U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REGULATORY RESEARCH

May 1994
Division 6
Task DG-6002

DRAFT REGULATORY GUIDE

Contact: J. Lubinski (301)415-7868

DRAFT REGULATORY GUIDE DG-6002

ESTABLISHING QUALITY ASSURANCE PROGRAMS FOR THE MANUFACTURE AND DISTRIBUTION OF SEALED SOURCES AND DEVICES CONTAINING BYPRODUCT MATERIAL

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).

This regulatory guide provides registrants of sealed sources or devices and other persons licensed pursuant to Part 32, and applicants for such registrations and licenses, with information on the essential elements needed to develop, establish, and maintain a quality assurance (QA) program that will encompass the QC requirements of Part 32.

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 is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received complete staff review and does not represent an official NRC staff position.

Public comments are being solicited on the draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Regulatory Publications Branch, DFIPS, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW., Washington, DC. Comments will be most helpful if received by August 12, 1994.

Requests for single copies of draft guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Office of Administration, Distribution and Mail Services Section.

This draft 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 (MNBB-7714), 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 all activities applicable to the design, fabrication, inspection, testing, maintenance, repair, modification, and distribution of the sealed sources or devices that contain byproduct material to ensure compliance with the representations made in the registration or license application or with the regulations.

All registrants and persons licensed to manufacture, distribute, or redistribute sealed sources and devices containing byproduct material must implement and maintain an approved QA program. Any persons, materials, processes, or services related to the manufacture, distribution, or redistribution of the sealed sources or devices must meet th -equirements of the QA program.

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) containing byproduct material 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.

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 replacement of a part or completing an operation that was not completed.

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 must submit information pertaining to their QA program to the NRC, for approval, as part of the application for the product registration or for a license. The information should be in the form of a manual that defines each component of the 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 activites 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 considered acceptable by the NRC staff.

1. ORGANIZATION

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.

1.1 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.

1.2 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.

1.3 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.

1.4 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. The 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 on 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, storage, 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 the document is released only after it has been reviewed and approved by someone other than the person who prepared the 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 While a document is being revised, the applicant should ensure that all known 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 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 procedures 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 critical materials should be inspected. The inspection may be sufficient if the materials and construction are verified as part of the operational check 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 the production supervisors 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 must be evaluated by the QA and engineering 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 up-to-date written procedures for each component of the QA program and records, indicating whether each component is implemented properly, are on file. 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.

This draft guide has been released to encourage public participation in its development. 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 to be described in the active 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

The following checklist is designed as an aid in auditing an applicant's quality assurance (QA) program. The checklist is designed as an aid and may not be all-inclusive. In addition, certain items may not be applicable to all applicants.

The checklist is designed to assign different ratings to the adequacy and implementation of each component of an applicant's QA program. When auditing QA programs, the following ratings should be assigned to each item listed in the table:

1 Superior
2 Meets the specifications of this document
3 Needs to be improved to meet the specifications of this document
4 Does not exist
5 Not applicable
6 Did not audit

QUESTIONS	RATING* PROGRAM/IMPLEMENTATION		COMMENTS
1. Does the vendor have a QA manual or set of instructions defining the QA program?			
2. Is the manual up to date?			
3. Is the manual approved and signed by a designated official from each department?			
ORGANIZATION			
4. Is the organizational structure of the applicant documented in the QA manual?			
5. Are all the QA personnel listed, along with all their responsibilities?			
6. Is the QA Director someone in upper management not directly responsible for manufacturing or production?			
7. Does the QA Director have continual involvement in the QA program?			
8. Is the NRC Contact listed and up to date?			
9. Do the QA Manager and QA Director have the authority to halt production?			
PERSONNEL			
Does the applicant have procedures to ensure up-to-date records of:			
10. All employees' qualifications?			
11. All employees' training?			
12. All employees' indoctrinations?			
13. All employees' medical records?			
14. All training procedures?			
15. All indoctrination procedures?			

