A. INTRODUCTION

In 10 CFR Part 32, "Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material," 10 CFR 32.210(c) requires applicants for registration of sealed sources or devices to submit information about the quality control (QC) program that the product will be manufactured under, and 10 CFR 32.210(f) requires the registrant to manufacture and distribute the product in accordance with the statements and representations of the QC program. In addition, other sections of Part 32 (for example, 10 CFR 32.25 and 32.29) require applicants to manufacture and distribute products in accordance with QC standards approved by the U.S. Nuclear Regulatory Commission (NRC).

Many manufacturers and distributors of sealed sources and devices find that marketing considerations make it very desirable for them to be qualified in accordance with international industry consensus standards. These documents provide information and guidance on acceptable...
quality assurance (QA) standards that is broader in concept than the QC requirements in the NRC regulations cited above. The sealed source and device manufacturers and distributors do not want to develop and implement two different (and in many cases redundant) programs, a QA program to satisfy international guidance and a QC program that meets NRC regulations. The NRC was requested, and agreed, to provide specific guidance on the essential elements needed to develop, establish, and maintain a QA program that will encompass the QC requirements of 10 CFR Part 32. This regulatory guide provides guidance on QA programs that are acceptable to the NRC staff for registrants of sealed sources or devices, other persons licensed pursuant to Part 32, and applicants for such registration and licenses.

Appendix A of this guide contains a checklist that may be used as an aid in auditing a QA program. Appendix B provides some examples of records and documentation for a QA program. Appendix C describes the minimum quality controls that must be implemented by persons licensed to manufacture or distribute certain products to persons exempt from licensing.

This regulatory guide proposes information collections that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). This regulatory guide has been submitted to the Office of Management and Budget for review and approval of the information collections.

The public reporting burden for this collection of information is estimated to average 160 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Information and Records Management Branch (T-6F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-3019 (3150-0001), Office of Management and Budget, Washington, DC 20503.

B. DISCUSSION

The QA program is intended to provide control over those activities applicable to the design, fabrication, inspection, testing, maintenance, repair, modification, and distribution of the sealed sources or devices that contain byproduct material; such a QA program is necessary to ensure compliance with the representations made in the registration or license application or with the regulations.

The following definitions apply for terms used in this regulatory guide:

Applicant--Any person, persons, or company licensed or applying for a license to manufacture, distribute, or redistribute devices.

Deviation--A departure from the specifications for a device, or a departure from the information supplied to NRC pertaining to the device.

Device--Any product (e.g., gauge, sealed source), registered in accordance with 10 CFR 32.210, that is manufactured, distributed, or redistributed by the applicant.

Document--Any drawing, procedure, instruction, or record pertaining to the production of the device.
Material--Any item that is raw material, subassembly, or a component used in the production of the device.

NRC Contact--The person identified by the licensee as being responsible for ensuring compliance with NRC regulations.

Operational Check--A test or set of tests performed on a completed device to ensure that the device operates in its intended manner and to its intended specifications. This includes verification of shutter operation, emergency stops, and device safety features.

Production--The process of assembling or fabricating a device or any part of a device. Production includes all operations associated with a device or any part of a device from the time it is received from a supplier until it is distributed to the customer.

QA Director--Person in upper management who does not have direct responsibility for production of a device but is responsible for ensuring that the QA program is established and maintained.

QA Manager--Person responsible for ensuring that an appropriate QA program is running properly and verifying that the activities affecting device quality have been correctly performed.

QA Program--The planned and systematic actions necessary to provide confidence that a firm or product will meet the required specifications. The program must provide a means to control and measure characteristics of an item, process, or facility to the established requirements of the program.

Quality Control--Actions taken to prevent or detect product deficiencies.

Redistributor--Any person, persons, or company licensed to redistribute completed devices or sealed sources that have been registered with NRC by the initial distributor.

Repair--Fixing an unacceptable item by a means different than that specified in the production procedures (as opposed to reworking an item).

Rework--Fixing an unacceptable item by methods included in an approved procedure.

