels, safety devices on life rafts, etc. They undergo various tests (resistance to fall, to pressure, etc.), making it possible to consider them as sealed sources.

Furthermore, they are designed so that breakage caused by tension in the glass does not give rise to instant release of the gas, but to a slow outflow.

Since they are only used for special cases, the risk to the general public may be considered as nil. Recently, however, they have found another use, in liquid crystal watches, but this application is currently prohibited in France.

The main use of the paint is for dials and hands of watches and clocks, from 3 to 7 μCi per article, together with the marking of various sign panels.

The different tests performed on painted articles indicate that tritium liberation is negligible, amounting to less than 1% after soaking in water for 24 hours (the standard imposes a maximum of 5%). If the article is covered with a varnish, the loss falls to below 0.1%.

The only risk incurred by users may derive from the breathing or ingestion of particles liberated by scaling, but this is reduced to the minimum by the glass in watches and clocks, or by a protective varnish when use of the article involves contact with the paint.

A Glance at Legislation

Owing to the amounts involved, companies that produce or use tubes and paint are governed, in France, by the Decree of 15 March 1967 concerning the protection of workers against ionizing radiation, which applies, in particular, to establishments holding more than 100 μCi of tritium. This Decree, together with its enforcement orders, defines the maximum allowable dose equivalents, conditions imposed for handling and storage, monitoring of the atmosphere or premises, and medical observations. It also states that an artificial radioactive substance can only be obtained with the authorization of the Commission Interministerielle des Radioelements Artificiels, or CIREA. With respect to paint, the CIREA has granted authorization for its use to decorate watch and alarm clock dials and hands and for sign panels.

Authorization for the use of tubes is granted only for special applications not affecting the general public, as in certain aircraft instrument panel devices, but their use is not authorized for illuminating liquid crystal watches.

Also available are the recommendations of the European Agency for Nuclear Energy and of the International Atomic Energy Agency (IAEA, 1968) concerning radiation safety standards applicable to radioluminescent watches and clocks. These standards are intended to protect users and the overall population, but do not cover safety problems affecting workers. They determine the following items:

- Selection criteria for the radionuclide to be used: tritium, promethium-147, and radium-226. However, use of the latter is not recommended and is prohibited for pocket watches,
- activities:
- tritium: average 5 mCi for watches and 7.5 mCi for clocks, with maxima 7.5 and 10 mCi, respectively,
- radium: average 0.1 μCi for wristwatches and 0.15 μCi for clocks, with maxima of 0.15 and 0.2 μCi, respectively,
- promethium: average 100 μCi for watches and 150 μCi for clocks, with maxima of 150 and 200 μCi, respectively,
- degrees of adherence of the radioactive material,
- enclosures: thickness equivalent at every point to 50 mg/cm^2, with sufficient mechanical strength to withstand stresses in normal service conditions or resulting from minor accidents,
- markings to be employed,
- tests to be performed.

These standards are merely recommendations. Each member State is responsible for matching its national legislation to them. In France, they are observed in full, despite the absence of any official text stipulating this. The distribution and use by the public of manufactured articles is not covered by any specific legislation.

CONCLUSIONS

An examination of the doses estimated above shows that the current use of radioluminescent product occurs in conditions that are far more satisfactory than in the past, both for workers and users. This is probably for three reasons:

First, the radionuclide employed, in effect, the replacement of radium by tritium, which has eliminated the external irradiation hazard and considerably reduced the internal contamination hazard.

Second, a better knowledge of the problems, which gave rise to the emergence of legislation governing the conditions in which the articles are produced and used, and hence improving the safety of handlers and users.

Third, a greater awareness of the hazards amoung company managers and workers themselves, which has led to the implementation of effective working methods and safety systems.

In conclusion, it may be stated that the products used today and the methods of use have produced consequences for workers that are far below the levels defined by prevailing standards and, for the public, present a negligible irradiation hazard in relation to natural irradiation.

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CHAPTER IV

MINING, AGRICULTURAL, AND CONSTRUCTION PRODUCTS CONTAINING RADIOACTIVITY

CHAPTER 4

MINING, AGRICULTURAL, AND CONSTRUCTION PRODUCTS CONTAINING RADIOACTIVITY

Many consumer products contain radioactivity intentionally added to enhance their usefulness, while other products contain radioactivity inadvertently, often as a result of man's activity in increasing their concentration. Fertilizers and gypsum boards are examples of these products. Large volumes of tailings containing radioactive materials, notably radium, are removed during uranium mining and milling operations. These operations have not only increased radium concentrations in the tailings, but have also enhanced its environmental availability. Similarly, phosphate mining results in tailings containing radium. Many of these operations have existed for a long time, but their public health impact in terms of population exposure has received proper attention only in recent years.

Although this chapter contains comprehensive and current information on this subject, it is expected that significantly more information will become available in the near future. The recent emphasis on implications of the well-established rule of keeping the population dose as low as reasonably achievable (ALARA), economic and social considerations being taken into account, has stimulated increased study and interest in this area by government agencies as well as academic institutions.

RADIOACTIVITY IN BUILDING MATERIALS

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During the past several years, there has been a tendency to reduce the allowable exposures of the population to various sources of artificial radiation. As these levels are decreased, they approach those existing in the natural environment, and the natural background has come to be used more and more as a standard of comparison with man-made sources. This overall process has stimulated interest in improving our estimates of actual human exposure to natural background and in particular in determining the range of exposures that might be experienced. One immediate effect has been an increase in the number of measurements of indoor exposures since a large fraction of the population spends at least three-fourths of its time inside houses, offices, or factories.

This paper is intended as a general review of indoor exposures both to external gamma radiation and to inhalation of the short-lived daughter products of radon. Where possible, these will be related to the radioactivity in the building materials themselves. The author has had the tremendous advantage of reviewing the draft material on this subject that will be included in the 1977 UNSCEAR report. This has helped considerably in evaluating the available data and in selecting the considerations to be emphasized.

EXTERNAL IRRADIATION

The external exposure of the population has been evaluated several times and most of the data for the United States are summarized in the National Council on Radiation Protection and Measurements Report 45 (NCRP, 1975). The majority of the United States would have an average outdoor absorbed dose rate in air of 46 mrad/yr. The Atlantic and Gulf Coastal Plain area would be about one-half that much and a small area in the Colorado Front Range about twice that much. These are mean values and small populated areas could be an additional factor of 2 higher or lower than these limits. While this may seem to be a considerable variation, it must be remembered that the mean value of 46 mrad/yr whole-body absorbed dose in tissue is only about one-half of the total whole-body dose received. The other contributions, which come from cosmic rays and internal emitters, are relatively constant so that the total variability is not so great as it might appear.

The absorbed dose rates in air are modified from outdoors to indoors both by shielding from the outdoor radiation and by the addition of radiation from radioactivity in the building materials themselves. In addition, there is a considerable change in the source geometry from a 2π situation to one approaching 4π. These three points will be discussed individually, after a word or two of caution.

There should be no uniform relationship between indoor and outdoor gamma exposure rates. A wooden frame house would reduce the terrestrial gamma radiation by about a factor of 2 although it would contribute relatively little from inherent radioactivity. Almost all other materials would have greater shielding effects and of course would be more likely to contain larger and variable amounts of radionuclides. The reported variation in indoor/outdoor gamma exposure levels ranges from 1.0 (Oakley, 1972) to 1.3 (Kolb, 1974) to 1.6 (Krisuk, et al., 1974). The measurements of Ohlsen (1969) have been criticized, but they fall into the same range as those given above. None of these ratios has any value except for empirically estimating the mean total external gamma dose to the specific population concerned.

Shielding

The average environmental radiation field is reduced to one-half by an absorber of about 10 g/cm^2. The shielding effectiveness of building materials ranges from about 4 g/cm^2 for 3 inches of pine to 27 g/cm^2 for a 6-inch-thick brick wall. It appears that wooden frame houses might very well give only moderate reductions in outdoor radiation, whereas masonry houses and apartments might reduce exposure by a large factor.

Useful data on shielding characteristics are available in an article by Cameras and Rickards (1973). Some generalities from their measurements would indicate that a 5-inch wooden frame wall would reduce outdoor contributions by a factor of 2, a 5-inch brick wall by a factor of 4, and an 8-inch concrete wall by a factor of 20. Windows and wooden doors would have a lesser shielding effect.

I believe that a large part of the variability in single-story housing levels is dependent on the floor and foundation construction. A heavy clean concrete pad over clean sand and aggregate should give a gamma dose somewhat lower than average soil, whereas the use of ash, slag, and other byproducts in or under a thin pad would lead to considerably higher doses.

Roof shielding against skyshine is probably not important since the unshielded contribution is only a few percent of the total terrestrial radiation.

Inherent Radioactivity

The radioactivity in building materials is essentially from the uranium and thorium series and from natural potsssium. These have a range of concentrations in the natural raw materials and can be either enriched or depleted in manufactured products. Therefore, we are not dealing with anything new but merely an adjustment in the quantitative composition of the radiation field.

We have two types of information on building materials, one describing the radionuclide content of various typical components, and the other describing the absorbed dose in air when exposed inside of a building. In both cases, the situation is highly complex since several components are combined to form a building material and several materials are combined during construction to form the floor, walls, and ceiling.

In reviewing the papers available, it is apparent that relatively few present data both for amounts of radioactive substances and for the radiation exposure within the building. More data of this type would be helpful in trying to correlate the two quantities.

We might consider the radioactivity in the average soil as a basis for comparison. The measurements by Lowder at al. (1964) for 200 locations in the U.S. give the following values for the radioactivity, and the corresponding absorbed doses in air from the soil have been calculated from the data of Beck (1975).

	Mean Activity (pCi/g)	Absorbed Dose Rate in Air (mrad/yr)
K-40	12	17
U-238	0.6	8
Th-232	1	22

The radioactivity of a number of building materials is summarized in Table 1. An attempt has been made to select a few similar materials rather than to give a compendium of all the data in the original papers. All the various units have been converted to pCi/g.

The tabulated data show that radioactivity in brick and granite tends to be higher than that in our average soil, while that in many concretes is significantly less. Even these classes are probably rather variable, and selection for low activity requires actual measurement, e.g., see Wollenberg and Smith (1966b).

The radium-226 values are generally not available but, where they are, they indicate that equilibrium is usually disturbed in processing the materials. This lack of data is important for external exposure consideration but is even more so when attempting to correlate composition with airborne radon concentrations.

Geometry

The most obvious assumption that exposure geometry changes from 2π outdoors to 4π indoors is an overestimate. Windows, wooden doors, metal panels, and wooden or metal furnishings tend to reduce the total. Calculations have been made for some specific cases; for example, Hultquist (1969) estimated the factor of 2 was up to 30% too high.

In wooden houses, the upper stories are further removed from the major source of radiation, and modest reductions of 10-20% in dose rate have been found on upper floors.

Position within a room generally has very little effect, and measured differences seem to be 5-10%. Exceptions might be found near stone fireplaces or similar sources.

Measurements

A number of authors have measured gamma-ray dose rates in several types of houses. A selection of these data is given in Table 2. Since most of the work was designed to give a ratio of indoor/outdoor radiation exposure, the outdoor values are also listed, even though the ratio has no particular significance.

The wooden frame houses obviously do not reduce the terrestrial dose rate by the factor of 2 that is possible, since materials in the floors, ceilings, and walls contribute some radioactivity. Masonry structures, particularly precast concrete multistory

TABLE 1

Radioactivity in Selected Building Materials

Source	Material	^{40}K	^{238}U	^{226}Ra	^{232}Th
Chang et al. (1974)	Wood	90	–	–	–
Taiwan	Red Brick	16	1.2	–	1.8
	Concrete	7	0.9	–	–
Hamilton (1971)	Clay Brick	18	3	1.4	1.2
U. K.	Silicate Brick (Gravel)	10	0.2	0.2	0.1
	Granite	30	6	2.4	2.2
	Aerated Concrete	19	0.4	2.4	0.4
	Natural Gypsum	4	0.4	0.6	0.2
	Concrete Block (Fly Ash)	(6-16)	(1-12)	(0.2-4)	(1.0-1.2)
Wollenberg and Smith (1966a and b)	Cement	3.4	1.1	–	0.4
U.S.	Silica Sand	9	0.3	–	0.5
	Commercial Sand	7	0.3	–	0.3
Krisyuk et al. (1974)	Red Brick	18	–	1.5	1.0
USSR	Silica Brick	6	–	0.5	0.4
	Light Concrete	14	–	2.0	0.9
	Granite	40	–	3.0	4.5
	Sand	7	–	(<0.4-1)	<0.4
	Cement	4	–	0.7	<0.4
Kolb (1974)	Granite	34	–	2.8	2.1
W. Germany	Brick	18	–	1.7	1.8
	Sand, Gravel	<7	–	<0.4	<0.5
	Cement	6	–	0.7	<0.6
	Natural Gypsum	<2	–	<0.5	<0.3
	Concrete	7	–	0.6	0.6

TABLE 2

Typical Absorbed Dose Rates in Air from Terrestrial Gamma Radiation Indoors and Outdoors (mrad/yr)

Source	Type of House	Indoors	Outdoors
Cardinale et al. (1971) Italy (Rome)	Not Stated	150(70-230)	175
Gustafsson (1969) Swedish Lappland	Wood	53	53
Lindeken et al. (1971) U.S. (California)	Wood frame, Stucco		
	Ground Floor	43(32-110)	about 50
	Second Floor	38	
Ohlsen (1969) E. Germany	Frame	70(0-210)	–
	Brick	70(15-150)	
	Stone	120(15-300)	
Pensko et al. (1969) Poland	Concrete – New Apartments	60	60
Solon et al. (1960) U.S. (New York)	Wood	(31-80)	58(40-100)
	Brick, Stone	(24-90)	
Storruste et al. (1965) Norway	Wood	62(41-93)	–
	Concrete	992(56-127)	
	Brick	104(66-133)	
Yeates and King (1973) Australia	Brick	76	26
	Timber/Asbestos	21	21
	Apartments	90	51
	Brick	73	90
	Granite	67	63
	Timber/Asbestos	82	98

buildings, could give the maximum shielding with only modest inherent radioactivity, but large window areas and finishing materials probably moderate this effect. We find, however, that masonry structures can have indoor dose rates that are essentially independent of outdoor dose rates. This is shown most clearly by the data of Yeates and King (1973).

Although Dr. Kolb's data from the Federal Republic of Germany is presented elsewhere in this book, it is interesting to look at the dose rate distribution of his studies. For the population considered, 98% of the people would be exposed to absorbed doses in air in the range of 30 to 60 mrad/yr outdoors and 40 to 80 mrad/yr indoors.

INTERNAL EXPOSURE

The only internal exposure of significance connected with building materials is the lung dose received by inhalation of radon daughter products. The high level of these radionuclides found in the houses constructed over uranium mill tailings in Grand Junction, Colorado, has led to a number of investigations of normal houses throughout the country. These have ranged from fairly simple measurements of the alpha-emitting daughter products to sophisticated surveys, including the necessary measurements of aerosol characteristics. The limited data on Rn-220 indicate that it is not usually significant, and I will limit this paper to Rn-222.

Any building acts as an enclosure in which the radon daughter products can build up toward equilibrium with ambient radon-222 with a half-life somewhat longer than a half hour, and the radon itself builds up from its radium parent. These same effects would be noted in any hole in the ground where the air does not mix into the lower atmosphere and become considerably diluted, and in the lower atmosphere itself when there is stagnant air during a temperature inversion. It is thus obvious that the most important factor in controlling indoor radon daughter concentrations is the degree of ventilation. Secondary considerations would include the radium-226 in the materials of construction, the dust loading of the air, the presence of air conditioning or similar systems involving air movement and filters, and such things as the type of wall coatings. Ventilation is such an overiding consideration, however that even a crack or similar opening can outweigh all the secondary effects.

Radon Emanation

As a general rule of thumb, about 5% of the radon formed in a porous material will diffuse into free air. The emanation of radon from building materials is of course similar to that from soil in that the radon concentration in the pore space is several orders of magnitude greater than in the adjoining free air. This means that diffusion is the driving force in bringing radon out of the materials and that an equilibrium would be established in a completely closed space. The rate of approach, but not the equilibrium, would be affected by temperature, and the effect of pressure would be that a modest decrease would tend to pump some of the radon out of the pore spaces and significantly increase the equilibrium concentration.

The mean outdoor radon concentration in the Northern Hemisphere is about 150 pCi/m^3. Indoor concentrations are many times higher, and values of several thousand pCi/m^3 are not uncommon even when uranium ores or tailings are not involved. If I may quote my paper from the 1973 Noble Gases Symposium: "Haque et al. (1965) measured the emanation from the walls in several rooms in England and found values ranging from 6 to 100 $pCi/m^2/h$ (0.2 to 3 $aCi/cm^2/sec$). If we consider a sealed room 5 meters square and 3 meters high, with walls and ceiling emanating at 30 $pCi/m^2/h$, the hourly emissions would be 2500 pCi. The equilibrium concentrations would be about 4400 pCi/m^3.

"High ventilation rates would reduce the concentration toward the outdoor level, for example, 4 air changes per hour with outside air at 70 pCi/m^3 would drop the room concentration to less than 80 pCi/m^3. This drop is possible because the emanation does not supply radon fast enough to replace the amount removed. Thus, for normal building materials, indoor concentrations of radon are only high in closed or poorly ventilated areas."

A number of studies have been made, and others are in progress, on the emanation rate of radon from various materials. A few points of interest emerge. One is that an increase in the water content of concrete or other porous material increases the emanation rate (Auxier, 1974). Another is that radon emanation can be successfully blocked by highly impervious coating such as epoxy paint (Auxier, 1974; Krisyuk, 1974).

As mentioned, the emanation of radon from walls, floors, and ceiling can be reduced by a factor of about 10 by suitable sealing techniques. This of course builds up the external gamma exposure by a factor of about 2 since the daughter products all decay in place rather than being partly removed by diffusion and ventilation. Thus the desired balance depends on the relative biological effects expected from these two radiation sources. This is discussed later under the heading "Comparative Risks." The alternate approach to reducing daughter product concentrations by increased ventilation is not always feasible because of the need to bring in outdoor air and heat it or cool it. Effective ventilation would require several air changes per hour and would certainly not help in conserving energy.

Measurements

The surveys of indoor radon daughter exposures are less extensive than those for external gamma radiation, and some of these are specifically aimed at special conditions. A number of the available papers are summarized in Table 3. Most of the measurements are in terms of radon concentration, but other units have been converted in the table.

As is noted in Table 3, many authors made their measurements intentionally in unventilated rooms. Depending on construction, there can be up to one air change per hour with all doors and windows closed. More usual home ventilation rates are up to four changes per hour, while commercial buildings can be much higher. Our own preference at HASL is to measure under actual living conditions but this requires sampling designed to cover both diurnal and seasonal variations. Some of the data (Breslin, 1977) are means of weekly average concentrations obtained from continuous samplers.

In many of the measurements, the diurnal variations, possibly a factor of 2 or 3, have been avoided by sampling only in the morning or afternoon. There has been no effort to consider possible changes in barometric pressure during or just before sampling. Jonassen (1975) has tested this effect in unventilated basement rooms with concrete walls. A 1% pressure change was found to cause a 60% change in radon concentration.

TABLE 3

Indoor and Outdoor Radon Concentrations (pCi/m^3)

Source	Building Type	Ventilation	Radon-222	
			Indoors	Outdoors
Davies and Forward (1970) U. K.	Houses	–	10-1500	10-430
Haque et al. (1965) U. K.	Housing	Good	160	42
		Poor	400	130
	Lab	Sealed	3600	50
	Office	Sealed	6900	150
	Factories	–	90-180	90
		––	450-550	90
	Offices	Air Cond.	80-260	40
Glauberman and Breslin (1957) U.S. (New York)	Brick and Masonary		2 210(70-410)	130(20-490)
Shem'izade (1971) USSR	Brick-1 story	None	6100	–
		Yes	1100	
	Brick-multistory	None	2100	
		Yes	500	
	Adobe	–	3900	
	Basements	–	13000	
Steinhausler (1975) Austria	Houses	Closed	750-3100	360
Toth (1972)	Houses-Mean	–	3000	200
	Houses-Slag Black	–	5200	
	Houses-Clay Brick	–	1600	
Yeates et al. (1972)	Wood Frame	–	70(<-230)	20(10-40)
	Concrete Basements	–	400(100-940)	
	Brick Apartments	–	90(10-190)	
	Office Buildings	–	50(20-100)	
Lowder et al. (1971) U.S.	Concrete, Tennessee	–	1400(130-4800)	–
	Concrete, Florida	–	1300(30-3600)	
Fisenne and Harley (1974) U.S.	Lab	Yes	95(60-170)	120(40-230)
	Lab	Poor	250(140-390)	120(40-230)
Breslin (1977) U.S.	Cellars	–	2700	–

The higher radon levels found in cellars may result from higher-activity wall materials, from being close to the earth source, or merely from poorer ventilation. Some of our own work (Breslin, 1977) would also incriminate cracks and other direct connections to the soil. In this study, the measured working level in 18 homes was half as high in the first floor as in the cellar.

Comparative Risks

If we take a value of 40 mrad/yr as the absorbed dose rate in the whole body (NCRP, 1975), the spread between a wooden frame house and a masonry house could easily be the difference between 30 and 50 mrad/yr, or 20 mrad/yr. The BEIR Committee (NAS, 1970) postulated 150 deaths for 10^6 individuals, each exposed to 1 rem. An equal number of nonlethal somatic effects would be expected. Thus, the difference between 10^6 people living in wooden frame and masonry houses would be six health effects for each year of exposure.

If we wish to compare the effects of changes in radon and external gamma radiation produced by sealing the walls of a building, some assumptions are necessary. Starting with a gamma dose rate of 40 mrad/yr, this would increase to 80 mrad/yr after sealing. This change would produce 12 health effects in 10^6 individuals per year of exposure. Assuming that the radon concentration before coating was 1000 pCi/m^3 and this is reduced to 100 pCi/m^3, we can calculate the health effects saved. The decrease of 900 pCi/m^3 would be (900)(0.6) = 540 mrem/yr to the whole lung (NCRP, 1975). The BEIR Committee would estimate 25 lung cancer deaths for 10^6 individuals exposed to a mean bronchial dose of 1 rem. Thus our change in radon concentration would save 14 effects per year. If we were to consider the dose to the segmental bronchioles to be equivalent to the BEIR quantity, the annual dose would be 2700 mrem/yr (Harley and Pasternack, 1972), and the number of lung cancers saved would be about 70.

I believe that these figures should be considered with reservations. Similar calculations of effects can lead to patent absurdities, and it is doubtful that they should be the basis for any action.

DISCUSSION

It is obvious that the radiation exposures from building materials can vary over a considerable range. The real question is whether modification of living habits and construction practices are worth considering as a means of dose reduction. I would personally doubt it, but regulatory control over high-activity materials is obviously on the way. This should be all that is required.

It is unfortunate that a number of waste products that are produced in bulk turn out to have a relatively high inherent radioactivity. As a result, alum shale is not used in Sweden for concrete, some byproduct gypsum is avoided for structural blocks in England (O'Riordan et al., 1972), and probably fly ash and slag materials are banned as components of brick and concrete in many countries. If the regulatory bodies become concerned, it may well become necessary that some of these materials be treated as low-activity wastes. Any restrictions, of course, limit the possible use of waste products as a conservation measure.

I have also previously mentioned another conservation problem, that is the increased use of energy required if we are to reduce radon exposure by increased ventilation.

I had hoped to avoid Grand Junction almost completely, but we must consider the Surgeon General's "guidelines for exposure levels in buildings constructed on or with mill tailings." These are expressed in working level (WL) units but, assuming radioactive equilibrium, remedial action is indicated when the indoor radon concentration is greater than 5000 pCi/m^3. In the range of 1000 to 5000 pCi/m^3, remedial action may be suggested. So many of the reported values fall into the latter range that the public might very well become highly concerned.

In summary, for many years we have attempted to compare man-made radiation with that received from natural radioactivity. In the 1950's, the statement was always made that a radiation exposure was not significant if it only doubled background. More recently, we have seen a continuing reduction in the permissible levels of radiation from nuclear power generation. The value of 5 mrem/yr is widely recognized as the goal, if not the absolute limit, at comparable variations in human exposure to natural background radiation. On the other hand, if the variations of natural background radiation are not significant, we are placing an unnecessary restraint on modern technology.

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BUILDING MATERIAL INDUCED RADIATION EXPOSURE OF THE POPULATION

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About 20 years ago B. Hultkrist published for the first time data on radiation exposure in Swedish houses (Hultkvist, 1956). For different types of construction, he found rather large variations depending on the inherent radioactivity of the building materials. In the meantime, reports of many other countries have been published, most of them are summarized in the UNSCEAR Report on the Effect of Atomic Radiation (UNSCEAR, 1972).

One of the reasons for the increased interest in the natural radiation exposure of the population is, that its mean value or its variation may be used as a guideline for determining the allowable additional exposure by manmade radiation. Since, at least in our latitudes most people stay most of their time in houses, the shielding effect of the walls as well as the activity of potassium, radium, and thorium contained in the building materials must be taken into account in this respect.

Recently, some new kinds of building materials are being used, such as byproduct gypsum and light concrete containing fly ash, in which radioactive elements are enhanced. The uncontrolled consumption of such materials could increase the radiation exposure of the population significantly (Pénsko, 1975).

For these reasons, the Federal Ministry of the Interior asked a group of eight institutes to investigate the influence of building materials on the radiation exposure of the population in the Federal Republic of Germany. A program was worked out including: (1) measurements of the external radiation exposure both inside and outside dwellings, (2) the specific activity of ^{40}K, ^{226}Ra, and ^{232}Th in building materials, (3) the relationship between the exposure rate and the specific activity, and (4) measurements of the ^{222}Rn concentration in dwellings. This paper deals mainly with the results of the first item.

Using a specially designed scintillation dosimeter described by Kolb et al. (1972), two people were able to survey up to 50 dwellings per day. The instrument H 7201 (Fig. 1) has 5 ranges with full scale between 3 μR/h and 300 μR/h. It is easy to handle and has low time constants. Its energy dependence is shown in Fig. 2 in comparison with that of a high-pressure ionisation chamber.

The results presented in the following tables and diagrams are based on surveys of nearly 30,000 dwellings and 25,000 outdoor measurements. The contribution of the cosmic radiation has been subtracted from the measured data. In Table 1 the average exposure rates due to terrestrial radiation inside ($\dot{D}_H$) and outside ($\dot{D}_F$) dwellings are listed for the eleven States (Lands) of the Federal Republic. The average difference in percentage figures ($\dot{D}_H/\dot{D}_F$-1) may be considered as the influence of the building materials. In some parts of Germany, for instance Hamburg, the exposure rates inside and outside dwellings are not very different, whereas in Hesse, Palatinate, and Saarland the exposure rates in dwellings are about 60% higher than outdoors.

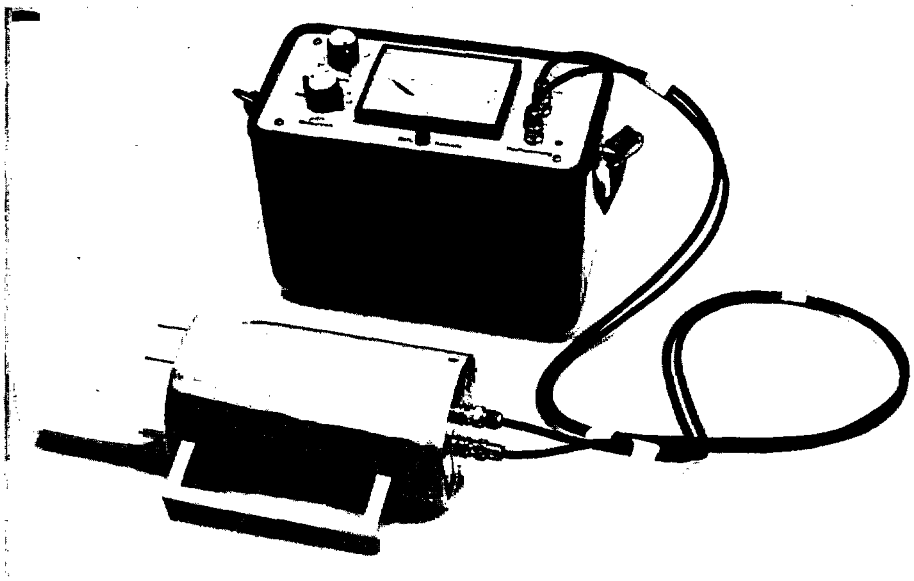

FIGURE 1. Scintillation exposure rate meter H 7201

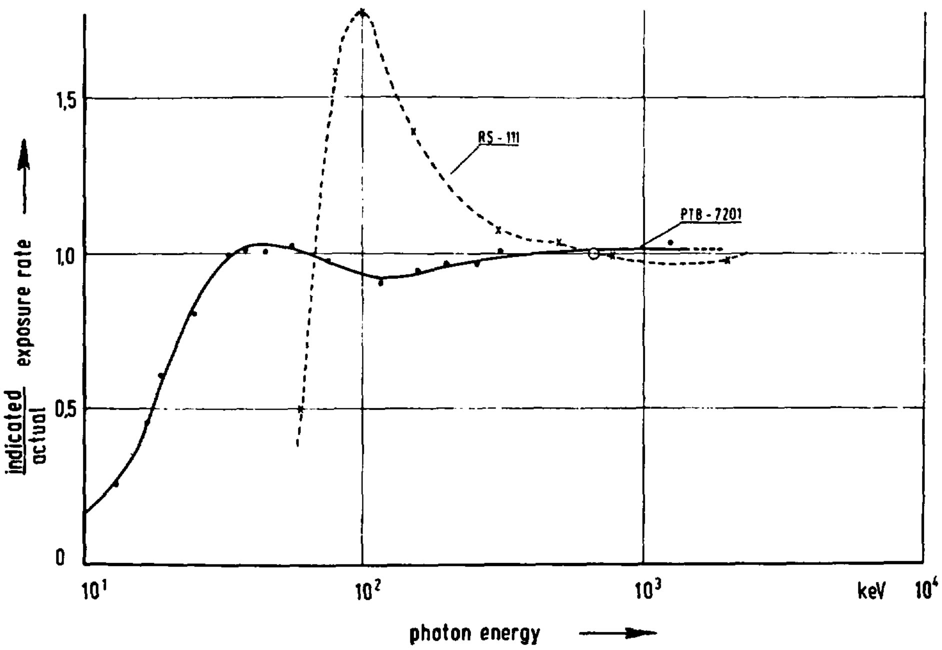

FIGURE 2. Energy dependence of two environmental survey meters:
a) Scintillation exposure rate meter H 7201
b) High pressure ionization chamber RS-111

TABLE 1

Exposure Rate Due to Terrestrial Radiation

State	in dwellings ($\dot{D}_H$) μR/h	outdoors ($\dot{D}_F$) μR/h	$\overline{\dot{D}_H/\dot{D}_F - 1}$ %
Sleswick-Holstein	6.0	5.7	8.5
Hamburg	5.6	5.6	2.4
Lower Saxony	6.5	4.8	39
Bremen	5.3	4.2	30
Northrhine–Westphalia	7.6	5.9	34
Hesse	9.0	6.0	55
Rhineland-Palatinate	10.1	6.8	58
Baden-Wurtemberg	7.9	6.2	34
Bavaria	8.5	6.9	31
Saarland	12.1	7.9	62
Berlin	7.0	5.8	26

Using a conversion factor of 0.8 mrem/mR (Bennet 1970) annual genetic doses may be derived from Table 1. This annual dose inside dwellings in Saarland is about 50 mrem higher than in Bremen.

The large amount of data allows the distinction between different ages and types of buildings. According to the year of construction, the data were devided into three groups (Fig. 3). In general, the exposure rate in new buildings is lower than in older buildings with one notable exception. In Saarland the exposure rate in buildings built after 1900 is 25% higher than in the older buildings. This corresponds to an average increase of the annual genetic dose of nearly 20 mrem. The higher exposure rate is caused by the rather high inherent activity of slag bricks made from blast furnace slag, the production of which started in that area at the beginning of this century.

Recently other byproducts have been used or proposed as building materials, such as calcium sulfate, a waste product of the phosphate industry, and red sludge, a waste product of the aluminium mills. Such a recycling of waste products should be promoted for the purpose of environmental protection and the preservation of resources, but the inherent radioactivity must be taken into account and compared with other commonly used building materials.

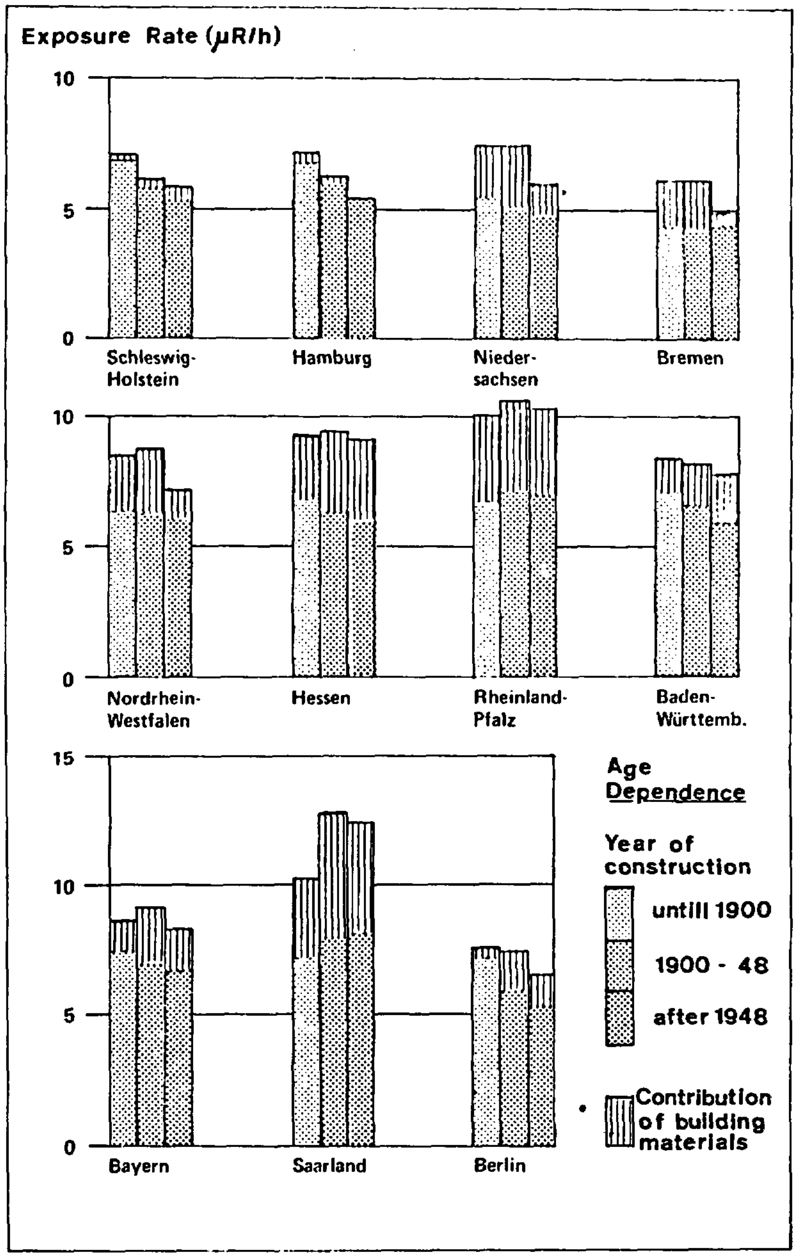

FIGURE 3. Exposure rate in dwellings, for different age-classes of buildings. The hatched parts of the columns indicate the contribution of the building materials, i.e. the difference of inside ($\dot{D}_H$) and outside ($\dot{D}_F$) exposure (contribution of cosmic radiation subtracted).

Several hundred samples of building materials have been analysed for ^{40}K, ^{226}Ra, and ^{232}Th. Some results are summarized in Table 2. Further and more detailed results will be published elsewhere (Schmier et al., 1977).

TABLE 2

Specific Activity (pCi/g)

Material	^{40}K	^{226}Ra	^{232}Th
Lime Bricks	0.7-8	0.2-0.6	0.2-0.5
Red Slime Bricks	8-13	2.5-6.7	3.9-10
Other Bricks and Clinkers	4-69	0.6-3.1	0.5-3.7
Pumice Bricks	13-30	0.7-3.6	1.1-4.6
Slag Sand and Slag Bricks	3-16	1.2-3.2	0.6-5.6
Cement	<0.5-7	0.3-5.3	0.3-5.2
Natural Gypsum	0.7-5	<0.7	<0.5
Byproduct Gypsum	<0.8-6	7-28	<0.5

The National Commission of Radiation Protection of the USSR has recommended that the specific activity C of building materials should not exceed the following limit:

$$\frac{C_K}{130\ \text{pCi/g}} + \frac{C_{Ra}}{10\ \text{pCi/g}} + \frac{C_{Th}}{7\ \text{pCi/g}} \leq 1; \text{C in pCi/g}$$

If this condition is fulfilled, the annual radiation exposure due to building materials will not exceed 150 mR, even under 4π geometry and saturated wall thickness. Only 12% of the analyzed samples failed to meet this recommendation. Most of them were red slime bricks and byproduct gypsum samples. In addition, however, some materials that have been used for years exceed the recommended limit, for example, some samples of Rhenish pumice and slag bricks manufactured in Saarland. Since under practical and more realistic conditions the annual exposure will be less than 150 mR, the limit given by the USSR formula should be considered as an action level rather than a maximum permissible value.

This would mean that a building material may be used without any restrictions if the action level is not exceeded. Above this level a notification should be required from the manufacturer that allows some control of the application and the produced quantities. One should not be too restrictive in this regard since it is better to re-use waste heaps of the phosphate industry than to destroy the landscape by open workings, as far as gypsum is concerned. There should be, however, a second limit, perhaps 2.5 times the action level. For building materials exceeding this second limit, an authorization by the competent authority on the basis of a risk-benefit analysis should be required.

Average annual genetic doses due to terrestrial radiation of people living in the Federal Republic of Germany are shown in Fig. 4, from which the following conclusions may be drawn:

1. The average annual genetic doses outside and inside dwellings due to terrestrial radiation are 43 mrem and 57 mrem respectively. A frequency distribution shows that 98% of the population are living in houses in which the annual genetic dose varies between 20 mrem and 115 mrem, i.e. the variation range is 95 mrem. As already mentioned, even the average values for the federal states varies within 50 mrem.
2. On an average, the terrestrial radiation in dwellings is 33% higher than outdoors. This means that in general the influence of the radioactivity of the building materials dominates over the influence of its shielding effect. In prefabricated timber houses, however, the contrary is the case.
3. In new buildings, the annual dose is on an average 5 to 7 mrem lower than in buildings built before 1949. In the State of Saarland, however, the annual dose increased by nearly 20 mrem in buildings built after the beginning of this century.
4. Amongst the presently used building material, those containing pumice, red sludge, shaft furnace slag, and certain kinds of chemical gypsum as well as granite have a radium and thorium content of 10 pCi/g or more. Particular attention must be paid to these materials with regard to the annual radiation exposure of the population, which may reach under certain conditions up to 150 mrem.

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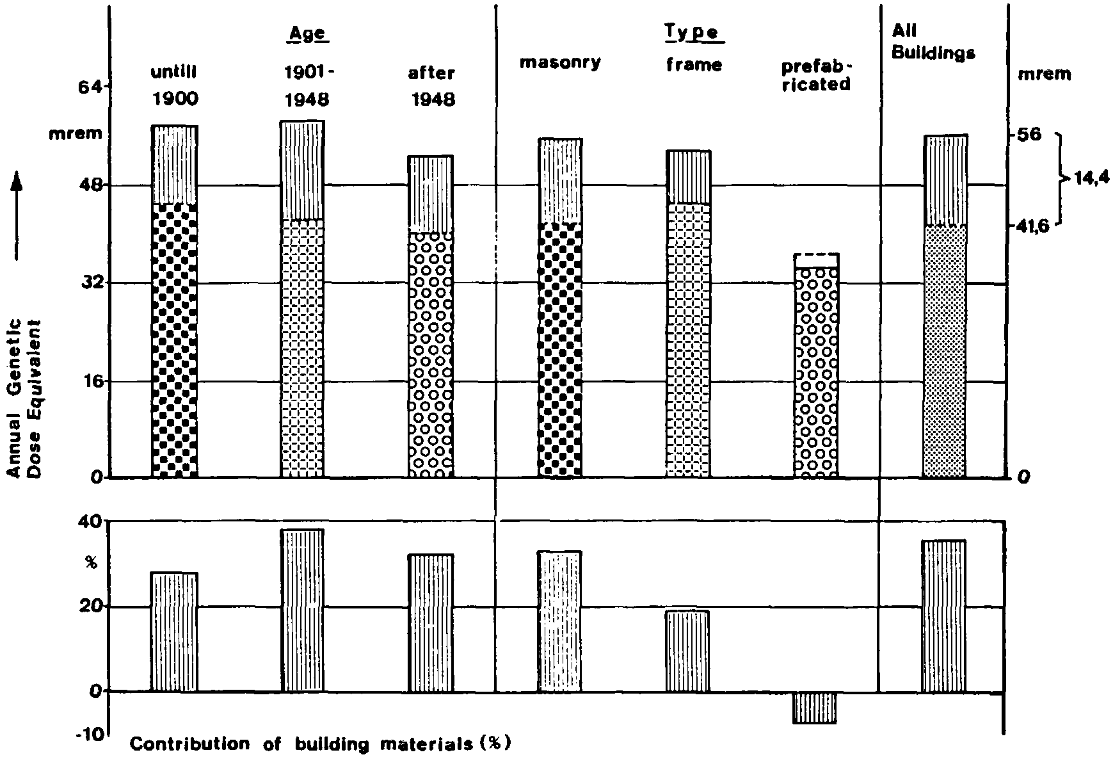

FIGURE 4. Average annual genetic dose due to terrestrial radiation in different kinds of buildings in the Federal Republic of Germany. The hatched parts of the columns indicate the contribution of the building materials, which is also shown in percentage figures.

