



U.S. Nuclear Regulatory Commission

REGULATORY GUIDE

Office of Nuclear Regulatory Research

REGULATORY GUIDE 8.15

(Draft was issued as DG-8022)

ACCEPTABLE PROGRAMS FOR RESPIRATORY PROTECTION

A. INTRODUCTION

Subpart H, "Respiratory Protection and Controls To Restrict Internal Exposure," of 10 CFR Part 20, "Standards for Protection Against Radiation," specifies the conditions under which respiratory protection equipment may be used and lists the procedural requirements that must be met by a licensee when using respirators to limit intakes of radioactive material or to take credit for the protection assigned to a respirator in limiting and estimating intake of airborne radioactive materials. If an evaluation shows that further exposure reduction is appropriate, and no other practical means are available to reduce exposure to airborne radioactive materials, respiratory protection equipment may be assigned or its use may be permitted consistent with the intent of the guidance in this regulatory guide.

This regulatory guide describes a respiratory protection program that is acceptable to the NRC staff. This guide also provides guidance on performing evaluations to determine whether the use of respirators optimizes the sum of internal and external dose and other risks.

Licensees are encouraged to limit the use of respirators to situations in which respirator use has been shown to keep total effective dose equivalent (TEDE) as low as reasonably achievable (ALARA). Other methods of protection against airborne radioactive material, such as the use of process or other engineering controls, limitation of exposure times, decontamination and so on, should be considered before the use of respirators.

The information collections contained in this regulatory guide are covered by the requirements of 10 CFR Part 20, which were approved by the Office of Management and Budget, Approval No. 3150-0014. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

B. DISCUSSION

Summary of Regulatory Requirements

It is widely recognized among safety professionals that

USNRC REGULATORY GUIDES

Regulatory Guides are issued to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the Commission's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and data needed by the NRC staff in its review of applications for permits and licenses. 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.

This guide was issued after consideration of comments received from the public. 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.

Written comments may be submitted to the Rules Review and Directives Branch, DFIPS, ADM, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

The guides are issued in the following ten broad divisions:

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

Single copies of regulatory guides may be obtained free of charge by writing the Printing, Graphics and Distribution Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; or by fax at (301)415-5272.

Issued guides may also be purchased from the National Technical Information Service on a standing order basis. Details on this service may be obtained by writing NTIS, 5285 Port Royal Road, Springfield, VA 22161.

the use of respiratory protection devices in the workplace can impose physiological and psychological stresses on workers, obstruct their vision, hinder their movements, and make effective communications difficult. These factors increase the risk of physical injury to respirator wearers that, in many cases, far exceeds any potential risk associated with the inhalation of a small quantity of airborne radioactive material. Therefore, in 10 CFR 20.1703 the NRC requires a minimum respirator program to control the risks associated with respirator use, even if the licensee does not intend to take credit for the protection provided by the respirators in estimating intakes.

Process or engineering controls are required by 10 CFR 20.1701 to be used to the extent practical to control the concentration of radioactive material in air. The use of respiratory protection devices should be contemplated only after other measures to limit intake have been considered.

In addition, 10 CFR 20.1702 states that, when process or other engineering controls are not practical, the licensee must increase monitoring and limit intakes by using access controls, limiting exposure times, using respiratory protection devices, or by employing other controls to keep TEDE ALARA. Guidance for performing ALARA evaluations (that is, determining whether the use of respirators optimizes the sum of internal and external dose and other risks) is provided in this regulatory guide in Regulatory Position 2.

If the licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material, the requirements stated in 10 CFR 20.1703 must be followed. The NRC considers a respiratory protection device is being used to limit intakes of airborne radioactive materials unless the device is clearly and exclusively used for protection against nonradiological hazards. Whether or not credit is taken for use of the device to reduce intake and dose, 10 CFR 20.1703 applies whenever respiratory protection devices are used.¹ The minimum respiratory protection program expected of any licensee who assigns or permits respirator use is outlined in 10 CFR 20.1703. This regulatory guide and 10 CFR Part 20 describe an exception for voluntary use of one type of filtering facepiece respirator when no assigned protection factor (APF) is applied.

The requirements that must be met before a licensee may use an APF to take credit for the use of any respiratory protection device to reduce intake and dose are in 10 CFR 20.1703.

According to 10 CFR 20.1704, the NRC may place additional restrictions on licensees' use of respiratory protection equipment that might further limit exposures to airborne radioactive materials, consistent with keeping TEDE ALARA. The extent to which a licensee may use respiratory protection equipment instead of using process and engineering controls can also be limited by the NRC pursuant to 10 CFR 20.1704.

Also, 10 CFR 20.1705 specifies that a licensee must

obtain authorization from the NRC before using APFs in excess of those specified in Appendix A to 10 CFR Part 20. The application for authorization must describe the need for the higher APF and demonstrate that the proposed equipment provides the higher APF.

Applicability of OSHA's Respiratory Protection Rules

The Atomic Energy Act (AEA) gives the NRC the statutory responsibility to protect public health and safety, which includes worker health and safety, in the use of source, byproduct, and special nuclear materials. The Occupational Safety and Health Act provides that this Act is inapplicable for working conditions under which another Federal agency exercises statutory authority to protect worker health and safety. Therefore, in implementing its statutory authority, the NRC preempts the application of the Occupational Safety and Health Act for working conditions that involve radioactive materials.

In 1988, the NRC and the Occupational Safety and Health Administration (OSHA) signed a Memorandum of Understanding (MOU) to clarify jurisdictional responsibilities at NRC-licensed facilities. NRC is responsible for three areas of interest:

- Radiation risk produced by radioactive materials
- Chemical risk produced by radioactive materials
- Plant conditions that affect the safety of radioactive materials and thus present an increased radiation risk to workers.

The MOU makes it clear that if an NRC licensee is using respiratory protection to protect workers against nonradiological hazards, the OSHA requirements apply. If the NRC has jurisdiction and is responsible for inspection, the MOU specifies that NRC will inform the licensee and OSHA if the NRC observes an unsafe condition relative to nonradiological hazards. In general, the NRC's revised rules are such that if a licensee is in compliance with the NRC regulations in Subpart H, the licensee is considered to be in compliance with the corresponding and comparable OSHA regulations on respiratory protection. Licensees are cautioned, however, that in situations involving mixed hazards, such as airborne radioactive materials and nonradioactive hazardous materials, compliance with 10 CFR Part 20 alone may not provide sufficient protection.

Additional Information

When a licensee permits or assigns the use of respiratory protection devices, such devices should be used in accordance with the manufacturer's instructions. Respiratory protection devices should also be used consistent with the intent of the guidance in this regulatory guide, which describes the elements of a respiratory protection program that is acceptable to the NRC. More detailed advice and technical information can be found in NUREG-0041, "Manual of Respiratory Protection Against

C. REGULATORY POSITION

1. ANSI STANDARD Z88.2-1992 AND EXCEPTIONS

The recommendations in the American National Standards Institute standard, ANSI Z88.2-1992, “American National Standard For Respiratory Protection,”³ are endorsed by the NRC and may be used by licensees in establishing a respiratory protection program with the following exceptions.

1.1 ANSI Z88.2, Paragraph 4.5.1, Program Administration

Paragraph 4.5.1 of ANSI Z88.2-1992 states “The responsibility and authority for the respiratory protection program shall be assigned by the employer to a single person.” It is acceptable to the NRC staff if the individual who administers the radiological respiratory program is different from the person who administers the industrial respiratory protection program.

1.2 ANSI Z88.2, Table 1—Assigned Protection Factors

In ANSI Z88.2-1992, Table 1, “Assigned Protection Factors,” permits the use of quarter-facepiece respirators (which seal over the bridge of the nose, around the cheeks, and between the point of the chin and the lower lip). These are not listed in Appendix A to 10 CFR Part 20 and may not be used in an NRC-regulated respiratory protection program.

ANSI also lists APFs for air-purifying respirators and for atmosphere-supplying respirators. With the minor exception of those filtering facepiece respirators that do not qualify as half-facepieces in NRC's view, the APFs listed in Appendix A to 10 CFR Part 20 now match the ANSI-recommended APFs.

Licensees are cautioned regarding the use of supplied air respirators and self-contained breathing apparatus (SCBA) that operate in the demand mode. Since these devices operate in a negative-pressure mode, any face-to-facepiece seal leakage will permit contaminants to enter the respiratory inlet covering where they could be inhaled. Since these devices are air-supplied, individuals might perceive them to be more protective than they really are and attempt to use them in situations in which a device with a much higher APF is indicated. This is especially true of two types of SCBA: demand-only and those that have a so-called “donning switch.”

For the first category, ANSI specifically prohibits the use of demand SCBA in emergency situations such as fire fighting. NRC concurs with this prohibition.

A SCBA with a donning switch operates as a pressure-demand unit when the switch is in the proper position. The purpose of the donning switch is to permit the

wearer to switch the mode of regulator operation from pressure-demand to demand while donning the device, or immediately prior to removing the facepiece in a safe area. The donning mode prevents the rapid loss of air from the SCBA cylinder when the facepiece is not sealed to the wearer's face. There are two potential problems with this type of device. The wearer will not have the benefit of a highly protective pressure-demand device if (1) the switch is mistakenly left in the donning position when the wearer enters a hazardous area or (2) the switch is inadvertently changed to the donning position while the worker is in a hazardous area. Licensees who have demand-only SCBAs or SCBAs with donning switches, especially those who might need to use them in a fire fighting application, should be aware that these devices do not meet the current National Fire Protection Association (NFPA) standards⁴ and the devices should either be modified to bring them up to the new standard or be replaced.

1.3 ANSI Z88.2, Paragraphs 9.3.1 and 9.3.2

Paragraphs 9.3.1 and 9.3.2 could be interpreted to mean that respirators from several manufacturers, or several different model respirators from the same manufacturer, are required to be available for use. The NRC staff's position is that one model of respirator from one manufacturer is adequate, so long as different sizes of facepieces are available and adequate fit factors are obtained for greater than 99% of test subjects who are free of facial characteristics that preclude an adequate respirator fit. For individuals who achieve a fit factor >500 with a negative-pressure full facepiece but who are unable to achieve a fit factor 10 times the APF, the NRC suggests consideration be given to assigning a positive pressure face-sealing device or to a device for which a face seal is not necessary.