Sample--One or more units of product drawn from a lot or batch, the units of the sample being drawn without regard to their quality.

Sample Size--The number of units of product in the sample selected for inspection.

Service--Any operation pertaining to production of the device or operation performed on any part of the device.

Specifications--Requirements imposed by the applicant, customer, or NRC that, if not followed, may affect the use or operation of the device.
Supplier--Any person, persons, or company that supplies material, equipment, or service to an applicant.

C. REGULATORY POSITION

Applicants for product registrations in accordance with 10 CFR 32.210 or for licenses to manufacture, distribute, or redistribute sealed sources or devices are required to submit information pertaining to their QC program to the NRC, for approval, as part of the application for the product registration or for a license. If the QC program is part of a broader QA program, the information submitted should be in the form of a manual that defines each component of the QA program. The information should be submitted as a supplement to the application described in Regulatory Guides 10.10, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Byproduct Material," and 10.11, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Sealed Sources Containing Byproduct Material." This document provides guidance on preparing applications for radiation safety evaluation and registration of devices and sealed sources containing byproduct material. Registrants or licensees who make changes to their QA programs that require changes to their QA manual are to submit applications for amendments to their product registration or license.

Establishing the QA program implies that all activities that ensure the sealed source or device is manufactured and distributed in accordance with the statements and representations included in the registration and license application and the requirements prescribed in the regulations are implemented. All activities applicable to the design, fabrication, inspection, testing, maintenance, repair, modification, and distribution are to have written procedures approved by appropriate levels of management and be contained in quality assurance and control manuals.

Proprietary information (i.e., information not to be disclosed to the public) should not be submitted unless it is the only means to adequately describe the QA program. If the QA manual contains information that the company considers to be proprietary, the information should be clearly marked for appropriate handling by NRC. In addition, the letter transmitting the application or manual should contain a request for withholding from public disclosure as discussed in paragraph 2.790(b) of NRC's regulations in 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders." It is essential that these procedures be followed so that the NRC can recognize that a request for withholding is being made and then consider the request on its merits.

Unless a formal request for withholding has been filed and properly supported with information required under 10 CFR 2.790, statements that manuals or documents are "confidential," "restricted," or "are to be the express property of Company X" should be removed from all submittals, or a statement should be made that the notes are to be disregarded.

A QA program should contain, at a minimum, the following components to be approved by the NRC staff. Each component contains a general description of the component, followed by additional, more prescriptive information that applicants may find useful in developing a QA program. The additional information within each section is intended to provide specific methods for meeting each component.

The methods given here for each component are not the only methods for developing a QA program that would be acceptable to the NRC.
The applicant's organizational structure, functional responsibilities, and levels of authority should be documented, starting with the Chief Executive Officer or equivalent, down to, at a minimum, the head of each department. Each person's responsibilities should be listed. All personnel in the QA department should be listed, along with their responsibilities. The applicant's NRC contact should be identified.

The QA Manager should report directly to the QA Director. The QA Director should have continued involvement in ensuring that the QA department is running properly. The QA Director and the QA Manager should have the authority, access to work areas, and organizational freedom to identify quality problems, recommend or initiate solutions, verify implementation of solutions, and halt production at any time to ensure that the device or production procedures conform to all regulations and specifications.

1. The organizational structure should be documented in the form of a flow chart, with a brief explanation of each position and the responsibilities associated with the position. Position titles may be used in the flow chart in lieu of the names of the persons occupying the positions.

2. In a small organization, the company president should be the QA Director, or the QA Director should report directly to the company president. This may not be possible in larger organizations. In larger organizations, the QA Director should be a person in upper management who does not have direct responsibility for production. This helps to ensure that quality is measured against the device specifications and not against other factors, such as production schedules.

3. The QA Manager should be responsible for the everyday workings of the QA program and should be responsible for reviewing and approving all changes to, or changes affecting, the QA program.

4. Involvement by the QA Director should, at a minimum, consist of reviewing the audits of the QA program and periodically reviewing any updates, changes, problems, or concerns with the QA program. The QA Director should initiate changes to the QA program as deemed necessary.