RADIATION EXPOSURE FROM CONSTRUCTION MATERIALS UTILIZING BYPRODUCT GYPSUM FROM PHOSPHATE MINING

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INTRODUCTION

The Environmental Protection Agency (EPA) is charged with carrying various programs to protect the public and the environment from unnecessary exposure to radiation. In meeting this responsibility, the Agency has been actively assessing the radiological impact of the phosphate industry. Previous surveys of phosphate ore mined in the United States have shown significant concentrations of uranium and thorium, ranging from 8 to 399 ppm (514 to 267 pCi/g) and 2 to 19 ppm (0.4 to 4 pCi/g), respectively (Guimond and Windham, 1975a). The processing of this ore to produce phosphoric acid, the integral feed material in phosphatic fertilizer production, leads to the formation of large quantities of gypsum as a byproduct, frequently called phosphogypsum. Phosphogypsum from Florida phosphates has been found to contain an average of 33 pCi/g of radium-226, 6 pCi/g of uranium-238, and 13 pCi/g of thorium-230 (Guimond and Windham, 1975b).

The sulfuric acidulation process which results in gypsum production can be expressed as follows:

$$\underset{\text{(phosphate rock)}}{Ca_3(PO_4)_2} + 3H_2SO_4 + 6H_2O \rightarrow \underset{\text{(gypsum)}}{3CaSO_4 \cdot 2H_2O} + 2H_3PO_4$$

As shown in Figure 1, ground phosphate rock is mixed with aqueous sulfuric acid within an attack vessel. The subsequent reaction results in the production of phosphoric acid and gypsum. The phosphogypsum is filtered off and pumped as a slurry to a nearby storage area where it is allowed to dewater. The phosphoric acid, with a P_2O_5 concentration of approximately 30% is either reacted with ammonia or phosphate ore to produce, respectively, ammonium phosphate or triple superphosphate. These compounds are two basic components of phosphate fertilizers.

Although the radium-226 concentrations for normal and triple superphosphate are similar to that for phosphogypsum, the total mass of gypsum produced exceeds that for all other major phosphate products, as shown in Table 1, with 4.5 tons of gypsum being realized via the chemical reaction described for every ton of P_2O_5 as phosphoric acid produced (Slack, 1968). The estimates provided in Table 1 are based on the average concentration for these products as noted in Figure 1. These data

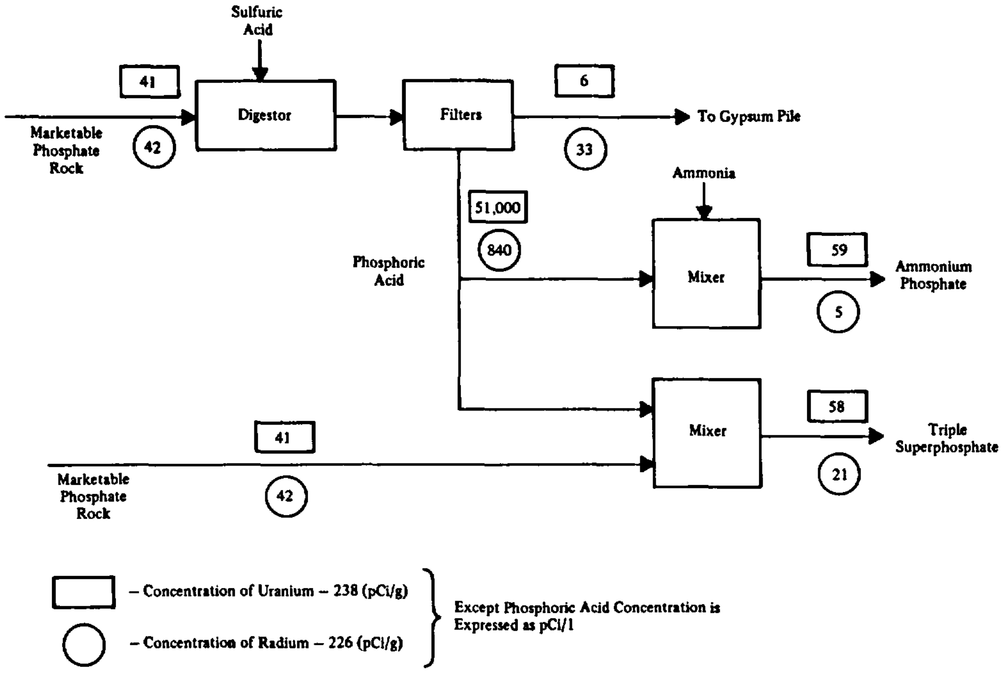

FIGURE 1
PRODUCTION FLOWSHEET FOR A WET-PROCESS PHOSPHORIC ACID PLANT (GUIMOND, 1976)

TABLE 1

Estimated Total Radium-226 and Uranium-238 Activity in Phosphate Fertilizer Products and Byproducts Based on 1973 Production Data

(Guimond, 1976)

Material	Production		Radium-226 (Curies)	Uranium-238 (Curies)
	(x 10^6 Tons)	(x 10^6 Tons P_2O_5)		
Normal Superphosphate	3.4	0.62	77	77
Triple Superphosphate	3.7	1.72	69	190
Ammonium Phosphates	5.8	2.67	30	330
Phosphoric Acid	11	5.62	5.5	600
Gypsum	25.3		760	140

show that approximately 80% of the total Ra-226 activity in phosphate fertilizer products and by-products is contained in the phosphogypsum.

The United States is the world leader in the mining of natural gypsum with 20% of total world output in 1973 at 13.6 million tons (Department of the Interior, 1975). Despite such production, the growing environmental and economic concerns associated with the long-term storage of waste gypsum are making by-product gypsum a potentially attractive alternative. Commercial utilization would primarily be in the construction materials industry with specific applications in prefabricated products, as shown in Table 2. Phosphogypsum has not yet achieved extensive commercial application in plaster and some cement products due to its unfavorable chemical properties and typically gray color resulting from impurities. These impurities are a result of not only the acidulation process itself, but also the composition of the raw phosphate ore. The more important ones are organic compounds (up to 2% C), soluble and insoluble P_2O_5 (up to 2%), and soluble fluorine (2% plus) (Steininger, 1974a). The cost of phosphogypsum purification (through calcination, recrystalization, etc.) and dewatering, balanced against the low cost availability of natural gypsum supplies, has discouraged development except where natural supplies are not economically available.

Certain countries, such as Japan, France, and the United Kingdom, possessing less such natural gypsum resources, have made extensive use of the by-product gypsum. Japan was the first country to develop commercial utilization in 1934 (Steininger, 1974b). Japan imports most of its fertilizer needs from the United States with 2.2 million tons of phosphate rock being shipped in 1973 (Department of Interior, 1976). Through phosphoric acid production, a sizable supply of phosphogypsum has become available to industry, where it has been used primarily in construction materials. At the present time, approximately 3 million tons of by-product gypsum is used in Japan annually for this purpose, half of it as a settling control in cement manufacturing (Steininger, 1974c). Due to the prohibitive economics of transoceanic shipping, however, these products have not been exported to any extent.

The French and British import most of their phosphate needs from North Africa, primarily Morocco. In 1970, 67% of total phosphate rock imported into the United Kingdom (1.1 million tons) originated there (Department of Environment, 1972a). The current output of gypsum from phosphoric acid production exceeds 2 million tons per year in Great Britain as compared to a production rate of 3 million tons annually for natural gypsum (Department of Environment, U.K., 1972b).

On a domestic and world basis, the wet-process phosphoric acid production rate, and thereby the phosphogypsum production rate, has steadily increased during the past two decades, and projections are for continued growth. From an annual growth rate exceeding 15% in the 1960s, domestic production is presently expanding at somewhat less than 10% primarily due to economic and capacity constraints. As Figure 2 shows, however, total phosphogypsum produced in the United States as of 1973 now exceeds 23 million metric tons per year, with a related Ra-226 activity upwards of 760 curies (assuming 33 pCi/g Ra-226). Since the development of the wet process industry in this country, roughly 300 million metric tons of phosphogypsum have been produced, half of it since 1970. Similarly, global phosphogypsum production has increased dramatically with total annual production projected at 130 million metric tons by 1980. Despite increasing production capacity in the developing countries, as Table 3 and Figure 3 show, at least two-thirds of total phosphoric acid, and hence, phosphogypsum, production will take place in the

TABLE 2

Gypsum Applications – 1973 (Dept. of the Interior, 1975)

Use	Quantity (thousand tons)	Fraction of Total
Prefabricated Products:		
Gypsum Board	13,875	0.61
Veneer Base	404	0.02
Sheathing	355	0.02
Lath	315	0.01
Predecorated Wallboard	210	0.01
Other	12	>0.01
Uncalcined:		
Portland Cement	4,563	0.20
Agriculture	1,598	0.07
Other	129	>0.01
Calcined:		
Building Plaster	848	0.04
Industrial Plaster	388	0.02
Total:	22,697	

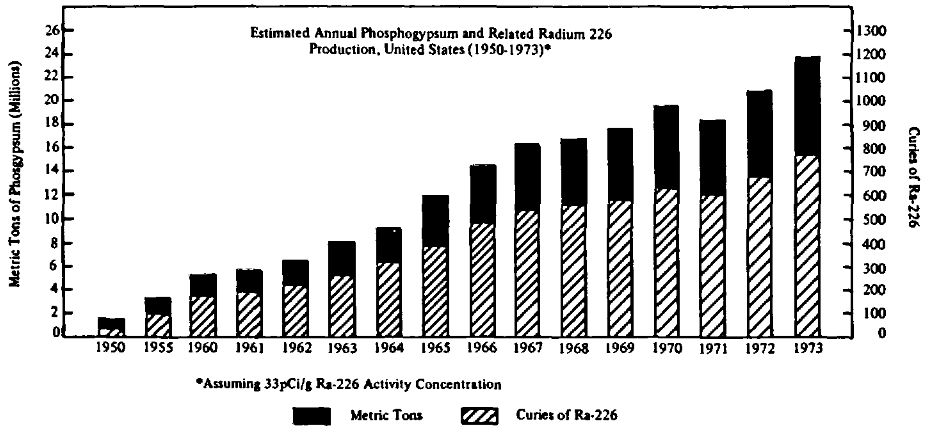

FIGURE 2

TABLE 3

Expected World Phosphogypsum Production (Tons)

Region	1973/74	1974/74	1975/76	1976/77	1977/78	1978/79	1979/80	1980/81
Developed Market Economies	54	64	70	72	75	75	76	76
North America	28	35	37	38	40	41	41	41
West Europe	20	22	26	26	26	26	26	26
Oceania	1	1	1	1	1	1	1	1
Other Developed	5	6	6	7	8	8	8	8
Developing Market Economies	11	14	20	26	28	29	30	30
Africa	3	4	8	10	12	12	12	12
Latin America	3	4	5	7	7	7	8	8
Near East	2	3	3	4	4	4	4	4
Far East	3	3	4	5	5	6	6	6
Centrally Planned Economies	19	24	24	25	25	25	25	25
Asia	–	–	–	1	1	1	1	1
USSR	19	24	24	24	24	24	24	24
World Total	84	102	114	123	128	129	135	135
RA-226 Content (Ci x 1000, Assuming 25pCi/g)	2.1	2.6	2.9	3.1	3.2	3.2	3.4	3.4

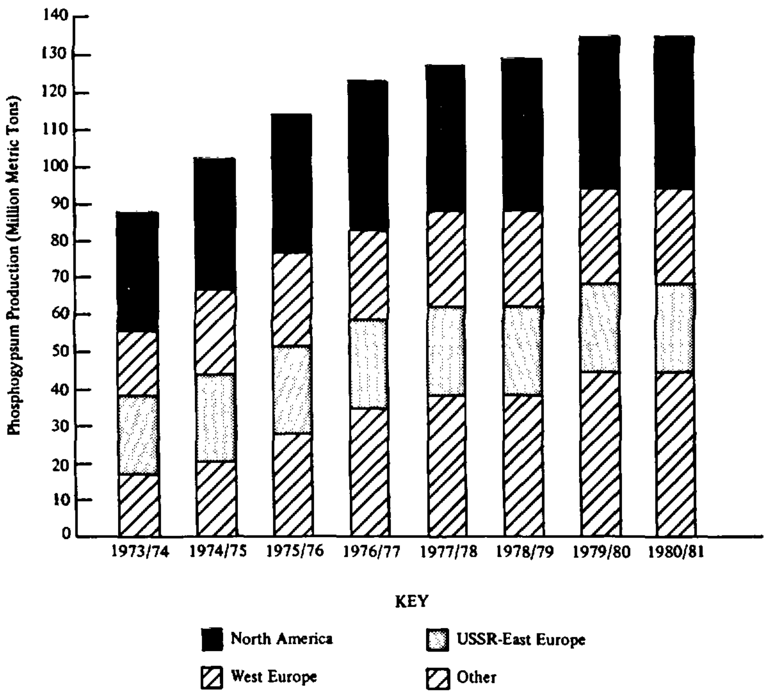

FIGURE 3
ESTIMATED WORLD PHOSPHOGYPSUM PRODUCTION GROWTH
(1973-1981)

industrialized nations of North America and Europe (the calculations assume 90% of capacity production rate as provided in Reidinger (1976). The long-term availability of this raw material for these areas in thus assured, and hence, the potential for commercial utilization will continue to be high.

RADIOLOGICAL IMPACT OF UTILIZATION

Naturally occurring radioactive materials in various construction materials, such as phosphogypsum wallboard, are a potential source of external and internal radiation exposure to the entire population. It is estimated that the average person in the United States spends 95% of his time indoors, with over three-quarters of this time at home (Oakley, 1972a). A large segment of the population (about 45%) reside in brick or masonry homes (HUD, 1969), which may cause annual external dose equivalents of approximately 10 to 20 mrem. In addition, "critical" population groups, as reported in the literature (Hultqvist, 1956; Storruste and Remstad, 1965; Ohlsen, 1970; Hamilton, 1972a; and others) may have annual dose equivalent rates exceeding 100 mrem. As such, construction materials contribute a significant fraction of the radiation exposure received by the population normally considered as part of natural background exposure.

Radiation exposure from construction materials such as phosphogypsum is due primarily to whole-body gamma irradiation and radon daughter alpha exposure of the lung. The dose equivalent from such exposure is a complex function of the geometric distribution of radionuclides in the building, the ventilation rate of the room, and the occupancy factor. Krisiuk *et al.* (1971a) have attempted to model external gamma exposures from these materials utilizing an empirical approach incorporating dose conversion coefficients derived through Monte Carlo calculations. Assuming a known radium-226, thorium-230, and potassium-40 content for the material in question, a maximum external dose rate can be calculated:

$$\text{D max (mrad/yr)} = 41\,C_{Ra} + 58\,C_{Th} + 3.2\,C_K$$

where,

C_{Ra}, C_{Th}, C_K = specific activities of respective radionuclides in building material of infinite thickness.

Feher *et al.* (1975) developed a similar model based on derived dose conversion coefficients, in which the external radiation burden was calculated for a room with a floor area of 20 m^2:

$$\text{D (mrad/yr)} = K_{Ra}C_{Ra} + K_{Th}C_{Th} + K_K C_K$$

where,

K_{Ra}, K_{Th}, K_K=dose conversion coefficients (mrad/yr per pCi/g), including dose rates from gamma emitting daughter activities of Ra-226 and Th-228.

With regard to these models, the gamma dose rate calculated for a given room is reduced through the presence of windows and doors, as well as other materials of different construction, which may introduce error. Likewise, the thickness and self-shielding characteristics of wall and ceiling constructions can contribute to miscalculation. The assumption by these models of a central exposure point in a room, though, is reasonably consistent with actual measurements which have shown a differential of only 10 to 15% for measurements near such apertures.

For radon daughter exposure in structures, a number of characteristics of the ambient atmosphere will affect the deposition of radon daughter and dose to the respiratory system: (1) ventilation; (2) free ion fraction or the fraction of unattached daughter products; (3) the concentration and particle size of aerosol or dust particles; and (4) degree of equilibrium between radon and progeny. Of these four parameters, the ventilation rate has the greatest effect on radon daughter concentrations and, hence, dose. Increased ventilation on the order of 1 to 3 air changes per hour, for example, will decrease radon daughter particulate concentrations by over 60% (Fitzgerald *et al.*, 1976a). Yeates *et al.* (1972) have determined from a survey of buildings in Boston that radon concentrations vary widely within a structure due to differences in ventilation. For basements, radon concentrations were found to be 4 to 23 times higher than first floor concentrations. These authors and others (Handley and Barton, 1973; Kaye, 1973; and Johnson *et al.*, 1973) have found average residential ventilation rates to vary between 1 to 3 air changes per hour. Measured office building rates, however, were a factor of five or more higher with a range of 5 to 14 air changes per hour.

Responding to the growing concern over the increased utilization of materials containing uranium in building construction, a number of comprehensive surveys have been and are being performed on the radionuclide content of various materials and their relative exposure rates. Hamilton (1971) measured the concentration of K-40, Th-230, and Ra-226 and calculated the relative radioactivity of construction materials in use in the United Kingdom, including phosphogypsum and phosphate ore. He concluded that the mean concentration of naturally occurring radionuclides in building materials varies widely by as much as a factor of 14 for conventional materials such as clay bricks, flint aggregate brick, and natural gypsum. As Table 4 shows, the radium equivalent for phosphogypsum is greater than the mean value for clay bricks (a conventional material with a relatively high mean radium equivalent) by a factor of about four and is higher than the mean value for natural gypsum by a factor of 14. Hamilton suggests that despite the high radium activity concentration of phosphogypsum, it is unlikely that its utilization in 1/2-inch wallboard will pose a significant population exposure hazard due to its small total mass. He notes, however, that the development of innovative materials, such as 3-inch preformed blocks, may increase the indoor radiation contribution to significant levels.

TABLE 4

Relative Radioactivity of Construction Materials in the United Kingdom (Hamilton, 1971)

	Mean Ra Equivalent (pCi/g)
Gypsum Type A (Waste Product)	17.0
Granite Bricks	6.9
Clay Bricks	3.8
Granite Aggregate Bricks (Reformite)	1.6
Natural UK Gypsum Type B	1.2
Calc Silicate Bricks	0.8
Flint Aggregate Bricks	0.3

Kolb (1974) surveyed a large sample of structures in the Federal Republic of Germany, measuring the radium, thorium, and potassium activities of respresentative materials, including artificial (phosphogypsum) plaster. As Table 5 shows, the artificial plaster has radium activities ranging from 7 to 28 pCi/g, a factor of about four higher than that of the next highest material (red brick) and over an order of magnitude higher than natural gypsum plaster.

TABLE 5

Radionulide Content of Construction Materials in the Federal Republic of Germany (Kolb, 1974)

	(pCi/g)		
	Ra	Th	K
Chalk Sandstone	00.19-0.60	0.19-0.50	0.75-0.8
Red Brick	2.5-6.7	3.9-10	8-13
Other Bricks and Tiles	0.6-3.1	0.5-3.7	4-69
Pumice Stone	0.7-3.6	1.1-4.6	13-30
Slag Sand and Stone	1.2-3.2	0.6-5.6	3-16
Cement	0.3-5.3	0.3-5.2	<0.5-7
Natural Plaster	<0.7	<0.5	0.7-5
Artificial Plaster	7-28	<0.5	0.8-6

In Table 6, the relative radiological impact of the utilization of selected construction materials is provided, with the sum of mean activity quotients as proposed by Krisiuk *et al.* (1971b) as the criterion for inclusion. From calculations by the authors, those materials having quotient sums of one or greater are likely to have correlating gonadal dose rates in excess of 150 mrad/yr. This value is based on the maximum exposure values of conventional materials which were found to have dose rates generally between 20 and 70 mrad/yr to the gonads, assuming 75% occupancy. Thus, most conventional materials would be exempted under their criteria with only a few innovative construction materials necessitating control. The basis of this correlation is a survey of 300 samples of 17 different types of construction materials in common use in the USSR. It should be emphasized, first, that radon daughter exposure is addressed separately with a recommended exemption concentration of 3 pCi/l Ra-222 relative to outdoor ambient concentrations (approximately 0.03 WL). Second, estimates by other investigators such as Spiers (1960) have indicated that the annual gonadal dose increment may be a factor of about two lower than that assumed for the proposed exemption standard. Such overestimation is due in large part to those factors discussed in relation to the aforementioned Krisiuk and Feher models; that is, the presence of windows and doors, and the finite thickness of construction materials. Relative to other building materials having significant concentrations of the primordial radionuclides, as Table 6 shows, Florida phosphogypsum is as much as a factor of two higher than the red mud brick, and a factor of three higher in radium-226 content; however, concrete with alum shale manufactured until 1975 is not considered, because large-scale utilization had since ceased. Another criterion by which population impact can be surmised is the utilization potential of the various materials, evaluated on the bases of

TABLE 6

Relative Radiological Impact of the Utilization of Selected construction Materials

Type of Building Material	Avg. Ra-226 Activity (pCi/g)	Sum of Mean Activity Quotients*	Utilization Potential
Phosphogypsum:			
Florida	33	3.0	High
Morocco	25	2.6	High
Idaho	23	2.4**	High
Khouribga	17	1.7**	High
Concrete w/Alum Shale:			
Old Type 1947-75	35	3.9	Limited
New Type 1974	9	1.1	Limited
Red Mud (Bricks)	8	1.7	Limited
Volcanic Tuff	4-7	1.5	Limited
Fly Ash	3-5	1.1	High
Slag Pumice (Bricks)	6	1.0**	High
Phosphorus Slags:			
USSR	6	1.0**	Limited
Florida	56	5.6**	Limited
Granite	3	0.8	High

* $\frac{Ck}{130} + \frac{Cra}{10} + \frac{Cth}{7}$, as suggested by Krisiuk, *et al.* (1971)

** Estimates based on Ra-226 activity concentration availability, quantity produced, and economic incentives. Of the materials evaluated, only phosphogypsum, fly ash, slag pumice, and granite can be considered as having high potential for the near-term.

Little in-depth radiological impact evaluation supported by actual measurements has been performed to date regarding phosphogypsum construction materials. A notable exception is the National Radiological Protection Board (NRPB) survey and analysis by O'Riordan *et al.* (1972). The authors found an average radium content of 25 pCi/g for phosphogypsum from commercial British wallboard. Assuming standard (U.K.) housing dimensions, wallboard construction, and occupancy, a whole-body dose rate of 7 μrad/hr corresponding to an annual combined gonadal and bone marrow dose of 30 mrad was calculated. Estimates of beta and radon daughter exposure were also made with maximum rates of 20 mrad/year (eye lens and skin) and 0.04 working level months calculated, respectively. These values all fall into the realm of natural background variability.

The NRPB concludes that although a relatively small increase in population exposure would result from phosphogypsum utilization, such an increase can be justified on the basis of the benefits to be accrued by such utilization. The NRPB recommended that unrestricted utilization of phosphogypsum be continued subject to the following provisos:

(1) Sources of the raw material giving rise to concentrations of radium in the finished product *significantly* in excess of 25 pCi/g should be avoided so that the average over the whole country shall not exceed 25 pCi/g. (Italics added.)

(2) Arrangements should be made for recording the production and utilization of the material and measuring its radioactivity. The information thus obtained should be reported to the Board annually to enable it to carry out periodic assessments of the population exposure.

Schmier (1974), in a survey of 400 residences constructed with various materials containing uranium, found that the 15% utilizing phosphogypsum had gamma dose rates of 30 to 100 mrem/yr. The higher measurements were obtained from surfaces covered with phosphogypsum plaster.

Hamilton (1972a), in evaluating the gamma exposure rate from British phosphogypsum plaster, estimates an air dose rate of about 70 μrad/hr, which is comparable to the value calculated by Mehl (1974a) of 50 μrad/hr for the same material in Germany. Natural gypsum plaster, in comparison, has an exposure rate typically about 5 μrad/hr (Hamilton, 1972b; Mehl, 1974b).

The EPA's Eastern Environmental Radiation Facility (EERF) has obtained samples of Japanese wallboard constructed with Florida phosphate-derived phosphogypsum. Radiological analysis has shown a Ra-226 activity range of 20 to 25 pCi/g which is roughly comparable to raw phosphogypsum. This wallboard has been used in the construction of a chamber with which the radon daughter exposure due to radon emanation from the wallboard can be better characterized. Pertinent data for the wallboard itself are presented below:

Width = 87 cm
Depth = 89 cm
Height = 180 cm
Thickness = 1 cm (0.8 cm gypsum, 0.2 cm paper)
Volume = 1.39 m^3
Weight = 24.18 kg

Estimated total Ra-226 = 0.484 μCi (based on 20 pCi/g)
Inside area = 7.1×10^3 cm^2

. The chamber is constructed of 10 sheets (3' x 3') of wallboard with two on each side and one each on the top and bottom. The supportive framework is constructed on the outer surfaces. A viewport and interior light are provided as well as a pass box for transferring detectors into and out of the chamber without disturbing the contents. A metal service port provides tubing connectors with flow meters and valves for adjusting flow rates to inside detectors. A small blower and 3.2 cm stainless steel tube are arranged to provide ventilation, internal or external, as required.

From modeling calculations, an estimate can be made for radon working levels:

Assumptions:

(1) maximum radon emanation rate: 2.1 pCi/s - μCi Ra-226 (O'Riordan *et al.*, 1972).

(2) 0.5 air changes/hour ventilation (leakage)

(3) 0.07 fractional emanation (O'Riordan *et al.*, 1972)

Rn emanation rate (Rn) = 2.1 pCi/s)(0.484 μCi)(0.07)/0.71 m^2 $\simeq$ 0.1 pCi/m^2-s

$$\text{Rn equilibrium concentration} = \frac{(\text{Rn})(\text{A})}{(\lambda_v + \lambda_d)\,\text{V}} \simeq 0.35 \text{ pCi/l}$$

where,

λ_v = ventilation constant (s^{-1})
λ_d = radon decay constant (s^{-1})
V = volume of chamber (m^3)
A = surface area (m^2).

From calculations in Fitzgerald *et al.*(1976b), this equilibrium concentration at 0.5 air change/hour corresponds to a working level of apprxomately 0.0025. This agrees favorably with preliminary radon measurements in the chamber (utilizing TLDs) which show a range of 0.002 to 0.003 working levels.

CRITERIA DEVELOPMENT

With the world demand for fertilizer products increasing dramatically, the estimated annual phosphogypsum production rate of 25 million tons in 1973 (Guimond and Windham, 1975c) is likely to be exceeded by a large margin over the next few decades. Even the eventuality of phosphate depletion in current mining areas will leave a legacy of millions of tons of waste gypsum. With a growing number of industries expressing interest in developing this resource, the EPA, with a responsibility to protect public health and the environment, is developing criteria and guidelines for acceptable population exposure levels from construction materials such as phosphogypsum.

A number of studies, both ongoing and completed, will serve as input to this effort. One necessary input is the determination of radium source terms for domestic phosphogypsum which has been carried out by several investigators. For phosphogypsum from representative Florida phosphoric acid plants, the average radium-226 concentration of 33 pCi/g compares favorably with that for representative North African phosphogypsum (25 pCi/g) as reported by O'Riordan *et al.* (1972b). The effects of building materials on population dose equivalents are also being evaluated by Moeller and Underhill (1976a), who have developed a computerized model for calculating dose equivalent rates to occupants of buildings constructed with materials such as phosphogypsum.

As mentioned previously, EPA's EERF staff has constructed a chamber from samples of Japanese wallboard constructed with Florida phosphate-derived phosphogypsum in order that radon working level measurements can be performed. The emanation rates measured, the relationship between ventilation and radon daughter concentrations, as well as the effectiveness of various sealants tested, will serve as input into the development of criteria and guidance concerning indoor radon daughter concentrations resulting from construction materials, such as phosphogypsum wallboard.

An area of potential concern is the radiological impact assessment of structures built with Florida phosphogypsum during the period from 1935 to 1946. It has been learned that during these 11 years phosphogypsum was shipped from Florida to the now defunct Structural Gypsum Company in New Jersey, which manufactured various construction materials such as wallboard, partition blocks, and plaster for distribution in the northeastern United States. A number of commercial and residential sites have been tentatively identified as containing phosphogypsum materials, and one can assume that numerous other structures of like construction exist in the same region. An investigation of this situation would involve the identification of structures containing phosphogypsum, the sampling and analysis of phosphogypsum materials for radium content, the measurement of indoor gamma and radon daughter levels, and, if possible, the correlation of calculated health effects to actual effects for long-term occupancy, assuming a statistically acceptable sample.

Another possible area of interest is the utilization of calcium silicate slag from the Tennessee Valley Authority phosphate fertilizer production plant in northern Alabama. Various construction materials, including concrete block, cement, and concrete, are produced from this by-product material. A radiological impact evaluation of structures built with such materials would be further background for the development of criteria and guidance concerning the utilization of phosphogypsum and other uraniferous raw materials.

DISCUSSION

Although O'Riordan *et al.* (1972c) suggest that dose estimates for phosphogypsum wallboard are an order of magnitude lower than the appropriate ICRP guideline, a review of their underlying assumptions and related literature indicate that further evaluation may be necessary. In brief, the bases for concern regarding the unrestricted utilization of this by-product material (as approved by the NRPB) are:

(1) the expanding utilization of phosphogypsum in products other than wallboard, such as partition blocks, plaster, and cement, which would likely have a significantly different exposure potential;

(2) the uncertainties implicit in the assumptions made by the NRPB in calculating total dose and population impact, including the choice of an "average" structure, radon emanation rate, and occupancy rate;

(3) the lack of NRPB criteria as to what Ra-226 concentrations would be considered "significantly" in excess of 25 pCi/g, as expressed in the Board's 1972 recommendations;

(4) the lack of actual survey data from a statistically acceptable sample of homes built with phosphogypsum materials; and

(5) the lack of a real measure of potential population impact related to the current and projected growth rate of phosphogypsum utilization.

The first two points are of particular relevance to the question of potential radiological impact. The expanding utilization of phosphogypsum worldwide is fueled by an immense reservoir of raw material. Domestically, due to tightening environmental restrictions on waste disposal and the location of much of this country's phosphoric acid capacity in Florida, a high growth recreation and retirement area, eventual utilization in some form is a strong possibility. The moldability of the gypsum permits its application in numerous consumer products, limited only by technology itself; and, of course, it possesses the chemical and physical characteristics which have made natural gypsum a major raw material in the construction industry.

Accepting the premise of expanding utilization, one must address the question of total individual exposure and average population impact and the uncertainties, as expressed in the second point, inherent in making such estimates. Although individual external exposures via beta and gamma radiation can be quantified to a fairly high degree, estimates of population impact and the long-term health effects associated with low-level radon progeny exposure are educated speculation at best. From studies by Auxier *et al.* (1972) and data from Lowder *et al.* (1971) and Oakley (1972b), for which an estimated dose rate averaging 200 mrad/yr for occupants of granite and low-density concrete buildings is given, it appears likely that the incorporation of phosphogypsum in like configurations will lead to even higher external doses. The maximum individual dose rate of 30 mrad/year, as calculated by the NRPB and utilized in their population calculations, may therefore be invalid for such applications. Further field study is necessary in order to further quantify dose estimates for various products.

Although a complete discussion of current theory on long-term health effects associated with indoor radon progeny exposure is not within the scope of this paper, it is evident that previous studies may have led to underestimations. Auxier (1976), in a review of current literature and research, suggests that it is not unlikely that the total dose (external gamma and internal alpha) to the bronchi of occupants of homes built with uranium-bearing materials over a 50-year period at an average of 15 hr/day would approach that at which the incidence of lung cancer in uranium miners is doubled. Also, Moeller and Underhill (1976b) suggest current changes in construction progeny exposure. Such changes would encompass housing types (smaller, higher density), architectural features (thicker walls, tighter construction, fewer nonfunctional windows, decrease in indoor air movement), and activities that may be transferred to the home environment or vice versa (occupational functions, leisure activities, etc.).

While a case has been made for utilization, the continued storage and/or disposal of remaining phosphogypsum also has ramifications which will bear further evaluation. Measurements need to be made of radon emanation rates from various storage piles and of the impact such emanation will have on adjacent populations.

For the continued utilization of those phosphogypsum materials and others identified as posing an unacceptable radiological impact, some form of control is necessary. The choice of technique would be, first, dependent upon the magnitude of the exposure impact over the long-term and, second, on cost/benefit aspects of implementing and maintaining control. A number of options would be available to manufacturers or builders which would decrease gamma and/or radon daughter exposure. These would include, for radon daughter exposure: (1) material substitutions, (2) improved manufacturing standards, (3) changes in basic building designs, (4) application of sealants, (5) increased ventilation, and (6) removal through adsorption, filtration, and/or chemical reactions (Moeller and Underhill, 1976c). Reductions in gamma radiation could be achieved by the first three means.

It should be noted that some control techniques in specific situations may actually increase exposure. The application of sealants, for example, does increase the gamma exposure to occupants due to the decay of trapped radon and daughters insealed surfaces as described by Culot *et al.* (1973) and Auxier *et al.* (1974a). The net effect of sealant application is presently being pursued, a current treatment of the subject via computer modeling being provided by Moeller and Underhill (1976d). Increasing closed-loop ventilation or high-efficiency particulate filtration of the indoor atmosphere for radon daughter reduction may increase the tracheo-bronchial dose, in addition, due to the resulting increased free-ion fraction (Harley and Pasternack, 1972; Jacobi, 1972; Auxier *et al.*, 1974b).

CONCLUSIONS

The utilization of phosphogypsum in construction materials poses a radiological impact to occupants of such structures, the acceptability of which deserves further evaluation. More than any other raw material, it has a potential for long-term exposure of large segments of the population for the following reasons: (1) the availability of phosphogysum is enhanced through the continuing expansion of phosphoric acid capacity domestically and throughout the world, coupled with the economic and environmental constraints of continued storage and/or disposal of phosphogypsum; (2) the source term concentration of radium-226 and other radionuclides for phosphogypsum is highly significant relative to that of other raw materials in common use in construction; and (3) phosphogypsum can be utilized in numerous construction and consumer product applications due primarily to its physical and chemical characteristics, e.g., compactability, ability to be molded, and relative inertness.

As the search for new raw material resources expands with the depletion of traditional ones, the problem of exposure from primordial radionuclides can be expected to grow. Promulgating standards for specific products or utilizations as they are developed can therefore be a lengthy, confusing, and possibly fruitless process. An alternative, the development of criteria and standards for broad classifications of construction materials, would allow the necessary flexibility while maintaining comprehensibility and efficacy of regulation. Such standards would provide:

(1) the necessary controls on radiation exposure received by the population from all present and future construction materials which by virtue of their radionuclide content have a potential for significant long-term impact;

(2) guidance to commercial industry to serve as input for the utilization of accpetable source term raw material and for the development of new products;

(3) numerical guidelines for construction materials being imported and exported from this country if such trade should be realized; and

(4) guidance on acceptable indoor radon daughter concentrations in structures constructed with such materials (as discussed by Caruthers and Waltner, 1975).

With phosphogypsum, such standards would provide the necessary guidance to industry and the States by establishing the quantity of specific Ra-226 source term phosphogypsum which would be permitted in various products. These acceptable concentrations would reflect prudent public health assumptions, as well as cost-effectiveness of control and alternatives. It is clear that the selection of such "exempt concentrations" solely on the basis of probable economic impact on the building industry is not in the best interest of public health. In a cost-benefit analysis, both the health and economic implications of utilization must be weighed carefully in order to determine acceptable radionuclide concentrations.

Finally, assuming that such standards will be implemented, it is necessary to assure that such utilization can be justified by virtue of the unavailability, both on economic and practical terms, of natural gypsum. This will be of special importance in the United States where such reserves are both large and economically available for extraction. If phosphogypsum utilization is to be seriously considered, alternative means for such use should be reviewed in order to determine if commercial applications other than residential construction materials, which have an unfavorable population interface, are possible.

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THE RADIUM–226 CONTENT OF AGRICULTURAL GYPSUMS

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Gypsum ($CaSo_4 . 2H_2O$) is widely used as an amendment to improve water movement in saline-alkali soils, and may also be substituted for limestone or lime to supply calcium to soils that are alkaline. Most agricultural gypsum is obtained by quarrying the mineral, but substantial quantities are also produced as a byproduct in various chemical processes. In 1975, 1,482,000 tons of agricultural gypsum were sold in the United States; byproduct gypsum accounted for 369,000 tons, or about 25% of the total sold for agricultural use (Minerals Yearbook, 1975a).

At present, the principal source of byproduct gypsum is the phosphate fertilizer industry, and in the United States, Florida is the major source of phosphate rock (Minerals Yearbook, 1975b). To produce phosphoric acid, the phosphate rock – commonly fluorapatite [$Ca_5F(PO_4)_3$] – is treated with sulfuric acid, and the $CaSO_4$ (termed phosphogypsum) is filtered from the acid. Florida phosphate rock may contain from less than 10 to more than 200 ppm of uranium (Guimond et al., 1975a). In a previous study, it was found that soils heavily treated with phosphate fertilizers contained elevated levels of ^{238}U over those expected from ^{226}Ra measurements (Lindeken et al., 1975). In the soil, the relative immobility of uranium with respect to plant uptake is well recognized (Spalding et al., 1972). However, since the properties of radium in the uranium decay chain are similar to those of calcium, the radium content of phosphogypsum is of greater health physics interest. This paper compares the ^{226}Ra and the ^{238}U content of quarried gypsums and phosphogypsums.

SAMPLE SOURCES

Samples of quarried gypsum were obtained from Nova Scotia, Iowa, Texas, and California. Phosphogypsum samples were derived from Florida land pebble phosphates. Commercially active land pebble areas are found principally in north Florida in Columbia and Hamilton Counties, and in west central Florida (the Bone Valley formation) in Polk, Hillsborough, Mantee, Hardee, and Desoto Counties (Roessler et al., 1976). Figure 1 is a map showing the location of these phosphate districts in Florida.

MEASUREMENTS

An aliquot of approximately 250 g from each sample source was sealed in a 200-ml thin-walled aluminum can. These samples were gamma-counted using an 80-ml low-background Ge(Li) spectrometer equipped with a Compton suppression system (Camp et al., 1974). Counting periods were nominally 6×10^4 s.

The ^{226}Ra activity can be determined from the counts in the gamma-ray spectrum at the energies shown in Table 1. Normally, the samples are stored after sealing in the container to allow secular equilibrium to be established between the

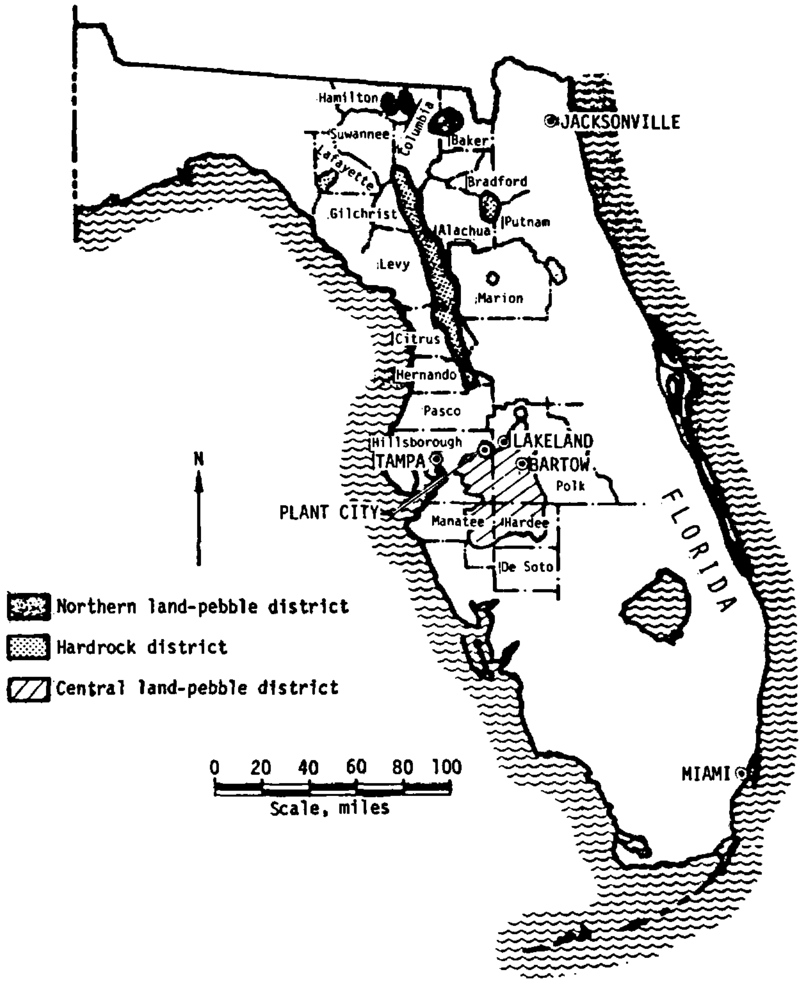

Figure 1. Phosphate deposits in Florida.

radium and radon since the ^{226}Ra measurements are usually based on the activities of the radon daughters, ^{214}Pb and ^{214}Bi. The 186.14-keV gamma ray directly associated with the ^{226}Ra alpha decay to ^{222}Rn is seldom employed because of its lower abundance and because of interference from the 185.72-keV gamma ray associated with the decay of ^{235}U. However, in the present samples, the concentration of ^{235}U is so low that this interference is negligible, and comparison of the 186.14-keV ^{226}Ra decay gamma with those of ^{214}Pb and ^{214}Bi serves as a check for ^{226}Ra – ^{222}Rn equilibrium.