***Ratings: 1-superior; 2-meets specifications; 3-needs improvements; 4-does not exist; 5-not applicable; 6-did not audit.**

QUESTIONS	RATING* PROGRAM/IMPLEMENTATION		COMMENTS
16. All employees qualified to perform special procedures or testing?			
17. Are items 10 through 16 up to date?			
EQUIPMENT			
18. Does the applicant have a historical log of all its equipment?			
19. Does the log include manufacturer, model and serial number, and instructions for use?			
20. Are there procedures for and records of routine and unscheduled maintenance of equipment?			
21. Does the applicant have a calibration log that includes: • manufacturer? • model and serial number? • calibration procedures? • frequency? • qualified calibration personnel? • date calibrated? • date due for calibration?			
22. Are all calibrations, either performed by the applicant or a supplier, traceable to the National Institute of Standards and Technology or equivalent?			
23. Are all calibration cycles reasonable and less than 1 year?			
24. Does the calibration system have a flag to ensure that all equipment is recalibrated before its expiration date?			
25. Is all equipment marked with calibration date, due date, and the person who performed the calibration?			
26. Is all equipment traceable back to calibration record?			

***Ratings: 1-superior; 2-meets specifications; 3-needs improvements; 4-does not exist; 5-not applicable; 6-did not audit.**

QUESTIONS	RATING* PROGRAM/IMPLEMENTATION		COMMENTS
27. Where applicable, is equipment labeled with special handling or storage instructions?			
28. Is all new equipment or equipment that has undergone maintenance calibrated before use?			
DESIGN AND DOCUMENT CONTROL			
29. Are there procedures for ensuring that all documents contain all pertinent information and conform to all pertinent regulations and specifications?			
30. Are there procedures for handling document and design changes?			
31. Do the procedures ensure that all appropriate departments are notified of the changes?			
32. Do the procedures ensure that documents under revision are not used?			
33. Are all changes documented?			
34. Do the procedures ensure the documents and changes are checked and approved before released?			
35. Do the procedures include notifying regulatory agencies of any changes?			
36. Do the procedures ensure alternative approaches in the absence of specifications?			
37. Is there a history file, for each document, that includes previous versions, document changes, and reasons for the changes?			
38. Are there copies on file of all up-to-date documents for each job?			

***Ratings: 1-superior; 2-meets specifications; 3-needs improvements; 4-does not exist; 5-not applicable; 6-did not audit.**

QUESTIONS	RATING* PROGRAM/IMPLEMENTATION		COMMENTS
MATERIAL AND SERVICE PROCUREMENT			
39. Are there procedures for verification of the adequacy of suppliers?			
40. Are there records of all audits of suppliers?			
41. Are audits of suppliers performed at intervals less than 3 years?			
42. Are there procedures for receipt inspection?			
43. Do receipt inspection procedures verify: • correct sizes? • quantity? • document and specification conformance? • paperwork?			
44. Are there procedures for receipt of nonconforming material?			
45. Are there records of receipt inspections, including nonconforming material?			
46. Do all purchase orders contain: • scope of work? • technical requirements? • identification of the documents that must accompany the order? • identification of the records that the applicant must keep? • signature of the appropriate individual?			
47. Are there records of all purchases?			

***Ratings: 1-superior; 2-meets specifications; 3-needs improvements; 4-does not exist; 5-not applicable; 6-did not audit.**

QUESTIONS	RATING* PROGRAM/IMPLEMENTATION		COMMENTS
INVENTORY			
48. Are there inventory procedures?			
49. Do inventory procedures include: • special handling? • marking? • tagging? • labeling? • segregating? • paperwork procedures? • handling of nonconforming material?			
50. Does the inventory system have provisions for material with shelf life?			
51. Does the inventory system have provisions to ensure that the correct material is used in production?			
52. Are periodic physical inventories performed?			
53. Does the system ensure that products that are marked or segregated as complete have passed their final inspections and testing?			
PRODUCTION PROCEDURES AND PROCESSES			
54. Are there procedures that describe production processes?			
55. Do the procedures include: • machinery and equipment to be used? • qualifications of workers? • equipment settings? • hold points for inspection and testing?			
56. Is there a flowchart describing the flow of material and inspection hold points?			

*Ratings: 1-superior; 2-meets specifications; 3-needs improvements; 4-does not exist; 5-not applicable; 6-did not audit.

QUESTIONS	RATING* PROGRAM/IMPLEMENTATION		COMMENTS
INSPECTION AND TESTING			
57. Are there procedures for in-process and final inspection and testing of the device?			
58. Do inspection procedures include: • acceptance criteria? • receipt inspection? • at what points to perform in-process inspections and tests? • procedures for determining sample sizes? • procedures for final inspection and testing? • provisions for nonconforming material?			
59. Are there procedures for inspections of production procedures?			
60. Are there records of all inspections and testing, including date and person performing the inspection or test?			
61. Is there a system for marking or segregating items that have been inspected or tested?			
62. Does final inspection include operational check and removable contamination test of 100% of the devices?			
NONCONFORMING MATERIALS			
63. Are there procedures for handling nonconforming items received from a supplier or customer or found during production?			
64. Are nonconforming materials tagged or segregated from production?			