2. PERSONNEL

The applicant should have written procedures to ensure that persons have appropriate qualifications and training for the jobs they are performing. The applicant should keep records of each employee's education, experience, training, indoctrinations on the technical obligations and requirements of his or her job, and either examination results or capability demonstrations, including re-evaluations.
records should also provide verification that an employee is qualified to perform special procedures or testing (e.g., welding, heat treating, weld inspections).

The applicant should have written procedures for all training and indoctrinations.

2.1 Training of personnel may be formal, including a written outline of the training with a written or hands-on objective examination, or informal, including on-the-job training that includes a qualitative determination of the trainee's ability. Both formal and informal training should be documented.

2.2 All employees should be subject to an initial evaluation of their skills and re-examination on an annual basis. The evaluation may be statistical analysis of inspection results of work performed by the employee or observation of the employee's work habits and skills, to ensure compliance with the appropriate specifications. All evaluations and re-evaluations should be documented.

2.3 The applicant should have a list of employees qualified to perform each operation. This may be achieved by maintaining a list of all persons qualified to perform an operation, or each employee's training and qualification file may list the operations the employee is qualified to perform. The employee's supervisor should have access to this information to verify the employee's qualifications.

2.4 Each employee's training and qualification file should include all necessary medical records that may affect the employee's job performance. One example is that welders and inspectors may be required to have their vision tested annually.

2.5 The applicant should have a list of all employees qualified to perform special processes, testing, or inspections (e.g., welding, heat treating, weld inspection).

2.6 A sample of an employee training form is included on page B-2 of Appendix B.

3. EQUIPMENT

All equipment used for measuring, testing, or inspecting should be controlled, calibrated, and maintained. The applicant should have records of all repairs and calibrations of the equipment used for measuring, testing, or inspecting.

All calibrations should be traceable to the National Institute of Standards and Technology (NIST) or a competent national authority. The calibration frequency should be dependent on the equipment's stability, purpose, and degree of usage and should be left to the discretion of the QA Manager. No calibration interval should exceed 1 calendar year.

All new equipment or equipment that has undergone maintenance that affects the accuracy of the equipment should be calibrated before use.

3.1 The applicant should have a historical log for each piece of equipment that is used in the production of the device, enhances the quality of the device, or ensures that all specifications and regulations are met. The log should include the manufacturer of the equipment, the model number, serial number, and instructions for use. The log should contain records of routine or unscheduled maintenance of all equipment and contain maintenance procedures, nature of the maintenance performed, date maintenance was performed, date equipment is due for maintenance, and the frequency of the maintenance.

3.2 Records of calibrations should be kept in the log for each piece of equipment that includes the manufacturer, model number, serial
number, calibration procedures, frequency of calibration, date calibrated, date due for calibration, and a list of persons qualified to 
calibrate the equipment.

3.3 Equipment and calibration logs should be kept on a computer or hard card system. To ensure that uncalibrated equipment is not used, 
the system should flag equipment that is nearing its due date for calibration.

3.4 All calibration cycles should be 1 year or less. The applicant may decide that the calibration cycle should exceed 1 year for specific 
equipment that is expensive to calibrate and is not likely to be out of calibration.

3.5 Each piece of calibrated equipment should be traceable to its calibration record. Each piece of calibrated equipment should also be 
marked with its calibration date, date calibration is due, and the person or company who performed the calibration. If it is impractical 
for the equipment itself to carry such a label, its case should be labeled and the equipment should be traceable to its case.

3.6 If calibration is performed by a supplier, a record of calibration from the supplier stating the date of calibration should be included in 
the calibration file. Suppliers performing calibrations should demonstrate that all calibrations are traceable to NIST or a competent 
national authority and should be audited like all other suppliers.

3.7 If any equipment has special procedures for handling or storage, the equipment should be labeled or its case should be labeled with 
these procedures. If it is not possible to attach the procedure to the equipment or its case, the procedure should be on file and a label 
specifying where to find the procedures should be attached to the equipment or its case.