Uranium-238 was determined by measuring the 63.3-keV transition from the decay of ^{234}Th (Coles et al., 1976). Such a measurement, although depending on

TABLE 1

Prominent Gamma Rays from ^{226}Ra and its daughters

Energy (keV)	Intensities/decay	Source nuclide
186.14	0.040	^{226}Ra
295.20	0.202	^{214}Pb
351.92	0.401	^{214}Pb
609.27	0.484	^{214}Bi
1120.28	0.160	^{214}Bi
1764.49	0.166	^{214}Bi

equilibrium between the 24-d decay of ^{234}Th and its parent ^{238}U, avoids the potential equilibrium problems associated with ^{238}U when measurements depend on daughters subsequent to the long-lived trio ^{234}U, ^{230}Th, and ^{226}Ra. Because many of the samples contained ^{238}U at levels below 1 ppm, several of these samples were also analyzed for ^{238}U by isotopic dilution mass spectrometry using ^{233}U as a tracer (Landrum et al., 1969).

RESULTS AND DISCUSSION

Table 2 shows the ^{226}Ra and ^{238}U activities in the samples analyzed. Samples 1 through 4 represent quarried gypsum, and it is clear that the natural mineral is generally characterized by low ^{226}Ra levels. By comparison, the average uranium content of the continental crust is about 3 ppm (Phair et al., 1964). Assuming that the uranium decay series is in secular equilibrium, the associated ^{226}Ra activity would be about 1 pCi/g. Livermore Valley soils contain about 0.6 pCi/g of ^{226}Ra (Silver et al., 1974). As indicated by the activity ratios in the quarried gypsum, near secular equilibrium exists between the parent ^{238}U and the ^{226}Ra. In the phosphogypsums, illustrated by samples 5 and 6, this equilibrium is disrupted. During the chemical processing of the raw material, the uranium tends to go into the acid phase – probably as a uranyl sulfate – while the radium coprecipitates with the gypsum as $RaSO_4$. As the sulfate, the radium is essentially insoluble in water – 2×10^{-6} g/100 ml at 25°C, or two orders of magnitude less soluble than the very insoluble $BaSO_4$ (*Handbook of chemistry and physics*, 1969).

The ^{226}Ra content of the phosphogypsum samples compares well with the approximately 14 pCi/g observed by Bolch *et al.* (1976) in typical phosphogypsums, but is lower than the 33 pCi/g reported by Guimond et al. (1975b). Again, assuming that the uranium decay series is in equilibrium and the removal of radium is quantitative, then 33 pCi/g of radium activity in the gypsum would correspond to about 100 ppm of uranium in the land pebble. It turns out that the partition of

TABLE 2

^{226}Ra and ^{238}U content of agricultural gypsums.

	Activity pCi/g		
Sample	^{226}Ra^{b}	^{238}U^{a}	^{238}U^{b}
1	0.500 ± 5%^{c}	0.509 ± 1.2%	0.414 ± 31%
2	0.143 ± 4%	0.163 ± 1.3%	0.200 ± 30%
3	0.064 ± 14%	0.067 ± 1.4%	(d)
4	0.090 ± 14%	0.076 ± 1.4%	(d)
5	18.4 ± 2%	–	3.66 ± 32%
6	10.8 ± 1.4%	–	0.618 ± 74%

a Mass spectrometry measurements
b Gamma spectrometry measurements
c All error values are at the 2 σ level
d Below minimum detection limit

radium and uranium is quite variable. Guimond et al. (1975c) found that approximately 80% of the product ^{226}Ra was in the phosphogypsum. However, the fact is that the radium content of phosphogypsum cannot be reliably predicted from the uranium content of the phosphate rock.

Any consideration of radiological hazard associated with the use of phosphogypsum must be based on how it is applied to the soil, as well as its radium content. In California, where most of the gypsum is used, applications are seldom at rates greater than 2.2 kg/m^2, and are usually 0.2-0.6 kg/m^2. Since the principal reason for adding gypsum is to improve drainage by replacing the adsorbed sodium on clay particles by the divalent calcium, it is important to thoroughly mix the gypsum into the soil. This mixing is usually accomplished by disking to a depth of about 15 cm. When greater till depths are required, plowing is employed. As long as the clay particles remain flocculated, a granular soil state and good drainage will prevail. Regularly cultivated, this soil should not require annual applications of gypsum; and when applied, such gypsum applications are more for soil quality maintenance than for soil reclamation.

Based on the above application practices and the average 15 pCi/g ^{226}Ra content from Table 2, the radium contribution from extended usage of phosphogypsum can be estimated.

Assume gypsum application = 0.66 kg/m^2, till depth = 15 cm, soil density = 1.5 g/cm^3, and number of applications = 10.

Using these assumptions, 0.45 pCi/g of ^{226}Ra will be added to the soil as a result of the 10 gypsum applications.

When applied to the soil in a matrix containing calcium in such excess, the use of gypsum can be expected to block the plant uptake of radium, since it has been demonstrated that increasing the calcium of plant nutrients reduces the uptake of other alkaline earth cations present (Hungate et al., 1958). This common ion phenomenon is illustrated by the data in Table 3 which compare the radium uptake in both root and leaf vegetables grown in test gardens containing two different levels of calcium.

The radium uptake by the vegetation is taken as the ratio of the radium in the vegetation to the radium in the soil. The data for garden No. 1 in Table 3 give the higher, more conservative uptake. This ratio, 5.6 x 10^{-2}, is then used with the ^{226}Ra content of the soil after 10 gypsum applications to estimate the radium in vegetation grown on that soil that can be attributed to the phosphogypsum. The estimated dry-weight radium content of this vegetation is, therefore, 5.6 x 10^{-2} x 0.45, or 2.5 x 10^{-2} pCi/g.

The radiation dose an individual would receive if his total vegetable diet consisted of items grown in soil containing 0.45 pCi/g of ^{226}Ra was calculated using methods outlined in ICRP-2 (ICRP, 1959a). The maximum organ burdens for the bone were obtained using the following assumptions: radium in the vegetation is soluble in biological fluids, radium concentration in the vegetation is 2.5 x 10^{-2} pCi/g, a hypothetical person consumes 400 g/day (wet weight) (*Agriculture statistics*, 1969) or 80 g/day (dry weight) of vegetables over a 50-year period, and absorption fractions, transfer coefficients, and other ^{226}Ra factors are as given in ICRP-2 (ICRP, 1959b) and ICRP-10a (ICRP, 1969).

Under these assumptions, the total 50-year integrated dose to the bone, which is the critical organ, is 160 mrem.

This radiation dose assessment is probably too conservative, but at present it is impossible to evaluate the probable reduction in radium plant uptake due either to the low solubility of $RaSO_4$ or the effect of the presence of calcium. However, the conservative approach taken does tend to assure that the radiation dose should be less than calculated. It follows then that, at present, there is little basis for concern regarding a radiological hazard from uptake of ^{226}Ra by plants grown on phosphogypsum treated soils.

TABLE 3. EFFECT OF CALCIUM ON ^{226}Ra UPTAKE BY PLANTS

Soil			^{226}Ra in plants, pCi/g (dry wt)	
Garden	Calcium, ppm	^{226}Ra, pCi/g	Broccoli	Turnip
1	3,100	0.477	2.83 x 10^{-2} ± 34%	2.55 x 10^{-2} ± 39%
2	5,200	0.482	1.09 x 10^{-2} ± 100%	1.32 x 10^{-2} ± 70%

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RADIOACTIVITY IN CERTAIN PRODUCTS IN BRAZIL

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WATER

In many countries bottled water is used rather than tap water for hygienic reasons. At times the radioactive content of this mineral water is advertised as proof of its health-giving properties. Samples of such waters were collected in plastic bottles at the source in all Brazilian States except Amazonas. The distribution of their measured radioactive concentration is given in Table 1.

These data might be compared with collections of published data. Radium-226 concentrations range from 10^{-2} pCi/l in river waters to 10^5 pCi/l in certain spring waters in Japan and Russia (Eisenbud et al., 1973). Two cautions should be kept in mind when thinking of radioactivity in drinking water. First, it seems that the greater the radioactivity concentration, the harder the water and the more distasteful. Second, in the case of bottled water, there appears to be an ion exchange process whereby the glass adsorbs the radium.

GAS MANTLES

In a northern suburb in Rio de Janeiro, an Aladdin Lamp factory manufactures kerosene lamps. Two kinds of wicks, or mantles, are made. By far the most popular is a hard, very brittle mantle formed of 98% thorium oxide and 1% each of the oxides of cerium and aluminum, with an average activity of 4.5 nCi ^{232}Th per mantle. A minor production item is the soft wick, impregnated with the soluble, and potentially more hazardous, thorium nitrate. At the burning end the nitrate turns into an oxide.

A radiological survey was conducted in the factory (Cullen et al., 1967). Special attention was given to the furnace sector. Here the cloth mantles, dried but impregnated with the nitrates of thorium, cerium, and aluminum, are fired by an intense flame jet. The supporting cloth is burned away and the nitrates are reduced to oxides. It was thought that long-lived radioactive contamination might be in suspended dust particles in this area either because of the flame jet, or because of mantle breakage which is not uncommon at this point.

A series of measurements with a cascade impactor separating dust according to particle size revealed a considerable concentration of the short-lived ^{212}Bi and ^{212}Pb attached to particles of the order of 0.5 micron, while the long-lived activity was attached to particles above 15 microns. (Cullen et al.-1967).

Repeated measurements of internal contamination of the same person in a whole body counter revealed a fascinating pattern. The low body burden in the morning grew steadily during the day, reached a maximum at the end of the work day, and decayed at night with a 10.6-hour half-life of ^{212}Pb. (Gonzales et al., 1974). Body burdens ranged up to 40 nCi.

TABLE 1

Radioactivity in Brazilian Mineral Waters

Data from Hainberger et al. (1974)

Range in pCi/1 ^{226}Ra or ^{228}Ra	Number of Samples Measured with with activities within range	
	^{226}Ra	^{228}Ra
10 – 100	9	13
1 – 9	9	8
1 – 5	39	28
0.8 – 1.0	6	2
0.6 – 0.8	10	6
0.4 – 0.6	12	7
0.2 – 0.4	36	14
0.1 – 0.2	39	3
0.08 – 0.1	21	–
0.06 – 0.08	10	1
0.04 – 0.08	20	1
0.02 – 0.04	26	–
N.D.	30	40

Whole body counter measurements of some 20 workers from the furnace section however, revealed no measurable long-lived contamination. Three who worked in the laboratory section where the thorium is in the nitrate form, and thus soluble, did show a long-lived body burden (Cullen et al., 1967).

From this we conclude that the hard, brittle mantle does not represent a great risk of producing long-lived body burdens. Concern should be expressed about the fate of waste paper baskets full of broken mantles. As refuse, they become concentrated gamma sources.

FERTILIZERS

In the Araxa radioactive anomaly, and similarly in that of Tapira, in the State of Minas Gerais, the radioactive material occurs in the form of pyrochlore, or of a complex niobium-tantalotitanate compound of rare earths with a certain concentration of radium isotopes. The phosphates are used as fertilizer. The production data are given in Table 2.

TABLE 2. PRODUCTION DATA OF APATITE FERTILIZER, BRAZIL

From Ferreira–1977

Source	Mineral Production* tons/yr	After Flotation tons/yr	P_2O_5 Production (planned) tons/yr
Araxa	1.7×10^6	7.4×10^5	2×10^5
Tapira	2.7×10^6	1.0×10^6	3.2×10^5
Catalao	1.5×10^6	6.5×10^5	1.7×10^5

*19% P_2O_5 and 180 ppm U_3O_2

This might be compared with data from other countries presented in Table 3.

TABLE 3. COMPARATIVE DATA ON CONCENTRATION OF URANIUM IN PHOSPHATE ORES

Country	Uranium ppm.
Jordan†	105 – 149
Tunisia†	32 – 47
Algeria†	110 – 132
Israel†	120 – 140
Brazil	∿153

†From Deleon and Lazarevic (1971)

Normally Brazilian minerals are rich in thorium. The soils and cements are also higher in concentration. It is normal that, in a counting room, especially a whole body counter, the background peak that gives the most problems is from ^{208}Tl. Measurements of thoron concentrations in closed rooms will be interesting, but these must wait for technological improvements in detection.

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THE RADIOLOGICAL ASPECTS OF FERTILIZER UTILIZATION

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INTRODUCTION

Fertilizer has become a mainstay in the world's agriculture community. Through increased reliance on fertilizers, high crop yields are available from limited land resources thus enabling the production of increasing food supplies to feed the growing world population. Over the years, the United States has played and continues to play a dominant role in the worldwide production and use of fertilizers. However, this massive production and use redistributes some elements contained in the fertilizers through the environment, thus giving fertilizers the potential to pollute the biosphere as well as benefit man.

Fertilizers are primarily composed of materials containing biologically available nitrogen, phosphorus, and potassium. The guaranteed analysis of a fertilizer lists the respective-available percent of each of these elements (%N – %P – %K). All fertilizers also contain various concentrations of trace elements such as heavy metals or radioactive elements that may cause undesirable impacts. The principal radionuclides contained in fertilizers are various members of the uranium and thorium decay series and potassium-40. The radionuclides from the uranium and thorium decay series originate mainly from the phosphorus component of fertilizers, whereas the potassium-40 originates from the postash component of fertilizers.

THE RADIOACTIVITY CONTENT OF FERTILIZERS

The radioactivity of phosphate rock was probably first observed in 1908 when the British physicist R. Strutt (1908) found that samples of phosphorite were many times more radioactive than the average rocks of the earth's crust. The uranium content of phosphate rocks ranges from 3 to 400 ppm worldwide. Studies of the variability of the concentrations of natural uranium and thorium in phosphate ores produced in the United States indicate that they range from 8 to 400 ppm and 2 to 20 ppm, respectively (Menzel, 1968; Guimond *et al.*, 1975). The highest concentrations reported were in South Carolina phosphate and the lowest were in Tennessee phosphate rocks.

In 1974, the total U.S. production of marketable phosphate rock was about 46 million tons (Stowasser, 1976). This is contrasted with a production of about 10 million tons in 1950 (Cathcart *et al.*, 1973). At present, the U.S. marketable phosphate rock production accounts for about 40 percent of the total world production. About 30 percent of the U.S. production is presently exported to various countries around the world principally for use by them in the production of fertilizer. Approximately 80 percent of the domestic production is utilized to manufacture various types of fertilizers in plants throughout the United States. For many years, the United States has been both the major producer and consumer of phosphate materials.

The richest U.S. phosphate deposits are in the form of marine phosphorite. These are located in Florida, North Carolina, Tennessee, and the Phosphoria Formation of Idaho, Montana, Utah, and Wyoming as shown in Figure 1.

It is widely believed that the uranium associated with phosphate rock is of marine origin formed by adsorption and coprecipitation with calcium and is closely held in the apatite structure (Cathcart *et al.*, 1973; Osburn, 1965; Habashi, 1959). Several investigators have indicated that, in general, the uranium content of a phosphate deposit increases with increasing P_2O_5 (McKelvey *et al.*, 1956). Habashi (1959) suggested that a better correlation may exist between uranium content and the product of organic substances and P_2O_5 thus implying that a small percentage of uranium is present in combination with the organic substances. Cathcart (1956) reported that the uranium content in the Bone Valley Formation in Florida increases with increasing particle size of the phosphate rock. It has been shown (Guimond *et al.*, 1975) that the uranium daughters in the phosphate ores, at least through radium-226, are in secular equilibrium. They also showed that the products and wastes from upgrading the P_2O_5 content through beneficiation are also in equilibrium. Table 1 lists the average radioactivity concentrations of the products and wastes from beneficiation of Florida phosphate ores. The marketable rock is the basic raw ingredient for the various chemical and physical operations performed to manufacture different fertilizer forms and grades.

In 1974, domestic consumption of marketable phosphate ore for fertilizer production was about 25.6 million tons. Based on the data from Table 1, this ore contained slightly in excess of 1000 curies of radium-226, uranium-238, and thorium-230. This estimate was derived based on analyses of Florida marketable phosphate ore. Since Western phosphate ores and North Carolina ores contain slightly smaller radioactivity concentrations, these estimates may be slightly excessive. However, since Florida marketable phosphate rock comprises approximately 80% of the total U.S. production and thus dominates the industry, the extimates are believed to be reasonable.

The radioactivity in potash is primarily due to potassium-40, although rubidium-87, an alkali metal similar to potassium may be present in minor concentrations as a replacement for potassium. However, little data are available on the concentration of rubidium-87 in various potash deposits. In nature, potassium-40 has an isotopic abundance of 0.0118 percent. Therefore, its concentration in potash ores as well as other materials is directly proportional to the concentrations of potassium in the material.

In 1974, the United States produced 2.6 million tons of potash (K_2O) which was approximately 10 percent of the total world production. However, since most potash used in the United States is for the manufacture of fertilizers, it was necessary to import approximately 3.4 million tons of potash to meet the ferilizer production demand. Approximately 96 percent of this imported potash originated in Canada. Domestic production of potash comes from deposits located in New Mexico, Utah, and California. In 1974, 82 percent of the total domestic potash was produced in New Mexico (Keyes, 1976). Potassium-40 has a half-life of 1.26×10^9 years. Coupled with its natural abundance of 0.0118 percent, the K-40 specific activity is 840 pCi per gram potassium. Therefore, approximately 4200 curies of K-40 were present in the 6 million tons of potash used to produce fertilizers during 1974 in the United States.

TABLE 1

Natural Radioactivity Concentrations in Florida Phosphate Mine Products and Wastes (pCi/g)

Material	Ra-226	U-238	Th-230	Th-232
Marketable Rock	42	41	42	0.4
Slimes	45	44	48	1.4
Sand Tailings	8	5	4	0.9

In considering the potential adverse biological impacts of these materials, it is important to note that the radionuclides of the uranium and thorium series include alpha, beta, and gamma-emitters and therefore can cause both internal and external radiation exposures. Potassium-40 is an emitter of both beta and gamma radiation. As ar result, it too can be a source of both an external and internal radiation exposure. Rubidium-87 is a beta-emitter only and therefore is of concern mainly as a source of internal radiation exposure (NCRP, 1975).

TECHNIQUES OF FERTILIZER PRODUCTION

The basic phosphate mineral used to produce phosphate fertilizers, fluorapatite, unfortunately is very insoluble, and in its original state as extracted from the earth, is practically unavailable as a plant phosphorus source (Slack, 1972). For this reason, drastic chemical treatment with strong acids (sulfuric, phosphoric, or nitric) is necessary to produce soluble phosphate products. Superphosphates and "wet process" phosphoric acid are the major products from phosphate rock acidulation. Figure 2 illustrates the phosphate fertilizers derived from phosphate rock.

In addition to chemical processing of phosphate rock, electric furnaces are used to reduce phosphate rock to elemental phosphorus which in turn is used to produce high-purity phosphoric acid and phosphate chemicals. However, these products are primarily used for industrial and chemical purposes and are not a significant fertilizer source.

In contrast to phosphate rock, potash ore can be used directly as potassium chloride (often called muriates) or sulfur without extensive chemical conversion (Slack, 1972).

As a result of these mining and processing steps, superphosphates, phosphoric acid, potassium chloride, and ammonium make up the building blocks of the fertilizer industry. From these basic materials, thousands of different formulations are produced to fit individual soil and crop needs. Fertilizer materials can be either in a solid form or liquid. The liquid fertilizer products usually have as their phosphorus base soluble ammonium phosphate, phosphoric acid, or superphosphoric acid. Liquid fertilizer now makes up approximately one-fourth of the total U.S. fertilizer consumption.

Different grades or formulations are achieved through bulk blending and mixing of various basic fertilizer materials such as ammonium phosphates, triple superphosphate, and muriate of potash. As a consequence, it is impossible to tell the basic

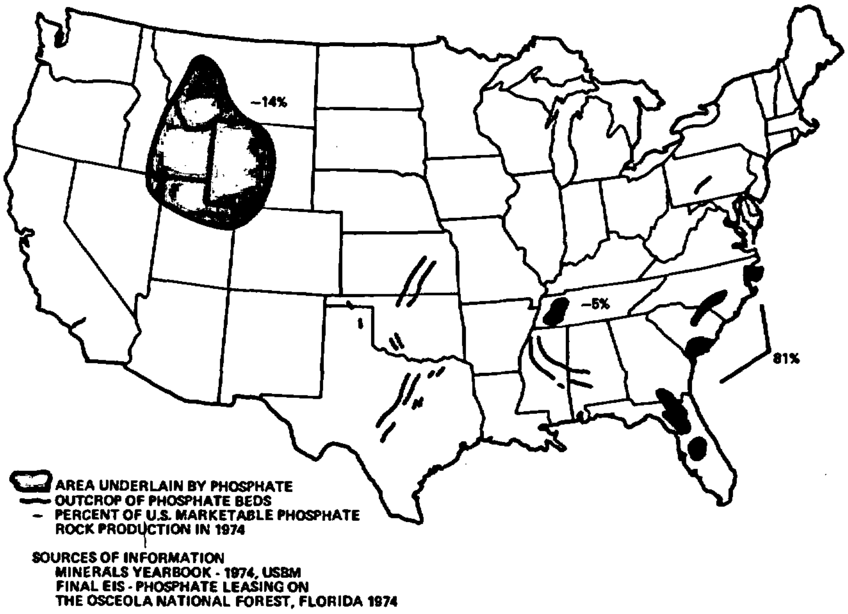

FIGURE 1. UNITED STATES PHOSPHATE DEPOSITS

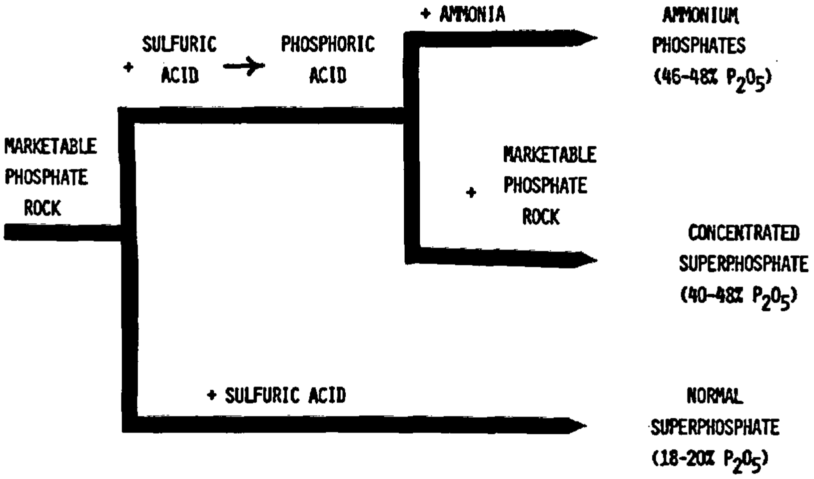

FIGURE 2. PRIMARY PHOSPHATE FERTILIZER PRODUCTION FLOW DIAGRAM

phosphate origin materials of a specific fertilizer formulation once it has been mixed. For example, a 10-10-10 fertilizer may have had its phosphorus content supplied by normal superphosphate, triple superphosphate, diammonium phosphate, or phosphoric acid. This is unfortunate because the origin of the fertilizer's phosphorus content is important in determining the radioactivity in the fertilizer. Although the phosphorus content of a 10-10-10 fertilizer product made from different basic phosphate materials would be the same, the uranium and decay product concentrations would greatly differ depending upon which basic phosphate material was used. Table 2 lists the average radioactivity concentrations measured in various basic phosphate fertilizer materials made from Florida phosphate rock. The differences in the radioactivity concentration of the various products are principally due to the partitioning during the chemical reaction in the acidulation phase of phosphoric acid production.

Gross radioactivity balancing of the input phosphate rock and the output products of the "wet process" operations indicates that approximately one percent of the radium-226, 60 to 80 percent of the thorium-230, and 80 percent of the uranium is dissolved during the acidulating by sulfuric acid (Guimond *et al.*, 1975). Samples of phosphoric acid contained about 1000 pCi/liter of radium-226, whereas the uranium-238 concentration ranges from 50,000 to 100,000 pCi/liter (Mills *et al.*, 1977).

Ammonium phosphates were observed to have radium-226 concentrations of about 5 pCi per gram. Uranium concentrations were a factor of 10 greater than the radium-226 concentrations. The relatively low radium-226 concentration and much higher uranium concentration was attributed to the fact that production of ammonium phosphates uses only ammonia and phosphoric acid with no direct reaction with phosphate rock. Consequently, the bulk of the radioactivity introduced to the reaction comes from the phosphoric acid which is enriched with uranium and deficient in radium-226.

Concentrated superphosphate contained about 4 times as much radium-226 and about the same concentration of uranium as ammonium phosphate fertilizer. This is because concentrated superphosphate is produced by acidulating phosphate rock with phosphoric acid. Therefore, the product, triple superphosphate (TSP), would be expected to display a compromise activity corresponding to the reactant mix, phosphate rock and phosphoric acid.

Table 3 lists the estimated radioactivity present in the various basic phosphate fertilizers produced in the United States during 1974. Of the total radium-226 present in the marketable phosphate ore used for domestic fertilizer production, about 833 curies or 77 percent ended up in the waste phosphogypsum which is generally stored adjacent to each phosphoric acid plant. Normal and concentrated superphospates contained most of the remaining radium-226. Most of the uranium and thorium activity was present in the phosphoric acid and ammonium phosphates although concentrated superphosphates and gypsum each contained sizeable activities of these radionuclides.

Our ability to mass balance the input and output of radium-226, uranium-238, and thorium-230 to within about 10 percent suggests that the bulk of these radionuclides present in the marketable ore is transferred to either the fertilizer

TABLE 2

Natural Radioactivity Concentrations in Fertilizer Materials Made from Florida Phosphates (pCi/g)

Material	Ra-226	U-238	Th-230	Th-232
Normal Superphosphate	21.3	20.1	18.9	0.6
Diammonium Phosphates	5.6	63	65	0.4
Concentrated Superphosphate	21	58	48	1.3
Monoammonium Phosphates	5	55	50	1.7
Phosphoric Acid*	1	25.3	28.3	3.1
Gypsum	33	6	13	0.3

*28 percent acid.

products or the phosphogypsum waste during processing. This implies that large quantities of these radionuclides are not released to the environment through air emissions from fertilizer plants. Additional studies are anticipated to verify this hypothesis through environmental and facility emission sampling. Thorium-232 mass balancing was not as successful. Further examination of the concentrations of this radionuclide in the input and output material is needed to clarify these results. Other radionuclides that could be significant in air emissions are polonium-210 and lead-210 which could be volatilized in calciners and related operations.

FERTILIZER CONSUMPTION IN THE UNITED STATES

Although inorganic fertilizers are employed to some degree in each of fifty States, approximately fifty percent of the total phosphate fertilizers consumed in the United States are used in the ten States listed in Table 4 (Dept. of Agr., 1975). As a result of the high application of phosphate fertilizers in these States, about 86 curies of radium-226, 610 curies of uranium-238, and 630 curies of thorium-230 were redistributed through the agricultural lands of these States in 1974. Similar quantities of these radionuclides are introduced to these States each year.

Table 4 also lists the estimated total radium-226, uranium-238, and thorium-230 activities present in the phosphate fertilizers consumed in each State during 1974. Since the actual amounts of each fertilizer grade used in these States were not available, the estimates were made by weighting the activities presented in Table 3 for each radionuclide by the total quantity (in metric tons P_2O_5) produced in the United States during 1974. Using this formula, a value was established for the number of curies/MT P_2O_5 for each radionuclide. Unfortunately, this formula does not consider the fact that some States use more of one basic fertilizer material than another. As a consequence, the actual total activities of each radionuclide present in

TABLE 3

Estimated Radioactivity Present in the Phosphate Fertilizers Produced in the United States During 1974 (Ci)

Material	Quantity (MT) $x10^6$	Quantity (MT) $x10^6$ P_2O_5	Ra-226	U-238	Th-230	Th-232
Domestic Fert. Prod.	25.6	8.0	1075	1050	1083	11
Normal Superphosphate	3.1	.6	66	63	56	2
Concentrated Superphosphate	3.4	1.6	69	190	160	1
Ammonium Phosphates	5.3	2.4	30	330	340	2
Phosphoric Acid*	10.0	3.1	10	253	283	31
Other Fert. Production	2.0	.3				
Gypsum	25.2		833	153	327	7

*Does not include phosphoric acid used to produce DAP and TSP

the fertilizers consumed in each State may be slightly higher or lower than listed. Data from the literature on phosphate fertilizer consumption in the individual States precludes a more exact estimate of the total radioactivity contained in these fertilizers. Illinois was the greatest phosphate fertilizer consumer accounting for nearly 10 percent of the total domestic usage and redistributing about 15 curies of radium-226, 108 curies of uranium-238, and 111 curies of thorium-230 during 1974.

Potash fertilizers are not consumed at the same rate as phosphate fertilizers in the various States because of differing soil characteristics and crop needs. Table 5 lists the potassium-40 activity present in ten major potash fertilizer consuming States. The three States consuming the most potash fertilizer, Illinois, Iowa, and Indiana, also consume the most phosphate fertilizer.

RUN–OFF AND LEACHING OF AGRICULTURAL LAND

Soluble nutrients and elements such as nitrogen, carbon, and sulfur are generally recycled to a large degree in the biosphere. Other elements such as phosphorus and potassium, which lack a naturally occurring gaseous phase, must be continuously

TABLE 4

Estimated Radioactivity Distribution in the Major States Using Phosphate Fertilizers During 1974 (Ci)

State	Consumption ($\times 10^3$ MT P_2O_5)	Ra-226	U-238	Th-230
Illinois	432	15.1	108	111
Iowa	360	12.6	90	93
Texas	269	9.4	67	69
Indiana	265	9.3	66	68
Ohio	246	8.6	61	63
Minnesota	243	8.5	60	63
Missouri	172	6.0	43	44
Kansas	162	5.7	40	42
California	161	5.7	40	41
North Carolina	142	5.0	35	37
Total U.S.	4657	163	1160	1190

renewed since they do not have a complete cycle. These elements, if not intercepted by plants or held by soils, have a one-way journey to the sea although some fraction of them may be deposited in river beds and other land during the journey. This is also the fate of many trace materials such as the various radionuclides that are incorporated with potassium and phosphate nutrients (Miller, 1976).

Although much of the precipitation in the country is lost through evaporation and transpiration, the amount lost as runoff carries with it large quantities of sediment. Natural erosion losses of sediment alone to U.S. waters have been estimated at over one billion tons annually. Man has accelerated this sediment loss to about four billion tons per year with about half of the loss resulting from agriculture. This sediment loss contains about 4.5 million tons of phosphate (P_2O_5) and 45 million tons of potash (K_2O). Most of this sediment-associated phosphorus and potassium is unavailable to plants. It is not clearly known exactly how much of the radioactivity present in ferfilizers is available in either soluble or insoluble forms. Nonetheless, the loss of sediment containing radioactivity in either form would contribute to increases in the radioactivity concentrations of receiving streams.

TABLE 5

Estimated Radioactivity in the Major States Using Potash Fertilizers in 1974

State	Consumption ($\times 10^3$ MT K_2O)	K-40 (Ci)
Illinois	549	382
Iowa	417	292
Indiana	366	255
Minnesota	293	204
Ohio	281	196
Wisconsin	246	172
Georgia	220	153
Florida	210	146
Missouri	197	137
North Carolina	185	129
Total U.S.	4610	3214

Spalding *et al.* (1972) examined uranium concentrations in numerous rivers that flowed into the Gulf of Mexico. Their studies indicated increased uranium concentrations when compared to data taken from the same rivers 20 years before. They attributed these increases to the widespread application of phosphate fertilizers in agriculture. Uranium is generally present in phosphate fertilizers in the hexavalent state (U^{+6}), which is partially soluble. Therefore, it is not unreasonable to anticipate some runoff to streams and rivers draining agricultural lands. Further, as previously noted, sediment losses would also be expected to carry uranium, both soluble and insoluble, to nearby rivers.

The Mississippi River borders ten States that account for about 38 percent of the phosphate fertilizers domestically consumed. As a result of the tremendous use of fertilizers in these States, runoff losses of nutrients to the river are large. It is estimated that about 395 million metric tons of sediment containing 1.3 million metric tons of P_2O_5 and 6.8 million metric tons of K_2O is lost to this river annually. In addition to these sediment losses, it has been estimated that about 3 times these nutrient losses are annually discharged in solution by the river (Miller, 1976). Estimating the uranium or radium-226 losses is difficult because of the paucity of specific data on agriculture runoff for these and other radionuclides. Table 6 lists the States that border the Mississippi River and the radium-226, uranium-238, thorium-230, and thorium-232 activities present in the fertilizers consumed in the States during 1974. Since the phosphate fertilizers used in these States contained over one-third of the radioactivity total distributed by fertilizer use in the U.S. during 1974, the Mississippi River and its water basin probably receive the greatest amount of radioactivity from agricultural runoff in the United States.

RADIOACTIVITY UPTAKE THROUGH CROPS

Since most of the fertilizers used in America are to improve edible crop yields, the potential uptake of the trace radionuclides present in the fertilizers is a key concern in examining the radiological aspects of fertilizer utilization. Potassium-40 is homeostatically controlled by the body and consequently the impact of K-40 in fertilizers from uptake should not be as variable as the uptake and resultant impact of the uranium and thorium series radionuclides. Consequently, the phosphate fertilizers are of special interest. The quantity of phosphate fertilizer applied to soils is usually expressed as pounds P_2O_5 per acre. Many crops such as potatoes, sugar cane, tobacco, and tomatoes have more than 200 lb P_2O_5/acre applied each year. The potential accumulation of radionuclides in agricultural soil due to phosphate fertilizer loadings was estimated by the use of the following equation:

$$C_s = (7 \times 10^{-8}) \times P \times C_p \times L$$

where: C_s = Concentration of the radionuclide in soil (pCi/g)
P = phosphate fertilizer application rate (lb P_2O_5/acre)
C_p = Relative concentration of the radionuclide per gram P_2O_5 as listed in Table 7
L = Plow layer thickness ($\sim$10 cm)

Applications of normal superphosphate and phosphoric acid result in the greatest additions of radium-226 and uranium-238, respectively. At an application rate of 250 lb P_2O_5/acre for each of these two fertilizers, one application would result in the addition of 0.02 pCi Ra-226/g and 0.03 pCi U-238/g of soil, respectively. A study by Shultz (1965) suggests that uranium, radium, and thorium are strongly absorbed in soil, as is phosphate. Therefore, the losses of these radionuclides may principally be in the sediment erosion loss and be similar to the phosphate lost. Such losses may be from 0-60 percent over many years (Miller, 1976; Pierre *et al.*, 1953). Over a period of fifty years the buildup of radium-226 and uranium-238 due to fertilizer use may be up to 1 and 1.6 pCi/g of soil, respectively, depending upon the types of phosphate fertilizers used over this period. Radium-226 and uranium-238 in soils in the United States typically range from about 0.1 to 3 pCi/g. Therefore, long-term application of phosphate fertilizers may add up to several times more uranium-238 series radionuclides to the plow layer of the agricultural soil than is normally present.

Studies by several investigators have indicated that food crops take up radionuclides such as radium-226, uranium-238, and polonium-210 from the soils in which they are grown (Watters *et al.*, 1970; Mistry *et al.*, 1970; Penna Franca *et al.*, 1965). The amount of uptake has been shown to be dependent upon several

TABLE 6

Estimated Radioactivity Present in Phosphate Fertilizers Used During 1974 in States Bordering the Mississippi

State	Consumption ($x10^3$ MT P_2O_5)	Ra-226 (Ci)	U-238 (Ci)	Th-330 (Ci)
Illinois	432	15.1	108	111
Iowa	360	12.6	90	93
Minnesota	243	8.5	60	63
Missouri	172	6.0	43	44
Wisconsin	127	4.4	32	33
Kentucky	102	3.6	25	26
Tennessee	87	3.0	22	22
Mississippi	79	2.8	20	20
Arkansas	73	2.6	18	19
Louisiana	65	2.3	16	17
Total	1740	61	434	448

TABLE 7

Relative Radioactivity of Phosphate Fertilizers

Phosphate Fertilizer	Ra-226	U-238	Th–230	Th-232
Normal Superphosphate	112	107	95	3
Concentrated Superphosphate	44	121	100	3
Diammonium Phosphate	12	137	141	1
Monoammonium Phosphate	10	115	104	3
Phosphoric Acid	3	169	188	21

factors, including solubility, crop type, soil type, and calcium concentration in the soil. In most cases, the relative concentration factors (concentration in dry plant material/concentration in dry soil) was less than 0.1, suggesting that the radionuclides are excluded to various degrees. Nonetheless, increases in soil radioactivity concentrations may be accompanied by increases in the radioactivity concentrations of the various food crops.

While present knowledge makes it extremely difficult to precisely quantify the national impact from the uptake of radionuclides in the food supply due to fertilizer use, the information available regarding radioactivity concentrations of various fertilizer materials may assist in decision-making regarding which fertilizers should be used to minimize radiological impact. It has been suggested that elevated concentrations of Po-210 and Pb-210 in tobacco leaves may be due to deposition on the tobacco leaves of these radionuclides due to radon-222 decay and the uptake of radionuclides through the plant roots. Therefore, to minimize the effect of these two mechanisms, fertilizers with relatively little radium-226 per gram P_2O_5 could be utilized. Table 7 indicates that a fertilizer with a phosphoric acid base would contribute the least radium-226 per gram P_2O_5, whereas a fertilizer derived from normal superphosphate would add the most radium-226 per gram P_2O_5.

OTHER EXPOSURE PATHWAYS

Umwelt (1975) calculated that, based on the fertilizer use in Germany, an external radiation exposure of 0.11 mrads per year could occur to the gonads and bone marrow from one application of phosphate fertilizer. By estimating the total amount of fertilizer applied over the past 80 years, he calculated that an individual member of the population could receive about 1.7 mrads per year from external exposure to phosphate fertilizers and agriculturally employed persons could receive about 2 mrads per year.

In addition to these exposures, phosphate industry workers may be exposed in the course of their work. Workers in the phosphate operations come in close contact with large amounts of phosphate ores, products, and wastes and are subject to the inhalation of dust generated by unloading, crushing, drying, and other activities. The highest potential exposures were observed in areas of high dust concentrations and in locations around the phosphoric reactor vessel. Windham *et al.* (1976) estimated that direct gamma dose equivalents for workers range from 30 to 300 mrem/yr. The maximum potential dose equivalent rate to the lungs is about 5 rem/yr. However, lower occupancy could reduce this dose equivalent rate by a factor to about ten. Workers in the phosphate industry do not appear to be exposed at levels greater than radiation protection guides for the general population. However, there is a need for more prudent "good housekeeping" measures, particularly with respect to dust levels in various operations. Agricultural workers may also receive some lung exposure due to inhalation of fertilizer dust. In a similar manner to workers at fertilizer production facilities, employees in large fertilizer warehouses may receive increased gamma exposure and radon daughter exposures, although little field data have been collected on such workers to date.

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CHAPTER V
PRODUCTS CONTAINING RADIOACTIVE SOURCES

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PRODUCTS CONTAINING RADIOACTIVE SOURCES

A number of consumer products utilizing sealed or semisealed (foils) radioactive sources and the radiation emitted from those sources for performing some function such as static elimination, smoke detection, or ionizing the air around a lightning rod. The use of a source in such products depends in most cases on the integrity of the source; therefore more than one manufacturer may be involved in producing such devices. This chapter includes papers discussing design and fabrication requirements for such sources in some depth.

The importance of the contribution of the radioactive sources to the function of the product is emphasized in the papers debating the use of radioactive sources for lightning arresters. As is often the case in issues related to innovative uses of radioactive materials, the results discussed in the individual papers in this chapter should be considered as interim findings presented for further study.

An allied issue raised by papers in this chapter is that of international commerce in such radioactive products as lightning rods and static eliminators. The development of internationally accepted standards for both safety and function of such products, as discussed in Chapter I, may assist in control in this area.

INTEGRITY TESTING OF RADIOACTIVE SOURCES USED IN CONSUMER PRODUCTS

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Evaluation of the integrity of radioactive source is an important aspect of a manufacturer's duty to assess the safety of his products. The subject of safety testing practice was dealt with in general terms by Andrews and Fletcher (1971), who considered it under four categories: during manufacture, for transport, for use, and during use. The main emphasis on testing has been concerned with sources for use in industry and medicine since these have been the main fields of application. However, there are a number of consumer product applications and an important example is that of ionisation chamber smoke detectors (ICSDs). These have been used in industrial, marine, and commercial environments for several decades, but more recently there has been a major increase in their use in private homes, and there are now many different designs available.