*Ratings: 1-superior; 2-meets specifications; 3-needs improvements; 4-does not exist; 5-not applicable; 6-did not audit.

QUESTIONS	RATING* PROGRAM/IMPLEMENTATION		COMMENTS
65. Are there procedures for disposition of nonconforming materials and for introducing materials back into production?			
66. Are there records of all nonconforming material?			
PACKAGING AND TRANSPORTATION			
67. Are there procedures for inspecting packaging and the form of transportation?			
68. Do these procedures ensure that all paperwork and manuals are included with the shipment or are being shipped separately to the customer?			
69. Are there records of all packaging and shipping reports and inspections?			
DEVIATIONS AND CUSTOMER COMPLAINTS			
70. Are there procedures for evaluating deviations and customer complaints?			
71. Are there procedures for informing the appropriate members of the organization and NRC of deviations?			
72. Are there procedures for informing customers of devices that may contain a deviation?			
73. Are there records of all deviations and customer complaints?			
74. Do customer complaint records contain: • name of complainant? • nature and date of complaint? • corrective action taken? • cause of the failure? • model and serial number of the device?			

***Ratings: 1-superior; 2-meets specifications; 3-needs improvements; 4-does not exist; 5-not applicable; 6-did not audit.**

QUESTIONS		RATING* PROGRAM/IMPLEMENTATION		COMMENTS
75.	Are there procedures for trend analysis of deviations and complaints?			
76.	Is trend analysis performed at intervals that do not exceed 1 year?			
	AUDITS			
77.	Does the applicant have procedures for auditing its QA program?			
78.	Do the procedures include acceptance criteria?			
79.	Do the procedures ensure that all records and procedures are up to date?			
80.	Do audits include verification of audits of suppliers?			
81.	Is the auditor responsible for any of the matters being audited?			
82.	Do records include deficient areas in the program and corrective action taken?			
83.	Are all deficient areas corrected?			
84.	Are all records signed and dated by the appropriate member of the organization?			

*Ratings: 1-superior; 2-meets specifications; 3-needs improvements; 4-does not exist; 5-not applicable; 6-did not audit.

APPENDIX B

EXAMPLES OF RECORDS AND DOCUMENTATION

The following documents are examples of records and documentation for quality assurance (QA) programs. It is not a complete listing of documents and records for QA programs. These samples are for guidance only and are not considered standard formats. The applicant should have documents and records tailored to its program.

EMPLOYEE TRAINING

Employee: _____

Department: _____

Supervisor: _____

Hire Date: _____

Training Date: _____

Training Type: _____

I, _____ (employee's name), have received _____ (type of training) training on ___/___/___ (Date) and understand its content.

_____
Employee Signature

_____
Trainer Signature

EQUIPMENT LOG

NAME OF EQUIPMENT: _____

MODEL NUMBER: _____ SERIAL NUMBER: _____

MANUFACTURER: _____

USED FOR: _____

_____

INSTRUCTIONS FOR USE, MAINTENANCE, CALIBRATION: _____

_____

MAINTENANCE FREQUENCY: _____ CALIBRATION FREQUENCY: _____

DATE	CALI.	MAIN.	PERFORMED BY	COMMENTS

CALIBRATION LABELS:

CALIBRATION

MODEL #:_____ SERIAL #:_____

DATE CALIBRATED:_____

DATE DUE FOR CALIBRATION:_____

CALIBRATED BY:_____

OUT OF CALIBRATION

DO NOT USE

CALIBRATION NOT

REQUIRED

ENGINEERING CHANGE REQUEST

ECR#

MODEL/PART NO.	CUSTOMER/ORDER NO.	INITIATOR	DEPT.	DATE

REASON FOR CHANGE	TYPE OF CHANGE
	NORMAL EMERGENCY

DOCUMENT NO.	DESCRIPTION OF CHANGE

REVIEWED/APPROVED			REMARKS/COMMENTS
DEPT.	SIGNATURE	DATE	
DESIGN ENG.			
PROD.			
QA ENG.			
PROD. PLAN.			
R & D			
OTHER			

NOTIFY SUPPLIER	YES	NO
NOTIFY CUSTOMER	YES	NO
NOTIFY NRC	YES	NO

ENGINEERING CHANGE NOTICE

ECN#

MODEL/PART NO.	CUSTOMER/ORDER NO.