3.8 A sample page from an equipment log and samples of calibration labels are included on pages B-3 and B-4 of Appendix B.

4. DESIGN AND DOCUMENT CONTROL

The applicant should have written procedures to ensure that all documents conform to the appropriate specifications and pertinent 
regulations. The procedures should ensure that the documents include all special instructions for labeling, cleaning, handling, equipment 
settings, packaging, and storage, as well as special procedures, a list of all materials, all dimensions with tolerances, and any special finishes 
that need to be applied. The procedures should ensure that the correct documents, reflecting all drawing changes and the correct revision 
level, are employed.

The procedures should ensure that each document is released only after it has been reviewed and approved by someone other than the 
person who prepared that document. The procedures should also ensure that any changes to the documents are controlled by measures 
commensurate with those applied to the original document and are conveyed to all appropriate departments. Minor changes, such as 
insignificant editorial corrections, are not required to undergo the same review and approval process as the original document. Any design 
or production changes that are different from those approved by a regulatory agency must be submitted to the appropriate regulatory 
agency, for approval, before implementation.

Records of all appropriate documents should be kept. The records should contain design and document changes and the reasons for the 
changes.

4.1 The applicant should ensure that all appropriate documents used in the production of the device are up to date. One mechanism to
accomplish this is to have a controlled list of recipients of the documents and have each recipient sign off that the most current
document was received and is being used.

4.2 As soon as a document is revised, approved, and effective, the applicant should ensure that all previous copies of the document are
pulled from production or ensure that the documents are not being used for production.

4.3 The applicant should ensure that the master copies of the documents are controlled so that no previous revisions of the documents
are issued or used.

4.4 The applicant should have a list that reflects all current documents and their appropriate revisions. Documents currently being revised
should be noted on the list.

4.5 To ensure that all documents are complete and accurate, each document should be reviewed and approved by someone of equal or
greater proficiency. The reviewer should sign the document to show approval. Other affected departments, such as QA and
production, should review the document before release. The NRC contact should review and approve all document revisions if the
document was submitted as part of the device registration or license application. The NRC contact should halt issuance of the
document if NRC approval is required.

4.6 A file should be kept for each document. The file should include all previous revisions of the document, all changes to the document,
the reasons for the changes to the document, and all persons who have received controlled copies of the document.

4.7 Procedures for reviewing the documents should include a checklist of the types of items that should be included in the documents. If
any item on the checklist is missing, the reviewer should ensure that it was not inadvertently excluded from the document.

4.8 If the applicant is a redistributor, the applicant may not need to approve all document changes. However, the applicant should receive
copies of all document changes.

4.9 If the applicant is a distributor of devices completely manufactured by persons who are not NRC licensees, the applicant should adopt
a program that ensures that all document revisions are reviewed and approved if the document was submitted as part of the device
registration or license application. The applicant should halt issuance of the document if NRC approval is required. The program
should ensure that the applicant receives copies of all document changes.

4.10 Samples of an engineering change request, an engineering change notice, and a drawing issue checklist are included on pages B-5,
B-6, and B-7 of Appendix B.

5. MATERIAL AND SERVICE PROCUREMENT

All materials and procedures used to produce the device must meet specifications and pertinent regulations. Procurement of materials or
services must be controlled to ensure conformance with specifications.

Suppliers should demonstrate that they are capable of supplying material or services in accordance with the requirements and specifications.

Inspections should be performed on all items received from suppliers upon receipt. The extent of receipt inspection should depend on the
supplier and should be left to the discretion of the QA Manager.
Before issuance of an order for materials or services, the applicant should provide to the supplier the scope of the work, technical requirements, identification of the documents that should accompany the material or service, identification of the documents that the supplier should keep on file, requirements for reporting and approving dispositions of nonconformances, and the signature of an authorized purchasing agent.

The applicant should have written procedures for, and records of, procurement of materials or services and inspection upon their receipt.