This paper is concerned only with the integrity testing of smoke detector sources, but the same general approach could be used for other radioactive sources in consumer products. In this assessment of integrity the response of sources to stress conditions and possible long-term effects in normal use have been investigated. The stress conditions have included those likely to arise from accidents and those conceivably encountered in normal use.

A considerable amount of work relevant to smoke detectors has been carried out on these aspects, but relatively little has been published. Niemeyer (1969) made a study of containment integrity of alpha sources employed in ICSDs which had been in use for a number of years. Rosenthal and Feige (1972) gave a review of sources most commonly used in smoke detectors and dealt with various aspects of their use including external radiation, contamination, handling in workshops, destruction by fire, and legal aspects of exemption from licensing.

The Radiochemical Centre has carried out an integrity testing program over a number of years, and this work has been summarized in an internal report (Hall, 1975).

In order to evaluate integrity, a comprehensive set of test procedures is necessary to cover a range of stress conditions. We have based our test programs on national and international standards, on special requirements from regulatory bodies and smoke detector manufacturers, and on our own assessment of what data are needed.

The investigation of possible long-term effects in normal use includes examination of sources from old detectors and a continuing laboratory study of stored sources.

This paper presents data which are particularly relevant to the use of radioactive sources in ICSDs used in private homes.

SOURCE DESIGNS

Alpha sources

The alpha sources described in this report are all based on a rolled foil where the radionuclide is contained in a gold matrix sealed between a silver backing and a thin gold or gold alloy cover over the alpha-emitting surface. The foil is produced by powder metallurgical and metal rolling processes such that the metal layers are consolidated to form a single strip of metal approximately 0.2mm thick. The general construction of a typical foil is shown in Figure 1. The foils are subdivided by cutting into strips or punching out small pieces to produce the sources used in ICSDs. In some cases the cut strips or pieces are mounted directly into holders without any separate process to cover the cut edges. In other designs, blanked pieces of foil

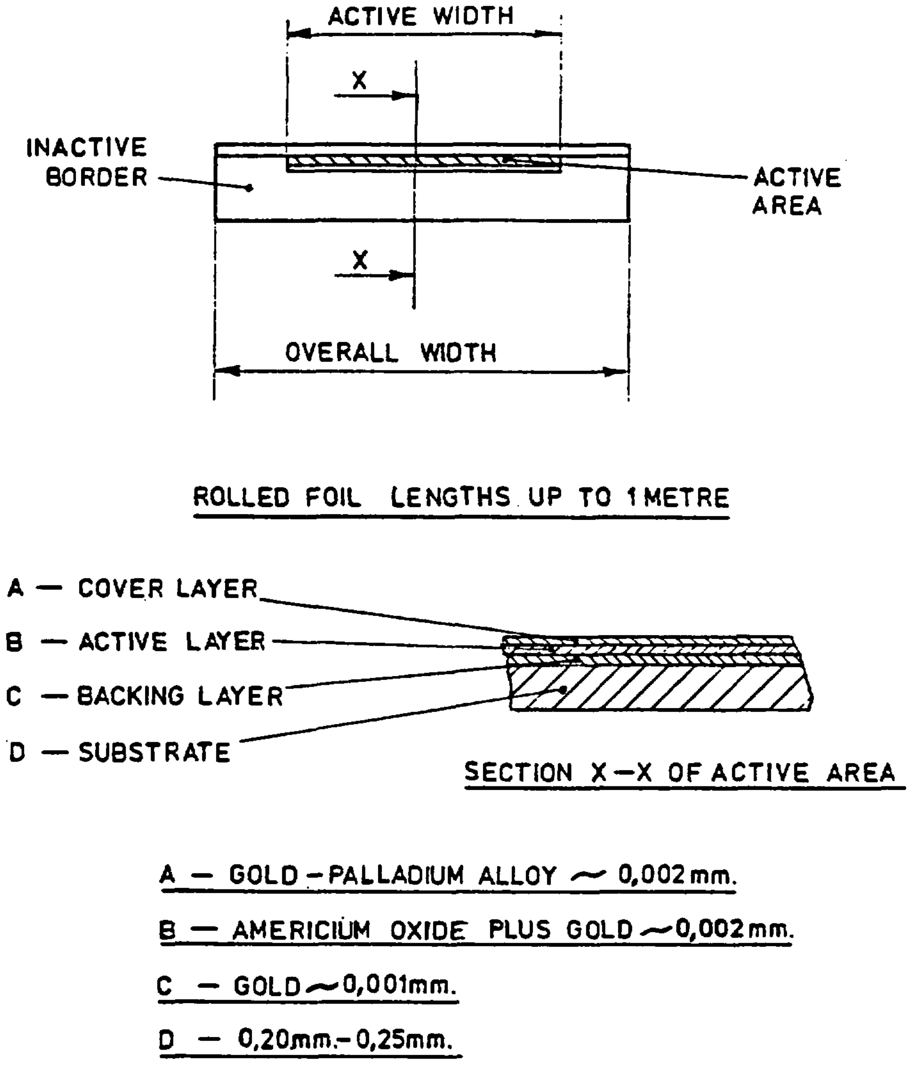


FIGURE 1. Construction of alpha foil

typically 5mm in diameter are mounted in metal holders of such a design that the cut edges are sealed. Examples of both types are shown in Figure 2.

There are a large number of different source designs, and it is impractical to test each one individually. However, the test program has been devised to cover as wide a range of product as possible.

Both ^{241}Am and ^{226}Ra have been extensively employed in smoke detectors, and a considerable amount of testing has been carried out on both types of sources. However, ^{241}Am is used in the majority of detectors currently being produced, and most of the data presented in this paper are for that nuclide.

The activity used can be up to almost 100 μCi, but for the majority of designs it is now less than 20 μCi. For detectors specifically designed for use as consumer products, the usual activity is less than 5 μCi. In the case of sources based on our rolled foil, this represents activity loadings of at most 100 μCi/cm^2 and typically below 40 μCi/cm^2.

The test program has included source activities and foil activity loadings well above those actually used in smoke detectors.

Beta sources

Krypton-85 and nickel-63 have been successfully used in ICSDs, but the test program has been restricted to the latter nuclide. The radionuclide ^{63}Ni is uniformly electroplated as metal onto a metallic backing strip. A very thin inactive front cover is applied by electroplating. Pieces are blanked out from the strip and may be mounted in holders similar to those used for alpha sources.

Nickel-63 sources are not in widespread use, and up to the present time only a limited number of designs have been considered. Their integrity is being evaluated by a test program similar to that described in this paper for alpha sources. The initial results indicate that satisfactory response to a range of stress conditions will be achieved from optimum designs;

The assessment of integrity of both types of sources has been based on measurement of surface contamination and leakage.

METHODS OF DETERMINING SURFACE CONTAMINATION AND LEAKAGE IN STRESS CONDITION TESTS

To determine surface contamination, sources were wiped on all available faces and edges with a cotton wool swab moistened with methyl alcohol. The activity on the swab was measured by liquid scintillation counting, the accepted limit of detection being 0.001 nCi. Although this test specifically measures surface contamination, it is also accepted as a test for leakage.

Leakage was determined by immersion in deionised water at 50°C for a minimum of 4 hours. The activity in the liquid was measured by liquid scintillation counting.

The test procedure was initially to wipe and immersion-test all sample sources and then store until required. Immediately prior to being subjected to stress conditions, they were wiped again and afterwards they were wiped and immersion-tested.

These leakage and contamination tests were applied to at least 5 and normally 10 samples of each source design for each of the stress conditions applied. The accumulated data thus represent the testing of thousands of samples.

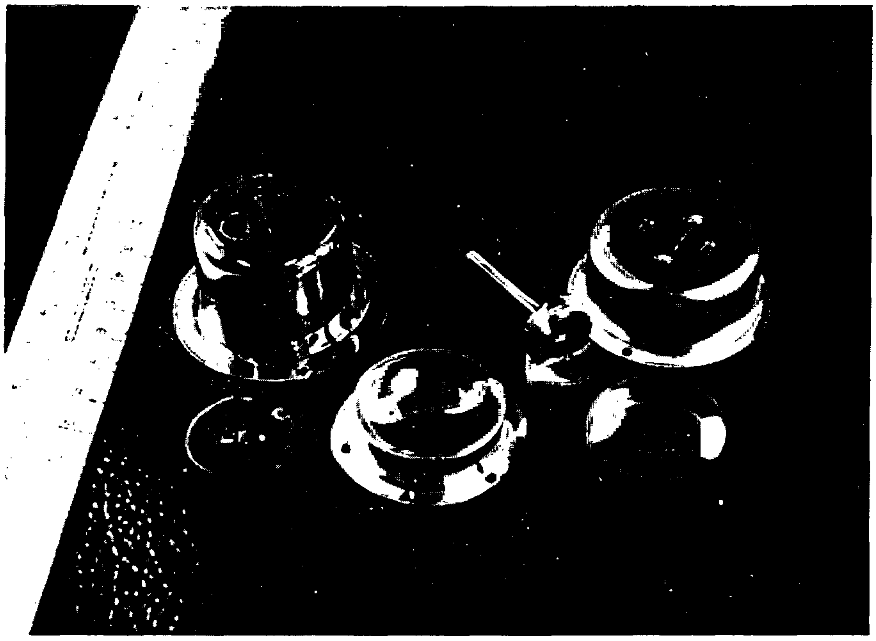


FIGURE 2(a). Examples of cut strips mounted on holders

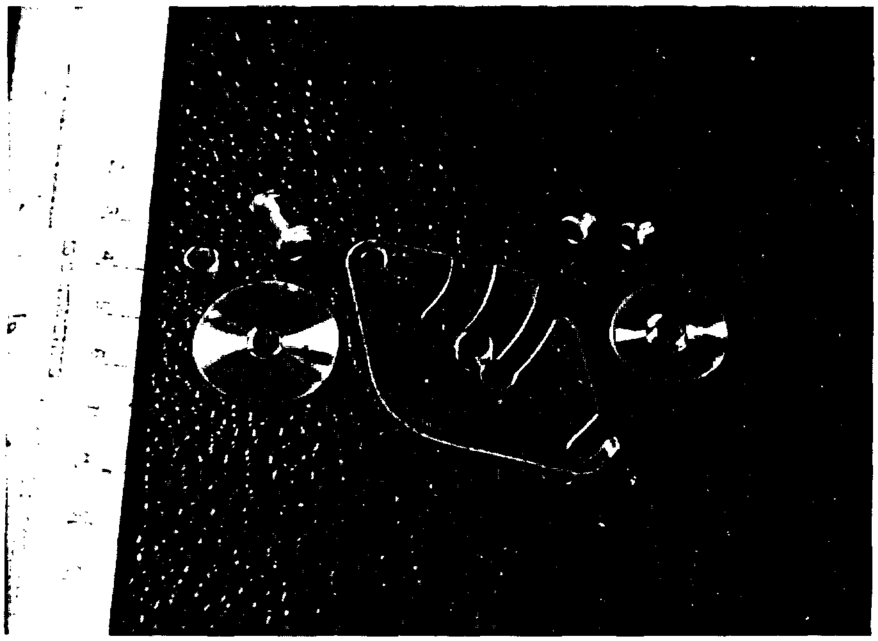


FIGURE 2(b). Examples of punched discs mounted and sealed in holders

TESTS TO DETERMINE THE EFFECT OF STRESS CONDITIONS

International Tests for a Range of Stress Conditions–Special Form Tests

The IAEA has published safety regulations (IAEA, 1973) which detail tests devised to show that the source will survive a transport accident without leakage, though not necessarily without damage. A separate source may be used for each test. The tests are shown in Table 1.

TABLE 1

TESTS SPECIFIED FOR SPECIAL FORM MATERIALS

Immersion	The sample is immersed for 24 hours in water at room temperature.
Impact	The sample is dropped from a height of 9 meters onto a flat, rigid horizontal surface.
Percussion	A steel billet weighting 1.4Kg is dropped from a height of 1 metre onto the sample placed on a sheet of lead supported by a smooth solid surface.
Temperature	The sample is heated in air to a temperature of 800°C, held at that temperature for 10 minutes, and then allowed to cool.

Note 1: To comply with the requirements, leakage after testing to the above conditions must be less than 50nCi in successive immersion tests separated by a 7-day interval.

2: A bending test is also specified for long slender sources, but is not applicable to ICSD sources.

Although these tests were specifically designed for transport purposes, they do give an assessment of ability to stand certain stress conditions and were the first set of tests which were internationally recognised.

The percussion test (Figure 3, 4) and temperature tests (Figure 5) showed significant visual effects. In the latter case, there was evidence of incompatibility between the foil and holder. All of the alpha sources we tested which were designed for use in detectors for private homes passed the tests. Wipe and immersion test results were below 5nCi. Results from one design of mounted source are shown in Table 2. However, it is probable that compatibility problems with some holder designs could result in failure to pass the temperature test.

TABLE 2

SPECIAL FORM TESTS ON 1.5μCi ^{241}AM IN TIN-PLATED BRASS HOLDER

	Range of wipe test results nCi	Range of immersion test results nCi
Immersion	0.00	0.02 – 0.12
Impact	0.00	0.00 – 0.01
Percussion	0.00 – 0.06	0.00 – 0.01
Temperature	0.15 – 1.71	0.09 – 0.60

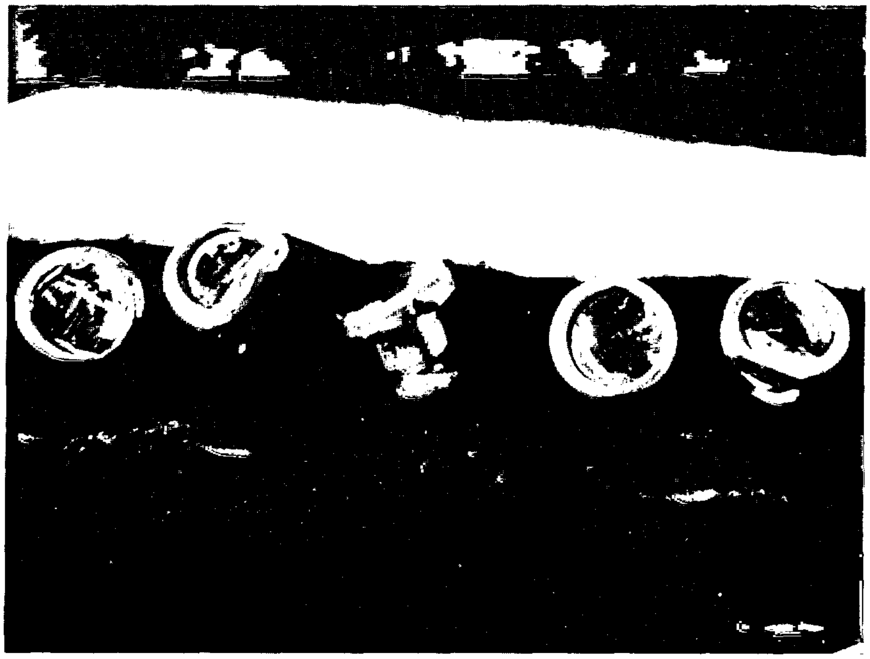


FIGURE 3. Mounted and sealed sources after special form percussion test

FIGURE 4. Cut foil strips after special form percussion test

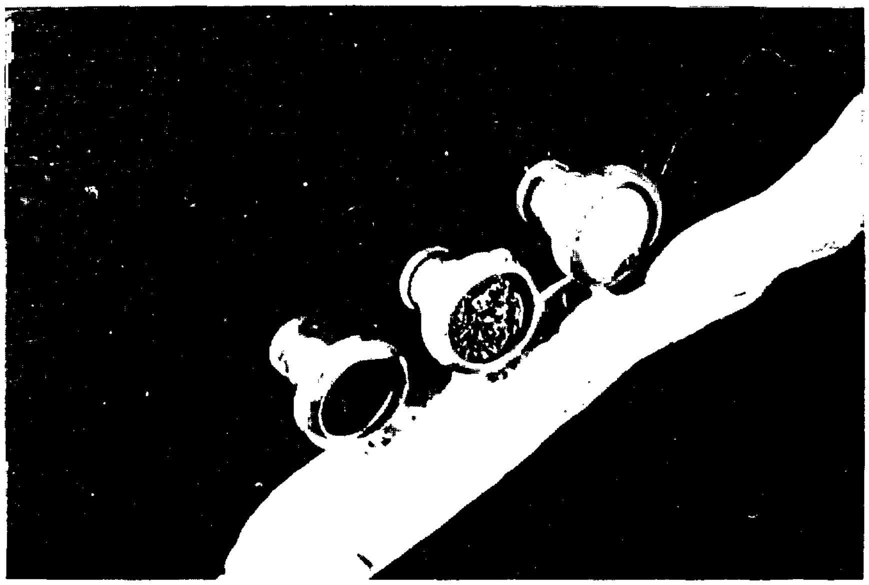


FIGURE 5. Mounted and sealed source in tin plated brass holder before and after special form temperature test — shows extremes of extent of reaction between foil and holder

Tests as Specified in Draft ISO Standard 2919

This standard was based originally on United States of America Standards Institute "Classification of Sealed Radioactive Sources," N5 10-1968. It describes a series of different tests of increasing severity designed to evaluate the safety of sources under working conditions. The tests involve exposure to temperature, external pressure, impact, vibration, and puncture. Full details are given in Table 3.

It also sets out minimum performance requirements for various types of sources, including those used in smoke detectors. These recommendations take into account normal usage and reasonable accident risks, but do not take into account any additional risk of exposure to fire, explosion, or corrosion. If these hazards exist, further testing may be required. The classification for smoke detectors is Temperature 3, External Pressure 2, Impact 2, Vibration 2, Puncture 2 (32222).

Compliance with the tests is determined by the ability of the sealed source to maintain its integrity after each test, integrity being determined by an appropriate leak test method. The acceptance level for wipe or immersion test is 5nCi.

All designs of smoke detector alpha sources we have tested would meet the minimum requirement. Most met a classification 44444 and, by selection of best holder material and foil type, a classification of 66646 could be achieved. Results for five typical source designs are shown in Table 4.

Typical sources after temperature, impact, and puncture tests are shown in Figures 6, 7 and 8.

Abrasion Tests

The following tests were devised to assess the effects of abrasion of the foil surface by dust particles being blown across it and by repeated wiping for cleaning purposes.

(a) By sand particles

500g of SiC grade 120 powder ($\sim 2.2 \times 10^7$ particles) were dropped from a height of 1 metre through a lcm bore glass tube onto the foil which was mounted at 45° to the direction of fall. The foil had an activity loading of $100\mu\text{Ci/cm}^2$ and was 3cm in length with a total activity of 375μCi. Total time for each drop was about 12 minutes, and 100 drops in all were made. After each drop, the foil was wipe tested.

After about 8 hours of abrasion (approximately 10^9 sand particles), 5nCi of activity could be wiped from the foil. After 20 hours of abrasion, the active layer of the foil was visible and the source leaked badly.

It is difficult to relate this test quantitatively to actual operational conditions where the foil surface could be abraded when removing dust or when dust particles could be continually blown across the surface. However, it is clear that the severity of the exposure needed before 5nCi was removed is far greater than would ever be experienced in normal conditions.

TABLE 3

Classification of Sealed Source Performance Standards

	Class						
	1	2	3	4	5	6	X
Temperature	No test	−40°C (20 min) +80°C (1 h)	−40°C (20 min) +180°C(1 h)	−40°C (20 min) +400°C(1 h) and thermal shock 400°C to 20°C	−40°C (20 min) +600°C(1 h) and thermal shock 600°C to 20°C	−40°C (20 min) +800°C(1 h) and thermal shock 800°C to 20°C	Special test
External pressure	No test	25 kPa abs. to atmosphere	25 kPa abs. to 2 MPa abs.	25 kPa abs. to 7 MPa abs.	25 kPa abs. to 70 MPa abs.	25 kPa abs. to 170 MPa abs.	Special test
Impact	No test	50 g from 1 m	200 g from 1 m	2 Kg from 1 m	5 Kg from 1 m	20 Kg from 1 m	Special test
Vibration	No test	30 min 25 to 500 Hz at 5 g peak amp.	30 min 25 to 50 Hz at 5 g peak amp. and 50 to 90 Hz at 0.635 amp. peak to peak and 90 to 500 Hz at 10 g	90 min 25 to 80 Hz at 1.5 mm amp. peak to peak and 80 to 20000 Hz at 20 g			Special test
Puncture	No test	1 g from 1 m	10 g from 1 m	50 g from 1 m	300 g from 1 m	1 kg from 1 m	Special test

TABLE 4

Results of Tests to ISO 2919

Source Description	Temperature	External Pressure	Impact	Vibration	Puncture
3μCi ^{241}Am cut strip crimped on mild steel holder	3*	4	2*	4	6
0.3μCi ^{241}Am cut strip crimped on aluminum holder	5*	4	6	4	5
0.3μCi ^{241}Am cut strip welded on tin plated mild steel holder	6	4	6	4	6
2μCi ^{241}Am disc sealed in stainless steel holder	6	4	5	4	6
1.5μCi ^{241}Am disc sealed in tin plated brass holder	4	4	4*	4	6

*Test discontinued, leak test below 5nCi but source parted from holder

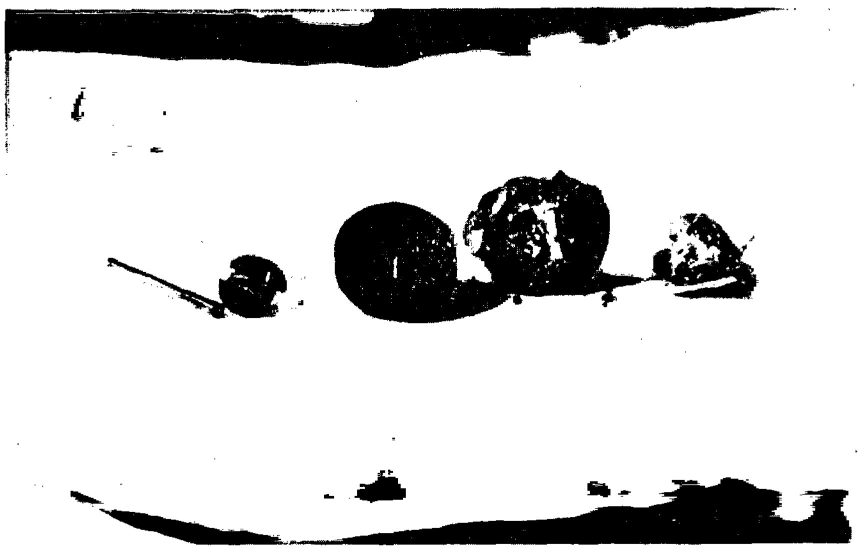


FIGURE 6. Examples of sources after ISO temperature testing

FIGURE 7. Examples of sources after ISO impact testing

FIGURE 8. Examples of sources after ISO puncture test

(b) By continual wiping

Dry cotton wool was fastened to a rubber bung which was then turned by a motor. The bung was drilled off-centre so that a sample could be positioned such that the wool would wipe the sample fairly vigorously. Each source was wiped a total of 10,000 times at a rate of 1 wipe/second.

5,000 wipes were carried out along two perpendicular axes, and the test was repeated using cotton wool moistened with methyl alcohol.

This test was carried out on a 12μCi ^{241}Am disc mounted and sealed in a stainless steel holder and on 3μCi, 2.5μCi and 0.3μCi cut strips mounted on mild steel, plastic, and aluminum holders.

Leakage tests did not give any results above 0.5nCi after 10,000 wipes. Activity accumulated on the swabs during the continual wiping amounted to only 2nCi in the most extreme case.

Special elevated temperature tests

Although the performance requirements for smoke detector sources specified in ISO 2919 is only Class 3 for temperature (-40°C to + 180°C), it is clearly of advantage if their integrity is retained at higher temperatures. The ISO test program enables assessment of sources up to the highest Class 6 (-40°C to 800°C then thermal shock to 20°C), but additional testing to assess the effect of exposure to even higher temperatures is necessary.

Tests on complete smoke detectors containing approximately 100μCi ^{241}Am have been reported previously (Andrews, 1971; Rosenthal, 1972). In these tests detectors were heated to 1100°C in a furnace tube through which an air stream flowed. The air was filtered, and measurement of total activity in the filter gave losses of activity of between 0.01% and 0.2%.

In a similar series of tests (Niemeyer, 1969) on unmounted cut strips of foil, average loss of activity deposited in the filters was 0.002% and average loss of activity including furnace tube debris was 0.31%.

The more recent test program has included a more comprehensive investigation of the response of sources with particular attention to the compatibility of foil and metal holders.

The effect of increasing temperature on unmounted pieces of foil is shown in Figure 9. The samples melted and formed spherical globules at temperatures above the melting point of silver. The results given in Table 5 show that there is no reduction in integrity until the foil melts. Once the foil has melted, active material is present on the surface of the solidified globules. The amount of removable activity range from 0.1% to 6% of the initial source content with a mean value of 1% for the 15 samples which melted.

An extensive series of tests have been carried out on cut strips of foil and discs mounted on a range of holders. Test temperatures of up to 1200°C have been used, and a number of effects observed. When holders which are compatible with the foil are used, there is little loss of integrity even at temperatures up to 1200°C (Figures 10 and 11). Such holders include those made from stainless steel, monel alloy, and aluminum, although in the latter case the holder loses its mechanical integrity on melting at 660°C.

TABLE 5

Results of Heating 2.3μCi ^{241}Am Discs for 10 mins at Elevated Temperatures

Temperature °C	Wipe Tests on 5 Samples nCi	Immersion Tests on 4 Samples nCi
100	0.01 Total	0.08 Total
200	0.04 Total	0.11 Total
300	0.01 Total	0.06 Total
400	0.01 Total	0.04 Total
500	0.04 Total	0.12 Total
600	0.05 Total	0.08 Total
700	0.03 Total	0.22 Total
800	0.05 Total	0.21 Total
900	0.94 Total	0.99 Total
1000	25, 139, 9.4, 9.5, 5.	3.2, 0.84, 1.2, 0.48
	35, 9.0, 8.3, 7.7, 2.3	2.1, 1.3, 1.1, 2.9
	18, 27, 19, 11, 11	5.7, 2.4, 2.9, 1.9

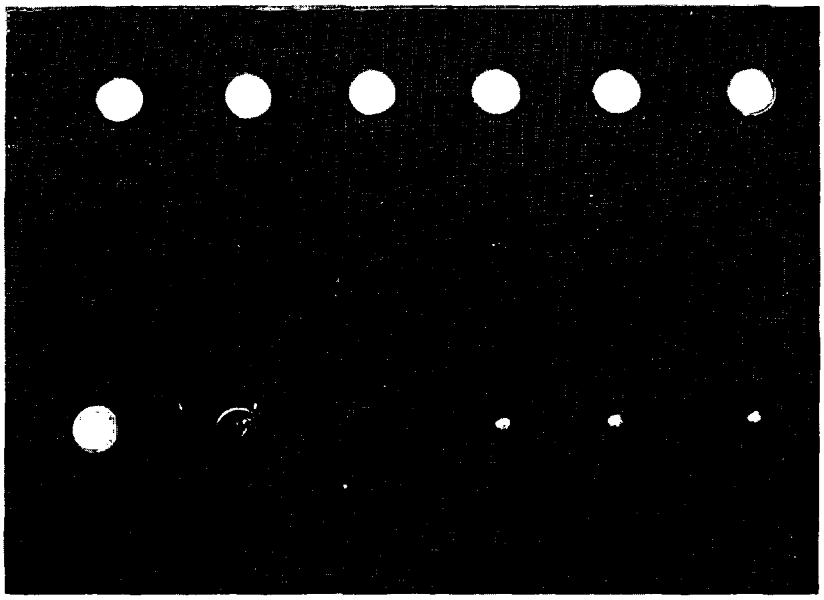
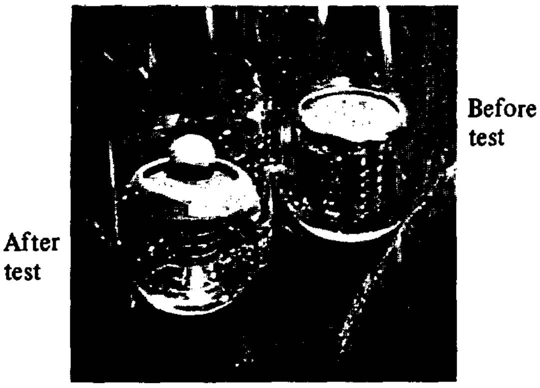


FIGURE 9. Blanked foil discs heated for 10 minutes at temperature 10°C to 1200°C



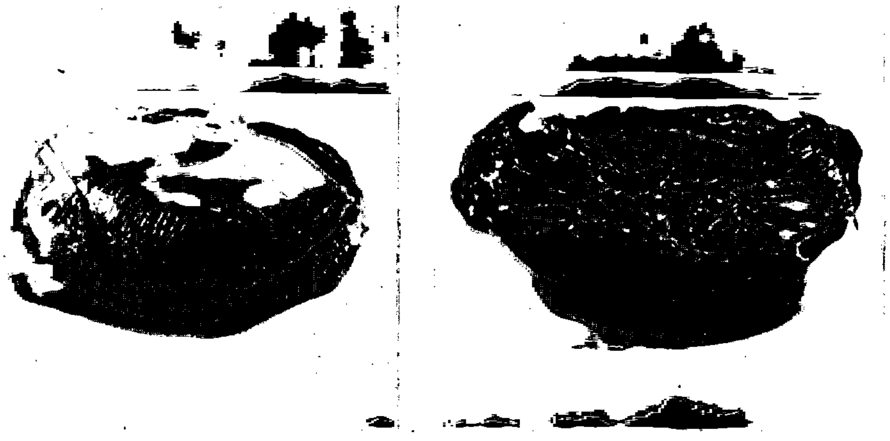
Stainless Steel
Wipe test 1.7nCi

10 minutes at 1000°C

Monel alloy
Wipe test ≤ 1nCi

30 minutes at 1000°C

FIGURE 10. Examples of high temperature tests (stainless steel and Monel alloy holders)



30 mins at 650°C
Immersion 0.37nCi

30 mins at 800°C
Immersion 0.13nCi

30 mins at 700°C
Wipe 0.04nCi
Immersion 10.48nCi

30 mins at 1000°C
Wipe 0.03nCi
Immersion 26.75nCi

FIGURE 11. Examples of high temperature tests on aluminium holders

Compatibility problems have been observed with brass holders and tin-plated holders. Reaction takes place at elevated temperatures, the extent of which varies with type and thickness of metal coating and geometry of holder. Wipe test results vary according to whether active material is trapped by a reaction layer. For most of our tests, there has been no loss of integrity below 600°C, but significant effects have been noted in some cases when this temperature has been exceeded. (Figures 12 and 13)

Many temperature tests have been carried out in a tube furnace with air flowing over the heated source and then through a filter outside the furnace. Tests for activity on these filters have not shown any significant activity compared with earlier tests on high activity detectors. However, in a few of the tests where serious incompatibility problems occurred which resulted in high wipe tests on sources, contamination has been found in debris in the furnace.

These tests have shown that compatibility of holder material has to be considered in any complete assessment of integrity. It is also clearly necessary to carry out heating tests or simulated heating tests on complete smoke detectors. A number of such tests have been carried out recently by The National Radiological Protection Board and ourselves which have shown further material problems. In one case effects were noted from tin-plated components in close vicinity to the source, and in another the use of an ABS plastic loaded with antimony and bromine was shown to have resulted in reaction with the source leading to high wipe tests. The results of one of these tests are shown in Table 6. Most other materials, however, used in a wide range of detectors have been shown to have no effect on integrity.

TABLE 6

Results of One Investigation into Compatibility of Detector Materials and Sources

Components Tested	Wipe Test after heating to 600°C for 1 hour nCi
1.5μCi ^{241}Am in stainless steel holder	0.16
As above, but surrounded by other metal components in detector	0.27
As above, but with addition of ABS plastic loaded with antimony and bromine	55.60
As above, but with normal unloaded ABS plastic	0.01

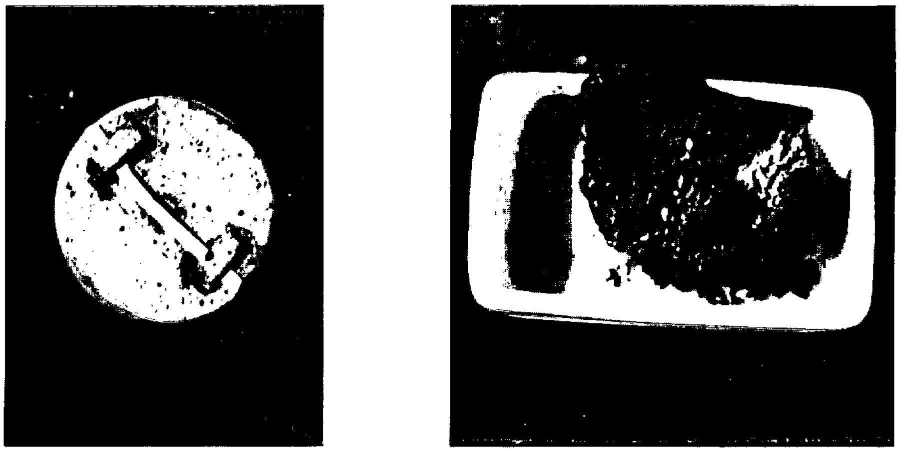
30 mins at 600°C
Wipe 0.16nCi
Immersion 0.1nCi

30 mins at 900°C
Wipe 49.8nCi
Immersion 14.57nCi

30 mins at 600°C

30 mins at 900°C

FIGURE 12. Examples of high temperature tests on plated brass holders



30 mins at 800°C

30 mins at 900°C

30 mins at 700°C
Immersion < 0.01nCi

30 mins at 800°C
Immersion < 0.01nCi

FIGURE 13. Examples of high temperature tests on plated brass holders

Although there are currently no standards specifying very high temperature tests for the ICSDs it is clearly an important aspect of any integrity testing program. Our results show that good performance can be achieved with optimum designs of source and detector, but that performance can be affected significantly even at temperatures as low as 600°C if compatibility problems occur.

Apart from high temperatures, the most important consideration is exposure to corrosive environments.

Corrosion Tests

The tests reported in this section assess the response of sources to relatively severe stress conditions, far more severe than are likely during use in private homes.

Exposure to ozone and salt spray

Exposure to these conditions was requested by regulatory authorities and the tests are described below:

Exposure to salt spray

This test was carried out in accordance with British Standard BS 3116:1970 BSI (1970). Samples suspended a few inches over distilled water in a desiccator were sprayed daily for 16 days with a synthetic sea water solution.

Exposure to ozone

This test involved exposure to ozone for 11 days at a level (4ppm) far in excess of the normally accepted level ($\sim$ 150ppb.)

There were no significant visible effects from either test and all subsequent wipe and immersion tests were below lnCi.

Exposure to sulphur dioxide and hydrogen sulphide atmospheres

Some national regulatory bodies specify that ICSDs should have particular operational characteristics after exposure to these atmospheres. Sources were subjected to these corrosive conditions to determine their effect on integrity.

Exposure to hydrogen sulphide

The test specified by one regulatory body involves exposure to an atmosphere containing approximately 0.1% hydrogen sulphide by volume in air saturated with water vapor at room temperature for 10 days.

A range of sources were tested under more severe conditions of 1% hydrogen sulphide, and no loss in integrity was found.

The same regulatory authority specifies a further test in an atmosphere containing approximately 1% carbon dioxide and 0.5% sulphur dioxide by volume in air saturated with water vapor at room temperature for 10 days. Two tests have been used to assess the effect of exposure to sulphur dioxide, one of which is similar to this, while the other specified by a European regulatory authority is very much more severe.

Exposure to sulphur dioxide

The first test based on British Standard BS 4292: 1968 (BS, 1986) involves exposure to 1 Vol% SO_2.

In this test, the only source samples giving wipe and immersion tests greater than 5nCi were from cut strips of foil of activity at least 24μCi and a loading of 192μCi/cm^2.

The second test is designed to represent exposure in severe industrial environments and is a very exacting check on source performance. The test is based on British Standard 3116:1970.

Samples were placed in a sealed 5-litre breaker about one inch above a 500cc solution containing 20g of sodium thiosulphate. The temperature of the atmosphere was maintained at 45°C, and 10cc of 0.156N H_2SO_4 was added to the solution twice daily for 8 days. Copper cooling coils were placed around the outside of the beaker to ensure condensation. The samples were removed after 8 days, the beaker emptied and cleaned, and the whole process repeated using the same samples for another 8 days.

A significant number of results above 5nCi were obtained for both wipe and immersion tests. In the case of sources with cut edges there were only a few isolated results above 5nCi when samples were less than 5μCi and had an activity loading less than 100μCi/cm^2. However, there were a significant number of high results mainly in the 10-50nCi region from strips above 10μCi and with loadings above 192μCi/cm^2 Two results at 250nCi and 460nCi were obtained from high activity samples of 150μCi content and 400μCi/cm^2 loading.

In the case of sources with sealed edges one design containing 12μCi with loading 40μCi/cm^2 gave two wipe tests results at 6 and 34nCi and nine immersion results between 6 and 150nCi.

It is clear that sulphur-bearing atmospheres cause the formation of silver sulphide. This can lead to surface discoloration and, in some cases, loss of integrity. However, for sources used in ICSDs designed for use in private homes, there is virtually no loss of integrity even with the very severe sulphur dioxide test. Table 7 gives the results of tests on typical designs used for this application.

A further series of tests in corrosive conditions has been carried out to assess the effect of accidental ingestion of sources.

Exposure to body fluids

These tests have been carried out in simulated body fluids. Tests recommended by the National Radiological Protection Board, UK (Webb, 1975) are as follows:

1. Blood

Immersion in lwt % NaCl in water at 37.5°C for 48 hours.

TABLE 7

Results of Exposure to SO_2 (BS 3116: 1959) on Typical Sources Used in ICSDs Designed for Use in Private Homes

Type of Source	No. of Samples	Wipe Test Result nCi	Immersion Test Result nCi
0.3μCi ^{241}Am cut strip on Aluminium holder	5	0.36 – 4.3	1.29 – 3.22
3μCi ^{241}Am cut strip on Mild Steel holder	5	0.28, 10 6.8, 0.38, 0.85	0.03 – 0.44
1.5μCi ^{241}Am disc sealed in Tin Plated Brass holder	10	0.01 – 1.74	0.00 – 0.55
2μCi ^{241}Am disc sealed in Stainless Steel holder	10	0.00 – 0.92	0.00 – 0.11

2. Stomach

Immersion in 0.1N HCl at 37.5°C for 48 hours.

3. Intestine

Immersion in a solution of lwt % sodium bicarbonate, disodium hydrogen phosphate made up to pH9 at 37.5°C for 48 hours.

The results of one series of tests are given in Table 8.

The most severe test is the one simulating stomach fluids where an average of 0.6% of the activity was leached out. Dolphin and Eve (1966) calculated a mean residence time for a radioisotope source in the stomach of 65 minutes, so a 48-hour test may be excessive. However, a previous series of 4-hour tests on a variety of ICSD sources also gave results of approximately 0.6%.

The tests outlined previously have all been aimed at assessing response of sources to stress conditions. The next section covers the investigation of aging effects during normal use which might lead to loss of integrity.

TABLE 8

Results of Body Fluid Tests on 2.7μCi Unmounted ^{241}Am Foil Sources

Test	Activity in Liquid nCi	% Leach	Test	Activity in Liquid nCi	% Leach	Test	Activity in Liquid nCi	% Leach
Stomach	4.9	0.18	Blood	0.18	.01	Intestines	0.25	0.01
	10.4	0.38		0.23	.01		0.43	0.02
0.1N	6.0	0.22	1% NaC1	0.22	.01	1% $NaHCO_3$	0.33	0.01
HC1	22	0.82		0.57	.02	1% Na_2PO_4	0.31	0.01
	33	1.23		0.10	.01		0.21	0.01
Mean	15.33	0.57		0.26	0.01		0.31	0.01

TESTING OF AGED SOURCES

The tests to investigate possible long term changes in integrity include a planned program of regular tests on stored mounted ^{241}Am sources of increasing activity, examination of old stored foil samples, and examination of sources taken from detectors which have been in service.

The results of the planned program are given in Table 9. The source activities and loading per unit area extend far beyond those used in ICSDs. The only visual changes were staining and discoloration of the foil discs. There were a few isolated results above 1nCi during monthly wipes in the first 6 months, but only one at 2nCi since then. After nearly 5 years, there is no evidence of any aging effect leading to loss of integrity.

The tests on a variety of old samples of foil and on foils from detectors used in service cannot be regarded as quantitative since we do not have records of surface contamination prevailing at date manufacture. The acceptance level at that time may have been 50nCi. The foil samples consisted of cut strips with activities ranging from 3-520μCi, loading 2-233μCi/cm^2.

They have been stored under laboratory conditions for between 6 and 12 years. There is no evidence of deterioration apart from staining and discoloration. The highest wipe test recorded was 12.7 nCi from a foil 12 years old, all others were below 10nCi.