1.4 ANSI Z88.2, Paragraph 10.2, Frequency of Inspection

Paragraph 10.2 recommends that each respirator stored for emergency use or rescue be inspected at least monthly, and that this inspection is to include the proper function of regulators, alarms, and other warning systems. The NRC suggests, consistent with the OSHA Act, that a monthly visual inspection of SCBAs is sufficient, and that an operational test (i.e., pressurizing the regulator, testing the low-pressure alarm) need only be done quarterly. Other devices stored for emergency use should be visually inspected monthly, but only need to be thoroughly examined two or three times per year (see Regulatory Position 4.3 of this Regulatory Guide 8.15).

2. ALARA REQUIREMENT

As stated in 10 CFR 20.1101(b), licensees must use, to the extent practical, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses that are ALARA.

According to 10 CFR 20.1702, licensees are to limit intakes by means of engineering controls or procedures, along with the use of respirators, consistent with maintaining the TEDE ALARA.

The NRC views the TEDE-ALARA requirement as a subset of the general ALARA requirement of 10 CFR 20.1101. That is, the focus should be on programmatic controls. The NRC does not expect or require the licensee to use all possible ways and means to reduce the TEDE. However, each licensee should have an ALARA program that is integrated into the site radiation protection program. Each licensee is required to track doses and to take measures to maintain worker doses ALARA. The NRC recognizes that, when evaluations are needed to comply with 10 CFR 20.1702, those evaluations (and the factors needed to make them) are not exact science. Assumptions for worker efficiency, stay-time hours, estimated intakes, etc., are by their very nature not precisely known. Therefore, when the evaluation results do not show a clear, obvious indication (to use or not use respirators), the NRC expects the licensee to use professional judgment as to whether or not to assign respirators.

2.1 ALARA Evaluations

When a specific ALARA evaluation is performed to justify the use or nonuse of respirators, the evaluation should consider the following:

2.1.1 The use of process and engineering controls, filtered ventilation systems, and decontamination before the use of respiratory protection devices,

2.1.2 Control of access, limitation of exposure time, and the use of other types of exposure controls before the use of respiratory protection devices, and

2.1.3 The estimated benefit. The evaluation should show that the TEDE for the job will be ALARA; that is, the internal dose avoided by using the respiratory protection equipment is likely to be greater than any additional external dose that may result from the use of these devices from respirator-induced inefficiency and other factors.

In performing an ALARA evaluation, when deciding which respirator is to be considered for assignment during a specific task, the licensee should divide the average ambient concentration of radioactive material in work place air (or the estimated average) by the appropriate DAC value for the contaminants present. The number obtained may be considered initially as an ideal minimum APF for the selected device. If the ALARA evaluation determines that use of a respiratory protection device might be justified, the licensee should consider a device with this APF or greater. If selection of a respirator with this APF is inconsistent with ALARA, however, the licensee may select a device with a lower APF. Worker safety factors other than radiological factors, such as heat stress or impaired vision, should be taken into account when performing such an ALARA

evaluation. Consideration should also be given to the possibility that the planned work will cause resuspension of radioactive material, thus increasing the average concentration during the task.

The extent and level of detail addressed in TEDE ALARA evaluations should be commensurate with the potential radiological and physical risks involved in the activity. The licensee should consider the following factors in an evaluation of whether respirator use is ALARA.

- Environmental conditions,
- Protective equipment and clothing, including the respirator, that would be required for the activity being evaluated and their effects on worker efficiency,
- Comfort level of the workers regarding the use of respirators,
- Experience and skill level of the individual with respect to the task,
- Process and engineering controls to be used,
- Specific details of the task to be performed (e.g., dose rates, estimated average airborne concentrations),
- Potential post-activity negative impacts (e.g., personnel decontamination and skin dose assessments, portal monitor alarms).

Such evaluations should be documented in accordance with implementing procedures, but they may either be job-specific or be performed for general job types. ALARA evaluations performed for general job types should be reviewed periodically to ensure that none of the assumptions or parameters upon which the evaluation is based have changed. The licensee, however, should be able to support the decision to use or not to use respirators in each circumstance. Supporting information could include the results of surveys, measurements and calculations, previous history with this or similar jobs, or other pertinent data. The judgment of individuals with extensive knowledge and experience in the field may also be sufficient in circumstances that are not amenable to quantitative analysis.

For ALARA evaluations, a respirator-induced worker inefficiency factor of up to 15% may be used without further justification. Larger worker inefficiency factors may be used, but the licensee should have test data to support them.

2.2 Estimated ALARA Benefit

The evaluation should demonstrate whether or not the TEDE for the job will be ALARA; that is, whether the internal dose avoided by using the respiratory protection equipment is likely to be greater than or less than any additional external dose that may result from the use of these devices from respirator-induced inefficiency and other factors. Nonradiological factors should be included. Examples are the benefit of an air-supplied suit that provides cooling or the

loss of efficiency because of impaired vision.

2.3 ALARA Evaluation—Records

Licensees who perform analyses to determine whether or not the use of respirators will optimize the sum of internal and external dose and who record these ALARA evaluations in accordance with the following guidance will be considered to be in compliance with NRC staff recommendations.

The licensee should establish a reasonable threshold value (in rem) for prospective external deep dose equivalent (DDE) from a task or job *below* which a record of an ALARA evaluation is not needed. When the licensee plans to use respiratory protection equipment, the licensee does *not* need to record ALARA evaluations for situations in which the projected external DDE to any individual is below the threshold.

The licensee does not need to record ALARA evaluations when the prospective radioactive material intake is below an established threshold, assuming no respiratory protection is provided.

Regardless of the magnitude of the projected external and internal dose, the licensee does *not* need to perform or record ALARA evaluations before requiring the use of respiratory protection equipment as a precautionary measure when there is a large uncertainty about the magnitude of the projected concentrations of airborne radioactive material to which the workers will be exposed (e.g., a new job with significant airborne contamination potential, but with no history of previous similar jobs). (See NUREG/CR-6204,¹ Question 60.)

2.4 Exceptions to ALARA Requirement for Respirators

The ALARA principle must be applied in a reasonable fashion when making decisions on respirator use. The NRC staff recognizes that there may be situations when the dose evaluation clearly indicates that respirators need not be used, but the licensee makes a professional decision to use respirators in spite of the evaluation for reasons that are valid but may not be quantifiable.

When the use or nonuse of respirators has no clear impact on TEDE, the licensee should opt to not use respirators in most circumstances. There could be some reasonable exceptions to this, however. For example, respirator use could be considered if a nonradioactive nuisance dust exists in the work area. In these cases, the respirators should be selected to have the least possible impact on worker stress, vision, and ability to communicate.

Other valid exceptions would be certain respiratory protection devices used to reduce heat stress on workers or used as contamination-control devices in high contamination but relatively low airborne radioactivity areas (e.g., the use of airline-supplied hoods for steam generator entries).

A reduction in TEDE for a worker would not be

reasonable if an attendant increase in the worker's industrial health and safety risk (e.g., from a vision limitation or other respirator-related problem) would exceed the benefit to be obtained by reducing the risk associated with the reduction in the TEDE. (See NUREG/CR-6204,¹ Question 387.) This determination is likely to be based on judgment rather than any quantitative comparison.

The NRC is aware of existing State OSHA regulations that require an employer to provide a worker with a respirator upon request (i.e., voluntary respirator use). Compliance with such State regulations is acceptable to the NRC. (See NUREG/CR-6204,¹ Question 386, and Regulatory Position 4.7 of this guide.) Also, the voluntary use of disposable filtering facepieces (dust masks) is permitted in Appendix A to Part 20 without fit-testing or medical screening.

3. PROCEDURES AND PROGRAMS

3.1 Applicability

Pursuant to Subpart H of 10 CFR Part 20, a licensee may assign and take credit for the use of respiratory protective equipment to limit intakes of airborne radioactive material. Unless the licensee can clearly show otherwise, any use of respirators under Subpart H is considered to be for the purpose of limiting the intake of radioactive material. Therefore, if respirators are assigned routinely or periodically, the licensee's respiratory protection program must include, as a minimum, all the requirements contained in 10 CFR 20.1703.

If a licensee does not use respirators routinely or periodically, but has determined that there is sufficient likelihood of an emergency situation to justify the maintenance of emergency-use self-contained breathing apparatus (SCBA) or other types of respirators for an emergency, a program is necessary to ensure the safe use of that equipment should it be needed.

Footnote d of Appendix A to 10 CFR Part 20 and Regulatory Position 4.8 of this regulatory guide describe an exception for voluntary use of certain types of filtering facepiece respirators when no APF is applied.

3.2 Written Procedures

According to 10 CFR 20.1703, written procedures must be in place. These procedures should address and implement the following respiratory protection program elements:

- Monitoring, including air sampling and bioassays,
- Supervision of the program, including program audits,
- Training and minimum qualifications of respirator program supervisors and implementing personnel,
- Training of respirator users, including the requirement for each user to inspect and perform a user seal check (for face-sealing devices) or an operational check (non-face-sealing devices) on a respirator each time it is donned,
- Fit-testing,
- Selecting respirators,
- Maintaining breathing air quality,
- Inventory and control of respiratory protection equipment,
- Storage and issuance of respiratory protection equipment,
- Maintenance, repair, testing, and quality assurance of respiratory protection equipment,
- Recordkeeping,
- Limitations on periods of respirator use and relief from respirator use.

Written procedures should also be in place for:

- Performing and documenting the required medical evaluation,
- Maintaining TEDE ALARA and performing ALARA evaluations with regard to respiratory protection.

Written procedures should also include a description of the following applications of respirators:

- Routine respirator use
- Nonroutine respirator use (e.g., in unassessed areas or for nonrecurring tasks for which engineering controls are

not in place or practical); and

- Emergency respirator use (e.g., recovery of an injured person from an area where air concentrations of radioactive material may be high, the breathing quality of the ambient air has not been assessed, or the area may become immediately dangerous to life or health (IDLH) because of the presence of nonradiological hazards).