5.1 Selection of a supplier should be based on the supplier's past history of providing identical or similar materials or services and the supplier's technical capability, as determined by direct evaluation of the facility or by analysis of the quality of previously supplied materials or services. If the quality of the product cannot be determined through inspection or testing, the selection of a supplier should be based on the results of an audit of the supplier's operations.

5.2 For each supplier, the level of receipt inspection should be based on past performance and the results of audits of the supplier's operations. Inspections on receipt may range from inspection of 100 percent of the materials or services received from new, nonaudited suppliers to inspection of a sample, based on an accepted sampling plan, of the materials or services received from audited suppliers with good past performance. The sample sizes should be increased if the quality of the materials or services received decreases. The decrease may be seen from the trend analysis performed on the inspection records or from the audits of the supplier's operations.

5.3 The applicant should develop a qualified supplier list. The list should include all suppliers who have demonstrated that they are capable of supplying the materials or services to the applicant. The applicant should then procure materials or services only from suppliers on the qualified supplier list. The qualified supplier list should be controlled so that no unqualified suppliers are included on the list.

5.4 In lieu of forwarding all the relevant information to the supplier each time an order is placed, the applicant may initiate a written contract with a supplier. The contract should contain the relevant information. If the applicant has a contract with the supplier, the applicant should ensure that the supplier has copies of, and is using, the most current documents pertaining to the order.

5.5 If the applicant is a redistributor or a distributor of devices that are not completely manufactured by NRC licensees, the applicant must ensure that an operational check is performed on 100 percent of the devices and inspect, to the extent possible, 100 percent of the devices to ensure that they meet their design specifications.

5.6 Samples of a purchase requisition and a purchase order are included on pages B-8 and B-9 of Appendix B.

6. INVENTORY

The applicant should have written inventory procedures that include procedures for special handling, marking, tagging, labeling, segregating, recordkeeping, and handling of nonconforming material. The inventory procedures should account for material that has a shelf life and ensure that the proper materials are used in the production process.

The inventory procedures should include provisions for in-process material and finished devices. The procedures should ensure that only items that have passed inspection are used in the production process, and that completed devices have passed their final inspections and

http://www.nrc.gov/NRC/RG/06/06-009.html
testing before distribution.

6.1 All inventory that has a shelf life, such as adhesives and gaskets, should be used on a first-in/first-out basis, and the inventory system must be controlled so that items that have exceeded their shelf life are not used. This may be achieved by marking the containers with the expiration date of the material.

6.2 Handling and inventory procedures should ensure that materials or devices that are segregated or identified as complete have passed their final inspections and tests. This may be achieved by having the inspector mark or tag the product as having been inspected, or by having the inventory area controlled and only having items that have passed inspection enter the controlled area.

6.3 To ensure that the correct materials are used in production and that the items have passed their inspection, the applicant may have a staging area in which all materials needed for production are brought together by inventory personnel. The inventory personnel should verify that the correct materials are used and that they have passed their inspection.

6.4 Inventory items should be clearly marked or segregated to prevent use of the wrong materials. Materials that are so similar that they may be confused with other materials (e.g., different alloys of steel, similar size springs) should not be located next to each other.

7. PRODUCTION PROCEDURES AND PROCESSES

The applicant should have written procedures for all production processes. The procedures should include all necessary instructions, including the machinery, equipment, and qualifications of the worker needed to perform the task. The procedures should also include inspection or testing hold points. Not all tasks need to be listed in the procedures. For example, procedures for cutting stock material to length may not need to be listed in the procedures.

7.1 Production procedures should be adequate for the operation to be performed. They may be as simple as a detailed engineering drawing of the part or device, with notes indicating any special instructions, cautions, or methods of construction. More detailed, step-by-step written procedures may be necessary for some complicated operations.

7.2 Production procedures should include appropriate hold points. These may be detailed as part of the production procedure or indicated as a note on the production drawing.

7.3 The applicant should specify the flow of materials and processes in the form of a flow chart or a traveler that accompanies the item (see example on page B-11). Inspection hold points should be included in the flow chart or traveler.