A further series of tests was carried out on cut strips removed from detectors which had been in service for 5-15 years. Wipe test results from some 9μCi strips showed contamination levels up to 50nCi, but most were below 10nCi. Our conclusion that these do not show any aging effects leading to loss of integrity is in agreement with that of Niemeyer (1969), who carried out a series of tests on similar sources.

TABLE 9

Long Term Tests on Mounted ^{241}Am Alpha Sources Consisting of 5mm dia Discs in Tin-Plated Brass Holder

Activity µCi	Activity loading µCi/cm	No. of Sources	Positive Tests in Period April 1972 – November 1972 Tested at Monthly Intervals		Positive Tests after		
			Wipe	Immersion	34 Months	40 Months	56 Months
2.5	12.5	6	–	Aug – 1nCi Oct – 7nCi	– –	– –	– –
6	30	6	–	Oct – 1nCi, 5nCi	–	–	–
8	40	6	–	June – 1nCi	–	–	–
11	55	6	May – 1nCi	Aug – 2nCi	–	–	–
25	125	6		July – 1nCi, 5nCi Oct – 2nCi	–	–	–
36	180	6		June – 2nCi July – 8nCi Oct – 2nCi	2nCi	–	–
74	370	6	Apr – 3nCi May – 1nCi Aug – 1nCi		–	–	–

CONCLUSIONS

The results of a comprehensive test program show that there are few stress conditions which will cause loss of integrity in sources used in ionization chamber smoke detectors. In the case of sources for use in consumer products, exceptionally good performance can be achieved with good design practice for all the stress conditions examined. The data accumulated should assist manufacturers in design of detectors and regulatory authorities in radiological hazard assessment.

The results of an investigation into possible aging effects in ^{241}Am sources based on rolled foil provide evidence that no loss of integrity will occur in normal use conditions for at least a period of 20 years.

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EVALUATION OF POLONIUM-210 STATIC ELIMINATORS*

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INTRODUCTION

Static elimination devices using alpha particles emitted from polonium-210 are manufactured and sold to the general public. These devices are used to remove dust from phonograph records, photographic negatives and slides, lenses, etc. Each static elimination device nominally contains about 500 μCi of polonium-210 at the time of manufacture. Twenty-two such devices were purchased from retail outlets and were subjected to a variety of tests to determine their potential release of radioactive material under conditions of normal use and during minor accidents and fires. While the tests were designed and conducted with consistent effort to simulate an expected use environment, they do not repfesent all possible situations.

Polonium is an exceedingly rare element since polonium-210, the most abundant isotope, has a radioactive half-life of only 138 days. A member of Group VI on the periodic chart of the elements, polonium tends to accept two electrons to form a -2 oxidation state. Like its homologues, S, Se, and Te, however, Po can also attain several positive oxidation states (+2, +4, +6). The +4 state is most common in aqueous solution apparently as Po^{4+}, PoO^{2+} or PoO_3^{2-} (Kleinberg et al., 1960).

In fabricating sources, polonium is sorbed from solution by silicate ion exchange beads, and the beads are then heated to form ceramic microspheres. These microspheres are fixed to an aluminum backing plate with epoxy adhesive (Fig. 1). In order to attain high source output, no covering is placed over the microspheres except for a metal grid, which prevents abrasion. The radiation source is typically mounted near the brush used to sweep dust from the object being cleaned (Fig. 2). An information plate is affixed to the plastic body of each device. At the time testing was begun, the sources had undergone radioactive decay so that they were estimated to contain between 125 and 250 μCi each of polonium-210. The devices were subjected to both "normal use" tests and to more severe "accident" tests, and the amount of polonium-210 released was measured after each test.

Loss of radioactive material from the sources could potentially occur either by abrasion of microspheres or by removal of more or less intact microspheres. In order to be better able to recognize whole microsphere releases, the size of individual microspheres was first determined. The diameters of 71 microspheres, arbitrarily selected from 3 different static eliminators, were measured under 400X magnification using a calibrated microscope. The range of diameters of the microspheres examined was 20-60 μm with an average of 38 μm (Fig. 3).

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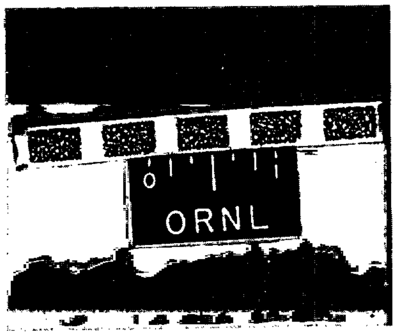

FIG. 1. POLONIUM-210 SOURCE

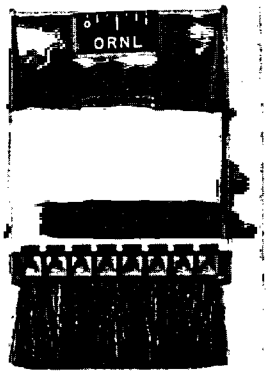

FIG. 2. STATIC ELIMINATOR BRUSH

NORMAL USE CONDITIONS

Wipe tests were made of the devices, their shipping containers, and the source surfaces using cotton-tipped medical applicators. Contamination of the cotton was determined by measuring alpha radiation from the cotton tip. Wipe tests of the original shipping containers and the devices, excluding the sources themselves, removed less than the minimum detectable alpha (0.5 pCi) or beta/gamma (17 pCi) activity in all cases. When the sources were wiped directly, without removal of the protective grid or removal of the sources, widely different amounts of contamination were removed (Table 1).

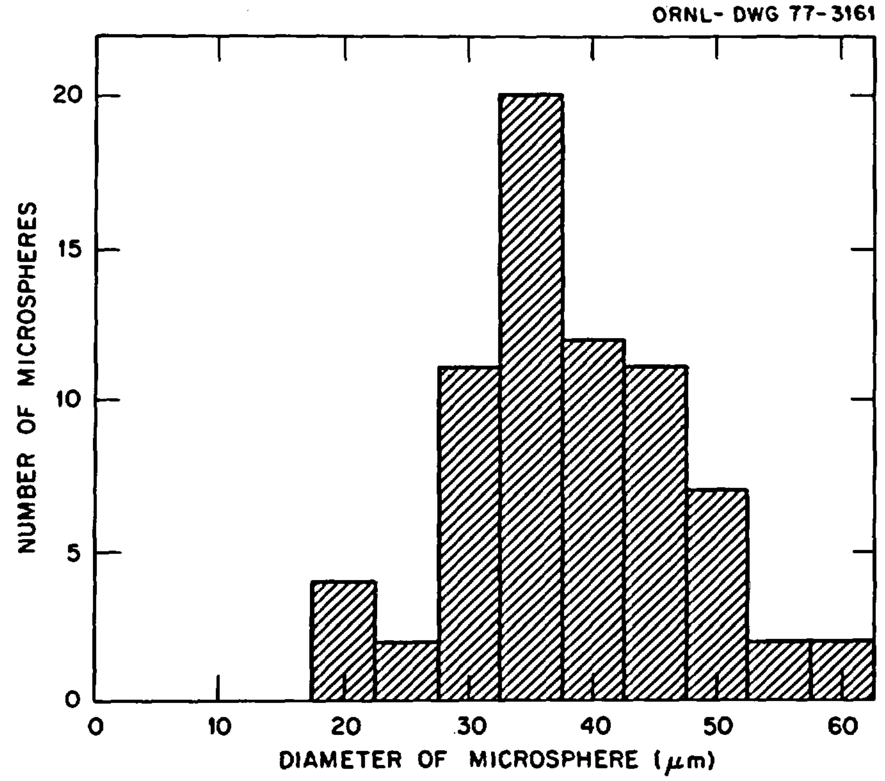

FIG. 3. SIZE AND FREQUENCY DISTRIBUTION OF MICROSPHERES

Several of the sources were selected at random and were wiped repeatedly to determine if all contamination could be removed by an initial wipe. Again the removal was widely variable (Table 2), and no distinct pattern of contamination resulted.

It appears that the degree of contamination depends, in part, on how effectively the cotton penetrated the protective grid to contact the source surface. Some of the sources (7, 9, and 10) consistently released substantially higher levels of contamination than others (11 and 15). It did not appear that wiping the sources either diminished or increased the probability of contamination of subsequent wipes.

Five of the sources were subjected to more vigorous wipe tests to determine the size of particles removed. Sources 6, 7, 8, 9, and 15 were removed from their mounts and a 4.1-cm-diam smear paper pressed firmly against their active surface so that the paper covered the five rectangular areas (0.64 cm by 0.79 cm) of microspheres (Fig. 1). The papers were then examined for particles under a microscope and were analyzed for alpha activity by measuring the radiation emitted from the papers. All the particles observed were very small. Of 90 particles whose size was determined,

TABLE 1
CONTAMINATION REMOVED BY WIPE TESTS OF ALPHA SOURCE SURFACES

Source Number	Alpha Activity, pCi
1	200
2	2,970
3	1,310
4	200
5	420
6	920
7	850
8	3,560
9	190
10	2,310
11	80
12	1,740
13	570
14	1,450
15	180
16	270

TABLE 2
CONTAMINATION OF TEN CONSECUTIVE WIPE TESTS OF SOURCE SURFACES

	Alpha Activity, pCi						
	Source Number						
Smear No.	2	7	9	10	11	13	15
1	4,635	7,679	9,504	5,195	226	1,938	113
2	559	12,321	2,371	2,817	107	2,444	200
3	1,712	5,401	1,858	6,520	60	8,571	866
4	2,131	1,459	3,330	3,177	160	2,817	127
5	999	2,957	3,510	937	53	1,725	286
6	3,936	4,103	2,624	15,425	224	3,616	147
7	1,998	2,344	1,732	3,110	147	2,824	127
8	1,479	2,458	1,798	1,092	253	2,824	120
9	1,259	3,390	1,205	1,558	73	2,380	93
10	733	8,971	1,492	1,081	360	1,638	80

only 35 were larger than 5 μm. No intact microspheres were removed from the source by this sampling procedure. Most of the particles were between 1 and 5 μm and all were irregular in shape. Alpha activities on the five papers used to collect the particles were 23,400, 7,940, 23,600, 400, and 1,590 pCi.

AIR SWEEP TEST

Static Eliminator No. 13 was placed inside a glass tube affixed with inlet and outlet air lines and a filter as shown in Figure 4, to determine if an airflow across the static eliminator would remove activity. Air at 25°C was passed through the glass tube at 0.4 cm/s for 30 minutes. The test was then repeated using air at 70°C and a new filter. The static eliminator and the glass tube were wiped, and the wipes were analyzed for alpha activity after each test. The filter was also analyzed for alpha activity. No detectable activity was removed by either test.

VIBRATION TEST

Source No. 16 was enclosed inside a small plastic box which was placed on top of a window air-conditioner as a simulation of vibration stress that might occur in homes where static eliminators were used. (Vibrational accelerations of the air-conditioner at a frequency of 100 hertz were as follows: along the source length—0.30 ms^{-2} average, 0.98 ms^{-2} maximum; across width of source—0.62 ms^{-2} average, 1.5 ms^{-2} maximum; and through thickness of source—0.64 ms^{-2} average 2.5 ms^{-2} maximum.) At the end of 16 days, the interior of the box, all surfaces of the static eliminator device except the source itself, and the source surface were wipe tested. The removable activity was 60, 60, and 726 pCi, respectively, indicating that very little release was caused by vibration.

An additional six sources were tested using a vibration test instrument. The sources were covered with cellophane tape with the sticky side of the tape positioned near but not touching the source surface. The sources were mounted on a rack so that the axis of vibration was perpendicular to the source surface and so that any particles dislodged would be caught by the cellophane tape. After each test, the tape was carefully removed and surveyed for alpha contamination. Three separate tests were run for 1 hour each: 5-mm amplitude at 7 hertz, 2-mm amplitude at 120 hertz (a resonant frequency), and 0.05-mm amplitude at 200 hertz. In no case was any alpha contamination detected on the cellophane tapes.

Leach Tests

Source surfaces were leached with tap water, soap and water, and chemical solutions typically found in photographic dark rooms where static eliminator brushes are used. Solutions included: Kodak developer, Kodak fixer, and acetic acid. In addition, one source was leached with saliva.

Two sets of tap water/soap and water leaching experiments were conducted. In the first set the sources were suspended in 5 milliliters for 24 hours. The solutions were analyzed by liquid scintillation counting. Surprisingly, almost ten times more polonium-210 was found in the tap water than in the soap and water solution (Table 3).

TABLE 3
LOSS OF POLONIUM-210 FROM SOURCES DUE TO LEACHING IN VARIOUS SOLUTIONS

Leach Solution	Alpha Activity in Leach Solution, nCi
Tap Water	219
Soap and water	21
Saliva	42
Kodak Developer	10
Kodak Fixer	No analysis*

*Solution interference with the scintillation liquid used in analysis.

The second set of tap water/soap and water experiments was designed to clarify this observation. Three static eliminator source strips were cut apart to yield 15 separate sources. Care was taken not to distort or otherwise damage the source material or its substrate. Each of these sources was leached with 10-ml quantities of tap water and soapy water for various time periods. The leaching solutions were decanted, dried, and analyzed to detect alpha activity. None of the individual sources consistently released detectable contamination and 2 of the 15 did not release activity in any test. In the second test series, soapy water was more effective in removing alpha activity from the sources (16 times out of 32 tests) than was tap water (2 times out of 31 tests).

Because the leaching effectiveness was so erratic and because soapy water appeared to be more effective than tap water, it was suspected that fine particulate material was loosened from the source surface rather than actual dissolving of the polonium. This suspicion was confirmed as follows: Another 15 sources were leached with about 10 milliliters of soapy water for 24 hours to yield a relatively highly contaminated solution. This solution was decanted and then passed through a Whatman No. 40 filter paper and evaporated. Both the residue and the dried filter paper were analyzed for alpha activity. Approximately 99% of the total alpha activity leached from the source was on the top side of the filter.

Leaching the sources with Kodak fixer or Kodak developer or with saliva removed amounts of radioactivity comparable to water or soapy water. Ten percent acetic acid removed traces of contamination from each of the three sources on which it was tested. The consistent effectiveness of acetic acid solutions may indicate some attack on the epoxy material of the source. Nonetheless, acetic acid solution did not remove as much activity as many of the soapy water tests and any chemical attack that occurred was very slight.

After the sources were removed from the leach solutions and allowed to dry, wipe tests of the leached areas and the interior surfaces of the leach test vessels were obtained. No intact microspheres were found on the wipes. The results (Table 4) of these wipe tests are also adjusted to the total active surface areas.

TABLE 4
WIPE TESTS OF SOURCE SURFACES AND LEACH TEST VESSELS

Leach Solution	Alpha Activity on Wipe, pCi	
	Source Surface	Interior Surface of Bottle
Tap water	13,100	22,200
Soap and water	1,400	50
Saliva	3,600	67
Kodak developer	50,600	518
Kodak fixer	113,000	500

MINOR ACCIDENT TESTS

Static Eliminator No. 14 was subjected to three tests that were designed to simulate conditions of greater stress than would occur under normal use but that might occur in household accidents.

Crush Test

The device was sealed in a plastic bag and stepped on once by a 165-lb man. The only damage was a minor dent to the metal grill used to prevent accidental contact with the source surface. No activity was found inside the plastic bag following the test.

Drop Test

The device was dropped once from a height of 3 feet onto a concrete floor and then placed inside the airflow test chamber shown in Figure 4. Air was blown across it at a velocity of 0.4 cm/s at room temperature for 30 minutes. No activity was found on the filter, inside surfaces of the glass tube, or surfaces of the static eliminator.

Dropping a One-Pound Weight on a Source Surface

The source was carefully removed from the static eliminator and a piece of adhesive tape was placed over the source surface. The source was sealed inside a plastic bag and positioned on a flat surface, and a flat-surfaced one-pound weight was dropped once on the back side of the source from a height of 3 feet. Examination under 400X magnification revealed no visible damage to the source surface, and only 6000 pCi of alpha activity was found on the adhesive tape. A wipe test of the inside surfaces of the plastic bag recovered 76 pCi of alpha activity which presumably came from the source backing since the source surface was covered during the test.

The adhesive tape was examined using the microscope to determine the size of the particles adhering to it. Unfortunately, the adhesive tape contained microscopic solid

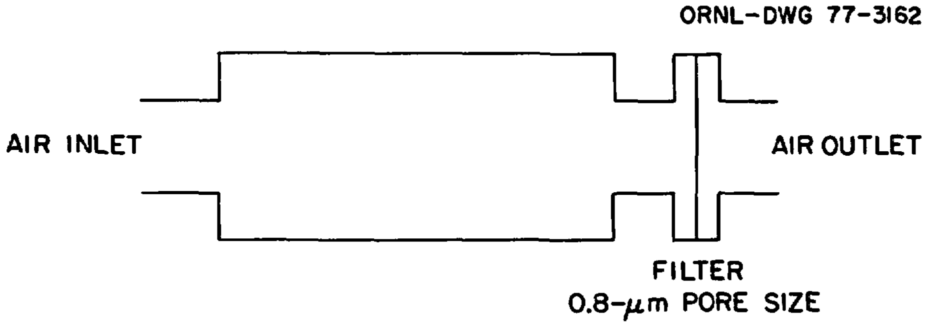

FIG. 4. APPARATUS FOR DETECTING AIR TRANSPORT OF ACTIVITY FROM SOURCE

particles that could not be distinguished from fractured polonium-210 microspheres. Undamaged microspheres, which would have been identifiable because of their spherical shape, were not found on the tape.

FIRE TESTS

Low-Temperature Test

Static Eliminator No. 5 was placed in a stainless steel container inside a furnace, and air was passed through the container at 0.4 cm/s. The outlet gas traveled through a water trap that would collect airborne activity. When the furnace was gradually heated from room temperature to 250°C (100°C each 15 minutes), smoke began to flow into the water trap. This smoke probably originated from the burning or decomposition of the hair in the brush or from the plastic handle (Fig. 5). At 420°C, black-colored solids began to deposit in the water trap and the 0.48-cm outlet line began to plug. At 440°C the outlet gas line was completely plugged, and the test was terminated. Analysis of water from the water trap by scintillation counting revealed 29,000 pCi alpha activity retained in the trap. The stainless steel container was opened and probed with a radiation detector to locate the activity. Samples of the charred material from the stainless steel container had small traces (16 pCi) of alpha activity. The source surface was completely covered with a thin adherent black-colored material, apparently partial combustion products from the brush and

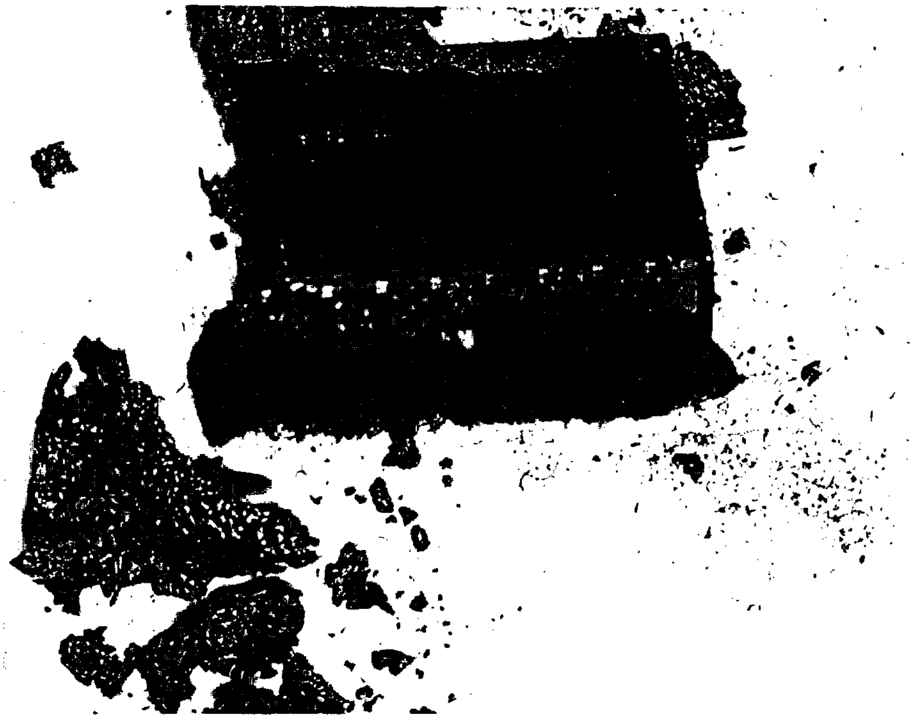

FIG. 5. AMBIENT TO 440°C TEMPERATURE TEST

plastic. A wipe of this material yielded 61,000 pCi alpha as removable contamination. Wipes of the charred plastic yielded only small traces (16 pCi) of alpha activity. The outlines of the microspheres were clearly visible. No loose microspheres were found after the test.

Ambient to 900°C

The source was carefully removed from Static Eliminator No. 10 and placed in a quartz tube inside the furnace. The tube had an inlet air line and an outlet air line containing a filter to collect airborne activity. A backup water trap was provided to trap any polonium-210 that might pass through the filter. The temperature of the source was continuously monitored using a calibrated thermocouple placed directly over the source, and air velocity through the tube was controlled at 21 cm/s using a calibrated rotometer. The source was heated from room temperature to 900°C at a rate increase of 100°C every 15 minutes. The filters were changed at 600, 700, 800, and 900°C and again after the source had cooled to room temperature. Various amounts of polonium-210 were found on the filters (Table 5). No microspheres were found on any of the filters when they were examined using a microscope.

TABLE 5
POLONIUM-210 ACTIVITY ON FILTERS FROM HIGH-TEMPERATURE TEST

Filter No.	Temperature Range	Polonium on Filter	Observations
	°C	µCi	
1	25-600	1.83	Source adhesive decomposed
2	600-700	0.038	Color of source unchanged
3	700-800	0.292	Color of source darkened
4	800-900	0.153	No visible change
5	900-25	0.0083	No visible change
	Total	2.32	

The source was removed from the quartz tube and examined at 400X magnification. Nearly all the microspheres were still on the surface of the source. The color of the source surface, however, had changed from light brown to black, and although the microspheres were still attached to the source, they were dislodged when lightly touched with a medical applicator.

The water trap beyond the filter contained only 0.068 µCi. Total polonium-210 remaining in the quartz tube was 86.8 µCi. Activity on the filters in the air outlet line was 2.32 µCi. The total amount of polonium recovered was about 90 µCi compared to the estimated initial level of 125 to 250 µCi in the source.

DISCUSSIONS AND CONCLUSIONS

No detectable radioactivity was released in any of the tests that did not involve direct contact with the source. Direct physical contact with the active source surfaces removed quite irregular amounts of detectable radioactive contamination. Even moderately vigorous direct smearing of the source surfaces failed to remove whole microspheres, however, and the particulate material removed was many times smaller than whole microspheres. Results of leaching tests were also highly variable and soapy water appeared to be more effective than tap water.

Results of both the wipe tests and the leaching tests are characteristic of small particulate removal from the sources rather than removal of ionic- or atomic-sized material. Effectiveness of filtration at removing contamination from leach solutions (ca. 99%) supports this conclusion.

Minor physical abuse that might reasonably be expected in a normal household such as dropping the device, stepping on it, or dropping an object on the device failed to dislodge radioactive material. Only the small amounts of contamination typically removable by direct surface contact with the sources were released by these minor accidents.

Heating the static eliminators to the point of charring the brush and plastic holder (∿440°C) increased the smearable contamination by about tenfold but the integrity of the source itself was not destroyed. Firing the devices at temperatures as high as 925°C volatilized a few percent of the source radioactivity. Almost all this activity was volatilized below 600°C and appears to be released by surface fracturing of the source under thermal stress rather than vaporization. Since the test was done only once, it is not clear that the observed release would consistently occur. After firing at 925°C, the source particles are effectively a loose power because the mounting cement has been destroyed. All in all, the source integrity is very high in the normal use situations simulated by these tests. Within the scope of the tests conducted, inhalation or ingestion of the particulate residue from burning the source at high temperature appears to be the greatest hazard to users.

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SMOKE DETECTORS CONTAINING RADIOACTIVE MATERIALS

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Each year in the United States, fires kill about 12,000 persons, cause more than 300,000 serious injuries and result in substantial property loss. The fire protection community is dedicated to reducing this horrendous toll. Vast sums have been spent in research and development in the areas of fire prevention, detection, extinguishment, and education to provide the tools to minimize such tragic losses.

The invention of the ionization chamber smoke detector in Switzerland 35 years ago represented a unique breakthrough in the history of fire fighting. For the first time it became possible to obtain a very early warning of a fire condition with the accompanying advantages of early evacuation and application of prompt countermeasures. Since fire experts soon recognized the value of the ionization detector for the protection of life and property, this early warning device rapidly gained international significance.

The operating principle of the ionization detector is relatively simple. Each device contains an ionization chamber in which the air between two electrodes is ionized by a radioactive source, thus permitting an electric current to flow across the air gap. Thermal decomposition during a combustion process produces millions of particles ranging in size from less than 0.01 to 10 μm and larger, the larger particles being visible to the human eye as smoke. These particles are carried upward by the heat or by Brownian motion to the detector which is normally located on the ceiling. The particles enter the ionization chamber through openings in the detector body and become attached to the moving ions comprising the electric current. Current flow is thereby reduced, and the potential between the electrodes rises. These changes trigger an electronic circuit, and an alarm is released.

The purpose of this paper is to discuss the radioactive sources contained in ionization smoke detectors and to review the public health and safety aspects related to such use. In principle, any kind of ionizing radiation can be used to ionize the air in the detectors. In practice, alpha or beta emitters are used. For technical reasons alpha particles are generally preferred because of their low penetration and the high density of ionization they produce.

The most widely used source material is americium-241. A few detector manufacturers still use radium-226, and one U.S. manufacturer recently introduced detectors using nickel-63 as the source material. The radionuclides in the form of americium oxide or radium sulphate are uniformly mixed with gold, formed into a briquette, and sintered above 800°C. The briquette is then mounted between a backing of silver and a front cover of gold and sealed by hot forging. The composite metal briquette is cold rolled in several stages to give the required active and overall areas, with thickness being reduced to approximately 0.2 mm. The metal sheet is then cut into small strips or punched out as discs for mounting onto metallic or plastic source holders used in detectors. Fixing of the source to the holders is by simple mechanical methods such as crimping, soldering, or welding or by using epoxy resins. The inactive zones of the strips are used for these fixing operations and the resulting foils are considered as sealed sources. Two manufacturers, Nuclear Radiation Developments, Inc., of Grand Island, New York, and the Radiochemical Centre Ltd., of Amersham, England, produce the foils for practically all ionization detectors being marketed in the U.S.

Ionization smoke detectors were first introduced into this country in 1951. At that time, the detectors used foils containing a total of 20 μCi of radium sulphate for each device. Since the Atomic Energy Act of 1954 did not cover the manufacture, distribution, and use of naturally occurring and accelerator-produced radioactive sources and devices, regulation was left to the discretion of each State. Currently, for guidance to the individual States, the U.S. Bureau of Radiological Health publishes NARM Guide 3, which provides criteria for the evaluation of gas and aerosol detectors of this type.

In late 1963, the manufacturer of the only ionization smoke detector being distributed in the U.S. elected to change the source from radium sulphate to americium-241, bringing distribution and use under the regulations of the Atomic Energy Commission (AEC). The stringent requirements of the regulations, which had never contemplated such a widely used device as the smoke detector, posed many difficulties to distribution. However, the growing demand for the product for needed property protection and life safety provided enough incentive that the restrictions could be tolerated. Examples of the requirements will illustrate the problem. The manufacturer/importer and all of his distributors throughout the country were required to apply and qualify for specific licenses. The end user of the product was generally licensed but was required to keep records and comply with certain requirements. The most expensive and time-consuming requirement was seeing that each detector was wipe tested and evaluated for leakage of radioactive material—at first this was required every 6 months but later the wipe test interval was extended to every 3 years.

Provision was made in Title 10, Code of Federal Regulations, Part 30, to permit exemption from regulation of gas and aerosol detectors after shipment from the manufacturer, provided all conditions could be met. The first specific license to distribute ionization smoke detectors was issued by the AEC on September 17, 1963. The first license granting exemption was issued September 5, 1969. The intervening six years were occupied by exhaustive testing, evaluation, and documentation to provide assurances beyond all doubt that exemption would not pose a hazard to health and safety of any individual or to the population as a whole.

Few products have received such thorough testing and evaluation in so many countries. The original testing and granting of exemption by the AEC, now the Nuclear Regulatory Commission (NRC), was in connection with an ionization detector containing 80 μCi of americium-241. Advances in the electronic technology associated with the ionization chamber have made possible drastic reductions in the quantity used, so that today the average quantity contained in commercial and industrial detectors is 15 microcuries or less. Detectors for residential or home use average about 1 μCi or less of americium-241 with those using radium sulphate containing amounts on the order of 0.1 μCi.

Containment integrity of the foils employed in smoke detectors is of prime importance. Niemeyer (1969) studied Ra-226 and Am-241 foils that had been in normal use for 5 to 14 years. The radium-226 foils contained 20 and 40 μCi and the Am-241 foils contained 80 and 130 μCi. The tests were a key ingredient in the granting of the exemption. More recently the Radiochemical Centre (1975) summarized an intensive testing program which included exposure of foils to corrosive environments, mechanical damage, and elevated temperatures, the stress conditions imposed being well above those that should be experienced in normal use.

To secure exemption it must be documented that, in manufacturing, storage, distribution, installation, and servicing of ionization detectors, no person or group of persons will receive external radiation doses in excess of the limits contained in §32.28, Part 30, Title 10 of the Code of Federal Regulations. Calculations under assumed worst case conditions, even from detectors containing 80 μCi of americium-241, demonstrate external radiation doses are far below the very low limits listed.

It must be further demonstrated that the dose commitment, the total radiation dose to a part of the body that will result from retention in the body of radioactive material, will also not exceed the prescribed limits. Intake into the body of the radioactive material can only occur by ingestion or inhalation.

First considering ingestion, it is difficult to conceive of an unauthorized person dismantling a detector, breaking into the ionization chamber by removing the tamperproof fastenings, prying the foil strip loose and then swallowing it—a piece of metal approximately 1/16 in. wide and 3/4 in. long or a disc 5 mm in diameter. However, assuming it is done, according to ICRPII (1959), less than 0.01% of the americium ingested ultimately reaches the critical organ, bone, and at least 500 μCi of insoluble Am-241 must be ingested to produce one bone burden of 0.05 μCi.

It is more conceivable, in theory at least, that a dose commitment could be received by inhalation of airborne radioactive particles released from detectors involved in fire tests. The critical organs for inhalation are the pulmonary lymph nodes as opposed to bone burden from ingestion. Tests have been conducted to explore this possibility. Battelle Memorial Institute (BMI, 1967) conducted fire tests on ionization detectors containing 80 μCi of americium-241 to determine how much of the activity contained would be released. The tests followed the standard Underwriters Laboratories time-temperature fire curve with 2000°F (1100°C) maintained in the 4-hour test and 1700°F (930°C) in the one-hour test. Maximum activity losses varied from a few hundredths of a percent to a few tenths percent in the four-hour test. The conclusion is that it is most unlikely for a detector that is exposed to fire to represent a hazard.

The Cerberus FES 6 detector contains 15 μCi of americium and may be considered typical of commercial detectors currently being marketed. In Switzerland, a study was conducted with the Cerberus FES 6 detector (The Swiss Reactor Institute, 1969). The study concluded that:—

> ". . . . a danger of radiation to members of fire brigades or salvage teams during or after a fire does not exist . . . ."
>
> ". . . . an inadmissible contamination of material and persons may therefore be regarded out of the question . . . ."
>
> "It may therefore also be regarded impossible that after a fire, a danger through incorporation (internal contamination) can appear; special protective measures like respirator masks or the like are not necessary."
>
> "A danger to drinking water may therefore be regarded negligible when depositing remains of the detectors with debris." and
>
> "In view of the extremely low level of radiation a recovery with the help of scanners is practically impossible, and after what has been said, not necessary either, because all kinds of radiation danger can be regarded negligible."

The final major point of consideration in connection with exemption of ionization smoke detectors is with regard to disposal. At some point in time, buildings protected from fire damage by these devices will become obsolete and will be demolished. The smoke detectors will be disposed of—either by return to the manufacturer as suggested by the label or by discarding in normal trash or debris. In the latter case, there are two possibilities—they will be incinerated along with other disposal of trash or they will be a part of a land fill used for trash and garbage disposal. In either event, the calculated projections under worst case conditions indicate that airborne release of contamination due to incineration or radiation from land fills are trivial compared with maximum permissible concentrations for members of the public.

In the thirty or more years during which commercial ionization smoke detectors have been in use, there have been fires and other accidents in which the detectors were involved. In the United Kingdom, a survey of known incidents has been carried out. Of 20 incidents reported from 1966 through 1975 involving detectors containing 60 μCi or more of Am-241, in no case has there been any detectable contamination of a member of the public or the fire brigade.

Commercial ionization smoke detectors have been used for more than 25 years in the United States. They are installed in factories, warehouses, business premises, stores, museums and libraries, hospitals and nursing homes, and public buildings. They protect air conditioning systems and electronic data processing equipment, control elevators during fires, trigger extinguishing systems, and are used in ships at sea and in aircraft and now will be in the space shuttle. For dose apportionment for exempt products based on risk benefit considerations, they are considered to be of outstanding benefit as life-saving devices with permitted dose limits to individuals up to 0.1 of the dose limits of the International Commission on Radiological Protection.

It is estimated that approximately 250,000 commercial detectors were installed in 1976. Fire codes and fire protection authorities are constantly increasing requirements for early warning fire detection. There has been practically no question of any public health aspects in connection with commercial installations, which include such examples as the Manned Space Center in Houston, the White House, the Library of Congress, the National Archives Building, the Pentagon, and countless other prestigious buildings.

The success of ionization smoke detectors in protecting industrial and commercial properties from loss by fire and in providing significantly added life safety for schools, hospitals, and nursing homes led to studies by fire protection authorities as to their potential effectiveness in reducing the approximately 7000 deaths in the U.S. each year from fires in residential occupancies. A study by the National Research Council of Canada, Division of Building Research, reviewed a series of dwelling fires in Ontario Province that resulted in 342 fatalities (NRC, 1962). It was estimated that 41% of the deaths would have been prevented by the installation of ionization detectors in the dwellings.

There were obstacles, however, to the use of smoke detectors in residences on a scale sufficient to provide a real impact on the fire death problem. Initially the detectors were available only in a system similar to commercial systems, and the cost was beyond the reach of most homeowners. Regulatory bodies were hesitant about accepting them for residential use because of the amount of radioactive material contained. The quantities were acceptable in supervised commercial installations because of the inherent controls involved. Such systems are generally required by building codes or fire insurance authorities—as such, they are well maintained, and no detectors can be removed from the systems by unauthorized persons without an alarm being sounded. Such built-in safeguards would not be possible in home situations.

The questions raised by regulatory bodies regarding the use of ionization detectors in residences were satisfactorily answered. The development of single station self-contained smoke detectors, especially battery operated detectors, and mass production techniques brought the prices within reach of every householder. The stable environment in the home does not require adjustable sensitivity. This, combined with advances in electronic technology, permitted the reduction of the amount of radioactivity in each home detector to 1.0 μCi or less of Am-241 or, in the few cases where used, 0.1 μCi of radium-226. Even so, general acceptance by the public was slow in developing.

In the fall of 1972, the Department of Housing and Urban Development, upon the recommendation of the National Bureau of Standards, purchased 16,000 detectors for use in mobile homes moved in to provide housing for Hurricane Agnes victims. It required several months for the combined manufacturers in the business at that time to supply this small number of units—this may be compared to the approximately 3,000,000 units distributed in 1976 and an expected much larger demand in the future.

Despite the rigid standards and exemption requirements of the NRC, the sheer magnitude of the potential number of residential detectors requires continuing documentation and demonstration that ionization detectors do not pose any threat to health and safety. It is not sufficient to simply say that home detectors contain only 1/80 or 1/15 of the radioactive material in exempt industrial units. Tests, calculations, and projections must indicate that any hazard is completely negligible.

From a radiation standpoint, the estimated dose to individuals and to the population as a whole can be calculated, based on certain conservative assumptions:

Activity of Am-241 (A) for one ionization detector: 1 μCi

Specific gamma ray constant at 1m for Am-241: $\tau = 0.009$ rad/h-Ci

U.S. population year 2000: about 287×10^6

Number of living units based on 2.5 persons per unit: about 114.8×10^6 living units

Number of installed detectors based on 50% of living units being equipped with 2 detectors each: $n = 114.8 \times 10^6$

Average distance from detector to people: $d = 2$ meters

90% of installed detectors (103.3×10^6) in hallways exposing 3 persons for 1 hour per day: $t = 1$ hour, $P = 3$

10% of installed detectors (11.48×10^6) in bedrooms exposing 2 persons for 8 hours per day: $t = 8$ hours, $P = 2$

Average individual dose rate: $Di = \tau \times A \times t/d^2$

Collective dose rate for 287×10^6 people: $Dc = Di \times n \times P$

Average population dose rate: $Dp = Dc/287 \times 10^6$

Using the above assumptions and formulae, the average individual dose rate is Di (8h/day) - 0.009 rad m^2/h Ci x 1 μCi x 365 x 8h/Y x 1/4m^2 = 6.6 μrad/year Di (1h/day) = 0.8 μrad/year

The collective dose rate Dc = 6.6 μrad/y x (11.48×10^6) x 2 man + 0.8 μrad/y x (103.3×10^6) x 3 man = 151.5 man-rad/y + 247.9 man-rad/y = 399.4 man-rad/year

The average population dose rate is Dp = (399.4 man-rad/y) / 287 x 10^6 man = 1.4 μrad/year

Since the appropriate quality factor for gamma radiation is 1, the average population dose equivalent rate is 1.4 μrem/year

The calculated individual dose rate of 7.4 μrem/year and the average population dose rate of 1.4 rem/year may be compared to the lowest permissible limit for external radiation dose equivalent to an individual of 500 μrem/year as specified in NRC regulations.

There are, however, other public health aspects than radiation from installed detectors that should be considered. Foil integrity, waste disposal, and accidents such as fire, explosion, misuse or mutilation, and theft or loss are considerations that have been documented numerous times in many countries.

Information mentioned previously regarding foil integrity for commercial detectors applies equally to residential units. The foils are of the same type and differ only in the lower activity required for the home detector.

The most complete and most recent information on waste disposal and accidents connected with single-station ionization detectors is found in Appendix 1 to a draft of "Proposed Radiation Protection Standards for Ionization Chamber Smoke Detectors." (OECD, 1977).

The latest draft of Appendix 1 assumes that most, if not all, single-station ionization detectors will be disposed of with normal refuse at the end of their useful life and that disposal would be either incineration or open-air disposal in a land fill.

Rational assumptions regarding numbers of detectors and conditions involved in incineration permits calculations showing that maximum downwind ground-level concentration from the incinerator plant averaged over a year is about 10^{-12} μCi/m^3 for Am-241. This quantity is small compared with the maximum permissible concentrations for members of the public of 2 x 10^{-7} μCi/m^3 for continuous exposure to Am-241 when in transportable form.

In connection with open-air disposal, the conclusion is that disposal of detectors will be associated with such large quantities of inactive waste and soil cover that there will be sufficient shielding of the very small amount of photon radiation to cover any conceivable condition.

Fire is one of the most common incidents involving ionization detectors. While the mission of the smoke detector is to signal the presence of an incipient fire to permit corrective action to be taken at the earliest possible time, worst case conditions must be total destruction with firemen fighting the fire being the most exposed individuals.

Also, according to Appendix 1 of the OECD Report, the Expert Group, using actual experience from past fires, results of the many experiments run with detectors under fire conditions, and rational assumptions, estimates worst case conditions might result in a fireman inhaling as much as 10^{-5} μCi of Am-241 in its transportable form. Since such intakes would be infrequent, they can be compared with half the maximum permissible annual intake (MPAI) by inhalation for occupationally exposed workers–in this case 8 x 10^{-3} μCi Am-241. Such a risk is insignificant in comparison with the other hazards faced by the fireman.

Following the fire, the most exposed individuals are assumed to be those involved in cleaning-up operations. Again the Expert Group calculations under assumed worst case conditions indicate the activity inhaled to be 2 x 10^{-8} μCi Am-241 vs. 1/2 MPAI for occupationally exposed workers of 8 x 10^{-3} μCi–again insignificant.

From available experience, it is apparent that radioactive sources in smoke detectors are relatively undamaged by explosions. The fire that might follow an explosion is likely to produce more damage.

Deliberate dismantling of a smoke detector by an unauthorized person is a possibility. This potential hazard is offset to a great extent by source shielding designs in most units requiring special tools to gain access to the source. In the event access is gained and the foil deliberately scratched, it is unlikely that a significant quantity of americium would be removed. If one assumes that, in this case, about 1% of the total activity of a home detector containing 1 μCi Am-241 would be transferred to the fingers and subsequently ingested, the activity ingested would be 0.01 μCi of Am=241. Since americium contained in smoke detectors is truly in an insoluble form, the fraction of ingested activity that is absorbed would be much less than 0.01 μCi as compared with the MPAI by ingestion for members of the public, which is 3.0 μCi Am-241.