3.3 Application of Assigned Protection Factors

3.3.1 The APFs listed in Appendix A to 10 CFR 20 are an indication of the predicted level of protection that a respirator user can expect to get from a given type of respirator. Use of the APF presumes that:

- The respirator user has been trained to properly don the device;
- The user has been satisfactorily fit-tested (face-sealing devices only);
- The user properly performs either a user seal check on face-sealing devices to ensure that there is no gross seal leakage, or an operational check on non-face-sealing devices to ensure that the equipment is operating properly; and
- The respirator performs properly.

3.3.2 APFs are intended to be used as follows:

- For selecting a type or types of respirators to be purchased by a licensee to address the expected range of potential airborne contamination levels at the facility and credible emergency situations;
- For selecting a specific type of respirator from among those available at the facility, to be used in the performance of a specific task, to keep the TEDE of exposed workers ALARA; and
- For estimating intake when bioassay and other evaluation methods are either not available or are not the method of choice.

3.3.3 For personnel for whom an internal dose-monitoring program is required pursuant to 10 CFR 20.1502 (e.g., an adult radiation worker likely to receive 10% of an ALI in a year), any intake must be recorded as specified in 10 CFR 20.1204. Using APFs to estimate intake and thus dose of record from internal sources is permitted.

3.3.4 If respirator wearers are not required to be monitored for intake of radioactive material, no record of internal exposure (DAC hours) or internal dose (mrem) need be calculated or retained if:

- The APF of the respirator is ten times greater than the multiple by which average ambient concentration of airborne radioactive material in the workplace exceeds the applicable DAC value and
- The licensee's respiratory protection program meets all the requirements of Subpart H of 10 CFR Part 20.

3.3.5 The following is an example of the use of the APF to estimate intake and then dose.

Two fully qualified respirator users wearing half-facepiece negative-pressure respirators (APF = 10) perform work for 4 hours in an airborne contamination area. Four 1-hour air samples taken during the course of a task indicate that actual airborne contamination concentrations were 11.2, 15.4, 24.8, and 12.6 times the DAC respectively. Taking credit for the APF=10, actual worker exposure can be assumed to be 1.1 DAC-hr + 1.5 DAC-hr + 2.5 DAC-hr + 1.3 DAC-hr = 6.4 DAC-hr. Since 1 DAC-hr = 2.5 mrem, the worker doses may be recorded as

$$6.4 \text{ DAC-hr} \times \frac{2.5 \text{ mrem}}{\text{DAC-hr}} = 16 \text{ mrem}$$

If the licensee desires, bioassay measurement may be performed, and the recorded dose may be adjusted in accordance with 10 CFR 1703(i).

3.4 Surveys

A survey program that is adequate to identify potential respiratory hazards, to permit selection of the proper respiratory protection method (not necessarily the assignment of respirators), and to evaluate actual or suspected intakes is required by 10 CFR 20.1703(c)(1) and (c)(2). Survey programs include (but are not necessarily limited to) surveys for radiation, contamination, airborne radioactive materials, and bioassay measurements. Other regulatory guides, some of which are listed below, describe methods and programs that are acceptable to the NRC.

Number	Title	Date
8.9, Rev. 1	Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program	7/93
8.11	Applications of Bioassay for Uranium	6/74
8.20, Rev. 1	Applications for Bioassay for I-125 and I-131	9/79
8.21, Rev. 1	Health Physics Surveys for Byproduct Material at NRC-Licensed Processing and Manufacturing Plants	10/79
8.22, Rev.1	Bioassay at Uranium Mills	8/88
8.23, Rev. 1	Radiation Safety Surveys at Medical Institutions	01/81
8.24, Rev. 1	Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication	10/79
8.25, Rev. 1	Air Sampling in the Workplace	6/92
8.26	Applications of Bioassay for Fission and Activation Products	9/80
8.30	Health Physics Surveys in Uranium Mills	6/83
8.32	Criteria for Establishing a Tritium Bioassay Program	7/88
8.34	Monitoring Criteria and Methods To Calculate Occupational Radiation Doses	7/92
8.36	Radiation Dose to the Embryo/Fetus	7/92

3.5 Supervisory Positions and Responsibilities

A program should be established that:

- Identifies the individuals who have supervisory and technical responsibilities in the respiratory protection program (including the respirator program administrator),
- States the responsibilities of each position,
- Specifies minimum training and retraining requirements for each position, and
- Identifies the minimum qualifications for appointment or assignment to these positions.

The radiological and nonradiological respiratory protection programs may have different administrators as long as adequate communication and coordination exist between the programs.

4. EQUIPMENT

4.1 NIOSH-Certified Equipment

The National Institute for Occupational Safety and Health (NIOSH) issues approvals for respiratory protection devices. A list of the manufacturers and model numbers of approved devices is available from NIOSH.⁵ The NRC requires that only NIOSH-certified equipment be used in a radiological respiratory protection program unless a variance has been granted as described in 10 CFR 20.1703(b). In addition, these devices must be used, maintained, and stored in such a manner that they are not modified and are in like-new condition at the time of issue.⁶ A reasonable amount of wear that does not affect performance is acceptable.

According to 10 CFR 20.1703(e), the licensee is to provide adequate equipment or material, as necessary to supplement respiratory protective equipment, to reduce the likelihood that respirator use might contribute to workplace accidents or injury. Examples of such equipment would be spectacle adapters, voice amplification equipment, material or equipment to prevent or reduce fogging of respirator lenses, and body-cooling equipment in environments with high temperature or high humidity.

Safety or protective equipment used in conjunction with respirators should not interfere with the proper fit or operation of the respirator. Manufacturer-supplied equipment (e.g., welder's shields, communications devices) specified on the approved subassemblies list for the respirator may be used in accordance with the manufacturer's instructions. Equipment or devices supplied by a company other than the respirator manufacturer may be used as long as they do not alter the form, fit, or function of the respirator. Any such device that attaches to or requires penetration of the respiratory inlet covering is likely to void the NIOSH approval for the device and should not be used.

4.2 Non-NIOSH-Certified Equipment

If a licensee identifies a need for a respiratory protection device that would adequately provide the needed protection but the device is not NIOSH-certified, is not listed in Appendix A to 10 CFR Part 20, and no comparable NIOSH-certified device exists, the licensee may apply to the NRC to use the noncertified device (see 10 CFR 20.1703(b)). NRC approval is required whether or not APF credit will be used, except that supplied-air suits may be used without such approval as long as no APF is used (see Regulatory Position 4.10.1). The application to use a noncertified device should:

- Explain why no existing NIOSH-certified device meets the licensee's need,
- Present evidence that the material quality and performance characteristics of the proposed device are capable of providing adequate respiratory protection to the wearer under the proposed conditions of use, and
- Show that using the device as proposed will not subject the wearer to undue physical or psychological stress or undue hazard.

Such test information may be provided by the licensee, the equipment manufacturer, or by a reliable third party. The manufacturer of such a device should have previous experience with the design and manufacture of respiratory protection equipment. The licensee may use such devices under controlled test conditions to develop information for the authorization application. When the NRC has granted authorization to use such a device to one licensee, subsequent applications by additional licensees may make use of test information in that original submittal. As a minimum for devices that have not yet been authorized for use by NRC, the licensee should be involved in at least one operational test of the device.

4.3 Inventory, Inspection, and Storage

Respirator facepieces that are routinely available for issue should be visually inspected at least every month or in accordance with manufacturer's instructions. If such devices are stored in clear plastic bags, they should be handled and examined, but need not be removed from the bags for this inspection as long as the licensee can determine that the device is ready for issue. Respirator facepieces (face-sealing types) must be checked for leakage (user seal check) prior to each use (see 10 CFR 20.1703(c)(3)). A user seal check performed by the person being issued the respirator, either at the point of issue or immediately prior to entering an airborne contamination area, fulfills this requirement.

Equipment used in conjunction with facepiece respirators (e.g., belt- or facepiece-mounted air regulators, air-supply hoses, portable distribution manifolds) should be inventoried and functionally tested periodically or prior to use.

When it is provided as emergency respiratory protection

equipment, SCBA should be visually inspected monthly and operationally tested at least quarterly. Escape-only devices should be visually inspected monthly.

Some other respiratory protection devices, such as air-purifying respirators specifically designated for emergency use, should be visually inspected monthly and should be removed from any protective container and thoroughly examined periodically (e.g., 2 to 3 times per year). Such devices might be stored at the Emergency Operations Facility at a commercial power reactor or at comparable locations at a materials licensee's facility.

Repair and replacement parts for respiratory protection devices should be inventoried and inspected periodically. The goal is to ensure that there are sufficient functional parts available to support the respiratory protection program when it is operating at full capacity.

When in storage and not available for use, respirators and component parts of respiratory protection devices should be stored in such a way as to prevent damage to such components and devices. Devices in storage should be inspected before they are made available for issue. Equipment stored for periods of a year or more should be inspected annually to ensure that they are in good condition in case they are needed unexpectedly.

Breathing air cylinders, including SCBA cylinders, must be tested as prescribed in the Shipping Container Specification Regulations of the Department of Transportation (49 CFR 173 and 178). Each breathing air cylinder should be permanently and legibly marked "Breathing Air" or "Compressed Breathing Air."

4.4 Maintenance and Repair

Respirators and component parts of respiratory protection devices should be maintained and repaired only by persons specifically trained to perform this work. Such repairs and maintenance should be performed in accordance with the manufacturer's instructions, but in general, training by the device manufacturer is not required.

Maintenance and repair of some components of certain devices require manufacturer-certified training (e.g., SCBA regulator, SCBA low-pressure alarm). The device manufacturer identifies the components that require manufacturer-certified training.

4.5 Control and Issuance

Licensees should maintain positive control over the issuance of respiratory protection devices. Sufficient control should be established and maintained so that persons not authorized to wear such devices are effectively prevented from obtaining them.

Personnel who issue respirators must ensure that each person issued a respirator has been medically screened, trained, and (for face-sealing devices) fit-tested within the period prescribed. Persons may only be issued face-sealing

respirators for which they have been fit-tested (i.e., same make, model, style, and size).