7.4 As necessary, the procedures should specify the qualifications of the workers needed to perform each operation. This may be accomplished by classifying workers to certain skill levels, such as classes of machinists, welders, or inspectors. If the worker's qualifications are not identified in the production procedures, the production department should have a mechanism to ensure that the worker performing the task is qualified to perform the task and to operate the equipment needed to perform the task.

7.5 If the applicant is a redistributor or a distributor of devices completely manufactured by other persons and is not performing repairs or rework to nonconforming devices, the applicant's production procedures may only include inspection, testing, and distribution procedures. If the applicant performs repairs or rework, the applicant should adopt appropriate maintenance procedures.

7.6 An example of an inspection traveler is on page B-11 of Appendix B, and samples of a fabrication flow chart and a logic chart for
preparing an inspection traveler are on pages B-15 and B-16 of Appendix B.

8. INSPECTION AND TESTING

The applicant must ensure that all materials, devices, and production procedures conform to the appropriate specifications and regulations. The applicant should have written procedures for in-process inspection and testing of materials, production processes, and final inspection and testing of the device. The procedures should include acceptance criteria and procedures for receipt inspection, generating sample sizes, final inspection and testing, packaging and transportation inspections, and audits of production procedures. The inspection should be performed by someone other than the person who performed the work being inspected.

The procedures should also include an inspection schedule that includes mandatory hold points beyond which work should not proceed without successful completion of the inspection or test. The procedures should include provisions for bypassing inspections or tests and provisions for nonconforming materials. Records should be maintained of all inspections and tests results and should include the date and person performing the inspection or test.

The applicant should have a means of segregating items that have passed inspection or testing.

8.1 Procedures used to generate sample sizes should be based on industry standards.
8.2 Hold points may be specified on a traveler that follows the device through the production process. The traveler would indicate the hold points and the types of inspections or tests to be performed. The traveler may be designed to be a record indicating that the inspections or tests have been performed. The traveler should be approved by QC personnel indicating that the inspection hold points are acceptable.
8.3 In-process inspection of some materials may be performed by sampling. However, 100 percent of materials critical to safety should be inspected. The inspection may be sufficient if the materials and construction are verified as part of the operational check of the device. Materials critical to safety include any item that, if not manufactured in accordance with its specifications, could by itself (i.e., in the absence of a failure of another component of the device) lead to an exposure higher than expected during normal use, handling, or storage of the device.
8.4 As part of the final inspection of the devices, NRC licenses require an operational check and a test for removable contamination on 100 percent of the devices before distribution.
8.5 After the inspections, the acceptable items should be tagged, marked, stamped, or segregated from unacceptable items. A number of methods may be used to achieve this. Segregation of items may be achieved by physically passing the items to the next worker, indicating successful completion of the inspection, or by having the items placed in a controlled stock room or holding area.
8.6 Inspection of production processes should follow a checklist that lists the acceptance criteria. Some inspections may be performed by qualified production staff instead of the QC department. However, the QC department should inspect the processes at least yearly. All inspections should be documented.
8.7 If a production process is found to be insufficient, the inspection results and their impact on previously manufactured products should
be evaluated by the QA, engineering, manufacturing, and other appropriate departments. Appropriate corrective actions should be taken.

8.8 Manufacturers and distributors of smoke detectors and sources used in smoke detectors should adopt inspection and testing programs that meet the "QC Program Specifications for the Manufacture and Distribution of Smoke Detectors" in Appendix C. Manufacturers and distributors of other products distributed to persons exempt from licensing should adopt the same inspection and testing requirements.

8.9 If the applicant is a redistributor or a distributor of devices completely manufactured by persons who are not NRC licensees, the applicant should subject each device to final inspection and an operational check before distribution.

8.10 Samples of a daily incoming inspection report, an inspection traveler, and a verification of conformance form are included on pages 10, 11, and 12 of Appendix B.