There have been some instances of thefts or losses of smoke detectors. Unrecovered units are likely to be abandoned in some remote place or disposed of with normal refuse. In either case, it is difficult to envisage a hazard more serious than that resulting from misuse or mutilation discussed in the previous paragraph.

The summary of the Expert Group in evaluating the benefit and radiation protection aspects of smoke detectors may well serve to summarize this review: ". . . . it seems clear that the benefit which can be obtained from the use of ionization chamber smoke detectors, both in terms of reducing property damage and saving lives, significantly outweighs any radiological risks involved in their use, misuse, disposal, etc.

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PUBLIC HEALTH ASPECTS IN THE USE OF RADIUM-226 AND AMERICIUM-241 IN LIGHTNING RODS

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In the two centuries since Benjamin Franklin introduced the principle of the lightning rod as a means of protection against one of the most awe-inspiring natural forces, many efforts have been made to clarify the aspects of the lightning discharge and the working principles of lightning conductors. A twofold action was attributed to these devices; it was thought that the discharge currents from the rods prevented the lightning stroke or failing that, the rods would discharge it to the earth. More recent studies have made it clear that the unique function of the rods is to intercept a disruptive discharge before it can strike a protected structure (Golde, 1967; Ridolfi, 1971). It was proposed for the first time in 1914 by Szillard (Delhove, 1970) that ^{226}Ra be used in Franklin rods; in 1932 Capart patented a radioactive rod in France and in the U.S. (Delhove, 1970). The sources were placed on Franklin rods to increase the air ionization in the hope of achieving better performance. After radium, other radioisotopes such as ^{85}Kr, ^{60}Co and ^{241}Am have been used.

In Italy only ^{226}Ra and ^{241}Am have been in use, and there is a trend to substitute ^{242}Am for ^{226}Ra. The metallic or ceramic plated sources are placed on a support below the tip, their activities ranging from 0.1 to 6 mCi. Such sources, which are produced in foreign countries, are imported by a few firms that mount them on the rods and provide for the marketing and, in some cases, installation of the lightning device.

In Italy if the total activity is not less than 0.1 μCi, the user of the lightning rod has to inform the medical officer of the Province. Moreover, if the activity is above 1 mCi he has to be licensed by the same authority. Only if the activity is above 10 mCi is he required to inform the Ministry of Industry.

The marketing of radioactive devices is subjected to licensing by various Government authorities. As one can see, Italian regulations in this field are rather complex.

From data obtained from the marketing firms, the Comitato Nazionale per l'Energia Nucleare could give an estimate of more than 12,000 lightning rods bearing ^{226}Ra and ^{241}Am sources that had been installed in Italy by the end of 1973. There are reasons to believe that this figure is an underestimation of the number of such devices and that it has grown in the meantime.

Through some provincial medical officers, the loss of some sources was brought to the attention of central Public Health authorities; it was also noticed that several of these sources had caused the spread of contamination. It was felt that these risks were enhanced by the lack of effective checks on the sources and also by the fact that the rods are usually difficult to reach.

These considerations prompted the Comitato Nazionale per l'Energia Nucleare and the Istituto Superiore di Sanità to evaluate the use of radioactive lightning rods from a radiation protection point of view. As in any other use of ionizing radiations, this particular type of use was examined following the philosphy of risk and benefit analysis outlined by the ICRP (1973).

As far as benefits are concerned, a review of the existing literature offers a certain number of laboratory tests carried out to ascertain whether the radioactive rod offers a better protection than the Franklin rod (Baatz, 1972; SAREF, 1976; Behounek, 1938; Dacos, 1972; Soci, 1976; Allibone et al., 1972).

Because the so-called "efficiency" of a rod seems to be rather an intuitive concept, some difficulty arises when one tries to give a measureable definition.

If the effective range of a lightning rod is defined as the maximum distance between the tip of a leader stroke and a lightning conductor over which the latter is capable of attracting the stroke, it follows that this distance increases with the intensity of the lightning current, which amounts to several kA (Golde, 1967).

The so-called protected space, often used as an indication of the efficiency, is a less clearly understood concept and different national codes give different definitions for it (Golde, 1967; Ridolfi, 1971). Therefore, for an evaluation of the relative efficiency of the two types of lightning rods in the laboratory and in the field, other parameters were taken into account, e.g., the discharge frequency, the breakdown voltage, or the current emitted in a given electric field (Baatz, 1972; SAREF, 1976; Behounek, 1938; Dacos, 1972; Soci, 1976; Allibone et al., 1972).

Opinions generally concur in considering laboratory results as not being conclusive because of the inherent differences in comparison with natural conditions. In addition, any quantitative extrapolation from the scale of laboratory tests to that of the lightning discharge should always be subject to some criticism (Golde, 1967).

Results from model tests, however, can be of considerable value for comparative investigations; in the authors' opinion, the differences between the two kinds of devices are very slight and no evidence can be established that indicates a better performance for radioactive rods.

From what has been said above, it follows that a particular significance has to be attributed to the only set of experiments carried out in real operating conditions to compare the performance of the two types of rods. The parameter under consideration is the current emitted by the two types of rods. Such experiments, carried out in Sweden and Switzerland, led to the conclusion (Müller-Hillebrand, 1962) that, in the laboratory, no difference could be established between the currents from radium-beaming rods and those from conventional rods; in the field, on the contrary, the current from the radioactive rods was smaller than that from conventional rods of the same height. As a matter of fact, corona charges coming from tall rods can have an influence on the lightning path; the currents emitted by radioactive rods are, however, too weak to build up the space charges necessary for the corona effect; they should be 100,000 times stronger to influence the electric field at a distance of several hundred meters.

The results of both laboratory and field experiments were discussed in two International Conferences on lightning protection. In one, Fritsch (1971) noticed that, based on theoretical considerations and experiments, radioactive rods were not included in the Austrian Code. He remarked also that one may use a radioactive rod instead of a conventional one; it must, however, be stressed that no larger protected space can be attributed to a radioactive rod than that pertaining to a simple Franklin rod with the same dimension.

Later Baatz (1973) observed that the radiation works only at a short distance which is of no importance for the last discharge step of the lightning; measurements of the currents emitted by radioactive lightning rods during thunderstorms and research on the striking distances with radioactive substances up to 100 mCi show that radioactive isotopes are of no importance in lightning rods. Radioactive lightning rods do not achieve better results than the normal ones, they cost more, and constitute only a source of risk for people.

Also, in the opinion of Berger (1973), because the atmospheric electric field during thunderstorms is at least a thousand times stronger than the one produced by the ionization, the radioactivity has no influence on the lightning process and the lightning stroke.

The possibility of a statistical approach to assess the performance was also considered. The marketing firms produced an array of statements by many users who claimed the protection offered by their radioactive lightning rod had been very satisfactory. It is noteworthy to remark that some of them report that they had no lightning strikes since their adoption of a radioactive rod whereas others claim to have noticed an increase in the lightning pickup performance.

No particular scientific significance can be attributed to these statements. It is evident that a statistical approach must be founded on a different basis, which, in the author's opinion, is not practicable.

It is worthwhile remarking that the Italian Agency supervising lightning protection installations does not consider the use of radioactive rods as substitutes for Faraday cages when these are required to protect high-risk buildings. Also, in the British code of practice, no artificial means are acknowledged by which to increase the range of attraction of a lightning conductor; in the German code of practice, no special improvement is recognized as a result of the use of radioactive sources (Golde, 1967; Ridolfi, 1971; ABB, 1963).

From the above considerations, the authors conclude that it has in no way been established that a radioactive rod can offer better protection than a Franklin rod with the same height.

As to the radiological risks, the authors believe that there is only a limited problem as far as the workers who are involved in installation and maintenance are concerned. In effect, these workers are only a small fraction of the population, and procedures can be devised to provide them a satisfactory degree of protection from both external and internal radiation risks.

An order of magnitude of the doses involved can be drawn from the figures reported by Delhove (1970); he calculated that a worker manipulating a 1 mCi ^{226}Ra source 40 hours per week could receive a whole body dose equivalent of about 156 mrem per week due to gamma rays, assuming he is working at a distance of 0.5 m with his hands 15 cm from the source and without any special protection. Obviously the above mentioned value can be conveniently reduced by the adoption of suitable protection procedures. For ^{241}Am sources the external radiation risk is evidently smaller.

Also, the internal exposure due to a contamination event during installation or maintenance could be minimized if precautions are adopted, although they may often be overlooked in practice.

However, a problem of some importance arises for members of the public because of the widespread use of the radioactive rods and the lack of any effective control of the sources, which are subjected to severe environmental stresses.

As for the external radiation risk, surveys carried out a few years ago (Besseghini et al., 1974) and more recently by the Comitato Nazionale per l'Energia Nucleare showed that exposure rates were always less than 0.1 mR/h in easily accessible areas near the rods.

As people do not usually stay long in such areas, it is readily seen that the external exposure is of no major concern for members of the public. This applies, of course, only if sources are not damaged and radioactivity is not scattered.

The situation for the internal radiation risk is somewhat different. Data from laboratory tests and monitoring surveys on installed rods show that transferable contamination can be detected in a number of cases. In Tables 1 to 5 some significant results are summarized.

In Tables 1 and 2 results are presented from wipe tests performed with dry paper or wet cotton at points easily accessible to members of public and on the sources (Besseghini et al., 1974; CNEN, 1975; CNEN, 1976; ENPI, 1976) In the tables the installations are divided according to the contamination value, C, measured in $\mu Ci/cm^2$.

TABLE 1

Results From Wipe Tests Performed at Points Easily Accessible to Members of Public

$C < 10^{-7}$	$10^{-7} \leq C \leq 10^{-5}$	$C > 10^{-5}$	Total
104	50	8	162

TABLE 2

Results From Wipe Tests Performed on the Sources

$C \leq 5.10^{-7}$	$5.10^{-7} < C \leq 10^{-5}$	$10^{-5} < C \leq 10^{-4}$	$C > 10^{-4}$	Total
98	33	36	36	203

In Table 3, results from immersion tests are summarized (Delhove, 1970). The measured activity of rain water in which sources were left for 8 hours at room temperature is shown. The reference activity of the water was $4.8.10^{-4}$ μCi.

Tables 4 and 5 present results from tests reproducing the protracted exposure of sources to atmospheric agents (Delhove, 1970).

Table 4 shows results obtained when sources were subjected to an artificial rain corresponding to a 50-year exposure in natural conditions (700 mm/year); the measured activity released to the water is listed. The reference activity of the water was $4.8.10^{-4}$ μCi.

Table 5 presents results from tests aiming at reproducing wind and powder abrasion effects. Sources were subjected to a 4-kg sand stream. The sand was subsequently washed with water whose measured activity is listed in the table.

From the data shown, it is clear that a release of radioactive material has indeed occurred or could possibly happen. Such a release can be ascribed to agents that can affect the rod in normal conditions, e.g., rain, thermal stresses, oxidation, wind abrasion, corrosion by fumes, and the lightning discharge itself.

An additional risk comes from sources that fall out of their sockets. Such events can be understandably ascribed to the same agents mentioned above. Also, the

TABLE 3

Results From Immersion Tests

Lightning Rod Identification Number	Released Activity (10^{-4} μCi)
1	19.0
3	7.7
2	3.9
5	7.2
4	844
9	108
6	45
10	43.7
17	24.9

TABLE 4

RESULTS FROM WASHING-AWAY TESTS

Lighting Rod Identification Number	Released Activity (10^{-4} μCi)
2	10.5
3	9.6
5	281.2
9	108.0
6	42
6U	34.6
10	591
17	26.1

TABLE 5

Results From Wind Abrasion Tests

Lightning Rod Identification Number	Released Activity Per Lightning Rod (10^{-4} μCi)
2	2,800
3	23,000
9	705
10	5,500
16	2,100

possibility of unsafe handling of the radioactive sources on the occasion of building demolition or rod dismantling has to be considered.

In the authors' opinion, patterns of contamination transfer to members of the public cannot reliably be determined because of the large variety of events and situations, the likelihood of which is extremely difficult to ascertain; therefore a risk evaluation cannot reliably be made in terms of dose commitment to members of the public. Nevertheless, the authors feel that the following conclusions can be advanced:

1. Contamination arising from the use of radioactive rods is the main risk for members of the public;
2. For the public at large, this risk can be considered to be limited although it cannot in any case be deemed as nonexistent.

Following the ICRP philosophy (ICRP, 1973), the implementation of a system of dose limitation should result (among other things) in the avoidance of the doses from unnecessary exposures, which is to say, any use of radioactive substances must be justified by adequate benefits in comparison with related risks.

When balancing risks and benefits, an additional element should be considered for the authors' country.

As the sources used in Italy for radioactive rods must be imported to be subsequently placed on the rods, persons employed in this field are very few (no more than 30, see CNEN, 1975). Social and economic implications of this activity are then of negligible interest in Italy.

From the above considerations the authors conclude that the use of ^{226}Ra and ^{241}Am sources in lightning rods should be considered as a risk not justified by demonstrated benefits.

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NUCLEAR LIGHTNING PROTECTION AND THE NEW COAXIAL LIGHTNING PROTECTION SYSTEM

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THE SEQUENTIAL STAGES OF AIR DISCHARGES

In the case of negative cloud lightning, a faintly luminescent leader leaves the base of a cloud and progresses rapidly toward the earth. This leader may branch into many fingers, with each progressing independently to the earth.

It is only when one of the leaders is in close proximity to the earth that the rapidly escalating electric field causes an upward moving streamer to be launched from an earthed object. The connection of a leader branch to the streamer completes the ionized channel for the main discharge to take place. It is important to note that the first streamer to meet a leader will determine the path of the main discharge current which may peak to values in excess of 150 kA.

Thus, the earlier a point can launch an upward streamer, the more chance it has of drawing the lightning discharge. It is this time advantage that gives the attractive ability to the ionizing electrode lightning protection system to be described.

The length of the upward streamer is known as the "striking distance" (*d*) and it varies with the strength of the subsequent discharge current (*kA*). Table 1 gives typical values of striking distance against peak discharge current. Examination of this table shows that low intensity discharges can pass quite close to a structure without generating a connecting streamer. The leader will then progress onward to earth and strike or discharge very close to the structure. Figure 1 shows this effect.

TABLE 1

Relationship Between Peak Discharge Current and Striking Distance

kA	(d) Striking Distance (in meters)
3	16
10	40
30	100
100	250

It is generally agreed that low intensity discharges follow an erratic course to earth. They have been frequently observed to approach a structure from an angle. This is shown, in Figure 2, clearly demonstrating the fallacy of relying on "cone of protection" concepts for tall structures.

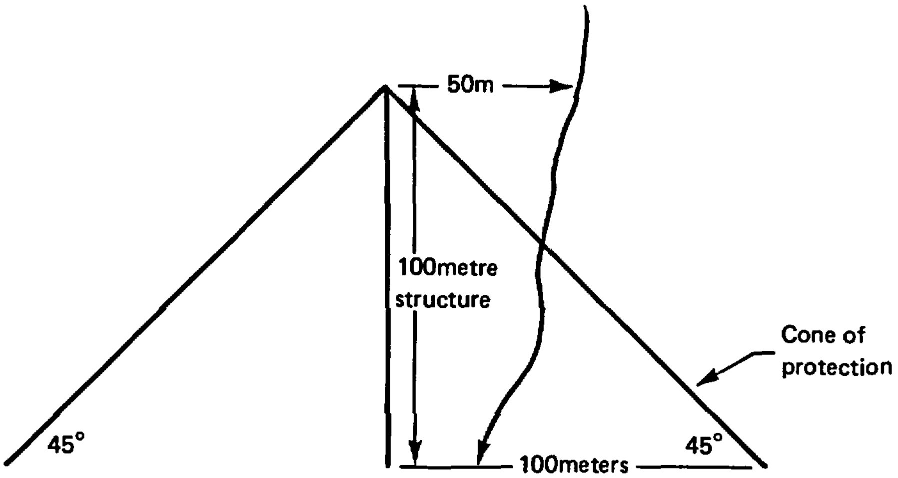

FIGURE 1. Lightning enters the conventional "cone of protection" due to inability of structure top to launch a streamer.

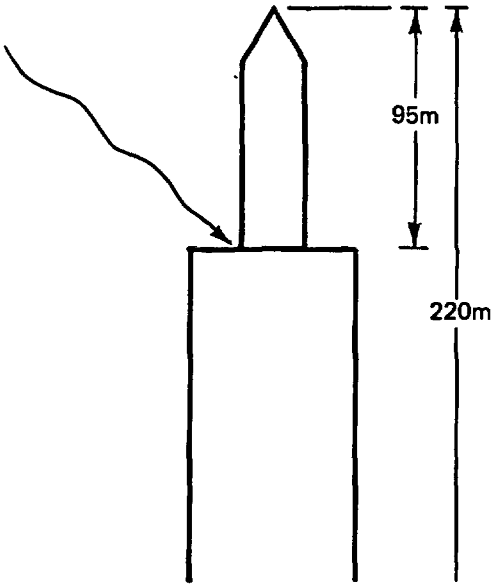

FIGURE 2. Example of how lightning struct 95 metres below tower in Warsaw.

NEW "E.F." LIGHTNING PROTECTION SYSTEM

The concept of using ionizing sources to enhance the attractive power of an electrode is not new. There are a significant number of manufacturers of this type of electrode in Europe. The "E.F." terminal is shown in Figure 3. The central rod is connected to earth, while each arm holds americium-241 sources. These sources provide up to 8.33 x 10^{12} electrons/second about the earthed tip. It will be shown that these electrons allow the early generation of a streamer, and in so doing, provide an attractive range for the terminal by capturing lightning in preference to other points (Table 2). The generation of free electrons is directed to the tip only. The design concept has been confirmed by a computer simulation of conditions leading to avalanche breakdown (Khaled, 1975).

COMPUTER SIMULATION

The aim of this computation was to determine the nonuniformity in the field distribution created by the presence of the rod in a uniform field region. If there is a 100-cm gap, the utilization factor (Khaled, 1975) is found equal to 6%. For the same gap, the field strength at the rod tip at corona inception is about 170 kV/cm. It will be the same for all gaps larger than 100 cm.

All fields are, of course, three dimensional, and for most cases of practical interest exact analytical solutions are not available. Numerical solutions often involve a prohibitive amount of computations. Therefore, a two-dimensional treatment with sufficient accuracy is used instead. In the actual case, the system is radially symmetrical, and hence only a two-dimensional computation is necessary. Recourse has been made to the charge-simulation method, which is basically a numerical method of solution, but the field strength is calculated analytically. It is a direct solution and not iterative, which makes it more efficient in repetitive operations.

In this method, a certain number of fictitious charges, located outside the space in which the field is to be computed, are to be found and ordered in such a way that boundary conditions are satisfied. A faithful representation of the configuration is secured as well as a reasonable accuracy in calculating the field at any point.

Point, line, and ring charges have been used for this purpose. The maximum field strength is located at the rod tip. To indicate the inhomogeneity of the field distribution, a factor is very often used relating the mean value of the field strength of an electrode system to this maximum value. This is called the utilization factor, according to Schwaiger, and is given by:

$$n = \frac{E\,av}{E\,max}.$$

In the case under discussion, n = 0.006%, which means an extremely nonuniform field with the high field concentrated very close to the rod and a very short critical distance.

The critical distance is that between the rod and the point from where a single electron can trigger an avalanche, the primary avalanche, and where at normal pressure the field is equal to 244 kV/cm.

Due to rotational symmetry of the system, the horizontal or radial component of the field is zero and the maximum field strength is along the axis of the

FIGURE 3. The "E.F." ionizing terminal assembly.

configuration, i.e., the y axis. Using the Newton Raphson iterative procedure, the critical distance at any stage of the operation could be updated as follows:

$$y^n = y^{n-1} - (E_y^n - E)/(dE_y^{n-1}/dy)$$

where E=24.4 kV/cm and E_y^{n-1}= calculated y component of the field at the (n-1)th step.

This computer simulation has confirmed an entirely favorable field experience with the "E.F." electrode. In the laboratory (Allibone and Dring, 1972; Allibone and Dring, 1973), ionizing sources have been used to reduce the scattering of breakdown voltages in nonuniform gaps, resulting from the absence of free electrons in the critical region when the voltage is applied. This is reflected by a certain time delay in the collapse of the gap, termed statistical time lag. If free electrons are made available (as in the terminal of the "E.F." system), this delay can be eliminated.

The success of the "E.F." terminal lies in the provision of continuous supply of free electrons in the critical region at the earth tip. Inadequacy of electrons simply leads to a time delay until the electric field creates sufficient numbers by natural collision phenomenon.

Once the initial avalanche has been commenced, the reducing distance between the streamer front and the leader head will create a rapidly escalating electric field.

TABLE 2

Comparison of Theoretical and Experimental Corona Inception Parameters

Gap (m)	*Electrode Shape*	T_{cr} (μs)	*No of Shots*	E_i (kV/cm)		(du/dt) $t = T_{i\,min}$ (kV/μs)	*Model Used*	E_i min kV/cm	*No of electrons N*	Avalanche *Length (mm)*
				min	med					
5	*Hemisphere*	130	6	30.2	32	10.2	Peeks (EDF)	33.5	–	–
		260	7	30.2	30.7	3.35	(Padova)	32.3	$4.8\ 10^7$	39.2
		500	25	31.3	31.7	2.22	Avalanche (CEGB)	31.1	$1.0\ 10^9$	37.2
	Hyperboloid	130	14	37.5	44.3	22.4	Peeks (EDF)	35.2	–	–
		260	6	33.2	35.4	7.35	(Padova)	36.1	$4.7\ 10^7$	21.5
		500	16	35.3	39.2	4.64	Avalanche (CEGB)	34.2	$4.0\ 10^8$	22.1
	Cone	130	12	88.0	119	39.7	Peeks (EDF)	44.5	–	–
		260	12	71.7	100	13.0	(Padova)	54.6	$4.3\ 10^7$	4.8
		500	12	72.4	86	8.4	Avalanche (CEGB)	47.8	$3.0\ 10^7$	4.9
10	*Hemisphere*	130	19	36.5	37.7	26.2	Peeks (EDF)	33.5	–	–
		260	23	32.9	34.2	10.4	(Padova)	32.5	$4.8\ 10^7$	39.0
		500	16	32.9	39.2	7.4	Avalanche (CEGB)	31.2	$1.0\ 10^9$	37.0
	Hyperboloid	130	10	40.0	47.1	41.5	Peeks (EDF)	35.2	–	–
		260	12	36.3	42.2	12.5	(Padova)	36.4	$4.7\ 10^7$	21.4
		500	12	39.6	42.8	7.85	Avalanche (CEGB)	34.2	$4.0\ 10^8$	22.1
	Cone	130	8	126	157	67.7	Peeks (EDF)	44.5	–	–
		260	12	83	99	25.9	(Padova)	54.8	$4.3\ 10^7$	4.8
		500	8	59	75	11.5	Avalanche (CEGB)	48.4	$3.0\ 10^7$	4.75

This, together with a process of photionization, causes the streamer to progress upward at approximately 2 x 10^6 m/s. That is, a striking distance of 40 meters is traversed in only 20 microseconds.

In ideal conditions, it is possible for the "E.F." terminal to provide a protective radius up to 250 meters. However, with increasing structure height it is necessary to derate the ground area protected because of the potentially erratic behavior of low-intensity discharges.

The "E.F." Coaxial Down Conductor

Since the time of Benjamin Franklin, bare conductors have been used to convey lightning discharges to ground. It has long been recognized that discharges can leave such conductors giving rise to a phenomenon known as "side flashing." Figure 4 shows how right-angle bends increase the inductance of standard down conductors and lead to an increase in the danger of side flashing.

The lightning discharge is noted for its extremely rapid rise in current. This is typically 10^{10} A/S, a value which makes self-inductance and capacitance important in determining voltage rise. This has led to travelling wave techniques being used to analyze the effectiveness of down conductors. Thus, the term "surge impedance" becomes one of the measures by which the efficiency of a down conductor is specified. Typically, a single wire has an impedance of 500-800 ohms, and for this reason many parallel conductors are specified in standard methods of protection. The recent development of the "E.F." coaxial down conductor has led to a drastic reduction in surge impedance while simultaneously overcoming the disadvantages of the bare wire.

Figure 5 shows how the outer screen acts to shield the inner conductor from nearby objects during the passage of the discharge current. It can be seen that, without the screen, a very high electric field would exist between the down conductor and the structure. This is the cause of side flashing.

The construction of the "E.F." cable provides for high capacitance between inner and outer conductors to provide low surge impedance. The effect is to reduce the voltage across the cable to a value readily handled by the insulating medium. The advantages of this proprietary cable can be summarized as follows: (1) the discharge is conveyed to the ground without electrifying the protected structures (buildings, boats, towers and phase wires, telecommunication towers, etc.); (2) the concentric screen shields the inner conductor from nearby objects, and the danger of side flashing is eliminated; (3) the cable offers a low surge impedance to the passage of the discharge; (4) a significant proportion of the current peak is absorbed due to the high capacitance between inner and outer conductors; and (5) the cable can run around bends and generally in a manner convenient to a particular installation.

Statistics

Considerable statistical data have been accumulated during three years on the field performance of 500 installations. The combination of "E.F." terminal and coaxial down conductor has produced significant results in the telecommunication field. One such example is located in an area of extremely high lightning activity. The Jatiluhur Intelsat Ground Station is jointly operated by ITT and the Indonesian Government.

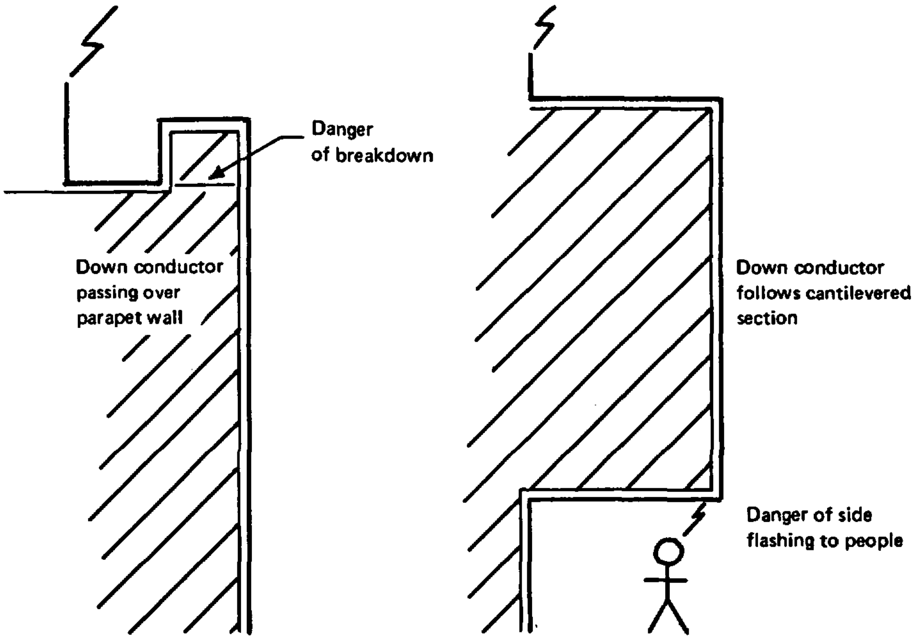

FIGURE 4. Example of how side flashing can cause damage to structures and injury to people.

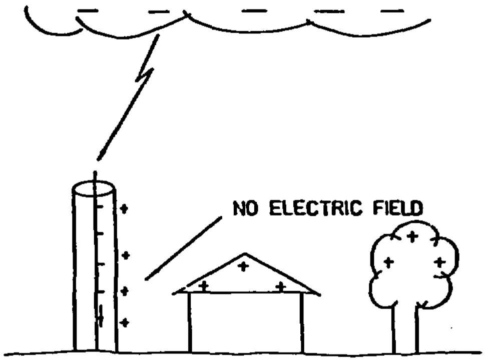

FIGURE 5. How coaxial cable outer conductor screens the discharge from other objects and eliminates side flashing.

The Station had a history of lightning-induced damage from commencement of operations in 1969 until the conventional lightning protection was replaced by an "E.F." system in August 1974. One of the many instances of damage taken from the station log is as follows:

Dec. 9th, 1973
Severe lightning hit the lightning protection. Equipment affected:
Paramp 2 klystron power supply unit defective
Elevation/Azimuth servo control rectifier defective,
Tracking down convertor defective. Down convertor 8 defective (its filter)
Servo repeater, Some unusual red indicators lighted on high power
Amplifiers 1 & 2, but didn't trip off"

In the two and half years since the installation of the "E.F." system at Jatiluhur (see Figure 6), lightning has been observed to strike the terminal, and this has been confirmed by burnmarks on the terminal tip. There has been no lightning-induced damage since the system has been operating, despite the strikes received. No modifications were made to the earth (1 ohm) of the original installation.

Figure 7 shows an "E.F." system installed on a television tower in Australia. The station suffered lightning-induced antenna damage when using conventional protection, but has been secure from the time of the "E.F." installation.

Figure 8 illustrates the severe beating taken over a two-year period by the "E.F." system on Portugal Serra Amarela television tower in the "Valley of Thunder." Each crater was caused by a direct lightning stroke. This tower was formerly protected by standard protection systems, radioactive or not, but it continued suffering severe damages. After the installation of the "E.F." system, the tower has been effectively protected for seven years.

The reason for the field-proven success of the "E.F." system is simple. The ionizing terminal attracts the lightning discharge in preference to other and vulnerable points, and the coaxial cable conveys the discharge to the ground without electrifying the protected structures. See Figures 9 and 10.

There are many examples of the terror that lightning has inspired in navigators: e.g., ancient pictures of boats in a storm always show lightning striking the ships; the name "Saint Elmo's fire" given to visible corona discharges comes from the name of the Saint who protects sailors; and Christopher Columbus described in his logbook the "spectral flames arising above the top of the sails."

After Franklin's discovery of the lightning rod, naval experts adopted it to protect their ships. It seems that the first experiment was conducted by an English man, Dr. Watson, who used a chain of copper links going from the top of the mast to the sea. It is reported that lightning was intercepted and conveyed to the sea by that means in 1762. Captain James Cook tried the principle on the "Endeavour" on his expedition to New Zealand and Australia (1768-1770). He wrote: "when we were tied up in Batavia, lightning struck the ship, but, thanks to our system, the chain conducted the lightning over the side of the ship. But though we escaped the lightning, the explosion shook us like an earthquake. A nearby boat, without our system, had her mast shivered all to pieces."

This chain was far from offering really efficient protection. Indeed, the Navy was still losing ships because of lightning. It was then that Sir William Snow Harris had the idea of using the masts as conveyors by nailing thin copper ropes along them and connecting these strips to copper plates on the bottom of the hull and keel. To convince the Admiralty, Sir William conducted a survey on 220 British naval ships

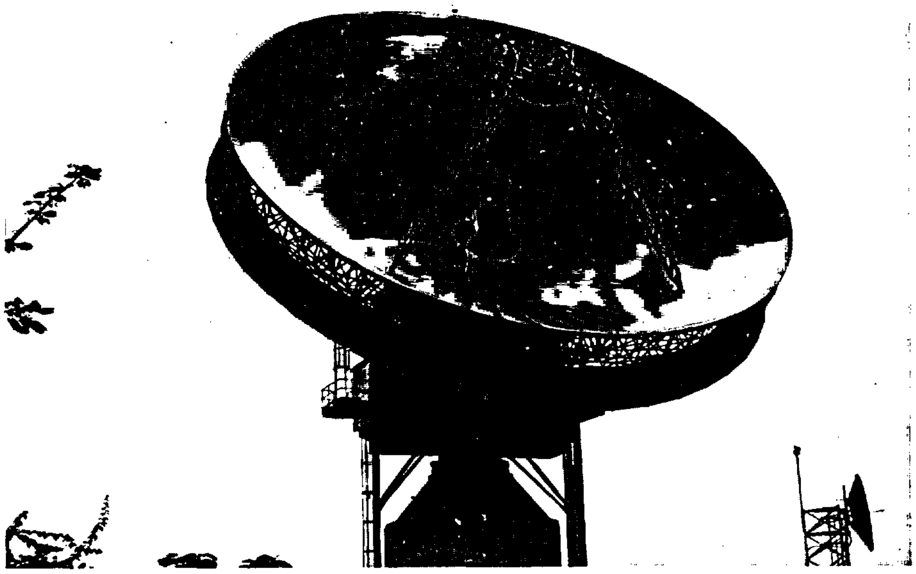

FIGURE 6. Installation of an "E.F." system on the Jatiluhur Intelsat Station.

struck by lightning. He found that about 75% were struck at the highest point of the main mast. Nearly 50 ships were set on fire, and 90 sailors killed.

Sir William could not, at that time, have a clear idea of the risks associated with the conveyance of lightning from the top of the masts to the sea. Besides, he did not know that the conveying cable should not make angles at the level of the decks. When lightning is conducted along the masts through bare cable of a lightning protection system, the risk of rebounding on other structures, equally grounded to the sea, actually remains the same. Such rebounding at temperatures of 20,000° C. is the cause of explosions, fires, and electrocutions. Lightning kills about 6,000 people each year and causes about 500,000 serious injuries per year.

Integrity Testing of Radioactive "E.F." Sources

The Am-241 sources used in the "E.F." system are produced by the same basic production processes used in the manufacture of sources used in smoke detectors, but they are subject to more stringent quality and integrity controls and they incorporate additional noble metal seals. Because of physical form and insolubility of Am-241 in body fluids, ingestion does not raise a problem and an inhalation hazard is extremely unlikely.

FARADAY CAGE AS A LIGHTNING PROTECTION DEVICE

The wires of an installation incorrectly called "Faraday" will give rise to self-induction phenomena in this network of wires and pipes and may cause damage. The lightning protection provided by a Faraday cage is, therefore, unattainable in

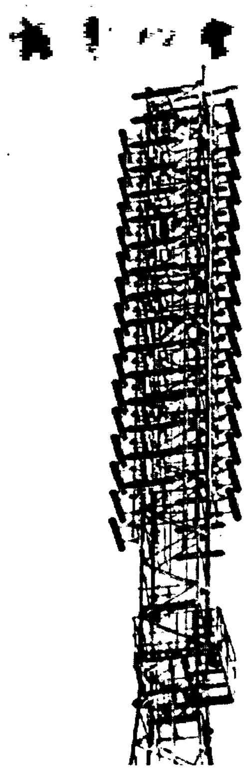

FIGURE 7. "E.F." system installed on Australian television tower.

practice. The only statistical data on the subject were those collected in the State of Iowa over a period of six years, and accumulation of these was apparently discontinued after 1962. These data indicate that buildings rodded according to standards in force have suffered damage comparable to non-rodded buildings (see Table 3). It is for that reason that caution is advised with respect to any publication dealing with lightning protection where the authors avoid reference to statistical data.

Laboratory Tests

There are no published laboratory test results. However, it is judicious to miniaturize a "Faraday Cage," to place a point on the link level, to move it inside, and to see where the discharges go. We have made such a test (CEB, 1969). Our results indicate that essentially 100% of the discharges go to the tip when it is placed on the link level.

FIGURE 8. 2 Burn marks on E.F. terminal received in 2-year period on Portugal's Serra Amarela television tower.

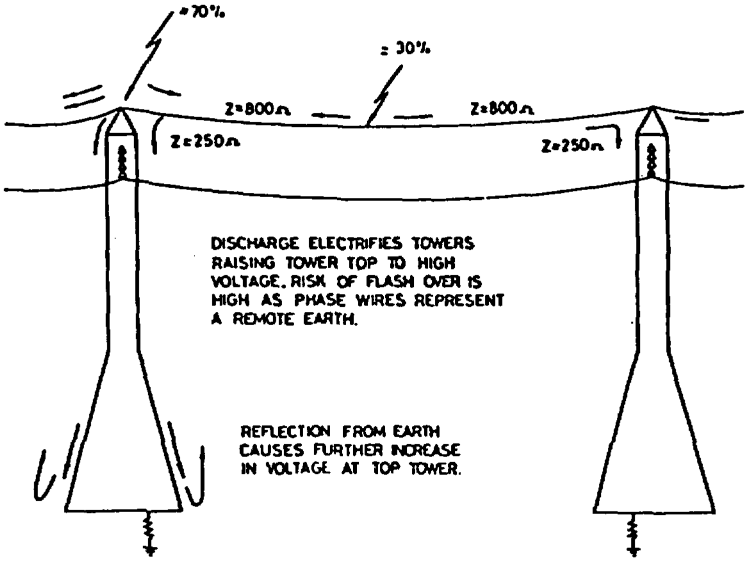

FIGURE 9. Conditions leading to flashover when using standard forms of protection.

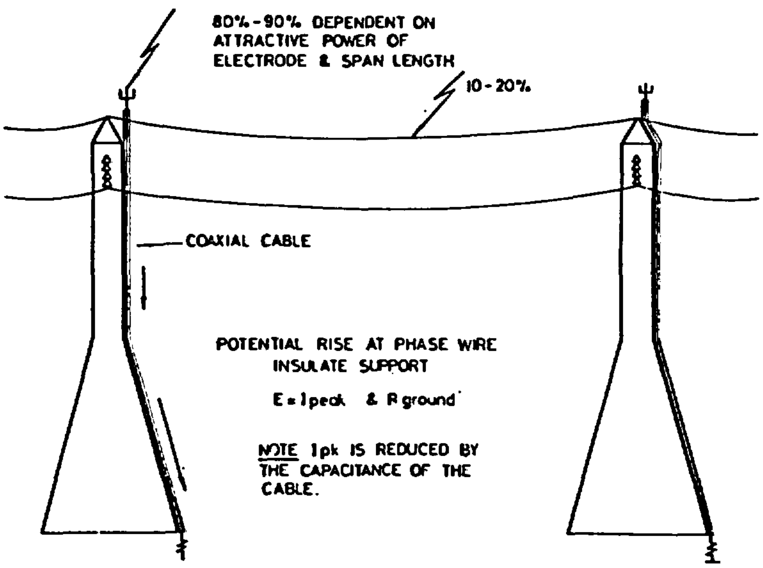

FIGURE 10. The E.F. system on H.V. transmission lines. Note: The E.F. system is of particular value on lines requiring a high degree of security, particularly if these lines can cause extended periods of blackout.

RADIATION SAFETY CONSIDERATIONS

Since radioactivity can be a hazard to health and safety, it is necessary to determine the relative hazard of the use of americum in "E.F." systems and whether the benefits of such usage outweigh any risks involved. Radiation levels from installed units at points where personnel exposure might occur are too low to be detected with ordinary detection devices. In the remote chance of an accident involving an E.F. system, there is little or no chance of scattering radioactive material.

TABLE 3

Summary of Lightning Data from the State of Iowa 1956-1962 (Herron, 1962)*

Rodded Buildings (with lightning protection)						Unrodded Buildings (without lightning protection)
Page in Book of Official Annual Report						
Page 15	Year	1956	Rodded Buildings	30	Property losses $178,933	
			Unrodded Buildings	89		$ 356,836.
20		1957	Rodded Buildings	10	62,788	
			Unrodded Buildings	41		$ 267,091.
27		1958	Rodded Buildings	10	87,934	
			Unrodded Buildings	22		$ 133,529.
Table III		1959	Rodded Buildings	12	117,284	
			Unrodded Buildings	51		$ 196,925.
24		1960	Rodded Buildings	14	112,812	
			Unrodded Buildings	26		$ 146,160.
27		1961	Rodded Buildings	16	141,102	
			Unrodded Buildings	33		$ 189,053
Page 27		1962	Rodded Buildings	15	152,400	
			Unrodded Buildings	40		$ 243,545
					$853,113.	$1,533,219

*Summary of reports, January 1956 to 1962, inclusive: 107 rodded buildings destroyed (burned); 302 unrodded buildings destroyed (burned); average loss $8,007 on rodded buildings and $5,077 on unrodded buildings.

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RADIOACTIVE LIGHTNING RODS, STATIC ELIMINATORS, AND OTHER RADIOACTIVE DEVICES

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Industrial application of ionization phenomena in lightning rods, static eliminators, and certain other devices represents some early practical uses of radioactivity. As early as 1914, Szilard proposed the use of a radium-226 alpha-emitting source to improve the effectiveness of the Franklin lightning protection rod. The practical introduction of this invention on a commercial basis dates back to the early 1930s. At present, radioactive devices based on air ionization include lightning rods, static eliminators, smoke detectors, and ion generators. Such radioactive devices have advantages as compared to conventional techniques in both performance and economics. These advantages are generally accepted by the users. Although alpha-, beta-, and gamma-emitting radionuclides are of potential interest and have been or are being used, alpha sources of low gamma radiation and high ionization efficiency are the most frequently used.

There is no one ideal radionuclide for each application. It is therefore necessary to make a compromise among the following factors:

*physical form of the source to suit the features of the system and environmental conditons,

*ionization efficiency,

*activity range,

*half life,

*undesired radiations (e.g., gamma radiation association with alpha emission),

*commercial availability,

*cost, and

*reliability and integrity under normal working and accident conditions.

Many national and international regulations and codes provide for this type of product to be considered as exempt from the general license required for radioactive products or radioactive installations. Particular regulatory treatment of such products differs consideably from country to country, but in general, exemptions are based on activity and dose limits.