4.6 Recordkeeping

Records of all the required activities in a respirator program should be kept in a manner that shows compliance with the requirements of the applicable regulations.

4.7 Half-Facepiece Respirators (APF = 10)

Half-facepiece respirators seal over the bridge of the nose, around the cheeks, and under the chin. Traditionally, half-facepiece respirators are made of rubber or an elastomeric material (e.g., silicone rubber), have at least two adjustable elastic head straps (4-point suspension), and use replaceable filter cartridges.

Two relatively new variations on the half-facepiece respirator are now available. They are sometimes referred to as "reusable," "reusable-disposable," or "maintenance-free" devices, and they are designed to be worn several times or for some period of time by the user. These devices are not intended for only a single use, and they can be divided into two general categories:

- Respirators that have a standard rubber or elastomeric facepiece with filters attached, but the filters are not replaceable. These devices are considered to be half-facepiece respirators.
- "Filtering facepiece" respirators in which the filter medium is an integral part of the facepiece structure and is not replaceable.

In order for a device in the second category to be considered a half-facepiece respirator in an NRC program, it must have **both** of two design characteristics:

- Seal-enhancing rubber or elastomeric material applied to the **entire** face-to-facepiece seal area, and
- An **adjustable** four-point (minimum) suspension strap system.

Most of the devices that qualify as half-facepiece respirators also have exhalation valves, but an exhalation valve, while desirable, is not an essential design component. Devices that meet these criteria are considered half-facepiece respirators and have an APF = 10. They are acceptable for use in an NRC-regulated program as long as the user can properly perform a seal check upon donning, and all other program requirements (e.g., medical screening, fit-testing, training) are fulfilled. It is important to follow the manufacturer's recommendations and in-house contamination control procedures to establish the length of time such facepieces may be used before being discarded.

The use of quarter-facepiece respirators (which seal over the bridge of the nose, around the cheeks, and between the point of the chin and the lower lip) is not acceptable in an NRC-regulated program because it has been observed that the fit becomes unstable when the wearer moves around in

the work place, especially when the wearer talks. These devices have never been permitted in an NRC-regulated respirator program, and good alternatives such as half-facepiece respirators are readily available.

4.8 Other Filtering Facepieces or Dust Masks (No APF)

Other NIOSH-certified filtering facepiece respirators are available that do not fit NRC's description of a half-facepiece respirator in Regulatory Position 4.7. These are generally considered to be single-use disposable respirators and are referred to in this regulatory guide as dust masks. An experienced respirator program administrator should be able to distinguish between these single-use, filtering facepiece dust masks and those that qualify as half-facepiece respirators in an NRC-regulated program. Table 1 of ANSI Z88.2-1992 does not divide facepiece respirators into two groups. The standard does not differentiate between single-use disposable filtering facepieces and half-facepieces, but allows an APF = 10 to all disposables and quarter- and half-facepieces.

Dust masks are relatively inexpensive; have little or no impact on worker vision, cardiopulmonary stress, heat stress, and ability to communicate verbally; and they create very little solid radioactive waste. These devices are permitted for use in a radiological respiratory protection program, but no credit may be taken for their use except as described below. Licensees are relieved of the requirement to medically screen and fit-test the wearers of such devices as long as no APF is used. A user seal check should be performed upon donning, if possible, in accordance with the manufacturer's instructions, and all other applicable program requirements listed in 10 CFR 20.1703 apply. Devices must be NIOSH-certified, and wearers must be trained in the proper use and limitations of the devices. The information contained in OSHA's Appendix D to 29 CFR 1910.134 constitutes acceptable training for users of these devices. The availability of the devices should be controlled so that untrained individuals cannot obtain them, and so that these devices are not mistakenly substituted for a more protective device in the field.

Single-use respirators might be appropriate in situations when a respirator is not necessary but is requested by a worker (i.e., voluntary respirator use). This type of respirator can limit intakes of nuisance dusts when use of a more protective device cannot be justified in an ALARA analysis. These devices should be discarded after each use, and a new device should be used for subsequent work.

If a licensee wants to use an APF for these devices, the rule (at footnote d to Appendix A to 10 CFR Part 20) permits the use of an APF of 10 if the licensee can demonstrate a fit factor of at least 100 by using a validated or evaluated, qualitative or quantitative, fit-test. If an APF is used for these devices, the requirement for medically screening the user is reinstated. Acceptable protocols for qualitative fit-testing can

be found in Sections B1 through B5 of Appendix A to OSHA's 29 CFR 1910.134, "Respiratory Protection."

4.9 Respirator Filters

NIOSH has changed the way nonpowered air-purifying respirator filters are certified and designated. Under NIOSH's old rule (30 CFR Part 11), respirator filters for protection against airborne radionuclides were required to be at least 99.97% efficient for the collection of 0.3 μm mass median aerodynamic diameter (MMAD) particles, the particles being produced by the vaporization and condensation of dioctyl phthalate (DOP). Filters that meet this criterion are commonly referred to as high-efficiency particulate air (HEPA) filters. Under NIOSH's new rule (42 CFR Part 84), filters are divided into three categories based on their performance characteristics when used against oil-containing and non-oil-containing airborne hazards. The categories are N (non-oil-resistant), R (oil-resistant), and P (oil-proof). Within each category there are three levels of efficiency: 95 (95% minimum efficiency), 99 (99% minimum efficiency), and 100 (99.97% minimum efficiency). Some examples of filter designations would be N-99, P-95, R-100. The decision as to whether N-, R-, or P-type filters should be used is left to the licensee.

Footnote b to Appendix A to 10 CFR Part 20 requires that, for air-purifying respirators operating in the negative-pressure mode that have an APF <100 (i.e., half-facepiece respirators), filters of at least 95% efficiency be used (e.g., N-95). For air-purifying respirators operating in the negative-pressure mode that have an APF = 100 (i.e., full-facepiece respirators), filters of at least 99% efficiency must be used. For air-purifying respirators operating in the positive-pressure mode that have an APF >100 (i.e., full-facepiece powered air-purifying respirators), filters of at least 99.97% efficiency are to be used.

NIOSH has determined that, effective July 10, 1998, particulate filters and respirators certified under 30 CFR Part 11 can no longer be manufactured and shipped as NIOSH-certified items. NIOSH has also taken the position that (1) distributors who purchased 30 CFR Part 11 particulate filters and respirators prior to July 10, 1998, will be able to sell them as "certified" until inventories of these products are depleted, and (2) end users who purchase said particulate filters and respirators from these distributors will be able to use them until their inventories are depleted or until the end of the shelf life or service life for these products.

Filters for powered air-purifying respirators will continue to require that dust-fume-mist HEPA filters be used until NIOSH amends its regulations.

Respirator filters can be re-used by the same person on the same day without being re-tested, as long as contamination control is adequate and the filters do not appear to be damaged. If the licensee's procedures allow for filter re-use beyond one day by the same person, or by other

persons, such filters should be re-tested before re-use occurs. Such re-testing should include a penetration test using any appropriate aerosol and a pressure-drop test. Filters to be reused should not have any apparent damage and should meet the licensee's criteria for residual contamination.

4.10 Service Life Limitations

If the respirator equipment manufacturer specifies a shelf life or service life limit on one or more components of a respiratory protection system, the licensee should comply with the recommendations of the manufacturer. This will ensure that the device continues to operate properly and that the "like-new condition" criterion is maintained as described in Regulatory Position 4.1 of this guide.

For example, some chin-style gas mask canisters for organic vapors are stamped with a "Use Before" date, which is 5 years from the date of manufacture. Such canisters should not be used after that date has passed. Also, the date that these canisters are first unsealed should be written on the canister label, and the canisters should be discarded one year from the unsealing date.

4.11 Supplied Air Hoods

In 1996, NIOSH issued a notice to respirator users to alert users to updated information relative to the performance of certain types of supplied-air respirators approved and used during abrasive-blast (sandblasting) operations. NIOSH assigned relatively low APFs for these respirators with certain types of respirator inlet coverings (e.g., the APF for a loose-fitting hood is 25).

The NRC staff recently became aware of an industry-sponsored testing initiative focused on hood performance. While the results have not been published, initial indication is that, while most models demonstrated APFs greater than 1000, some designs did not provide test subjects with APFs that exceeded 1000.

Until the study is completed and the results are made available, licensees should use hoods with anti-aspiration devices and use supplied air flow rates at the maximum allowed by NIOSH certification, consistent with wearer comfort (noise limitations). Anti-aspiration devices minimize penetration of the hood by contaminants. These devices include neck dams or other neck-sealing features that fit snugly around the user's neck. These devices limit the "bellows effect," as do bibs or hood shrouds that may be tucked inside a worker's protective clothing. These bibs help form a lower barrier to minimize the backflow of contaminants.

4.12 Supplied-Air Suits

4.12.1 Supplied Air Suits Used With No APF

One-piece and two-piece supplied-air suits are permitted for use in nuclear industry respiratory protection programs, but no APF is assigned and no protection credit may be

taken except as discussed in Regulatory Position 4.12.2 of this guide. NIOSH certification procedures do not currently include a method for testing and certifying these suits. NRC believes, however, that in certain nuclear industry applications (e.g., control-rod drive removal at boiling water reactors) they might be the best overall choice, taking into account respiratory protection, contamination control considerations, heat stress, and ALARA.

Users of supplied-air suits must be medically approved and trained, and the air supplied to the suit must meet the minimum quality requirements specified in CGA 7.1-1997, "Commodity Specification for Air,"⁷ for other (NIOSH-certified) supplied-air devices. The equipment must be stored, maintained, and tested (as applicable) in accordance with the manufacturer's recommendations and the licensee's respirator maintenance and quality assurance program.

When selecting such devices for use in a respiratory protection program, the licensee should determine that the material quality and performance characteristics of the proposed device are capable of providing adequate respiratory protection to the wearer under the proposed conditions of use, while not subjecting the wearer to undue physical or psychological stress or undue hazard. Such material and performance information may be provided by the licensee, the equipment manufacturer, or by a reliable third party. The manufacturer of such a device should have previous experience with the design and manufacture of respiratory protection equipment.