CHANGED BY	DATE	CHECKED BY	DATE	RELEASED

DOCUMENT NO. REV.	DESCRIPTION OF CHANGE

UNITS AFFECTED		STOCK DISPOSITION	
DATE	INVENTORY	SCRAP	REWORK
FIELD UNITS	NEXT RUN	DEPLETE	OTHER USE
IN PROCESS	SEE STOCK DISP.	DESCRIPTION OF OTHER USE:	

REMARKS	DISTRIBUTION

NOTIFICATION REQUIRED: SUPPLIER CUSTOMER NRC

DRAWING ISSUE CHECKLIST

TO	DATE
FROM	ORDER NUMBER

The following drawings and/or documents have been sent to you since ___/___/___ . Please review your recent receipts of documents and check the column as to whether you have received them or not. Sign and date this form where indicated. Return the marked original to me immediately and keep a copy for your records.

DRAWING OR DOCUMENT NUMBER	ISSUE NUMBER	REC'D

I certify that the previous revisions of the documents and drawings have been recalled or accounted for:

Signature _____ Date _____

FIELD CHECKED BY:	DATE:

PURCHASE REQUISITION NO. _____

___ PURCHASE REQUISITION ___ PURCHASE CHANGE	REQUISITIONED BY:	DEPARTMENT:

P.O. NUMBER	CHANGE NO.	DATE	DATE DELIVERY REQUIRED

ORDER DATE	DELIVERY DATE	__ COLLECT __ ALLOWED	__ ALLOWED & PREPAID __ PRE-PAY & CHARGE ON INVOICE	SALES TAX __ YES __ NO

F.O.B.	VIA

ITEM NO.	QUANTITY & UNITS	PART NUMBER	SUPPLIER NUMBER & DESCRIPTION	PRICE

SUPPLIER: _____

_____

_____

CONFIRMED: ___ YES ___ NO BY: _____

SIGNED	APPROVED DATE

PURCHASE ORDER NO. _____

TO:	SHIP TO:
	BILL TO:

P.O. DATE	DATE DELIVERED	PROMISED DELIVERY DATE	TERMS	SUPPLIER NO.

F.O.B	SHIP VIA	SUPPLIER CONTAC

DESCRIPTION	QUANTITY	UNIT	PRICE	EXTENSION

NOTE: This purchase order is subject to the provisions on the face hereof and the instructions, terms, and conditions on the reverse side. Please review them carefully. They will constitute our contract unless we agree in writing to changes or additions.

COMPANY NAME

BY: _____
Authorized Agent

DAILY
INCOMING MATERIALS INSPECTION
REPORT

DATE	PO#	SUPPLIER#	PART#	TOTAL	INSP.	REJECT	NCMR#	BY:

INSPECTION TRAVELER

JOB #:_____ BATCH #:_____ ITEM #:_____

INSPECTION AND TEST TO BE PERFORMED	POINTS TO PERFORM INSPECTION/TEST

DATE	INSP./TEST PERFORMED	PERFORMED BY	PASS/ FAIL	COMMENTS

VERIFICATION OF CONFORMANCE

Date:

Company:

Address:

Purchase Order:

Item/Part Number:

Contract:

This certificate assures that the items listed below conform to all the conditions of Purchase Order (P.O.#), Contract (contract #), and their engineering drawings.

ITEM NUMBER	PART NUMBER	DRAWING NUMBER	DESCRIPTION

COMPANY NAME

BY: _____
SIGNATURE DATE

_____
TITLE

_____ (Witness)
SIGNATURE DATE

NONCONFORMING MATERIAL REPORT NCMR#_____

SUPPLIER

_____

_____

_____

PURCHASE ORDER NO._____ BUYER_____

INSPECTOR_____ DATE INSPECTED_____

DATE RECEIVED_____

ITEM NO.	PART NO.	REV.	DESCRIPTION

LOCATION	QTY. ORDERED	QTY. REC'D.	QTY. INSP.