Moreover, since the early 1950s these applications of the isotopes and radiation technology have shown a commercial boom because of their wide acceptance by the users, as well as the active encouragement from the national and international atomic agencies that most frequently were responsible for both research and development and regulatory functions. In recent years, some regulatory authorities and international agencies have showed a certain degree of concern regarding the proliferation of products of this type, i.e., products containing radionuclides that are available to the general public.

The expressions "consumer products" and "products available to the general public" should not lead to misunderstanding, since they are only acceptable when one refers to products intended for nonlicensed users. The specific products considered here are industrial equipment, and their availability to the general public is rather restricted. This paper presents evaluations of the safety and control of radioactive lightning rods and static eliminators with minor reference to other similar products.

RADIOACTIVE LIGHTNING RODS

Radioactive lightning rods (RLR) manufactured under several patended designs are claimed to improve the effectiveness of the conventional Franklin conductor, extending its zone of protection by artificial ionization of the air above the rod. The practical principle and effectiveness of this principle have been questioned by a few authors, but no definitive proof has been provided, either theoretically or experimentally. However, we can conclusively demonstrate the practical effectiveness of reliable RLR and the soundness of their specified zone of protection based on a statistical study, which, owing to the very nature of the ligthning phenomenon, is an appropriate method.

As a conservative figure, we estimate the number of RLR installed worldwide to be 200,000, mainly in areas of high frequency of occurrence of lightning discharge. Table 1 shows the calculated dose contributions due to RLR for Spain. The data are based on an annual production and installation of 1,500 units, with a total of 12,000 units installed by the end of 1976. Table 2 summarizes the benefits and risks for Spain.

TABLE 1

Dose Contributions Due to Radioactive Lightning Rods* (Spain)

Doses Contribution	Number of Persons	Percentage	Individual Average mrem/year	Total Dose Contribution mrem/year-person
Background	35×10^6	100	150	150
Professional Exposure 1,5000 RLR/year	12	3.4×10^{-5}	875	0.3×10^{-3}
Exposure of 120,000 Individuals During 2,000 Hours Under Each Lightning Rod	120,000	0.34	0.05	0.17×10^{-3}
Contamination due to Rain/Year	35×10^6	100	6.17×10^{-5}	0.06×10^{-3}
Contamination due to Air/Year	35×10^6	100	8.9×10^{-5}	0.09×10^{-3}

(*) Calculations based on americium-241.

TABLE 2

Risks and Benefits Summary (Spain)

BENEFITS	RISKS
Technological improvement	0.6×10^{-3} mrem/year*
$2,850,000 saving for the same performance	1 death by radiation each 476 years

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*Equivalent to increase by 2 cm the average height above sea level.

The development of a standard or code of practice to regulate the manufacture, installation, maintenance, and disposal of these devices would be of great benefit to the public, the manufacturing firms, and the appropriate governmental authorities. Such a standard could be developed either by consensus of the technical community involved or by an international regulatory authority.

Static Eliminators

With respect to static eliminators, the static charge poses a serious problem for several industries such as textile, plastic, and printing, as well as for those who use explosive and combustible materials. Radioactive static eliminators give satisfactory results and are advantageous compared to conventional methods.

A risk/benefit analysis is difficult to perform for static eliminators. The most popular types use americium-241 (half life 458 years) or polonium-210 (half life 138 days), the latter being normally supplied on lease. Polonium-210 is practically free from associated gamma radiation. Eliminators fitted with americium-241 need additional screening to absorb associated gamma radiation. Provided the eliminator design is adequate, radiation dose rates are below internationally accepted values.

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CHAPTER VI

MISCELLANEOUS PRODUCTS

CHAPTER VI

Miscellaneous Products

Owing to the diversity of consumer products, it is impractical to deal with each one of them individually. There are certain consumer products that are unique or are produced on a limited basis. These and others are covered in this chapter. The addition of uranium to ceramic materials and ceramic glazes is associated with a certain radiation exposure. Although the application of uranium for this purpose has been fairly limited, this chapter contains two papers dealing with that subject.

To indicate potential radiation exposure of the population, another subject that is included in this chapter is the use of natural gas and liquified petroleum gas with a naturally occurring radon content. There are various other radioactive materials that contribute to the population dose, but no significant data regarding these sources are available at this time.

A very interesting paper in this chapter deals with use of radioactive materials and its associated pecularities for military applications. The military procures commodities that collectively incorporate large quantities of radioactive materials, and release of these commodities through surplus channels could be of significance in terms of population exposure. The paper dealing with the radioactive military commodities contains information indicating the procedures to keep the radiation exposure as low as reasonably achievable.

This chapter includes a summary prepared by the editors containing information that is significant to the population exposure from radioactive materials incorporated in consumer products. Although an attempt has been made to review all possible radioactive materials, undoubtedly certain consumer products have been omitted. The readers are encouraged to bring to the attention of the editors any major radioactive products or consumer applications not addressed.

THE USE OF URANIUM
IN CERAMIC TABLEWARE

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Uranium was first identified in 1789 by the German chemist Klaproth. It was used shortly afterwards in coloring of glazes and glass. As early as 1896, as the result of fogged photographic plates, it was ascertained that uranium was radioactive.

Lenchner (1926) discussed the use of various uranium compounds as an additive in the manufacture of greenish or yellow glass and glazes. This was further developed by Lorah (1927) who refined the technique. Shortly thereafter, McMaster (1932) obtained a patent for various formulas containing uranium to produce different hues in glazes.

The U.S. Atomic Energy Commission (1961) permitted the use of "exempt" quantities of uranium not to exceed 20 percent in the glaze of ceramic tableware and 10 percent in glassware. It was the opinion of the AEC that these levels of uranium did not constitute a significant radiation hazard. However, according to Crawley (1959), uranium-containing dishes were being used as "convenient sources" in high school radiation measurement experiments in the late 1950's. Public alarm escalated in the early 1960's as reflected in several news articles with such headlines as "Radiation Danger in the China Closet," "Radioactive Dishes Buried – in Backyard," "Hot Pottery Breakup," etc.

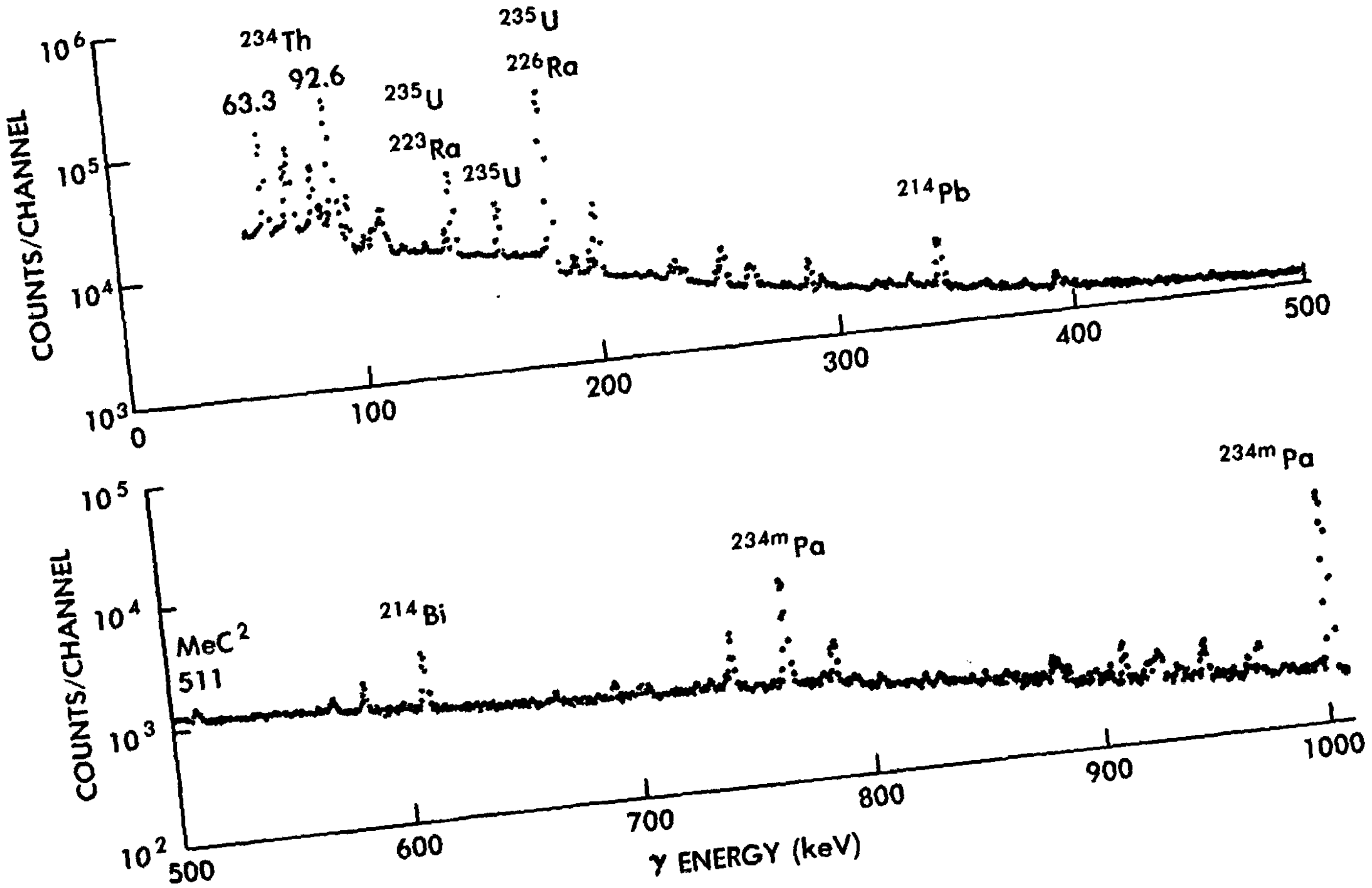
In 1963, the New York regional office of the Public Health Service obtained some radiation measurements of a typical place setting of uranium-containing dishes. Survey-meter open-window readings ranging from 15 mR/h at contact to 3 mR/h at 1 inch were reported. A person seated before such a setting would receive $\sim$ 3 mR/h beta and gamma exposures to the hands and arms. The exposure to the torso at 25 cm would be eass than 0.1 of this value.

Similar readings were recorded from a sample of Fiestaware collected in December 1976 by the Radiological Health Representative of the Philadelphia district office of the Food and Drug Administration (FDA). Using a GM survey meter, open-window readings at contact ranged from 5 to 7 mR/h with the highest readings obtained from the inside areas of a soup bowl. The reading at $\sim$25 cm from a dinner plate (23.5-cm diameter) was $\sim$0.7 mR/h.

A plate analyzed by the Bureau of Radiological Health, FDA, indicated the Ge(Li) spectrum of Figure 1, which confirmed the presence of natural uranium in the glaze.

An estimate of the skin dose due to beta emissions from the surface glaze may be made following a few conservative assumptions using the formula for beta dose from a point source to the arms and hands of an individual exposed to the beta radiations. For a single beta emitter,

$$D(\text{rad}) = \frac{4.1(t)(b)(C)(P\beta)}{X^2}$$



10⁶
10⁵
10⁴
10³
COUNTS/CHANNEL
²³⁴Th
63.3
92.6
²³⁵U
²²³Ra
²³⁵U
²³⁵U
²²⁶Ra
²¹⁴Pb
0
100
200
300
400
500
10⁵
10⁴
10³
10²
COUNTS/CHANNEL
MeC²
511
²¹⁴Bi
²³⁴ᵐPa
²³⁴ᵐPa
500
600
700
800
900
1000
γ ENERGY (keV)

where

4.1 is a constant arising from the choice of units for the variables in the equation,
t is the exposure time in days and is taken as 45.6, which represents 3 hours per day per year,
b is the fraction of disintegrations that result in beta emission,
C is the activity of the source in curies,
X is the distance from the source to the arms and hands which is taken to be 7.6 cm (3in), and
P_β is the mass stopping power, given by

$$P_\beta = \frac{(10^6)(\mu m)(\overline{E})e^{-\mu_m x}}{\rho_m},$$

where

μm is the absorption coefficient in cm^{-1} for betas in tissue,
$\overline{E}$ is the average energy in MeV of the beta emitter,
x is the depth of tissue in cm, in this case equal to 0 since we are interested only in the surface of the skin, and
ρ_m is the density in g/cm^2 of the skin.

In computing the dose, beta emitters with maximum beta energy less than 70 keV were eliminated from consideration since these betas would be completely absorbed in the 3 inches of intervening air. The doses from the five remaining beta-emitting daughters are indicated in Table 1. Assuming them to be present in equal activities, the total dose rate is ∿2.4 rem/yr, which is 1/3 of the 7.5 rem/yr maximum permissible dose (MPD) to the arms and hands of the general public as given in 10 CFR Part 20.

TABLE 1

RADIONUCLIDES IN TABLEWARE BETA ENERGY DOSES

U-DAUGTHER	β-MeV	rad/yr
^{234}Th (UX_1)	0.19	0.97
^{234}Pa (UX_2)	2.31	0.27
^{214}Pb (Ra-B)	0.70	0.49
^{214}Bi (Ra-C)	0.60	0.25 (77%)
^{210}Bi (Ra-E)	1.17	0.38 (23%)
		2.42

O'Donnel et al. (1974) estimated the total dose to the population assumed to be possible due to the distribution, use, and disposal of tableware containing radioactive material if used in eating establishments. Included in the study was tableware assumed to contain 20% natural uranium in the glaze. It was also assumed that such radioactive tableware was used in restaurants instead of the usual nonradioactive dishes. In addition, assumptions were made as to the duration of direct external exposure times of various subjects involved in the use of such dishes. Of these it was calculated that dishwashers, exposed for 2000 hours, would receive 34.4 mrem/yr; waiters, at 1000 hours of exposure, would receive $\sim$7.9 mrem/yr; and a patron seated before a setting of radioactive tableware for a total of 4 hours would receive no more than 0.2 mrem/yr.

Claus (1958) suggests uranium as "a powerful chemical nephrotoxin." Once absorbed in the bloodstream, uranium, as the hexavalent ion, complexes with protein and bicarbonate. The diffusible bicarbonate complex enters the glomerular filtrate. In the proximal tubules, the complex breaks down freeing the uranyl ion which, by blocking carbohydrate metabolism, injures the epithelial cells. According to Claus, the injury is a chemical one; it is independent of the amount of radioactivity, and the effect is acute. Fortunately, only trace amounts of uranium are absorbed from the GI tract and the skin. The International Commission on Radiation Protection (1964) made special mention of the chemical toxicity of natural uranium saying" . . . the ingestion (of soluble uranium) averaged over two days should not exceed 150 mg . . . "

Converting the ICRP maximum permissible concentratin for uranium in water (MPC)w of 6×10^{-7} μCi/ml chronic intake for the general public to mass units, a value of 1.8 mg/l is obtained. Over a 13-week period at 2.2 l day this equates to 360 mg intake. The National Committee on Radiation Protection and Measurements (1963) cites an (MPC)w of 7×10^{-4} μCi/ml based only on radiotoxicity. The more conservative ICRP value will be followed in this paper.

In 1971 an inspector from the Detroit district of the FDA collected some samples of red pottery dishes. In addition to radiation measurements, analysts in the Bureau of Foods, FDA, conducted 24- to 60-hour "soak" experiments using 4 percent acetic acid solutions to duplicate storage of certain acid foods such a sauerkraut. A concentration of 55 ppm of uranium was reported to be present in the 50-hour leach solution. This was equivalent to 1.66×10^{-5} μCi/ml for uranium. This exceeds the (MPC)w of 6×10^{-6} μCi/ml occupational exposure recommended by the ICRP by a factor of 2.7, or 27 for the public, from the continuous ingestion of drinking water based on chemical toxicity of uranium. However, according to the Bureau of Radiological Health (BRH) investigators, following the assumed aforementioned short-term limit recommended by the ICRP, the ingestion of 100 ml of the 60-hour leach solution averaged over a 2-day period would constitute an intake of $\sim$7% of the permissible 150 mg.

The International Expert Committee on Food Additives (1972) published some permissible chronic intake levels for cadmium, mercury, and lead (Table 2). The ICRP (1964) limit for uranium is included for comparison. As indicated, cadmium is the most toxic of the four, mercury next, with lead and uranium being the least toxic of these elements. However, it was the opinion of the BRH that the exposure levels of uranium, albeit admittedly low, constituted an unnecessary and avoidable exposure to the public. In addition, based on the leach data, such tableware is subject to the food additives clause of the Food, Drug, and Cosmetic Act and thus subject to regulations.

TABLE 2

COMPARATIVE CHRONIC INTAKE LIMITS OF FOUR HEAVY METALS

Element	mg/Week
Cadmium	0.4
Mercury	0.5
Lead	3.0
Uranium (360 mg/13 wks, ICRP-6)	27.7

Following inspections in 1972, it was determined that other glasses (candlesticks, ashtrays, etc.) containing uranium were ornamental and not used in food handling and therefore exempt from FDA regulatory controls. It was learned that because of the adverse publicity and the threat of regulatory controls, manufacturers were no longer using uranium as a color additive in tableware. However, according to an article appearing in a 1974 issue of the Louisville Times, radioactive dishes were still available to the public from back inventories. As is evident in the most recent incident in Philadelphia, radioactive dishes as well as other ceramics are still available in antique shops as collector's items. Clearly, the problem is still with us today!

The levels of radioactive material in ceramic tableware are not considered hazardous. However, such exposures are clearly avoidable and of no benefit to the public. Therefore, the use of such products should be avoided as unnecessary exposure to radioactive materials.

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RECOMMENDATIONS ON THE USE OF URANIUM IN PORCELAIN TEETH

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One of the more successful examples of modern prostheses is the porcelain tooth. It matches the function, the durability, and the appearance of the natural tooth. In the latter respect, the artificial device is so attractive that unsightly natural teeth may be replaced by, or crowned with, porcelain. The cosmetic quality of porcelain teeth is due in large measure to the addition of small amounts of uranium. This element, when present at levels of only a few hundred parts per million, enhances the finished tooth or crown by imparting a fluorescent property that imitates natural fluorescence under all lighting conditions. The need for broad spectral response in dental restorations is important. It is undesirable when white crown turn to dull green under the ultraviolet light at the local discotheque, or a bridge appears black under the mercury vapor lamps at the shipping mall. The benefit from the use of uranium in dental porcelain is well established, but the concomitant risks are somewhat uncertain.

Approximately half of the artificial teeth used in this country are not porcelain, but methacrylate or similar substances that do not use uranium or other radioactive fluorescing agents. These are somewhat less expensive than porcelain but have disadvantages in that they do not match the surface appearance of natural enamel as closely, are less durable, and do not imitate natural fluorescence to the same degree.

The Bureau of Radiological Health of the Food and Drug Administration was involved recently in the task of evaluating the radiation hazard consequent to dental use of uranium. Data from that study have been published (Thompson, 1976).

The maximum concentration of uranium in a ceramic product that is license-exempt is 500 ppm or 0.05 percent (10CFR 40.13). Since porcelain must match the variation in intensity of fluorescence occurring in natural teeth, the range of uranium concentration extends from zero up to near 500 ppm. Few teeth have a brilliance requiring more than about 300 ppm so the mean concentration in dental porcelain in the U.S. is approximately 200 ppm. Both alpha and beta particles are emitted by the ceramic teeth, and of the two, the alpha delivers the larger amount of energy to the adjacent tissue. Fortunately, alphas cannot penetrate beyond the superficial cell layer and thus expend their energy in that layer. Beta particles are not so easily attenuated and may reach the basal layer of tissue.

In addition to the beta particles from uranium, a beta flux can be observed from the naturally occurring potassium-40 present in the mineral feldspar, a basic ingredient of porcelain. As shown in Table 1, the combined beta dose rate from uranium and potassium-40 can reach about 1.5 rem per year in the worst case, though the mean dose rate is probably about 0.7 rem per year (Thompson, 1976). There is no appropriate guideline by which to evaluate this dose rate. The International Commission of Radiological Protection has recommended an upper limit of 1.5 rem per year for exposure of entire organs other than the skin (ICRP, 1965). In the case of dental porcelain, we are dealing with only a small portion of an organ. The probability of tumor induction decreases when the entire organ is not irradiated.

TABLE 1

Beta Dose Rates From Uranium and Potassium-40

Uranium Conc. (PPM)	rem/yr βU	rem/yr βK-40	rem/yr Total
500 (max)	1.35	0.20 (max)	1.55
200 (mean)	0.54	0.17 (mean)	0.71

Depletion of potassium-40 in raw material is not feasible, nor can much of a dose reduction be effected by the selection of low-potassium feldspar. Reduction and elimination of uranium is the practicable way to significantly decrease the dose from dental porcelain. The report on the Bureau's technical study concluded with the recommendation that an upper limit of 370 ppm be allowed for uranium. By direct proportion with the values in Table 1, this would represent a potential dose rate of 1.0 rem per year. Assuming the presence of the maximum observed potassium-40 with a dose contribution of 0.20 rem, and allowing a margin of 0.25 rem for the uncertainties in these estimates, the combined potential beta dose rates would be held below the ICRP recommended limit of 1.5 rem per year. The 370 ppm limit is intended to serve only as an interim bound because the report has also recommended that the dental products industry develop nonradioactive fluorescing agents and cease using uranium. This recommendation is consistent with that recently proposed by authorities in the United Kingdom (O'Riordan, 1974).

The American Dental Trades Association (ADTA, 1976) representing domestic manufacturers, has produced a voluntary standard that prescribes an upper limit of 300 ppm in uranium. This standard is not only compatible with the Bureau's recommendation, but is one that should have only a minor impact on the composition of current product lines.

The development of a nonradioactive substitute is expected to present a much greater challenge for the industry. Dental ceramists have tested other fluorescing agents during the past 50 years. The formulation of dental porcelain is a ceramic art where small changes in critical components can greatly alter the final product. Substitution for uranium will involve attempts at reproducing hundreds of different shades of porcelain powder.

Data that clearly define the hazards of low dose and low dose rate irradiation are not available. Personnel responsible for radiation protection have usually adopted the conservative approach in assuming that the linear responses observed at high dose and high dose rates may be extrapolated to lower exposures. In oral cancer, the relative risk at high levels of exposure has not been established, so crude extrapolation based on other somatic effects could be associated with considerable error.

The etiology of oral cancer has been established with respect to several agents (Tiecke, 1954). The incidence of such lesions is three times as great for persons with syphilis as it is for the rest of the population (Tiecke, 1954). It is about four times as great for cigarette smokers as for nonsmokers. It has similar high incidence for those who use the leaf in other forms such as pipes, cigars, and chewing tobacco (PHS, 1969). Alcoholics have an elevated rate of oral cancer (ACS, 1973). Farmers, sailors, and others with excess exposure to sunlight are vulnerable to lip cancer. No causal relationship has ever been reported for oral cancer and dental porcelain. Two of the three more common sites of oral cancer, the palate and the faucial arch, are located at some distance from the teeth (ACS, 1973). In summary, these facts strongly suggest that if any link exists between cancer and uraniated dental porcelain, very few deaths could be ascribed to it.

A possible explanation for a low incidence of cancer from porcelain is that many wearers are in an elderly age group. Statistical surveys show that 43 percent of edentulous persons are over 65 years of age (NCHS, 1971). The balance of the population in this age group is missing an average of 18 teeth (NCHS, 1974). It is unlikely that these persons have a remaining lifespan sufficient for induction of the cancer, the latent period to the appearance of the lesion and the period of growth before the tumor is evident.

In the initial stages of the Bureau of Radiological Health study, (Thompson, 1976) an epidemiological review was considered as a means to resolve the questions of a causal relationship between oral cancer and dental porcelain. The proposal was rejected as impracticable, and a basis for rejection probably should be explained here for the benefit of those who would still advocate such a program.

For a 95 or 99 percent chance of detecting an increased risk at the 5 percent level of significance, it would require a study population in excess of the total U.S. population (Goss, 1975). For only a 50 percent chance of detecting an increased risk, it would require following 44 million exposed persons, 44 million persons who wear non-uraniated dental prostheses and 44 million persons who do not wear a dental prosthesis, all for a 25-year period. It is likely that a substitute for uranium in dental porcelain could be found in less time and at less cost than it would take to conduct such a survey.

We are left with the theoretical possibilities that: (1) no one ever contracts a cancerous lesion solely from exposure to uraniated teeth, or (2) some number of persons actually are subject to such a fate, or (3) uranium irradiation acts in synergism with alcohol, tobacco or other agents to further increase an already elevated risk. It is because these last two possibilities are, in our view, the more likely, substitution for uranium has been urged.

If a chance of cancer induction exists, why not propose immediate replacement of all uraniated porcelain teeth and crowns? Why not immediately prohibit the sales of this product?

Initiation of a replacement program may be expected to generage anxiety among denture and crown wearers grossly out of proportion to whatever risk exists. An even more substantial objection to replacement, however, is based on the logistics and economics of the task. Since approximately half of all dentures and bridges are porcelain, there are roughly 10 million of each to be replaced. There may be as many as 25 million porcelain crowns. Some dentists perform all the work on a prosthesis in their own laboratory, others only do impressions, fitting, and finishing, with construction performed for them by a separate laboratory. If we exclude construction time, it still takes at least 4 hours to complete a denture and about 3 hours of the practitioner's time to finish a bridge or crown. A total replacement program could involve a minimum of 145 million man-hours. There are 108,000 active dentists in the U.S. (ADA, 1976). If we ask them to take one full day per week from their usual obligations and devote it to this program, it would require over three years to complete the task. The cost in time and material would rise into the billions with retired, elderly persons the most affected.

A moratorium on sales of uraniated products would also have an enormous impact. One domestic manufacturer has estimated that over 100 million of his artificial teeth are in storage at warehouses and dental laboratories throughout this country. Add to this his stock of porcelain powder and the loss to just this one manufacturer would be in the tens of millions of dollars. It cannot be justified on presently available evidence.

In summary, the Bureau of Radiological Health recommendations provide guidance for the use of uranium in dental porcelain at levels that yield dose rates below the maximum permissible levels proposed by the International Commission of Radiological Protection. The dental industry has been urged to find a nonradioactive substitute within a reasonable period. If implemented, these recommendations can lead to the elimination of a potential radiological hazard. The recommendations were developed with a view to inflict a minimum negative impact on the consumer, the professional, and the industry.

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CONTROLS EXERCISED BY THE ARMY OVER RADIOACTIVE CONSUMER-TYPE ITEMS

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Approximately 100,000 curies of radioactive material are contained in some 300 kinds of equipment used by the soldier. The radioactive material is used mainly for radioluminosity, check sources, and calibration. Tritium, promethium–147, radium–226, carbon–14, cobalt–60, strontium–90, and krypton–85 are the commonly used radionuclides and normally range from a fraction of a microcurie to a few curies per device. With the exception of the calibrators, the equipment is similar to that available for consumer use.

Beyond the need to paint equipment olive drab for camouflage purposes, there are certain other considerations in the selection of products for military use that are of less consequence in consumer use. At military installations, large quantities of such equipment are likely to be stored, repaired, or accumulated for disposal. Military equipment is exposed to extreme physical and thermal shock. Equipment loaded in the cargo compartment of a military transport plane standing in the direct sun can reach 155°F. During high–altitude flights, the cargo quickly reaches frigid temperatures only to rise again upon landing. There is a possibility that the equipment may be dropped during multiple handling or bounced while being transported overland. Another consideration is that military equipment may be stored two or more years before it is finally used. Still another reason is the large number of persons who are likely to handle the equipment and who are of childbearing age. Because of these differences, the Army and the other military services exercise control over radioactive commodities for military use.

Army safety policy requires that proponents of any equipment or system ensure that:

a. Maximum safety consistent with military operational requirements is designed into the materiel and equipment.

b. Adequate controls over known hazards are established to protect personnel, equipment, and property.

c. Minimum risk is involved in the acceptance and use of new materiel.

d. Hazards associated with each system, assembly, or subassembly, are identified and corrected in an expeditious manner, thereby reducing costly retrofit actions.

In addition, the various military services have collectively published interservice policy, procedures, and guidance concerning development, procurement, storage, maintenance, control, shipment, and disposal of radioactive commodities and the training of personnel. Interservice policy contains the following requirements:

a. Personnel exposure to ionizing radiation shall be kept as low as practicable consistent with operational necessity and within Federal and applicable Military Service or Agency (hereinafter referred to as Service or Agency) radiation protection standards.

b. Personnel who work with radioactive commodities shall be instructed on potential hazards, on precautions to minimize exposure, and on operating procedures.

c. Life cycle controls shall be established for each commodity containing radioactive material as early as possible in the development/design stage. Licenses and service authorizations, as applicable, shall be obtained by the responsible Service or Agency prior to awarding procurement contracts.

d. The use of radioactive materials in items of supply shall be kept to the minimum consistent with DoD needs. Practical, nonhazardous substitutes shall be procured and used when possible. Radium shall not be procured or used until it has been established that a nonradioactive substitute or a less hazardous radioactive substance cannot be used feasibly.

e. At the earliest practicable stage in the planning process, including the development stage of a radioactive commodity, and in all instances prior to the decision to procure the commodity, the environmental consequences during each element of the life cycle shall be assessed in accordance with Federal and Service or Agency environmental assessment directives.

While these policies express an ideal situation, they are not always achievable. The Army attempts to ensure consistency by internal licensing in those cases not under U.S. Nuclear Regulatory Commission (NRC) specific license control and by centralized processing of applications where NRC specific license controls apply.

Hazards are identified in the conceptual stage, and provisions for their control are included through the stages of design, research, development, test, evaluation, procurement, production, inspection, acceptance, transportation, handling, storage, use, and disposal.

All Army materiel designed for general Army use must undergo engineering and service testing by an independent command (US Army Test and Evaluation Command) to establish that the items are suitable and safe for Army use. Such equipment is also reviewed by the Army Health Services Command as to the health hazard. Military specifications are written and reviewed by interested parties. The health and safety requirements are reviewed at several different command levels and also by staff personnel in The Surgeon General's Office.

Proposals to procure and field radioactive commodities are submitted as applications for NRC licenses or service authorizations. The applications must contain the following information:

a. A complete description of the commodity, e.g., narrative description plus drawings, purchase description, or specifications.

b. Procedures to ensure that quality audits are performed by an independent testing laboratory (Governmental or industrial) on random samples from production lots.

c. Detailed procedures for radiation protection of DoD employees and the general public to be followed during the complete life of the commodity from adoption through ultimate disposal. The procedures must include an abbreviated organizational chart in which key agencies and offices are identified and their responsibilities with reference to life cycle controls are enumerated. Pertinent sections of implementing Service or Agency regulations, orders, instructions, manuals, and bulletins must also be included or referenced (if available at reviewing Agency).

d. Internal procedures for use within other DoD components authorized to use the radioactive commodity. The receiving service must accept complete responsibility for providing the licensee with information concerning control, investigation, reports to the NRC, and enforcement. The NRC conducts all of its regulatory activities (licensing, compliance inspection, and enforcement) with the organization to which the license is issued.

e. The total activity of each radioisotope, maximum radioisotopic content of each individual item, and the chemical and physical form of the radioisotope and its containment.

f. Summary of significant research, development, test, and evaluation effort and results.

g. Quality assurance procedures for surveillance and verification of quality and integrity of material throughout the item's life cycle.

h. Control procedures applicable during the commodity life cycle. Special qualifications required of users must be stated in the procedures. Consideration should be given to adoption of directives as bi- or tri-Service or Agency documents. Specific information should be provided for each handling activity, i.e., acceptance inspectors, surveillance inspectors, supply (storage) and maintenance personnel, users, and transportation and disposal personnel. The instructional material should be prepared so as to separate that required by each of the foregoing groups from each of the others. Life cycle control directives for nonlicensed (authorized) radioactive commodities must be as thorough as those required for commodities that have a specific license.

i. Procedures for the distribution and control of the commodity among the Services or Agencies when the commodity is governed by a single license for more than one DoD element.

j. Summary of controls for maintenance and repair.

Army personnel are protected against associated hazards by instructions contained in Army regulations and publications pertaining to the equipment. In the cases where sufficient activity or risk is involved, training is provided. All suspected excessive exposures to ionizing radiation are required to be investigated by the immediate commander. A copy of these investigations is furnished to the Office of The Surgeon General for final determination.

Radioactive commodities are consigned only to installations, agencies, or individuals that are authorized by an NRC license or Service or Agency authorization or receive them and that are known to have a capability for safe handling of the specific commodity. Transportation and shipping is consistent with Federal and applicable international requirements. Marking of all shipping containers is required even when exempt from DOT marking to eliminate need for multiple relabeling while in depot storage. The radioactive commodities are stored and repaired in designated posted areas. Such areas are routinely surveyed and physical inventories are conducted. Any shortages or unusual situations are reported and reconciled.

Electron tubes and major end items of equipment containing installed license-exempt items must be disposed of in accordance with normal transfer, donation, or sales procedures. Other license-exempt items are offered for use by other DoD components or Federal civil agencies. They are disposed of as radioactive wastes if unwanted by those agencies.

Microwave receiver protector tubes, marine navigation devices containing tritium gas, and radium sources other than those used for production of light may only be transferred within DoD or disposed of as radioactive wastes. These items are not authorized for donation or sale.

Usable licensed items containing radioactive materials are transferred, donated, or sold only to persons having a proper license to possess them. Only the item manager or owning activity will screen these items for utilization and donation. If the items cannot be transferred, donated, or sold, they will be disposed of as radioactive waste. Inspections, surveys and user feedback are used to verify the adequacy of both the control over the equipment and its adequacy.

The foregoing controls evolved from adverse experience and poor product performance.

During World War II, radium was used by the Army for self-luminosity. Significant personnel exposure potential existed when multiple devices were used in instrument panels or when large quantities were stored in close proximity to work areas. Usually, the items were not labeled as to their content. Internal radiation hazard existed during bulk, unventilated storage and during rework of equipment. Useful luminosity lasted for about 12 months. With the advent of safer radionuclides, procurement of self-luminous items containing radium has been prohibited since 1968. Approximately 100 curies are estimated as remaining in the system. Care is exercised to prohibit repair or sale of the radium items.

Around 1960, the Army began to use tritiated paint to replace radium. The inefficiency of gas proportional instruments to measure tritium misled proponents as to the permanency of the tritium bonding, and therefore longer periods of useful luminosity than the 12 to 18 months actually achieved were expected. To be of military use, a 36-month minimum luminosity life is desired. This need and the advent of liquid scintillation counters led to the use of ceramic-bound radioactive luminous materials and tritium gas light sources. To achieve the benefits of these two approaches, better specifications and acceptance inspection had to be introduced.

Although some commercial off-the-shelf products have been used successfully, the risk to the Army is too great in the case of radioactive commodities. In some cases, radioactive product safety standards are nonexistent or inadequately enforced. In other cases, the rationale for the standard may be undocumented.

On rare occasion, the controls fail when radioactive materials are introduced without the Army's knowledge as a result of contractor or Army material proponent failure to comply. Most commercial suppliers are responsive to the Army's needs and requirements. The Army has had a very few problems related to procurement of "off-the-shelf" items that raised questions as to consumer risk or value or as to the need for consumer protection. The radioluminosity manufacturers have actively participated in ANSI 43.2 to establish minimum acceptability standards for products offerred to the military and to the public.

Among the unresolved problems affecting both the Army and private users are the need for a practical means to ensure that optical glass does not contain excessive radioactivity and for better information as to the radioactive content and the hazards and controls needed during repair, bulk storage, and disposal. The lack of such information can lead to either excessive or inadequate controls.

CERTAIN TOPICS RELATED TO RADIOACTIVITY IN CONSUMER PRODUCTS

Several radiological topics regarding radioactivity in air, food, and water have consumer interest. The concentrations and quantities of various radionuclides incorporated in the consumer products as air, food, and water also have public health and environmental significance. Although food is clearly a consumer product, the availability of a rather voluminous literature and excellent review (UNSCEAR, 1972) makes it unnecessary to review this subject here. Similarly, the radioactivity content of drinking water has been repeatedly studied and reported on in the literature.

The management and control aspects of radioactivity in these consumer related products can present regulatory considerations of a special interest. In addition, detailed regulations have been established dealing with all radionuclides (40 CFR–141). The Food and Drug Administration (1977) proposed quality standards for bottled water, although measured values are limited or nonexistent. Although the impact of the radioactivity content of bottled water is probably small, the availability of measured values would be desirable.

A product of particular interest is mineral water. Often an increase in the mineral content is associated with an increase in the concentration of naturally occurring radionuclides, notably radium-226. Therefore, routine monitoring of mineral waters is desirable.

NATURAL GAS

Studies dealing with the radioactivity content of natural gas were enhanced by the program to stimulate natural gas using nuclear explosives. After several experiments, the program was abandoned. However, those experiments offered the opportunity to measure radon and fission products in the stimulated natural gas (Smith, 1971). Appropriate studies were also conducted to develop standards for tritium (Moghissi, 1971) and to relate the tritium dose to that of radon-222. (Carter, 1974).

Radon-222 constitutes the major source of radioactivity in natural gas. Johnson (1973) and Gesell (1977) reviewed radon-222 in natural gas and liquefied petrolum gas. Their reviews included a compilation of analytical data and inhalation dosimetry. Tables 1 and 2 show radon concentrations of natural gas at production wells and in distribution lines in various parts of the U.S. These authors indicate a wide range of radon concentrations in natural gas at production wells. As expected, the average radon concentration in distribution lines in somewhat lower than that at production wells, primarily because of the elapsed time in the transportation line before the gas reaches the consumer.

Johnson (1973) calculated the tracheobronchial dose equivalent for the U.S. population using the method applied by Barton (1973). Table 3 contains the findings indicating a radiation dose of 2.7 x 10^6 person-rem to the tracheobronchial section

TABLE 1
RADON-222 CONCENTRATIONS (pCi/1) IN NATURAL GAS AT PRODUCTION WELLS
(GESELL *et al*, 1977)

Area	Average	Range
Ontario, Canada	169	4-800
Alberta, Canada	62	10-205
British Columbia	473	390-540
Colorado, New Mexico	25	0.2-160
Texas, Kansas, Oklahoma	<100	5-1450
Texas Panhandle	– – –	– – –
Colorado	25.4	11-45
Project Gasbuggy Area	15.8-19.4	– – –
Project Gasbuggy Area	29.4	12-59
California	– – –	1-100
Gulf Coast (Louisiana, Texas)	5	– – –
Kansas	100	– – –
Wyoming	10	– – –

TABLE 2
RADON–222 CONCENTRATIONS (pCi/1) IN NATURAL GAS DISTRIBUTION LINES

(Johnson *et al*, 1973)

AREA	AVERAGE	RANGE
Chicago	14.4	2.3-31.3
New York City	1.5	0.5-3.8
Denver	50.5	1.2-119
West Coast	15	1-100
Colorado	25	6.5-43
Nevada	8	5.8-10.4
New Mexico	45	10-53
Houston	8	1.4-14.3
Overall Average	23	

TABLE 3
TRACHEOBRONCHIAL DOSE EQUIVALENT TO THE U.S. POPULATION FROM RADON IN NATURAL GAS

(Johnson, 1973)

State	Dwellings with unvented heaters	Average Annual Degree-Days	Dose, 10^3 person-rem/yr	Dwellings with gas ranges	Dose, 10^3 person-rem/yr	Total Dose, 10^3 person-rem/yr
Calif.	214	2.76	44.7	4,350	261	306
N.Y.	58.7	6.27	27.9	4,190	251	279
Tex.	942	1.94	139	2,150	129	268
Ill.	48.6	5.90	21.8	2,510	150	172
Pa.	47.9	5.53	19.8	1,950	117	137
Ohio	33.2	5.84	14.7	1,670	100	115
N.J.	24.9	4.80	9.1	1,610	96.8	106
Mich.	40.4	7.37	22.6	1,260	75.5	98.1
La.	373	1.63	46.2	763	45.8	92.0
Okla.	204	3.79	58.7	515	30.9	89.6
Ga.	280	2.44	51.8	446	26.8	78.6
Mass.	21.5	6.52	10.7	914	54.3	65.0
Ala.	246	2.37	44.3	296	17.8	62.0
Miss.	271	2.19	45.2	233	14.0	59.2
Ark.	166	3.02	38.0	320	19.2	57.2
Mo.	27.2	4.92	10.2	780	46.8	57.0
Ind.	23.1	5.69	10.0	778	46.7	56.7
Md.	21.6	4.62	6.6	706	42.3	49.9
Wis.	22.1	7.68	13.1	511	30.6	43.7
Minn.	19.2	8.89	12.9	442	26.5	39.4
W. Va.	61.6	4.84	22.6	280	16.8	39.4
Ky.	39.1	4.87	14.5	389	23.3	37.8
Va.	40.3	3.78	11.6	424	25.5	37.1
Fla.	289	0.74	16.3	323	19.4	35.7
N.C.	93	3.28	23.2	136	8.2	31.4
Tenn.	68.6	3.49	18.2	211	12.7	30.9
Iowa	8.9	6.87	4.7	393	23.6	28.3
Kans.	10.8	5.28	4.3	358	21.5	25.8
Ariz.	29.3	3.30	7.3	299	17.9	25.2
Conn.	10.0	5.92	4.5	327	19.6	24.0
Colo.	8.4	6.31	4.0	284	17.0	21.0
S.C.	75.9	2.34	13.5	99.7	6.0	19.5
Wash.	30.0	5.37	12.2	69.2	4.1	16.3
N. Mex.	19.1	4.65	6.7	146	8.8	15.5
D.C.	4.6	4.62	1.6	226	13.6	15.2
Nebr.	6.0	6.68	3.1	186	11.1	14.2
Oreg.	16.5	6.05	7.6	54.3	3.3	10.9
R.I.	5.4	5.88	2.4	138	8.3	10.7
Utah	5.4	6.11	2.1	83.3	5.0	7.1
Mont.	5.5	8.09	3.4	54.4	3.3	6.7

TABLE 3 – Continued
TRACHEOBRONCHIAL DOSE EQUIVALENT TO THE U.S. POPULATION FROM RADON IN NATURAL GAS

(Johnson, 1973)

State	Dwellings with unvented heaters	Average Annual Degree-Days	Dose, 10^3 person-rem/yr	Dwellings with gas ranges	Dose, 10^3 person-rem/yr	Total Dose, 10^3 person-rem/yr
Me.	5.4	8.64	3.5	33.7	2.0	5.5
S. Dak.	4.9	7.80	2.9	43.1	2.6	5.5
Del.	2.5	5.93	0.9	65.6	3.9	4.8
Nev.	4.8	6.19	2.3	41.5	2.5	4.8
Idaho	8.5	6.13	4.0	12.6	0.7	4.7
N. Dak.	3.5	9.31	2.5	27.8	1.7	4.2
N.H.	2.7	7.38	1.5	38.8	2.3	3.8
Wyo.	2.1	7.59	2.5	41.2	1.2	3.7
Vt.	3.0	8.27	1.9	14.3	0.9	2.8
Hawaii	0.2	---	---	36.5	2.2	2.2
Alaska	2.1	8.09	1.3	9.6	0.6	1.9
TOTAL	3,950.7		854	31,234.6	1,874	2,728

of the lung for the U.S. population. Gesell (1977) indicated difficulties in estimating the radiation dose as a result of consumption of liquefied petroleum gas. Because this kind of gas is usually bottled for distribution to the consumer, the time lag between production and consumption could vary and result in large inaccuracies in dose calculations. Gesell (1977) measured radon-222 concentrations in liquefied natural gas in the Houston, Texas, area. The range of radon concentrations was large, and the average concentration was about 50 pCi/1, STP.