9. NONCONFORMING MATERIALS

The applicant should have written procedures to ensure that materials and devices that do not conform to the specifications are not used in production or distributed. The procedures should have provisions for nonconforming materials found through receipt inspection, in-process and final inspection and testing, and devices returned by customers. The procedures should include identification of the nonconforming materials, disposition procedures, and provisions for returning reworked items back to production. Before nonconforming materials are returned to production or distributed, they should pass all appropriate inspections and tests. The applicant should keep records of all nonconformances and their disposition.

9.1 Nonconforming materials should either be segregated in a controlled area or be marked as nonconforming.

9.2 Rework may be performed without prior approval. However, repair to material should not be performed without appropriate approval.

9.3 Records of all nonconforming materials should be kept for trend analysis and for verification that the materials have not been used in the production process.

9.4 A traveler form should be used to identify nonconformances. The traveler should indicate the inspections and approvals needed. The QA and engineering departments should approve the disposition of nonconformances.

9.5 If the applicant is a redistributor or a distributor of devices completely manufactured by persons who are not NRC licensees, the applicant should have procedures indicating the disposition of nonconforming materials, including who is responsible for repair or rework.

9.6 Samples of a Nonconforming Materials Report and nonconforming material tags are included on pages B-13 and B-14 of Appendix B.

10. PACKAGING AND TRANSPORTATION

The applicant should have written procedures to ensure that all materials or devices shipped by the applicant are packaged and transported according to the regulations and specifications governing the material. The procedures should include provisions for inspections of packaging and transportation. The packaging and transportation should have no adverse effect on the material or device.
The procedures should also have provisions to ensure that appropriate paperwork or manuals (instructions, maintenance procedures, packing list, operation manuals, etc.) accompany the device.

Records should be kept of all packaging and shipping reports and inspections.

10.1 The applicant should have either a standard procedure for packaging all items leaving the facility or a unique packaging procedure for each item as it leaves the facility. The packaging procedure should include the form of transportation (e.g., name or type of transportation company, picked up by customer) and the labeling of the packaging.

10.2 Before distribution of any material or device, it should be verified that all items, including paperwork, are included with the material or device or are being shipped separately. The customer should be notified if items are missing and that they will be sent at a later date. The system should ensure that back-ordered items are sent when they become available.

10.3 If the applicant is a redistributor or a distributor of devices completely manufactured by persons who are not NRC licensees, the device may be shipped from the manufacturer or initial distributor to the customer, and therefore packaging and transportation procedures may not be necessary. If the device is shipped from the applicant’s facility, the applicant should have procedures for packaging and transportation of devices.

11. DEVIATIONS AND CUSTOMER COMPLAINTS

The applicant should have written procedures for evaluating and recording deviations, whether reported by customers or suppliers or found through inspections or customer complaints, either by telephone or in written form. The procedures must adequately address the evaluation and notification requirements listed in 10 CFR 21.21. Records should be kept of each deviation or complaint that the applicant receives. The records should contain the device type and model number, serial number (if applicable), name of complainant, nature and date of the complaint, reply to complainant, corrective action taken, and root cause of the failure if known. The procedures should ensure that the QA Manager and the department that was responsible for the failure are notified of the deviation or complaint and the corrective action. All known customers that may be affected by the failure or complaint should be instructed to take appropriate corrective action.

Trend analysis should be performed on all deviations. The analysis should be on-going and be performed at least yearly.

11.1 The applicant should have a log of complaints received from customers by phone or in writing. The log should include: device type and model number, serial number, name of complainant, nature and date of the complaint, reply to complainant, corrective action taken, and root cause of the failure, if known.

11.2 Trend analysis should be, at a minimum, by type of failure and model number of the device. Any trends arising should be investigated for possible generic problems.

11.3 The applicant should have written procedures for contacting affected customers and procedures for determining whether customers are affected by a failure or complaint. If it appears that the failure or complaint is a result of a generic design or manufacturing problem, all known users of a device that may have the same failure should be notified. The procedures should ensure that the NRC
is notified of failures or generic design or manufacturing problems that may be related to their license or registration of the product.
11.4 The department responsible for the deviation should be notified as soon as practicable to prevent additional deviations.
11.5 A sample customer complaint form is included on pages B-17 and B-18 of Appendix B.