4.12.2 Supplied Air Suits Used With an APF

If a licensee needs to apply an APF to a supplied-air suit, a written application may be made to the NRC in accordance with the requirements of 10 CFR 20.1705. Conditions of use to be described in the application would include the anticipated length of air supply hose (minimum and maximum) and breathing air supply pressure (minimum and maximum). The NIOSH approval criteria for supplied-air hoods (42 CFR Part 84) may be useful to licensees who anticipate applying for use of an APF for supplied-air suits.

4.13 Combination Devices

Some devices are available that combine two respirator types in one unit (e.g., a combination of negative-pressure air-purifying and continuous-flow airline respirator). When taking credit for use of such a combination device, the licensee must ensure that the proper APF is applied to the exposure time and airborne concentration that exists while the respirator is functioning in each mode of operation. For example, when using the combination device described above, an APF of 100 applies during the time the wearer is in the airborne contamination area and not connected to an air supply hose. Once the worker reaches the work site and connects the device to a supply of breathing air, the APF

increases to 1000.

Another type of combination device of interest to nuclear reactor licensees is the combination particulate/organic vapor respirator canister, commonly referred to as a "radioiodine canister." When used in conjunction with the appropriate facepiece, this canister is not specifically certified for protection against airborne radioiodine because iodine does not have good user-warning properties and the canister is not equipped with an end-of-service-life indicator (ESLI). It is certified, however, for protection against airborne particulates (P-100) and for organic vapors. Therefore, an APF of 100 may be used for airborne particulates. Licensees who wish to use an APF for radioiodine for this device must apply to NRC for authorization. Alternatively, they may use representative air sample data to estimate and control worker doses, then perform post-exposure bioassay to confirm or correct the estimated doses to workers. Otherwise, licensees must use representative air sample data from the workplace to assign doses to exposed workers. Requirements for determining internal doses are contained in 10 CFR 20.1204.

4.14 Emergency and Escape Equipment

4.14.1 Equipment for Emergency Entry

The equipment preferred for emergency entry into an unassessed environment, or into an area with high concentrations of a chemical hazard, is the open-circuit self-contained breathing apparatus (SCBA) operated in the pressure-demand mode, with a minimum rated service life of 30 minutes. Also acceptable are a combination full-facepiece pressure demand supplied air respirator with an auxiliary self-contained air supply of at least 5 minutes duration and a positive-pressure, closed-circuit (recirculating) SCBA with a minimum rated service life of 30 minutes.

4.14.2 Other Emergency Equipment

Other equipment may be designated for emergency use against airborne radioactive material. An example would be air-purifying respirators stored at the Emergency Operations Center at a commercial power reactor facility. At nuclear power plants, where emergency responders might receive a radiation dose from airborne radioiodine in a credible accident scenario, organic-vapor cartridges or canisters may be used for whatever protection they provide and radioiodine doses should be controlled and accounted for as stated in 10 CFR Part 20.

4.14.3 Escape Equipment

Some short-duration SCBAs are certified for escape only. Other escape-only devices are available that are hazard-specific (e.g., mouthpiece and bit respirators for escape from chlorine environments). These devices must be NIOSH-certified for escape from the atmosphere in which they will be used. They may be used for escape from, but

never for entry into, hazardous areas.

4.15 Decontamination and Disinfection of Facepieces; Contamination Control

Licensees should decontaminate and disinfect respirators and associated equipment in accordance with the manufacturer's instructions, paying particular attention to the cleaning or sanitizing agents used and to the maximum temperature of the water used for cleaning, to avoid degradation of the respirator. Chemical residues should not be hazardous or irritating to the user. Radiological limits for reuse of respirators after they have been cleaned and sanitized should be established by the licensee.

5. RESPIRATOR USERS

5.1 Medical Evaluation

5.1.1 The Licensee's Physician

A physician selected by the licensee should determine which screening methods and tests are appropriate, should set the acceptance criteria for those methods and tests, and should periodically review the implementation of the program. This screening process should be sufficient (in the opinion of the licensee's physician) to identify any persons who should not use respiratory devices for medical reasons, or who should be limited to the use of specific types of devices. The NRC regulations do not require a "hands-on" physical examination by a physician.

The licensee should choose a physician with an appropriate specialty (e.g., internal medicine, industrial medicine, family practice), and the licensee's physician should be licensed to practice medicine in the United States.

5.1.2 Establishing and Performing the Evaluation

ANSI Z88.6-1984, "Respirator Use—Physical Qualifications for Personnel,"³ provides guidance that is acceptable to the NRC staff for the physician to use in determining medical fitness. The screening method may include a medical history questionnaire (the OSHA Respirator Medical Evaluation Questionnaire in Appendix C to 29 CFR 1910.134 is acceptable) and spirometry testing. The licensee's physician, however, establishes the precise screening method.

The medical evaluation program should be carried out by the physician, or by a certified, medically trained individual such as a registered nurse (RN), licensed practical nurse (LPN), emergency medical technician (EMT), or someone who, in the judgment of the licensee's physician, has adequate experience, education, training, and judgment to administer the screening program.

Medical evaluations performed by a physician other than the licensee's physician may be acceptable as long as comparable screening tests and acceptance criteria are used for screening individuals.

5.1.3 Timing of Medical Evaluations

According to 10 CFR 20.1703(c)(5), the initial medical evaluation to determine a worker's fitness to use respirators must be accomplished prior to respirator fit-testing for tight-fitting facepieces and prior to the first field use for loose-fitting devices, since no fit-test is required for these types.

The worker must be re-evaluated medically every 12 months thereafter or at some other frequency established by the licensee's physician. ANSI Z88.6-1984 suggests a range for reevaluation from every 5 years for workers below age 35, to annually for workers over age 45.

If necessary, a re-evaluation "grace period" of up to 90 days is considered to be reasonable.⁸ In unusual circumstances, an otherwise fully qualified respirator user whose medical screening has expired within the past 90 days may be issued a respirator with the concurrence of the Respirator Program Administrator. Licensees should not interpret this grace period to mean that re-screening can be accomplished every 15 months. For example, the Health Physics Position referred to above specifies that, if annual rescreening is indicated, three consecutive examinations should not exceed 39 months.

5.1.4 Failure To Meet the Acceptance Criteria

Individuals whose screening results fall outside the range of the criteria established by the licensee's physician may have their cases evaluated by the licensee's physician. This evaluation might consist only of a review of the written record, or it might involve a hands-on examination. In these situations the licensee's physician might permit the individual to use one or more types of respirators judged to impose less stress, and prohibit the use of other more stressful devices. The licensee's physician may confirm the outcome of the screening by prohibiting the individual from using any respirator.

5.1.5 Privacy of Medical Records

Medical records and the results of medical screening tests should be kept private. The only information that should be transmitted from the medical department to the respirator department is whether or not an individual may use respirators, or which devices may be used and which may not be. A simple medical-approval form is adequate.

5.2 Training

A training program, including hands-on training, must be established and implemented for respirator users (see 10 CFR 20.1703(c)(4)). When face-sealing respirators will be used, this training should take place prior to fit-testing. As a minimum, each trainee should:

- Be informed of the hazard to which the respirator wearer may be exposed, the effects of contaminants on the wearer if the respirator is not worn properly, and the

capabilities and limitations of each device that may be used.

- Be shown how spectacle adapters, communications equipment, and other equipment that will be used directly in conjunction with the respirator are to be attached and operated properly.
- Be able to demonstrate competency in donning, using, and removing each type of respiratory protective device that may be used.
- Be instructed in how to inspect each type of respiratory protective device that may be used and be instructed to perform such an inspection before donning any device.
- Be instructed in how to perform a user seal check on face-sealing devices and be instructed to perform this user seal check each time this type of device is donned.
- Be informed that any respirator user may leave the work area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communications failure, significant deterioration of operating conditions, or any other condition that might necessitate such relief.
- Be advised that in case of respirator malfunction or wearer distress, the respirator may be removed as the respirator user exits the airborne contamination area.

5.3 Fit-Testing

A fit-testing program is to be implemented for all face-sealing respirators (see 10 CFR 20.1703(c)(6)), even if they will be used in a positive pressure mode in the field. The employee should be fit-tested with the same make, model, style, and size of respirator that will be used in the field.

Each person being fit-tested should already have been trained in how to properly don, and perform a user seal check on, a face-sealing respirator. Therefore, during the test, no person (including the person administering the fit-test) should assist or coach fit-test subjects who are not obtaining a satisfactory facepiece seal.

Qualitative fit-testing (QLFT) and quantitative fit-testing (QNFT) must be accomplished with the facepiece operating in the negative pressure mode, regardless of the mode of operation in which it will be used in the field. QLFT can usually be accomplished with unmodified respirators. For QNFT, some respirator manufacturers provide a fit-test adapter to accomplish this. Otherwise, respirators used for fit-testing will need to be modified. While this modification voids the NIOSH certification for the test device, certification is not required since occupational exposures are not involved during fit-testing.

Filters used during fit-testing should be at least 99.97% efficient, even if less efficient filters will be used in the work place. The fit-test is intended to measure only face-to-facepiece leakage, so filter efficiency on the test respirator should be as high as possible.

The size of the particles that make up the challenge aerosol during fit-testing is unimportant. The following challenge aerosols have been used successfully.

Corn oil (QNFT)

Sodium chloride (QNFT)

Ambient dust particles (QNFT)

Sodium saccharine (QLFT)

Bitrex (denatonium benzoate) (QLFT)

Amyl acetate (or isoamyl acetate or isopentyl acetate),⁹ commonly called "banana oil" (QLFT)

Stannic chloride (irritant smoke) (QLFT)

All these are acceptable challenge agents as long as the sensitivity of the detection system (QNFT) or the ability of the test subject to sense the challenge agent (QLFT) meets the test protocol requirements.

During training or operation, perceptible outward leakage of breathing gas from the face-to-facepiece seal area of any SCBA is unacceptable, and the wearer should not be permitted to continue to use the device. Such leakage will quickly deplete the available breathing gas and if used in an emergency could easily place the wearer in jeopardy.