PREVIOUS METALS

Application of radon needles or "radon seeds" dates back to the early history of the practice of radiology. Experiments with glass tubes were unsuccessful; therefore, the glass tubes were replaced by gold capillaries approximately 4 mm long, with a 0.75 mm wall thickness and an internal diameter of 0.45 mm (Boggs, 1969). These radon seeds contained up to several mCi of radon. After the radon had decayed, the only remaining radionuclide of concern was Pb-210. Because the application of radon seeds has considerably decreased in recent years, there may be an economic incentive to use the gold for other purposes. The literature contains reports of at least three cases of dermatitis resulting from wearing jewelry products made from spent radon seeds (Simon, 1967; Gerwig, 1968). Because of the limited quantity of gold used for production of radon seeds it is unlikely that a large segment of the population will be exposed to radiation from this source. It is advisable, however, to evaluate unusual cases of dermatitis considering the possibility of Pb-210-contaminated jewelry as a probable cause.

EDUCATIONAL MATERIALS

Regulations of the Nuclear Regulatory Commission and various States permit the possession and use of radioactive materials by the general public without a written license, provided the quantity of the radionuclide is below a certain activity level. Under these regulations, small "exempt" radiation sources may be received by educational institutions for demonstration purposes. In a limited survey, the Bureau of Radiological Health (BRH, 1969) determined the extent of use of radiation sources in secondary schools. This survey indicated that radioactive sources were widely distributed. Table 4 contains a summary of the kinds of radioactive materials incorporated in sources used in 181 secondary schools. Most long-lived radioactive materials such as Co-60, Cs-137, and Ra-226 were used as sealed sources. Other materials such as P-32 were used as unsealed sources in biological experiments. Because of the small quantities of radionuclides incorporated in these demonstration sources, the exposure from their use in education is low.

RISK/BENEFIT ANALYSIS

Brodsky (1965) developed a method for classifying permissible levels of radioactivity in consumer products. He categorized consumer products into several classes, each class having a societal value one order of magnitude higher than the preceding class. Also, within each class, a series of reducing terms that limit the total radiation exposure from each class was proposed. The radiation dose for each class was therefore proportional to the value assigned to it. Brodsky's method requires that the society establish a consensus value for various consumer products. It appears unlikely that such a consensus is to be reached in the foreseeable future.

TABLE 4

NUMBER AND TYPE OF RADIONUCLIDES IN 181 SECONDARY SCHOOLS

Radionuclide	No. of Sources
$^{3}\mathrm{H}$	4
$^{14}\mathrm{C}$	65
$^{22}\mathrm{Na}$	21
$^{24}\mathrm{Na}$	1
$^{32}\mathrm{P}$	60
$^{35}\mathrm{S}$	13
$^{36}\mathrm{Cl}$	1
$^{45}\mathrm{Ca}$	5
$^{51}\mathrm{Cr}$	1
$^{54}\mathrm{Mn}$	2
$^{59}\mathrm{Fe}$	8
$^{60}\mathrm{Co}$	102
$^{65}\mathrm{Zn}$	23
$^{79}\mathrm{As}$	1
$^{90}\mathrm{Sr}$	36
$^{106}\mathrm{Ru}$	1
$^{109}\mathrm{Cd}$	5
$^{131}\mathrm{I}$	24
$^{133}\mathrm{Ba}$	2
$^{134}\mathrm{Cs}$	15
$^{137}\mathrm{Cs}$	22
$^{144}\mathrm{Ce}$	12
$^{203}\mathrm{Hg}$	1
$^{204}\mathrm{Tl}$	38
$^{226}\mathrm{Ra}$	26
$^{235}\mathrm{U}$	2
$^{238}\mathrm{U}$	2
$^{241}\mathrm{Am}$	5
$^{237}\mathrm{Np}$	1
others	666

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CHAPTER VII

NATURAL AND MAN-MADE RADIOACTIVITY IN CONSUMER PRODUCTS: LABELING REQUIREMENTS AND RISK/BENEFIT ASSESSMENT

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Summary of a Panel Discussion

During the Symposium, "Public Health Aspects of Radioactivity in Consumer Products," a panel discussion was organized on the topic of the symposium in general and the title of this chapter in particular. The members of the panel were E.D. Bailey (State of Texas), R.B. Minogue (NRC), K.Z. Morgan (Georgia Tech.) R.H. Neill (FDA), and A.C. Richardson (EPA), A.A. Moghissi was the chairman.

Moghissi:

I would like to welcome you to this panel discussion. In the past these panel discussions have proven to be most profitable. I am proud and pleased that we have a distinguished group of people together here. I shall briefly introduce the members of the panel and ask them to say a few words. After that you may direct questions to one or more of the members of this panel, who will answer your questions. The panel discussion will be edited and the editing will be essentially the correction of English, deletion of redundancies, and things of that nature.

I shall start from my extreme left. Bob Neill is from the Bureau of Radiological Health. Bob and I have known each other for many years. Bob is the Associate Director of the Bureau of Radiological Health.

The next gentleman is Dr. Karl Z. Morgan, and although he doesn't need an introduction, he is going to get one. One of the pleasures of being at Georgia Tech is having been on the same faculty with Karl. He is one of the most distinguished health physicists that we know of and he can be rightfully called the "father of health physics." He was the first president of our National Health Physics Society and of the International Radiation Protection Association, and he has authored in excess of a few hundred papers.

On my extreme right is Robert Minogue of the Nuclear Regulatory Commission. Bob has been in the standards business for a long time. Bob was with the Atomic Energy Commission and, upon the formation of the Nuclear Regulatory Commission, became Director of the Office of Standards Development. It is a pleasure to have him.

Our next gentleman is from the State of Texas. Ed Bailey represents the State's view in the discussion.

Last but not least is Allen Richardson. He has also been involved in standards development for several years. He has been involved in developing various guides for the Environmental Protection Agency.

Minogue:

There were two topics identified for this panel. The first of them was labeling and the second was risk-benefit. I will make most of my remarks on the subject of risk-benefit analysis. The regulation of consumer products that contain radioactivity in a way that will assure the public safety presents to any regulatory agency involved a particularly unique and difficult set of problems. That is, the regulator must make decisions of public policy in which a particularly complex balance is required between risk and benefit. In some ways this decision is far more difficult than that involved in regulating large nuclear power facilities. When you deal with large facilities such as power plants, you can impose very stringent requirements to contain any radioactivity that is produced, and releases can be cut to extremely low values. This regulation can, to a large extent be based not just on limits in the environment but on assuring that no undue releases are made. This isn't the case at all with consumer products. By the nature of their use, these products are dispersed and are beyond control. Even though the individual exposures may be very low, large numbers of people may be affected, and retrieval of the material in the event that some unforseen consequences should develop cannot be assured. In particular research and review are needed on such questions as "What is the benefit of the use of the radioactive material? Is it a unique benefit? Are there other ways of achieving the same goal that do not involve radioactivity? What differences in effectiveness are there? Do the alternatives themselves have adverse impacts? Is there a benefit to be gained by the person at risk or are others affected? What special problems are there in shipping a product?" All of these are very difficult questions to balance when you are in an area of limited risks and limited benefit. Even the cost of the analysis is a factor. If you are dealing with a potential product that may be marketed with a relatively small dollar volume and you want to do a completely satisfactory scientific job of making a cost-benefit analysis along the lines of the environmental impact assessments that are required by NEPA, the dollar cost of doing this very careful analysis in the interest of public policy formulation may far exceed the value of the product being marketed. All of this careful analysis also has to be done in recognition of the proper role of government. Regulatory officials are concerned with public health, and they should try to find a way of meeting their public health responsibilities. It should not involve undue or unjustified suppression of orderly commerce. With that preamble I would sum up by saying that this whole issue is extremely complex. The NRC, as I indicated earlier in my prepared talk, is reexamining the criteria for approval of consumer products that were developed over ten years ago. I realize that this is a session where the audience will ask questions, but I hope that, among all the questions, we get some good ideas, suggestions, and proposals on ways to attack these problems. I, for one, am here to learn. I have a very open mind on the subject.

I will say just one word on labeling. The public is entitled to know and understand the hazards of any product that is marketed.

Neill:

A few facts that I would like to add relate to some of the risk-benefit comments and studies. Obviously, to compare benefits and risks it is necessary to express each in similar units. Quite often this is very difficult. For instance, it is very difficult to assess the value of entertainment of color TV. In the area of ultraviolet radiation emanating from sun lamps, the American public is convinced that a tanned skin is more attractive. It is very difficult to assess this in either units of dollars or some other units that one can compare to the risks associated with it. I could go on with other illustrations. My point on benefit/risk is that it is very difficult to get units of benefit and risk in similar units whether one is dealing in terms of dollars or effects or time lost versus time saved.

The second point of consideration is the proliferation of multiple sources; I think we are going to have to face up to that more and more in the future, not only within the ionizing field but in the nonionizing field as well. One can apportion or allow a certain level of exposure from one source. But when there is a whole host of these sources, how does one limit the exposure? If one were to draw up a list of consumer products 20 years ago, it would have been far less than today, and 20 years hence it will certainly be far greater. Other problems arise from attempts to make each product safe by design. In such cases, the design must relate to the conditions of use and possible carelessness or misuse on the user.

Unlike hospitals, laboratories, and industrial facilities, the consumer area must, in general, be termed an uncontrollable environment. I am reminded of my colleagues in FDA in the Bureau of Drugs, where a manufacturer will submit volumes of data regarding the efficacy of a drug; it will include a list of side effects or deleterious effects and will show the data of how beneficial the drug is to society. Their job is to weigh the data and come to a conclusion as to whether one clearly outweighs the other. Those people are not as fortunate as we are in the ionizing radiation area where, since World War II, the American people have probably invested a billion dollars in research relating to its health effects.

The last point I would like to make is the necessity for sufficient monitoring to insure that lost and discarded sources truly do not pose hazards to people. The public will be more likely to be convinced there is no hazard if one has the basic data to support that statement. I am reminded of illustrations in the past where press releases were written and sitting on the shelf. A radiation accident would occur, and a press release saying that no hazard exists would be handed to the press before even a rudimentary survey was made.

Richardson:

I, too, would like to comment mainly on the question of benefit vs. risk. I would like to remind us first that the question of acceptable usage and control levels for consumer products is, as Bob pointed out, a risk vs. benefit problem, and we handle it in accordance with the basic guidance that was given to us and was codified as a requirement in this country way back in 1960 by the Federal Radiation Council. It advised Federal agencies that regulations for these things should be based upon a determination that there was a benefit that exceeded the detriment and that the exposures associated with the product, once it was determined that there was a benefit, were to be maintained as low as practicable (ALAP) below the exposure limits. That guidance is as good today as it was in 1960. I think we know as little today as we did in 1960 about how to balance risks against benefits in this particular area. As Bob Neill pointed out, it is because we do not have common terms for the risks and the benefits. There are a few cases where we can do it. One example is medical diagnostic x-rays. There we are dealing with a health benefit. In the case of a screening process, for example, if we do enough study, we can properly measure the chance of detecting what we are screening for and then make an assessment of what we think the radiation hazard is. That is a health hazard being balanced against a health hazard in common units. The fact that the cost of the x-ray has been left out of the equation is perhaps permissible because we don't care how much we pay for medical expenses when we are worried that we are sick; at least we don't care enough not to pay the expense. A similar situation sometimes arises in other areas such as smoke detectors. There we are saving lives in return for a tiny health hazard. For most consumer products, I suspect, the dominant risks and the dominant benefits are not in terms that are common, and we have to depend on judgment on the part of government officials concerned with the health of the public and public hearings, etc., to make these decisions. We do know, however, how to assess ALAP, which is a process of minimizing the hazard. I assume we will continue to do that using, I would hope, total population dose rather than individual dose as the criterion.

In addition to those basic considerations that have always been with us, I think today we are coming to the realization, at least in some areas, that we have some additonal things that have to be taken into account. We need to know how to take into account supply and demand in natural resources because we are beginning to recognize that we have limitations. Take the phosphate industry, for example, the byproduct gypsum. It is conceivable that, at sometime in the future, this byproduct gypsum may have to be used because other supplies are not available. We do not know how to take that sort of thing into account.

There are some more theoretical questions associated with the distribution of risks and the distribution of benefits. How do we balance benefits to individuals against risks to society as a whole and risks to individuals in order that society can benefit? We have some ideas on how to handle individual risks; we have heard the idea expressed many times that, when individual risks are comparable with those associated with normal variations of background, we ought not to worry about them any more. That is probably perfectly true, but it doesn't give us any ansers on how we should consider the total population risk associated with those kinds of variations, because they are different – they are in addition to background. In this connection, we need to continually remind ourselves of the dual objectives of radiation protection: first, to protect the individual to reasonable limits of risks, but in addition, to look at the total societal impact of any action independent of any risks to individuals.

I would like to make one final comment. There are many critics of the concept of risk-benefit balancing using quantitative estimates of health risks, i.e., using population dose commitment calculations and assumptions such as the linear dose/effect relationship. I think these critics may be missing a major point, i.e., that this kind of methodology provides what I think is the only rational means to avoid silly and unnecessarily restrictive regulations. It is not only a means for deciding when we need additional regulations; it is also a means for deciding when we don't need them. It provides us with a mechanism for justifying to the public, in terms they can understand, why certain regulations are not needed.

Bailey:

Probably one of the first questions that comes to most people's minds is what role do the States play in regulating consumer products containing radioactive material. For the most part, over the history of the State Radiation Control Programs, the States have actually had very little influence. Most of the consumer products contain material that fell under the purview of NRC, formerly AEC, and since they were distributed to persons exempt from regulations, NRC did all the licensing and evaluations of these products. There are now two isotopes occurring fairly frequently in consumer products that fall into what we have chosen to call NARM, i.e., naturally occurring and accelerator-produced radioactive materials. When I first saw that acronym I though it meant nonagreement materials.) The Conference of Radiation Control Program Directors, about two years ago, appointed a task force to write up some guides for the uniform evaluation of products, not only consumer products, but industrial gauges and sealed sources, etc. In developing these guides, we tried to apply the same criteria that NRC had applied to agreement materials. That, in my own opinion, is somewhat limiting what we should have been doing. We have in the States something that NRC does not take into account in their risk-benefit analysis, and that is the nuisance value of things that contain radioactive material. In developing or in approving a consumer product containing radioactive material, there should be a weighing of the risk and the benefit. Also, if there is not a decided advantage in using a product with radioactive material in it as opposed to a similar product that will do the same job, it should not be authorized. By that I mean, the one with radioactive material should do a better job or cost less or offer some real significant benefit over the nonradioactive alternative. This goes a long way toward doing away with any unnecessary radiation.

I trend to agree on the need for labeling, but all of us here, mostly technical people, get wrapped up in what the real facts are, whether there are hazards or not. The consumer wants to know instead, whether they is radioactive material in the product or not. There should be labeling on each package and on the product saying that it contains radioactive material. If the only reason consumers have for not selecting a product is that it contains radioactive material as opposed to one that does not, they should have that choice. One of my favorite examples of this is the laser watch that we all see in the airline magazines. In two places the word tritium is mentioned; but to someone who does not know what tritium is, nothing informs him that the watch contains radioactive material. I think we should have warning labels very similar to those on cigarette packages. I smoke, I will take the risk. I think that one of the requirements of NRC and the States should be that the advertising and the packaging clearly state that the product contains radioactive material.

Morgan:

I am in an unfortunate position in that the other panel members have said all that I would really need to say.

I, for one, take a very dim view of permitting natural or man-made radioactive material into the environment, and I feel that this is especially true in the case of the radionuclides of intermediate half-life. When the radionuclides have a very short half-life, I do not feel there is any great problem in general at the proper levels and nuclides with extremely long half-lives, of course, approach stable nuclides. Radionuclides with half-lives of a few months to perhaps a few tens of thousands of years are of greatest concern. I feel we should avoid, when practicable, putting these radionuclides into man's environment through consumer products. During the past few decades we have found the radiation risks are far greater than we anticipated them to be some years ago. The risk of malignancy is now estimated to be ten times what we though it was a few years ago. There is a question about the genetic risk, whether it is greater or less, and we know almost nothing about the long-range genetic risks to man.

I feel that we must be particularly cautious because of recent information that indicates the very high risk of exposure to young children and in-utero exposure, especially in the case of exposure to high LET radiation. Some years ago when I first became interested in this field, most of us were led to believe in the threshold hypothesis. We had the impression that as long as you did not exceed a certain dose you were safe, that the rate of repair was equal to the rate of production of damage and so there was nothing of great consequence. At least I am convinced now that that is not a tenable hypothesis. And then we passed through a period during which we began using the linear hypothesis, and there were many who would say that this was very conservative; you use this as a convenient exercise, you use this to set standards but we all know that it is very conservative. I am pleased that the BEIR Report and most of the ICRP reports did not stick their necks out this far. They indicated that the linear hypthesis might be either conservative or nonconservative, and it turns out now that there are many cases in which the linear hypothesis appears to be nonconservative. In the case of exposure to high LET radiation, to neutrons and to alpha particles, it appears that the linear hypothesis would probably be nonconservative. Protraction of the dose, for example in the case of radium-224, increases rather than decreases the risk as co-pared to the case of X or gamma radiation. We have every reason to be cautious in permitting exposure to radiation ionizing and nonionizing from consumer products. We should keep in mind that nonionizing radiation, in some case, may present unknown risks that are much greater than we have ability to estimate today. We all realize, of course, that we can't set zero as the permissible concentration of radionuclides in the environment and consumer products. We have to accept the fact that potassium-40, carbon-14, and the daughter products of uranium and thorium are in our bodies, and in our food, and in natural products, as already mentioned. We have the case of phosphate in Florida, the shells and the granites, and we know at least in the United Kingdom they have taken some measures to restrict the use of gypsum as building material or certain types of building material and are not using it for certain purposes if the radium content is greater than 25 picocuries per gram. I think that the situation in Florida presents a very important and serious case that deserves and calls for more attention from the EPA and responsible agencies.

Then you have the question of man-made radiation. I think there are many devices where we can use something like tritium and to me it is quite acceptable. I consider tritium to be one of the least hazardous radioactive materials. I would not approve using it in devices where it serves no useful function or where other principles would serve a better function. I think there might be a question about its use in something like heart pacers because there might be better ways of making heart pacers. There might be better ways to make smoke detectors, but if we can use certain of the radionuclides here I think that they should be given a chance. I have been one for years who opposes the spread of plutonium and the transplutonic elements, and I would resist including them in any of our commodities that go on the public market, even in nuclear power plants. As all of you know, I have for years opposed the LMFBR (liquid metal fast breeder reactor). I oppose the use of radionuclides in toys. I see no point in putting them in toys of any kind for children. You might say it teaches them a lesson. When I went to school I took Latin and Greek because that was suppose to teach me how to speak English. I think I would have done better to have spent that time learning English or learning some modern language. I feel the same way here with toys – there are other ways to teach these lessons to children without running these risks. We have of course mentioned the question of TV and sun lamps. I don't see any useful purpose of having x-radiation in association with TV. It might be more expensive to design a TV set that had zero x-rays. Of course, the medical problems present a different case. We know the misuse of radiation in the treatment of tinea capitas, etc. I think that there we should avoid the use of radiation. Wherever possible, I would like to see a system set up where we don't have to depend on administrative control. I was attending hearings in California and that was quite an issue with some of us. I feel that whenever you have to rely on administrative control, if you build something into a system where man can make a mistake, it is only a matter of time until he will make that mistake. If we can design equipment so that it is fail safe, so that it doesn't have radionuclides, or so that the levels are such that they will not harm the individual, I think we have made real progress and we don't have to depend on labels and administrative control.

Ehrlich (Consumer Product Safety Commission): Dr. Morgan, you said you were opposed to the use of radionuclides in toys. Can you offer some specific examples where this has been done or is being planned to be done?

Morgan: I do not know of any radionuclides being used at the present time in toys, but I know that it has been proposed repeatedly through the past 30 years. There have been proposals from various companies to use radionuclides in toys or to demonstrate certain principles, to operate little Geiger counters and things of this sort.

Ehrlich: You must accept that some people think that their children are unusually bright and they should start the demonstrations that occur later in school in their toy experience in the home. I would not approve of such uses.

Taylor (NCRP): The concept of balancing risk against benefit is a very sound concept. It is also a very moving concept, and I don't think this is appreciated by the public. The public has heard so much chatter about balancing risk against benefit in all sorts of areas in the last few years that they have the feeling that this can be done. As a matter of fact there are only a very few cases where this can be done in an authoritative way. I am sure people who are working with this recognize the concept, as has already been brought out, that there are situations where, because of lack of suitable quantities and units for comparison, you simply cannot balance, in the ordinary sense, a risk against a benefit. Now I suspect that you will find cases where you can compare risks in comparable terms and you can do something that is helpful for solving your problem by balancing risks against risks. Risk of accomplishing something one way against the risk of accomplishing something another way, or the risk of not attempting to accomplish a given end. I wonder in that connection whether it would be helpful to try, sometime, to evaluate the overall risk of not evaluating the risk. I am sure there are instances where a study of a particular risk situation would show it is almost unimportant to waste a great deal of effort on that kind of situation.

Dr. Richardson used the acronym ALAP. There is another one floating around called ALARA, as low as reasonably achievable. I am repeatedly asked about the difference between those two terms and since I was deeply involved in the generation of both of them, I would say that it was the intention that there be absolutely no difference between the two terms. The first one, ALAP, originated in this country; ALARA originated in the ICRP, which is largely dominated by the British, and that is simply their way of saying the same thing.

Tapert, (BRH): Up to now I have heard much generalization on who is the consumer and what is the consumer product? Does the panel have any specific limits they would like to suggest as to what a consumer product is and who is a consumer?

Bailey: I have a definition. I think a consumer product is any product that is transferred to an individual without a regulatory agency reviewing that individual's training, experience, and facilities; in other words, without issuing a specific license. That would include generally licensed gauges, for instance.

Brodsky (NRC): Speaking as an individual, I think so far this meeting has given a very good summary of many of the principles and philosophies that have been developed over the years such as minimizing radiation exposure, maximizing benefit/risk, etc. However, I think that there is still a lot of despair in regard to what we don't know and I don't think we put enough emphasis on what we do know about radiation hazards and effects. There has been some despair in converting the benefit/risk to common units. However, we are here to do the difficult and learn some lessons on how we are going to quantify these, not only on each individual item, but also on all items. In 1965, I suggested a method to convert all risks into a common unit which could be used.

Kolb, (Germany): I would like to ask the panel whether there should not be a level of exposure below which it would not be worthwhile to make any risk/benefit evaluations. This afternoon I saw some valves in the order of a few microrems and we know that, from some building materials, we have exposures several orders of magnitude higher.

Neill: A very essential question is the size of the population at risk, and as soon as you accept that, even very low levels of exposure from any material that is generally dispersed automatically involve a significant number of health effects. It seems to me this raises the necessity of evaluating the benefit to be gained from the action that is contemplated.

Richardson: I would like to both agree and disagree with Bob Neill. His first point, which is, that before you can discuss the proposal to establish a minimus exposure level, you have to know the size of the population you are dealing with, is exactly correct. Having gotten that far, I think it becomes fairly simple to establish a range of exposures to individuals for that size of population that indeed involve impacts not worth worrying about. One microrem to 100,000 people does not add up to enough rems at any dollar valuation per rem to justify a regulatory examination or regulation. Again, having said that much, one has to wonder about how such a thing would be used. I can see it being used by a regulatory agency to decide which problems it is going to concern itself with and which it is not going to concern itself with. The general public is probably going to want to know should this product be used or not be used with all the calculations laid out. At that point you can't avoid the issue by appealing a minimus exposure.

Moghissi: I don't think either of you really hit the question he was asking. These building materials are widely used. He is suggesting should we worry about a few microrems that are man-made vs. a lot of millirems that are coming from building materials and not worrying about them. That is really the essential question.

Kolb: I would like to give an example from my paper. We have a population of about 4 million people, exposed to an average of as much as about 50 mrem per year from building materials, with a similar size population in Southwest Germany. I have the impression that the people make the difference between natural radioactivity and artificial radioactivity.

Blackburn (State of Ill.): As a second comment and to sort of underline the data from Germany, in a study we did in 1973 in 18 counties in central Illinois within a distance of approximately 35 miles, the difference in environmental radiation was about 55 mrem per year. I have to raise the question of how siginficant is 1 mrem based on this type of a natural variation. If one is that concerned with 1 mrem, maybe we can close down some counties – and keep people from living in them.

Richardson: That sort of question was raised when we were proposing 25 millirems for the uranium fuel cycle by the industry, which is going to require control of krypton by 1983. One of the questions raised in connection with the now existing standard, was why do we worry about 1 mrem. If you do that you are going to move all the people from Denver to Florida. That is a difference of 100 mrem. I think there is a very simple answer to that kind of logic. The decision to move from Denver to Florida, in this country, is a decision taken by free individuals who have freedom of choice. In our derivation of the standards for the uranium fuel cycle we estimated that the average dollar expenditure per man-rem that was required by that standard at its limiting point, i.e., at its maximum expenditure, was on the order of a few hundred dollars per man rem. At a few hundred dollars per man-rem, we are talking about a few tens of dollars to swing the decision for moving from Denver, for an individual, to Florida and I don't believe anybody would base his decision on whether to live in Denver or Florida on a $10 or $20 difference in value.

Freke (United Kingdom): I wonder if Mr. Richardson might just raise the control laws for some of the emotional questions. The concept to me, and I speak personally here, is that everything we know does have some sort of risk attached to it. America would not be where it is if certain risks had not been taken in the past. Some might say it would have been better had there been regulatory control at that time. A number of us obviously have the best of interests in this business, whether it is radiological protection or whether we are on the regulation side. I am wondering in terms of cost/benefit, benefit/risk, risk/cost, etc., if we do not sometimes beg the question. Most of these statements in consumer products, from our particular experience, involve a low risk and a low benefit; therefore any judgment must, to some extent, be subjective, and scientists are no more objective in their judgments than anyone else. Now, can we really and honestly say that, if you make the assessment and you agree that, although the benefit is small, the risk is equally small, you are allowed to take away the free choice of individuals? In terms of the economic benefit, I would have though that the solution might be relatively simple. The National Radiological Protection Board is not a statutory authority – it is only an advisory body – but under government policy we have to make a charge for some of the services we give. We can give advice, so that if somebody comes to the regulatory authority on the assumption that they want to market some consumer product that will contain radioactivity, you can give them some estimate of the cost of the assessment and they can pay fort it. If their return is only 1% of their investment, obviously that is their business and I doubt in that case whether they would do it. So in these terms we do confuse what the cost is in terms of relation to the benefit and the risk. I might amplify this. I think it was Mr. Johnson who talked this morning on smoke detectors. We would accept that these are radiologically safe. If they are involved in a fire, and we have had several fires, there are perhaps up to 50 of these units of 60 microcuries in each unit for a total of 3 mCi of americium-241. The statutory authority, for evnrionmental considerations, insisted on requiring an authorization to dispose of the radioactive residue. Thus it is regulated for reasons quite apart from the hazard from radiation.

Duncan (EPA): I have a few comments for the gentleman from Germany. We have come a long way in convincing people that because it is natural radiation doesn't mean you don't have to worry about it.

EPA is at the present time evaluating these naturally occurring radiation topics that have come up, and there are more each year, and is trying to determine if there is any need for further work. Often a paper study is made with out best assumptions as to exposure conditions so that an estimate of population exposure can be made using assumptions like those in the BEIR Report, you can come up with some of health effect estimate. Then some technology control cost are calculated and one comes up with some kind of cost of reducing that health effect. It is obviously very simple, but in many cases in doing this we come up with the fact that, to reverse this one theoretical health effect, one cancer death, let's say, it would cost $50 million. We make a decision that that is unreasonable.

Utech (The Fire Independent): I hesitated to make this comment because I can't really decide whether it is terribly profound or terribly trivial, but I decided finally to take a chance on it. I have been very interested in the comments that have been made earlier in the day, particularly by the panelists, about the problems that government regulators have in weighing risks and benefits and deciding what is best for us, the consumers. My question is why do you have to decide this at all in the United States where you have this marvelous thing called the market place? It seems to me that every one of us consumers make hundreds of these decisions every day, thousands of these decisions every month and before we are very old we have made millions of these kinds of decisions. The kind of thing that the consumer needs in order to make this kind of decision intelligently, however, is good, sound, solid, factual information. There are two points I would like to raise that relate to smoke detectors:

1. This afternoon Mr. Johnson gave a presentation in which he quoted from five or six different papers evidence that smoke detectors were safe without in any way challenging the credibility or correctness of the papers. I would only like to note here that every one of those items is in the nature of a government report or some kind of privileged communications; not a single one of them has been published in the open literature. Now it seems to me that the results of studies on questions of this importance should appear in the open literature – I am speaking of journals, in particular, or at least conference proceedings. I am very pleased to see that a step in that direction is being taken here. Nevertheless, this kind of information, on which apparently a very important decision has been made, is buried in rather obscure documentation, and it has been difficult for me to get hold of it. Mr. Johnson was very kind to provide me with copies of the reports which he happened to have with him and which I will be looking at overnight. I don't think for a subject this important that this kind of information ought to be stuck away in some government files for the government regulators to make decisions on and for the public to be left completely in the dark.

2. I was very interested in the comments made about labeling. Again, ionization smoke detectors. If you walk into any number of the stores in the Washington area, and I am sure it is the same way elsewhere, you will notice that the box that these detectors are sold in is usually covered with plain black and red, with an attention – getting kind of display. There are prominent kinds of information about the product and then some kind of an appeal to save the lives of children, etc. However sincerely that message might be presented, the point that I am trying to make here is that there is no information there at all about the two major types of smoke detectors, which are ionization detectors, the type we are talking about here, and photoelectric detectors. Just to bring my original observation down to earth, why do you have to make all of the decisions in the consumer product area for the rest of us. Why don't you take it upon yourselves to inform the public better generally about what the hazards are and, before you know it, the public is going to make up its own mind. If ionization smoke detectors don't sell, it is not going to be any problem with a lot of radioactive sources around unecessarily.

Neill: It is, very true that each of us must make benefit-risk decisions every day of our life: buy a house, build a garage, ask someone to marry you. The reason why the governments, Federal and State, are imposing these regulations that really restrict and prevent people from buying this is that it is the will of the people. The Congress of the United States in the late 60s passed a series of acts ranging from the "Dirty Chicken Act" to insure that poultry being caught and brought to the marketplace would be safe to the Radiation Control for Health and Safety Act. It specifically charged the various agencies with the responsibilities of insuring that when people buy various types of gadgets they are not going to be hurt. It is true that, as a result of this, we have lost some of our freem, e.g., freedom to buy electrical wiring that doesn't meet any minimum code and may result in a fire in one's home; one could have a whole plethora of illustrations. We must clearly recognize that the reason why the Federal agencies are passing regulations intended to prevent hazards from getting into the marketplace, whether from toys that children will put into their mouths and choke to death or from color television sets that may emit x radiation and pose a hazard, is that it is the intent and will of the people.

Minogue: I think a frank question deserves a frank answer. The simple answer to the question why we are doing what we are doing is that we have been charged by the Congress to do it. We act as agents for the public. Why is that? I can speak as a consumer for all consumers, that many people in this country have neither the time nor the expertise to undertake an in-depth analysis of some of the public safety and public welfare questions that are involved. many decisions that are made; uses of fertilizer, fungicides, and pesticides in agriculture are good examples of the many forms of pollution that result from complex modern technological activities. One of these is the kind of thing that we are talking about here today. If the people through the Congress as their agent elect to establish a regulatory agency to oversee these particular complex areas, I think they are exercising their privilege and their prerogative. Basically, we are doing this job because we were hired to do it.

The other point that was raised I strongly second. There should be full public disclosure of the basis for these decisions that we take it on ourselves to make in the public interest. What we do, the basis for it, and any technical data on which it is based should be fully and freely available and to the best of my knowledge that information is made available to the public. There has been a tendency for this sort of material not to be fully distributed, picked up by the press or picked up by the public. I point out, for example, the speaker who commented favorably on this meeting. A large part of the financial support for this meeting was provided by the regulatory agencies involved. Those same agencies are represented at this table in an effort to provide in a public forum exactly the kind of in-depth discussion of these technical issues that is required and should be made publicly available.

The third point is another suggestion that possibly has some merit. There are people who work on my staff who have suggested a product be authorized and let the market place decide whether it sells, particularly where the benefit and the risks are extremely low. Work on the principle that here are all the facts, and let people make their own decision whether to buy and use a product or not. The fatal defect to that approach is that the risk assumed by the buyer may not be entirely his risk – it may affect other people. They are not in this by themselves. If you adopted that policy across the board, you would have a situation where a manufacturer and some selected user between them would be making a judgment in the marketplace to use and distribute a product that might have a general effect on the public with the affected public having nothing to say about it.

Garfield (Technical Instruments): I agree wholeheartedly with Mr. Bailey's comments regarding labeling on products and some of the subjects we are discussing right now. However, I feel that it is very important, as has been brought out, that if in fact labeling be on a consumer product, the consumer also be given the necessary information to make his own benefit-risk analysis. In dealing with consumer products, you have to get that information down to the consumer level. The subject matter here is very complex, and the normal consumer cannot understand it. You put a radiation caution symbol and those words on the consumer product and immediately the reaction is going to be "I am not going to buy it no matter what the connotation." For example, smoke detectors – if you put "radioactive material" so that it is visible in its use state, the consumer is not going to buy it. I am sure we will all agree with that fact. It is very difficult to get the information that we have to get down to the consumer level. I think in weighing the labeling and risk-benefit analysis, it is extremely important to consider the transfer of that information to the consumer.

Bailey: I think that most people are going to get the idea that I am anti-nuclear but I am really not; I am very much pro-nuclear. But wouldn't it be better if you made the decision in the store not to buy a smoke detector, for example, instead of when you arrive home and open it up and say that you had been ripped off, because you wouldn't have brought it if you had known it contained radioactive material. I don't think the labeling necessarily has to be the standard radiation caution label. I just think the fact that a product should be clear and not hidden with words like technetium, americium, and that sort of thing.

Garfield: I agree. We should begin to get that information to the consumer on his level so that he can make his own decision.

Minogue: Just so my own personal positon is quite clear, I repeat what I said in my opening remarks. I think that the purchaser of any material in this country, whatever it may be, which is hazardous to him as a user should be fully informed of that hazard. I would apply this argument to materials containing radioactive products and any other toxic or poisonous or harmful materials. We have the right to know what we are buying. I think some of the recent progress in the direction of regulatory agencies requiring tighter labeling, etc., is a move very much in the right direction. That way the individual user, as it affects him individually, is in a position to make an informed judgment in his own interest.

Garfield: I think that we should also continue in some areas which are currently not regulated or very weakly regulated; for example, radioimmunoassay kits are very hazardous to people who use them if they do not know how to use them.

Richardson: I think we are all in favor of labeling and rightly so, but we have to recognize that the labeling should be in terms that the consumer can understand. That is precisely where the difficulty arises. Simply putting a label on something that says it is radioactive does not give the consumer all the information that he needs to make a decision.

The next question that arises, do you ask a regulatory body also to write underneath: "This product has been deemed safe for use"? Or do you put on the package an exact calculation of what the estimated cancer risk is for a certain distance from the body? Or what? Simply putting a label on something stating that it is radioactive material may even do more harm than good. It is not sufficient information for a consumer to make a judgment.

Neill: Just a quick comment. Every microwave oven that is sold bears a label that states that microwave radiation is hazardous and, if there is any danger of it operating with the door open, adds a caution to the purchaser. They are selling like hotcakes.

Siegel: (TIMEX): Regarding labeling, we are all in favor of informing consumers of what they are buying. I do believe that a lot of good points have been brought up about how much labeling can be put on the outside of the box. I agree with the statement that if you put on something like "caution – radioactive material" you should also inform the consumer as to what that means, why this product is on the market, and the fact that, in the case of smoke detectors containing americium, for example, that the Nuclear Regulatory Commission has done a risk-benefit analysis and considers the risks negligible compared to the benefits.

We try to include this information in the owner's manual that we supply with the material. With respect to the point that you don't know if the smoke detector has radioactive materials until you open it, the other kind of smoke detectors, photoelectric, emit cyanide gases when they burn. Do you want to put that on the outside of the box, too? There is a limit to what you can or should put on the outside of a box.

The Nuclear Regulatory Commission approves these products and considers them safe and it is their function to inform the consumers. I note that the Bureau of Radiological Health of the State of New York has set up a consumer hotline to answer questions like this. I would suggest that this is something that the Nuclear Regulatory Commission has the responsibility to do. They permit the product to go to the market place, and it is their responsibility to see that the consumers are fully informed about it.

I would ask Mr. Bailey if he feels that he wants a warning in the advertising about it. I feel that trying to prepare a warning as is used in cigarette advertising is totally ridiculous. It is a warning stating that there is a known risk and by using this product you are exposing yourself to the risk. A warning that it contains radioactive materials is the same as putting the warning on the box. If you don't give the rest of the information with it, that is, if you don't also imply that competent scientific bodies consider the benefits far outweigh the risks, then you are destroying the purpose of it. Our company manufactures ionization smoke detectors because we consider them a better product than other types of smoke detectors and they can be made available to the public at a lower price. Just take a look at the market and see how many photoelectric detectors there are and how many ionization detectors there are. How many fewer people are going to buy a smoke detector if it is photoelectric and it costs more? How many more lives will be lost because of the difference in the price?

Finally, I would ask if Dr. Morgan, who opposes the use of transuranics entirely, opposes this use in smoke detectors without considering what the alternatives are? The only other product that doesn't use a transuranic doesn't perform as well and has some other disadvantages. Our company could just as well manufacture these others if everything was equal. If NRC would say we should get rid of transuranics because photoelectric detectors do just as well, we would be happy to make them. But they are going to cost more and for the most part they are not going to be the equivalent. Whether they are better or worse has not been determined, but they are not going to be the equivalent.

Morgan: As I indicated, I oppose the use of plutonium where it isn't necessary. I oppose the LMFBR and I oppose any system that spreads these contaminants, or potentially would spread them, to the environment because I feel that there are other choices. You have limited your questions primarily to smoke detectors and that isn't my specialty, but I dare say that, with some study, one could find other radionuclides such as sodium, tritium, or maybe P-32 or some other things that could be substituted in places that we are now using the transplutonic elements.

Ehrlich: A personal observation. My mother-in-law went ahead and bought an ionization smoke detector after I assured her that, if the detector was handled properly, the risk was minimal. Perhaps retailers could use that sort of reassurance in a carefully worded label or handout or instruction.

Paras (BRH): I would like to bring up another view – the incentive of profit making vs. protection of the people. In the case of comOressed air, we have the example of a required warning label. The question is how to balance profit with consumer protection. We can have regulations and do agree about regulations. I do agree on labeling requirements but let us look at the advertisement. Does it tell the right thing? Does it speak of the risks associated with particular products?

Moghissi:

Let me make a few observations. This discussion indicates the validity of holding this symposium. I am very grateful to Bob Minogue who personally expressed his interest in this undertaking very early in the game and made it possible for us to work together with four or five agencies. His personal interest and his encouragement made it possible for us to undertake it. I think it is very fitting that I express my appreciation to him and to the other agencies, whose names will appear in print, for supporting us in this undertaking.

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