12. AUDITS

The applicant should have written procedures for auditing and evaluating its QA program and for auditing its suppliers. Audits should ensure that the program encompasses all the requirements of the applicable regulations. Audit procedures should include acceptance criteria and assurance that all procedures are up to date.

The person performing audits should have no responsibility for the matters being audited.

Records of all audits should be kept on file and reviewed by the personnel responsible for the matters being audited. Audit records should indicate deficient areas in the program and corrective actions. Follow-up actions should be taken to verify that corrective actions are accomplished. All records should be signed and dated by the appropriate company officer.

Internal audits should be performed at intervals not to exceed 1 year. The frequency of audits of suppliers should be left to the discretion of the QA Manager, but the interval between audits should not exceed 3 years.

12.1 The applicant should have standard written procedures for auditing its QA program and for auditing its suppliers. A written checklist specifying the necessary components of the QA program should be completed as a record of the audit.
12.2 The completed audit checklist should include the signature of the auditor, signature of the person responsible for the area being audited, and the date of the audit. If the audit reveals deficient areas of the program, the deficient areas should be noted on the checklist, and the deficient areas should be re-audited. The auditor should again sign the checklist when all deficiencies have been corrected. If the deficiencies are minor, the auditor may allow them to be corrected before completion of the audit or may agree with the corrective action to be taken. In these cases a re-audit is not necessary.
12.3 If audits are used to verify employees' performance, the procedure for the audits should specify the acceptance criteria for the job being performed. A record of the audit should be kept.
12.4 In small companies, it may not be possible for the auditor to have no responsibility for the matters being audited. If this is the case, the applicant should consider having some of the audits performed by outside auditors.
12.5 If the applicant is a distributor of devices completely manufactured by persons who are not NRC licensees, it is extremely important that the applicant perform frequent detailed audits of the manufacturer’s operations.

13. RECORDS AND DOCUMENTATION

The QA Department should ensure that all appropriate pertinent records are maintained and filed. This includes the results of tests, inspections, and audits, as well as copies of up-to-date written procedures. The objective is to ensure that each component of the QA
program has been properly implemented. The records should be accessible to each appropriate regulatory agency and should be kept for the useful life of the device.

13.1 Records may vary in form and content and are dependent on the size of the operation and past performances. The record may consist of as little as a signed log or checklist indicating that the inspection or audit has been performed, or it may include the actual values identified during the inspection. More detailed records may be necessary if past performance has been below acceptable levels. Analysis of the records may indicate procedural or design weaknesses.

13.2 Records of audits and inspections and all necessary documentation should be available to the necessary departments.

13.3 The QA Department should have access to the master copies of all records and documentation.

13.4 Samples of records and documentation for QA programs are included in Appendix B. Appendix B is not an all-inclusive listing of records and documents. The records and documents are for guidance only, and applicants are not required to have identical documents and records. Applicants should have documents and records tailored to their own programs.

D. IMPLEMENTATION

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

Except in those cases in which an applicant or licensee proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the method described in this guide reflecting public comments will be used in the evaluation of (1) submittals by applicants to establish QA programs for manufacture, distribution, or redistribution of the sealed sources or devices and (2) registrants' and licensees' performance with respect to developing, establishing, and maintaining such QA programs.

Appendix A -- Checklist for Auditing QA Programs

Appendix B -- Examples of Records and Documentation

Appendix C -- Quality Control Program Specifications for Certain Exempt Products

VALUE/IMPACT STATEMENT

A draft value/impact statement was published with the draft of this guide when it was published for public comment (Task DG-6002, May 1994). No changes were necessary, so a separate value/impact statement for the final guide has not been prepared. A copy of the draft value/impact statement is available for inspection or copying for a fee in the Commission's Public Document Room at 2120 L Street NW, Washington, DC, under Task DG-6002. The PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202) 634-3343.