5.3.1 Quantitative Fit-Testing (QNFT)

QNFT is acceptable for testing all face-sealing devices. If QNFT is used to test facepieces that will be operated in the negative pressure mode in the field, an overall fit factor of at least 10 times the APF (given in Appendix A to 10 CFR Part 20) should be demonstrated. Requiring that the **overall** fit factor meet the acceptance criterion means that the fit factor for one or more of the individual test exercises might be less than the acceptance criterion, but a satisfactory overall fit-test can still be achieved.

If QNFT is used to test facepieces that in the field will be operated **only** in a positive pressure mode, an overall fit factor of at least 500 (**not** 500 times the APF) should be demonstrated with the facepiece operating in the negative pressure mode. Face-sealing devices that operate in a positive pressure mode are powered air-purifying respirators (PAPR), continuous flow supplied-air respirators, pressure-demand supplied air respirators and SCBA, and positive-pressure recirculating SCBA.

For combination devices (e.g., a combination of negative-pressure air purifying and continuous-flow airline device), the minimum acceptable fit factor is 10 times the APF for the negative pressure mode of operation, or 500, whichever is greater.

During all quantitative fit-tests, the sample point inside the facepiece should be midway between the mouth and the nose of the test subject.

5.3.2 Qualitative Fit-Testing (QLFT)

While no numerical measure of facepiece leakage is directly obtained from QLFT protocols, they are designed and validated quantitatively. Each validated protocol first tests the subject's ability to detect (i.e., smell or taste) a small concentration of the challenge aerosol (C_2). After donning the device to be tested, the seal area is then exposed to a higher concentration of the challenge aerosol (C_1) and the subject performs a sequence of head, neck, and body movements while the concentration of challenge aerosol is maintained. If the challenge concentration is 100 times the wearer's detection threshold, and the wearer isn't able to detect the challenge aerosol, the test has in essence measured a fit factor of at least 100 (i.e., $C_1/C_2 \geq 100$).

QLFT is acceptable if the method used is capable of:

- Verifying a fit factor 10 times the APF for facepieces that in the field will operate in the negative pressure mode, or
- Verifying a fit factor of 500 (**not** 500 times the APF) for facepieces that in the field will operate in a positive-pressure mode. Devices that operate in a positive-pressure mode are listed in Regulatory Position 5.3.1.

Currently available QLFT methods are only capable of verifying a fit factor of 100. Therefore present QLFT methods are only appropriate for devices with an APF of 10 or less, unless and until new QLFT methods that can confirm higher fit factors are developed and validated. Licensees may use QLFT to test respirators with APF greater than 10, but may only take credit for an APF of 10 even though the listed APF is higher for the device in Appendix A to 10 CFR Part 20.

5.3.3 Irritant Smoke

The currently used irritant smoke QLFT protocol has never been validated. However, it will evoke an involuntary response in virtually anyone who smells it, and it is therefore less subjective than the other QLFT protocols. NRC considers that this protocol has been sufficiently evaluated to permit its use in nuclear industry respirator programs for half-facepiece respirators that will be used in the negative pressure mode of operation.

When stannic chloride hydrolyzes with moisture in the air it forms hydrochloric acid (HCl) and stannic oxychloride. Licensees should ensure that only stannic chloride smoke tubes are used. Similar tubes that generate smoke of a different chemical composition may not be sufficiently irritating to the test subject to be sensed at low concentrations. Smoke tubes that use chemicals other than stannic chloride are not acceptable.

If irritant smoke is used as the challenge aerosol during QLFT, the licensee should take steps to protect the person administering the test from repeated exposures to the irritant smoke. These steps could include using a containment chamber around the head and torso of the fit-test subject to contain the smoke, providing the test area with a ventilation

or air filtration system, assigning a respiratory protection device to the person performing the fit-testing, or other measures. The fit-test protocol should also be designed to limit the test subject's exposure, especially when performing the sensitivity screening checks that determine whether the test subject can detect the irritant smoke.

Because of exposure to both the fit test subject and the fit test administrator to the chemical irritant, NIOSH does not recommend the use of irritant smoke for respirator fit-testing.

5.3.4 Fit-Test Protocols and Procedures

Fit-testing should be performed in accordance with an established protocol.¹⁰ Each time fit-testing is required, only a single satisfactory fit-test need be performed.

Protocols that can be used for developing QLFT and QNFT procedures may be found in Sections B1 through B5 and in Sections C1 through C3 of Appendix A to OSHA's 29 CFR 1910.134, "Respiratory Protection." Fit-testing performed in accordance with these protocols will comply with NRC's requirements.

5.3.5 Retesting

Retesting must be done annually. If necessary, a retest "grace period" of up to 90 days is considered to be reasonable.⁸ In unusual circumstances, an otherwise fully qualified respirator user whose fit-test has expired within the past 90 days may be issued a respirator with the concurrence of the Respirator Program Administrator. Licensees should not interpret this grace period to mean that fit-testing can be accomplished every 15 months. Three consecutive fit-test periods should not exceed 39 months.

Retesting should be performed before the next respirator use when a potential respirator wearer, since the last fit-test, has had

- A weight change of 10% or more,
- Significant facial injury or scarring in the area of the facepiece seal,
- Significant dental changes (e.g., multiple extractions without prosthesis or acquisition of new dentures),
- Reconstructive or cosmetic surgery in the area of the facepiece seal,
- Any other condition that might change the fit of a face-sealing respirator.

Licensees should take steps to make these retest criteria known to respirator users (e.g., during training and retraining) and should work with site medical or health personnel to identify persons who meet any of the retest criteria. Adding or revising some questions on a medical screening questionnaire (if used) might be considered.

Licensees are cautioned that Federal regulations that apply to some nonradiological hazards (e.g., 29 CFR 1910.1001 on asbestos) may require retesting at more

frequent intervals, and they may require more than one satisfactory fit-test.

5.4 User Seal Checks

Each respirator wearer must perform at least one type of user seal check each time a face-sealing respirator is used. A user seal check is performed immediately prior to exposure to ensure that the respirator is properly seated on the face. Some licensees may require the respirator user to also perform such a user seal check at the point of respirator issue to ensure that the respirator is in good working order before the worker proceeds to the job site. In this case, the respirator user must perform another user seal check after donning the facepiece at the work site.

A user seal **check** is not a substitute for a **fit test**. Acceptable user seal checks are described below.

Positive-pressure check. Close off the exhalation valve and exhale gently into the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of outward leakage of air at the seal. For most respirators this method of leak testing requires the wearer to first remove the exhalation valve cover before closing off the exhalation valve and then carefully replacing it after the test.

Negative-pressure check. Close off the inlet opening of the canister or cartridge(s) by covering with the palm of the hand(s) or by replacing the filter seal(s), inhale gently so that the facepiece collapses slightly, and hold the breath for ten seconds. The design of the inlet opening of some cartridges cannot be effectively covered with the palm of the hand. The test can be performed by covering the inlet opening of the cartridge with a thin latex or nitrile glove. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.

Manufacturer's recommended seal check. The respirator manufacturer's recommended procedures for performing a user seal check may be used instead of the positive and negative pressure check procedures provided that the employer demonstrates that the manufacturer's procedures are effective.

Also acceptable as a seal check is the use of an irritant or odorous test agent, such as stannic chloride (irritant smoke) or amyl acetate (or isoamyl or isopentyl acetate).⁹ While seal checks that use these agents are more involved than other methods, require a test substance, and might require the assistance of others to properly administer, they are still permitted to be used by licensees.

5.5 Operational Checks

Non-face-sealing respirators (e.g., airline-supplied hoods) should be operationally checked to ensure proper operation a short time before the wearer enters the radiological environment for which the device is to be used

for protection. For example, once an individual has donned a supplied-air hood, the air should be allowed to flow for a period of time (e.g., one minute) before the wearer enters the contaminated area. During this time support personnel should verify that the air pressure at the distribution manifold is within the proper range specified by the manufacturer and that the wearer feels that the airflow is adequate.

5.6 Communications

Respiratory protection devices limit the wearer's ability to communicate. NRC regulations require that respirator users be able to communicate well enough to be able to work safely and to keep radiation doses ALARA. How these goals can best be met is left to the judgment of the respirator program administrator. In many situations, adequate communication can be maintained by training the respirator wearers to speak slowly and distinctly. In other situations, especially where ambient noise levels are high or where respirator wearers must communicate across long distances, voice-amplification devices or other types of systems might have to be employed.

Licensees are reminded that if these devices are attached to the respirator or require a modification of the respirator, they must be listed on the manufacturer's schedule of approved subassemblies. This ensures that the NIOSH approval for the device remains in force with the addition of the communications equipment.

After-market communications devices supplied by a company other than the respirator manufacturer may be used as long as they do not alter the form, fit, or function of the respirator. Any such after-market device that attaches to or requires penetration of the respiratory inlet covering is likely to void the NIOSH approval for the device.

5.7 Vision

Some types of respirators prevent the wearer from using standard spectacles or from using them properly. The ear pieces of standard spectacles pass through the seal area of full-facepiece respirators and are therefore not allowed. Half-facepiece respirators seal around the bridge of the nose and prevent standard spectacles from being worn as designed. NRC requires that respirator users be able to see well enough to be able to work safely and to keep radiation doses ALARA. How these goals can best be met is left to the judgment of the respirator program administrator.

Most manufacturers of full-facepiece respirators offer a spectacle adapter kit. Non-manufacturer-supplied adapters may be acceptable if they do not interfere with the facepiece seal and if they do not cause any distortion of vision, damage the lens of the facepiece, or cause any harm to the wearer during use. It is not advisable to use home-made adapters, or to simply tape the spectacles inside the facepiece.

Contact lenses are permitted for use with respirators provided the wearer has demonstrated successful experience

in wearing such lenses. Contact lens wearers should be required to practice wearing the respirator while wearing the contact lenses, for example, during training or fit-testing.

Another option is to select a respirator that does not interfere with the use of standard spectacles, such as a hood or helmet.

5.8 Use of Respirators in Low Temperatures

5.8.1 Lens Fogging

Fogging of the inside of the respirator lens is commonly experienced in full facepiece respirators operating in the negative-pressure (including demand) mode or the pressure-demand mode. The fogging is caused by the condensation of the moisture in exhaled breath that comes in direct contact with the inside of the lens. Most full facepiece respirators have air inlet ducts positioned to direct the inhaled air across the inside of the lens as it enters the facepiece. This clears off the accumulated condensation, but the lens fogs again during exhalation. The cooler the ambient air temperature, the less effective the lens clearing provided during inhalation. At temperatures below freezing, lens frosting can occur that will not be removed during inhalation and may eventually seriously obscure the wearer's vision. Lens fogging and frosting, therefore, can present a significant safety hazard by restricting the wearer's ability to see clearly in the work place. Some possible solutions to the fogging and frosting problems are:

Nose cup. Most full-facepiece manufacturers provide an optional component called a nose cup. It is attached to the inside of the facepiece in such a way that it directs the stream of exhaled air directly into the exhalation valve, minimizing the amount of moist air contacting the interior of the lens.

Anti-fog applications. Most full-facepiece manufacturers provide an anti-fog material that limits fogging when applied to the interior of the respirator lens.

Plastic inserts. Thin plastic inserts that are applied to the inside of the facepiece lens to form a double-pane insulating barrier may effectively reduce fogging.

Before using commercial anti-fogging products (that are not supplied by the respirator manufacturer), check with the respirator manufacturer regarding the compatibility of these products with their facepieces.

Licensees should be aware that NIOSH requires that facepieces used with SCBA be designed to prevent lens fogging. This means that, in order to maintain the NIOSH certification of the device, a nose cup or some other method must be used when fogging might be a problem.

5.8.2 Exhalation Valve Freezing

Another potential problem when using any type of face-sealing respirator in subfreezing temperatures is the possibility that the exhalation valve could freeze. If the valve

freezes shut, exhaled air will be exhausted through the face-to-facepiece seal area and the respirator wearer will be aware of the malfunction. In this case, the respirator will probably provide adequate protection as the wearer exits the work area.

If the valve freezes in the open position, or if ice forms on a portion of the exhalation valve seat, a path is created for contaminated ambient air to enter the respiratory inlet covering. If the device in use were a powered air-purifying respirator or a continuous-flow supplied-air respirator, it is likely that the respirator wearer would not be aware of the malfunction, although the internal dose consequences of this type of failure would probably be limited.

If the device in use were a pressure-demand supplied-air device (e.g., air line-supplied or SCBA), it is likely that the respirator wearer would recognize that a malfunction had occurred since air would leak out of the facepiece through the exhalation valve. Even though the wearer would continue to be adequately protected, he or she should exit the work area immediately since a respirator malfunction has occurred. If the device in use is a SCBA, the duration of the air supply will be reduced because of the loss of breathing gas from the supply cylinder.

If the device in use is operated in the negative-pressure mode, it is unlikely that the respirator wearer would be aware of the malfunction. The air breathed by the wearer would, at least in part, be unfiltered ambient air entering the respiratory inlet covering through the open exhalation valve during the negative-pressure (inhalation) portion of the breathing cycle.

5.8.3 Conclusion

Licensees should recognize the potential problems associated with respirator use in subfreezing environments and take special care when face-sealing respirators are used in subfreezing temperatures. When possible, respirators assigned under these circumstances should be non-face-sealing types (that have no exhalation valve) or should be a type that continues to provide protection to the wearer even if the exhalation valve freezes in the open or partially open position.

6. SAFETY

6.1 Standby Rescue Persons

According to 10 CFR 20.1703(f), standby rescue persons must be provided when workers wear supplied air hoods or suits, possibly in conjunction with other protective equipment, that are difficult to remove without assistance. Such standby rescue persons must be equipped with respiratory protection devices that are appropriate for the potential hazards, must observe or otherwise be in direct communication with such workers, and must be immediately available to assist them in case of a failure of the air supply or any other reason that necessitates relief from distress. A

sufficient number of standby rescue persons (not necessarily one-for-one) must be available to effectively assist all users of this type of equipment. Standby rescue persons must be sufficiently trained or experienced to render effective assistance if needed.

6.2 Face-to-Facepiece Seal Integrity

Anything in the face-to-facepiece seal area of a tight-fitting respirator that is under the control of the respirator user is prohibited by 10 CFR 20.1703(h). Materials in this area might interfere with the seal of the respirator, might prevent proper exhalation valve function, or might impair the operation of a facepiece-mounted air regulator. The list of prohibited materials includes (but is not necessarily limited to) facial hair of any kind in the seal area (the worker must be clean-shaven), hair from the head intruding into the seal area, cosmetics, spectacle temple bars, protective clothing, and equipment. A respirator wearer should not be required to shave more than once during each 12-hour period.

6.3 Unassessed Environments

For entry into areas where the level of hazard has not been assessed because of the existence of unusual conditions, or in response to unanticipated releases of radioactive material, the licensee must use only SCBA operated in the pressure-demand mode. The use of SCBA to circumvent the pre-exposure sampling requirement (10 CFR 20.1703(c)(1)) is not permitted for nonemergency activities.

6.4 Emergency Escape

For emergency escape from normally safe environments, where a respiratory hazard might develop suddenly, any type of device authorized for use in Appendix A may be used as long as it provides adequate short-term protection against the type of hazard that might be encountered.

6.5 Breathing Air Quality

6.5.1 Breathing Air Systems

The breathing air supply system used by licensees may be either a dedicated system or a multi-purpose air system. While a dedicated breathing air system with non-oil-lubricated compressors has its advantages, the only requirement (10 CFR 20.1703(g)) is that air of the minimum quality specified below be delivered to each supplied-air respirator. Licensees are cautioned, however, to avoid contaminating the internals of the system used for breathing air. This includes both radiological and non-radiological contaminants. There are two primary ways in which air systems become contaminated: allowing contaminants to be drawn into the compressor intakes and connecting the air system to a contaminated system which then reaches a higher pressure than the air system and causes

contaminated fluid to flow into the air system.

Air pressure or flow gauges used to show compliance with NIOSH certification requirements should be calibrated at regular intervals consistent with the calibration frequency of other similar gauges at the facility. Calibration annually and after gauge repair is reasonable.

Quick disconnects and other breathing air couplings should be incompatible with outlets for non-respirable air or other gas or fluid systems. Breathing air hoses may not be used for any other purpose. No asphyxiating substance may be introduced into any lines used for breathing air.

6.5.2 Air Quality Requirements

The quality of the air delivered to all atmosphere-supplying respirators must meet the requirements of Grade D air for breathing air systems as defined in CGA G-7.1-1997, "Commodity Specification for Air"¹¹ (10 CFR 20.1703(g)).

Intake points for breathing air compressors should be located and protected in such a way as to prevent airborne contaminants from being drawn in.

6.5.3 Moisture Content in Breathing Air Cylinders

OSHA requires (29 CFR 1910.134(i)(4)(iii)) that the moisture content in breathing air cylinders, in addition to the Grade D requirement, does not exceed a dew point of -50 EF (-45.6 EC) at one atmosphere pressure. CGA G-7.1-1997 states that air in SCBA cylinders should not exceed a dew point of -65 EF (24 ppm v/v), or 10 EF lower than the coldest temperature expected in the area where the SCBA will be used. NRC requires compliance with the OSHA requirement (29 CFR 1910.134(i)(4)(i)) for all cylinders and suggests meeting the CGA G-7.1-1997 Grade L requirement for moisture content, if practical.

6.5.4 Testing Frequency

The air from compressors that furnish breathing air to an in-plant header used as a breathing air supply should be tested periodically. The time interval between tests should be reasonable under the circumstances and conditions of use. For example, combination breathing air/service air systems that are in continuous or daily use should be tested at least monthly; whereas a dedicated breathing air system with a non-oil-lubricated compressor need only be tested quarterly. Breathing air systems that are only used periodically should be tested immediately prior to use, then periodically during use.

The air from compressors used to supply breathing air to cylinders should be tested periodically. This applies to cylinders filled by the licensee and to those filled by a vendor. If the air is tested and shown to meet the quality criteria at the beginning of the filling process, it is reasonable to assume that cylinders may be filled for the following 24 hours without retest. Other reasonable retest periods may be acceptable.

6.5.5 Test Methods

The test methods described in CGA 7.1-1997 are acceptable to the NRC staff. Licensees who perform weekly or more frequent air quality tests should use detector tubes filled with color-reactive chemicals sensitive to the various possible contaminants. The breathing air should be tested two to four times per year using more rigorous analytical methods (e.g., gas chromatography).

6.5.6 Sampling Breathing Air for Radiological Contamination

When breathing air supply manifolds are permanently or temporarily located inside contaminated or airborne radioactivity areas, covers or caps should be used to protect them from contamination. Wipe samples should be taken at the air connection points prior to attaching a respirator supply hose. The breathing air should be sampled periodically for radiological contaminants.

6.5.7 Oxygen Purity Requirements

When any respiratory protection device uses an oxygen supply rather than an air supply (e.g., closed-circuit SCBA), that oxygen must meet the United States Pharmacopoeia requirements for medical or breathing oxygen.

6.6 Use of Higher or Lower APFs

According to 10 CFR 20.1705, licensees may apply to the NRC for permission to use higher APFs than those specified in Appendix A to 10 CFR Part 20. Such applications should describe the situation for which the higher APFs are needed and should demonstrate that the respiratory protection equipment proposed provides these higher protection factors under the intended conditions of use. This demonstration should be based on either licensee testing or reliable test information.

Licensees may use APFs lower than the ones listed in Appendix A to 10 CFR Part 20 without notifying or obtaining approval from NRC.

6.7 Limiting Duration of Respirator Use

Licensees should establish reasonable limits on the length of time that individuals are required to work while using respirators (10 CFR 20.1703(c)(4)(ix)). The NRC recognizes that such limits will vary considerably and will depend on a variety of factors such as temperature and humidity in the work area and the type of respirator being used. Limits may be based on input from medical personnel and from experienced respirator users. Additional guidance for limiting duration of respirator use is provided in NUREG-0041.

6.8 OSHA Requirements

Licensees whose respiratory protection programs fulfill the requirements of Subpart H of 10 CFR Part 20 will meet the basic program requirements for an OSHA-regulated

respiratory protection program described in 29 CFR 1910.134. This is intended to relieve licensees of the burden of developing and maintaining two parallel respiratory protection programs to comply with OSHA and NRC requirements. Radiological considerations are incorporated into the NRC-regulated program to achieve full compliance.

Minor differences between NRC and OSHA respiratory protection requirements are described below along with the resolution of or justification for the difference. The NRC requirements that are not in full agreement with OSHA rules are not likely to place any significant burden on licensees.

- OSHA's 29 CFR 1910.134(c)(2) permits individuals to provide their own respirators for voluntary use. While this is not specifically prohibited in an NRC program, contamination control issues would recommend against this option.
- OSHA exempts voluntary wearers of filtering facepieces (dust masks) from all program requirements, but such volunteers must be provided with the information contained in Appendix D to 29 CFR 1910.134. NRC differentiates between disposable filtering facepieces (no APF) and half-facepiece respirators (APF = 10), which include certain filtering facepieces. This distinction is described in Regulatory Position 4.7 and 4.8 of this guide. NRC only permits voluntary use of single-use disposable filtering facepieces and exempts such voluntary wearers from the requirements for medical screening and fit-testing, but still requires that minimal training be provided, including how to don and use the facepiece effectively. This training requirement is compatible with OSHA's 29 CFR 1910.134 Appendix D.
- OSHA's 29 CFR 1910.134(d)(1)(i) requires that, if the employer cannot identify or reasonably estimate the employee exposure, the employer must consider the atmosphere to be IDLH (immediately dangerous to life or health). This leads to very specific requirements in 29 CFR 1910.134(d)(2) for the assignment of respirators. The term IDLH does not realistically apply to airborne radioactivity but could apply to certain nonradiological hazards at an NRC-licensed facility, in which case OSHA rules apply. Such nonradiological hazards include oxygen-deficient environments (e.g., inerted structures and vessels), chemical hazards (e.g., chlorine, hydrazine), and fire fighting.
- OSHA's 29 CFR 1910.134(d)(1)(iv) requires the employer to select respirators from a sufficient number of respirator models and sizes so that the respirator is acceptable to, and correctly fits, the user. While NRC requires that respirator wearers demonstrate an adequate respirator fit, no specific requirements are placed on licensees regarding the provision of respirators in various sizes and from several different manufacturers. The NRC approach permits exercise of the licensee's judgment with respect to how many

different devices and sizes to provide. Additional information about this requirement, which is repeated in ANSI Z88.2-1992, is in Regulatory Position 7.3 of this guide.

- OSHA does not currently promulgate APFs for respirators but reserves the ability to do so (29 CFR 1910.134(d)(3)(i)(A) and Table I). The maximum APFs that may be used in an NRC-regulated program are listed in Appendix A to 10 CFR Part 20, and these are consistent with the APFs listed in ANSI Z88.2-1992.
- OSHA's 29 CFR 1910.134(d)(3)(iii) requires the employer to provide specific types of respirators for protection against gases and vapors. In an NRC-regulated program, exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations. Respirators do not necessarily have to be assigned for protection against airborne radioiodine vapors since personnel dose can be controlled by limiting stay times or by other methods. Airborne tritium gas and tritiated water vapor are not effectively removed by air-purifying respirators, so APFs do not apply for these devices for protection against tritium. The APF of atmosphere-supplying respirators is reduced to 3 for protection against airborne tritium since approximately one-third of the intake occurs by absorption through the skin.
- OSHA's 29 CFR 1910.134(e)(2)(i) permits a "physician or other licensed health care professional (PLHCP)" to set up, administer, and make medical decisions about the medical status of potential respirator users, and it contains a number of prescriptive requirements. In an NRC program, a physician (the licensee's physician) must set up or approve the medical screening program for respirator wearers and set the medical acceptance criteria. A licensed health care professional may carry out the screening process and medically approve as respirator users those who fall within the acceptance criteria established by the licensee's physician. However, the individuals who fall outside the established acceptance criteria must be evaluated by the licensee's physician before being designated as medically qualified to use respirators. Precisely how this additional evaluation is accomplished is a medical decision to be made by the licensee's physician and does not necessarily have to include personal contact with the person being screened.
- OSHA's 29 CFR 1910.134(e)(2)(i) requires that medical evaluations obtain all the information requested in Sections 1 and 2 of Part A of OSHA's medical questionnaire, which is Appendix C of the OSHA rule. NRC permits, but does not require, the Appendix C questionnaire to be used in medical screening programs.
- OSHA's 29 CFR 1910.134(e)(6)(ii) requires that a

powered air-purifying respirator (PAPR) be provided to a worker whose physical condition does not allow the use of a negative-pressure device. NRC places no such requirement on licensees, but the OSHA approach is an acceptable option under the NRC rules.

- OSHA's 29 CFR 1910.134(f)(7) requires a fit factor of at least 100 for tight-fitting half facepieces and at least 500 for tight-fitting full-facepiece respirators. NRC requires 10 times the APF for negative-pressure devices (i.e., 100 for half facepieces, 1000 for full facepieces), and 500 for tight-fitting respirators that will operate in a positive pressure mode in the field.
- OSHA's 29 CFR 1910.134(h)(3) requires that all respirators maintained for use in emergency situations be inspected at least monthly and in accordance with the manufacturer's recommendations, and be checked for proper function before and after each use. It also contains other specific requirements. NRC suggests a monthly visual inspection of SCBAs and a quarterly operational test (i.e., pressurizing the regulator, testing the low-pressure alarm). Other devices stored for emergency use should be visually inspected monthly, but under NRC guidance only need to be thoroughly examined 2 or 3 times per year. It is suggested that licensees also consider manufacturers' recommendations in establishing their inspection schedule.
- OSHA's 29 CFR 1910.134(i)(5)(iii) requires that suitable in-line air-purifying sorbent beds and filters be used on the intakes of breathing air compressors, and that they be maintained and replaced or refurbished periodically following the manufacturer's instructions. NRC requires only that air of Grade D quality, described in CGA G7.1, be delivered to each supplied-air respirator. How that is accomplished is left to the licensee.
- OSHA's 29 CFR 1910.134(i)(7) requires the presence of a high-temperature alarm or a carbon monoxide alarm on the discharge of oil-lubricated breathing-air compressors. As stated above, NRC requires only that breathing air of Grade D quality be provided.

Licensees are reminded that OSHA hazard-specific regulations, many of which are listed in Appendix A to this guide, may contain requirements for using respiratory protection equipment and for monitoring or controlling workplace hazards that might occur separate from or concurrently with airborne radiological hazards. Some of these hazards to be considered are heat stress, oxygen deficiency, chemical toxicity and confined spaces.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants regarding the NRC staff's plans for using this regulatory guide.

Except in those cases in which an applicant proposes an

acceptable alternative method for complying with specified portions of the NRC's regulations, the methods described in this guide will be used in the evaluation of respiratory protection programs described in a licensee's operating procedures, applications for new licenses, or license amendments and for evaluating compliance with Subpart H of 10 CFR Part 20.

APPENDIX A
OSHA Regulations

The sections of the OSHA regulations listed below, among others, may contain requirements that are in addition to those required by the NRC. They may also contain requirements for limiting or controlling hazards that are not under the jurisdiction of NRC.

29 CFR 1910.120	Hazardous Waste Operations
29 CFR 1910.134	Respiratory Protection—General Industry
29 CFR 1910.146	Permit Entry Confined Spaces
29 CFR 1910.155	Fire Protection
29 CFR 1910.401	Commercial Diving Operations
29 CFR 1910.1000	Air Contaminants (PELs)
29 CFR 1910.1001	Asbestos
29 CFR 1910.1025	Lead
29 CFR 1910.1028	Benzene
29 CFR 1910.1048	Formaldehyde
29 CFR 1926.103	Respiratory Protection—Construction Industry

REGULATORY ANALYSIS

A separate regulatory analysis was not prepared for this regulatory guide. The regulatory analysis, "Regulatory Analysis of Proposed Revisions to 10 CFR Part 20, Subpart H, Respiratory Protection and Controls To Restrict Internal Exposure," was prepared for the amendments, and it provides the regulatory basis for this guide and examines the costs and benefits of the rule as implemented by the guide. A copy of the regulatory analysis is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC, as Enclosure 2 to SECY-99-207.

1. See NUREG/CR-6204, "Questions and Answers Based on Revised 10 CFR Part 20" (USNRC, May 1994), page 44, Question 91. Copies may be purchased at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202) 512-1800); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161; phone (703)487-4650; <<http://www.ntis.gov/ordernow>>. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC. The PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202) 634-3273; fax (202) 634-3343.
2. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW, Washington, DC. The PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202) 634-3273; fax (202) 634-3343
3. Copies may be obtained from the American National Standards Institute, Inc., Sales Department, 11 West 42nd Street, New York, NY 10036.
4. National Fire Protection Association, "Open Circuit Self-Contained Breathing Apparatus for Fire Fighters," ANSI/NFPA 1981, 1997 edition.
5. This list is available from Publications Dissemination, DSST, National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, 4676 Columbia Parkway, Cincinnati, Ohio 45226.
6. See "NIOSH Approval Requirements for Respiratory Protection Equipment," Radiation Protection Management, Vol. 14, September/October 1997.
7. Available from the Compressed Gas Association, Inc., 1235 Jefferson Davis Highway, Arlington, VA 22202.
8. G.D. Kerr et al., "Health Physics Positions Data Base," Health Physics Position 219, NUREG/CR-5569, Revision 1, Page 120, February 1994.
9. A fit-test using amyl or isoamyl or isopentyl acetate requires that an organic vapor respirator cartridge be used in the test respirators.
10. See "Respirator Fit Testing and the Exercise Protocol," Radiation Protection Management, Volume 6, September/October 1989.
11. Available from the Compressed Gas Association, Inc., 1235 Jefferson Davis Highway, Arlington, VA 22202.