ITEM	DESCRIPTION OF NONCONFORMANCE

QUALITY

__ AS IS __ REPAIR/REWORK __ RETURN TO SUPPLIER __ SHORTAGE

COMMENTS/REWORK INSTRUCTIONS:_____

_____

_____

_____

REWORKED AND RE-INSPECTED: _____

SIGNATURE DATE

NONCONFORMING MATERIAL TAG:

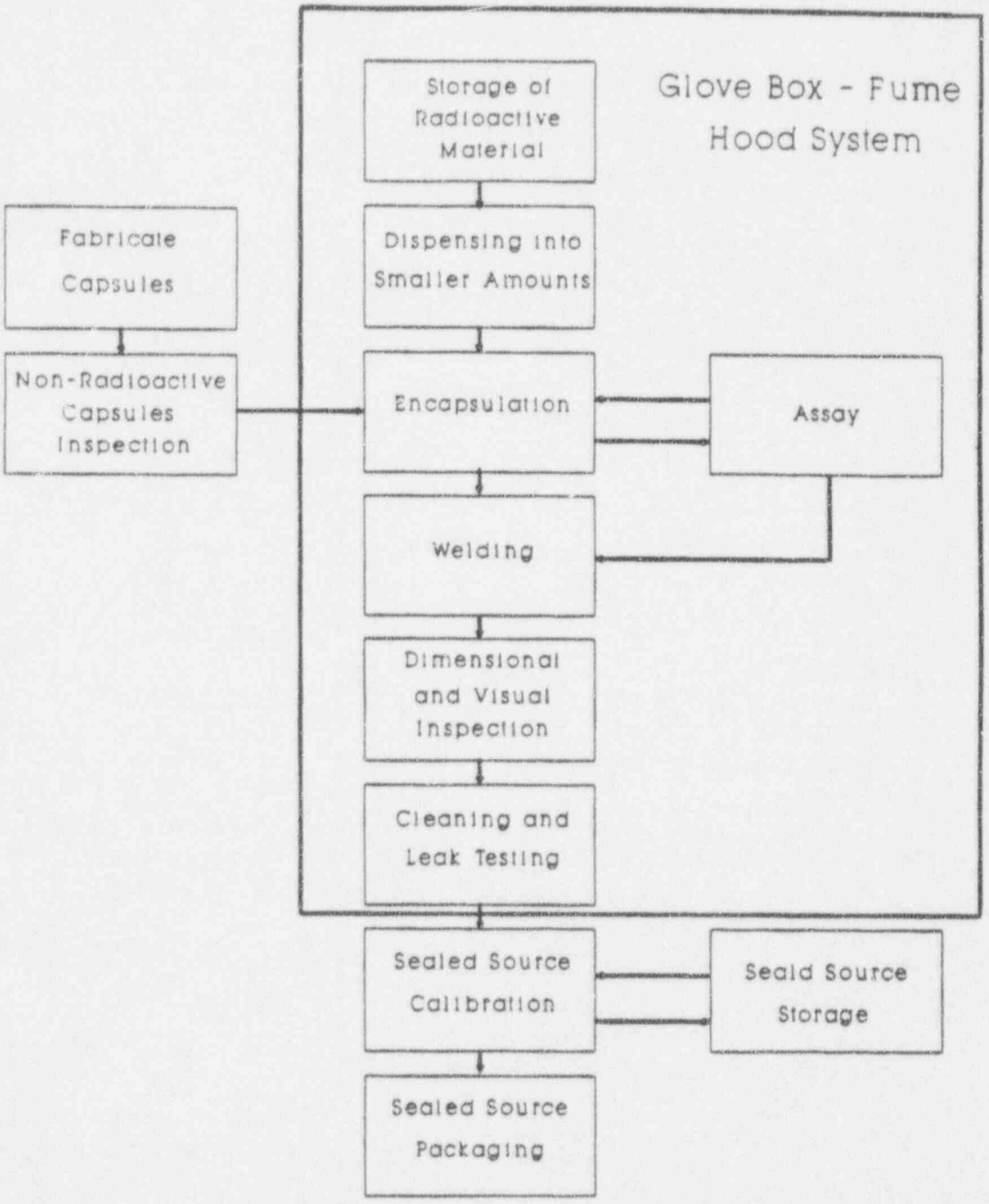
NONCONFORMING MATERIAL

TYPE:_____ LOT #:_____

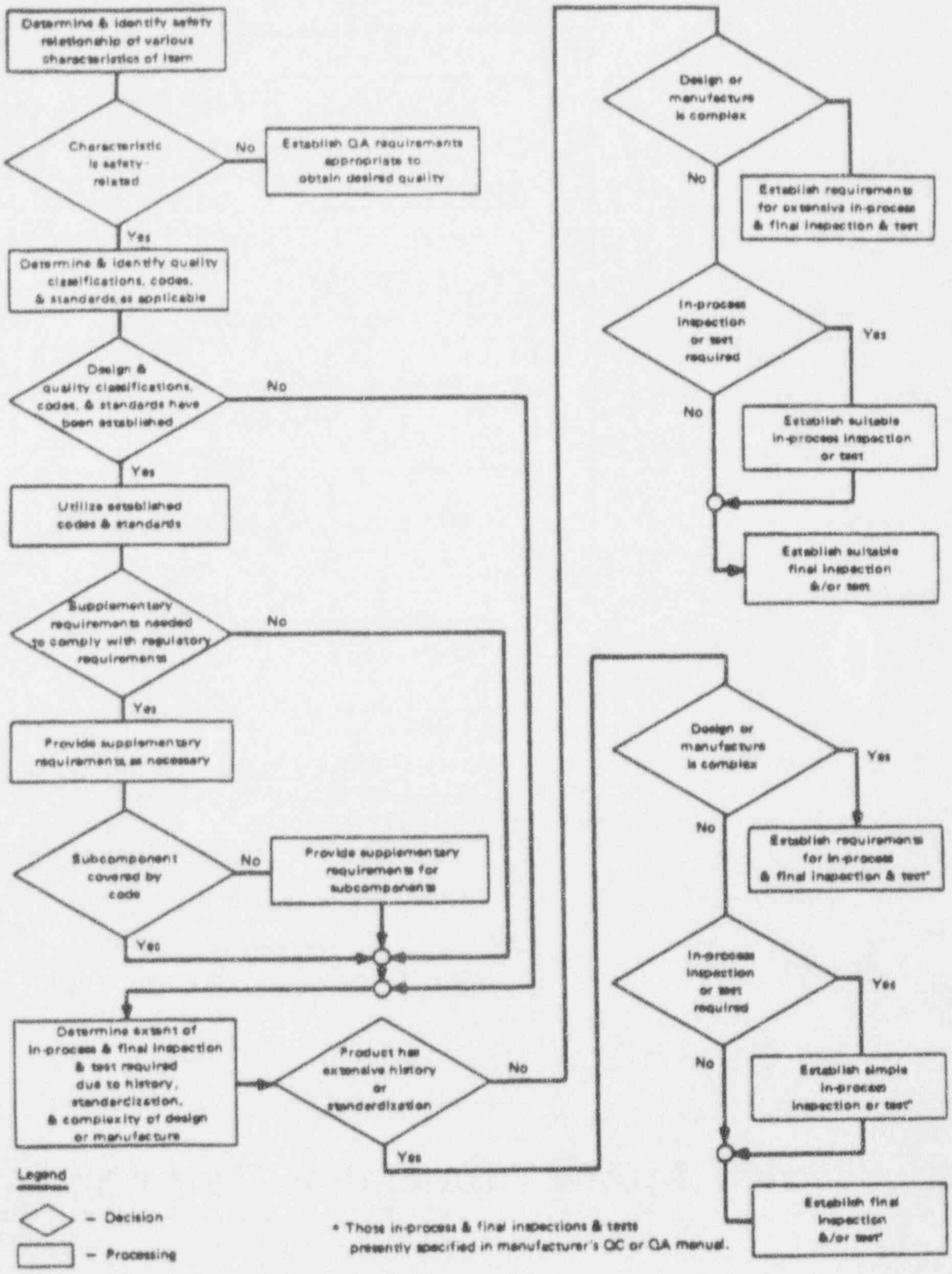
PART #:_____ SERIAL #:_____

MATERIAL CANNOT BE USED UNTIL RELEASED BY:_____

DATE:_____ INSPECTOR:_____



Sealed Source Fabrication Flow Chart



Inspection Traveler Logic Chart

CUSTOMER COMPLAINT FORM

Date: ___/___/___

Time: _____

Call Taken By: _____

Customer Name: _____

Customer Address: _____

_____

_____

Contact Name: _____

Contact Phone #: _____

Device Model: _____ Device Serial #: _____

Isotope: _____ Activity: _____ mCi

Complaint:

Reply to Complainant:

CUSTOMER COMPLAINT FORM, Cont.

Corrective Action:

Cause of Failure:

List of Customers Affected and Notified:

Actions to be Taken by Affected Customers:

Reviewed by: _____
(Corporate Officer)

NRC was notified: ___/___/___
(date)

APPENDIX C

QUALITY CONTROL PROGRAM SPECIFICATIONS FOR CERTAIN EXEMPT PRODUCTS

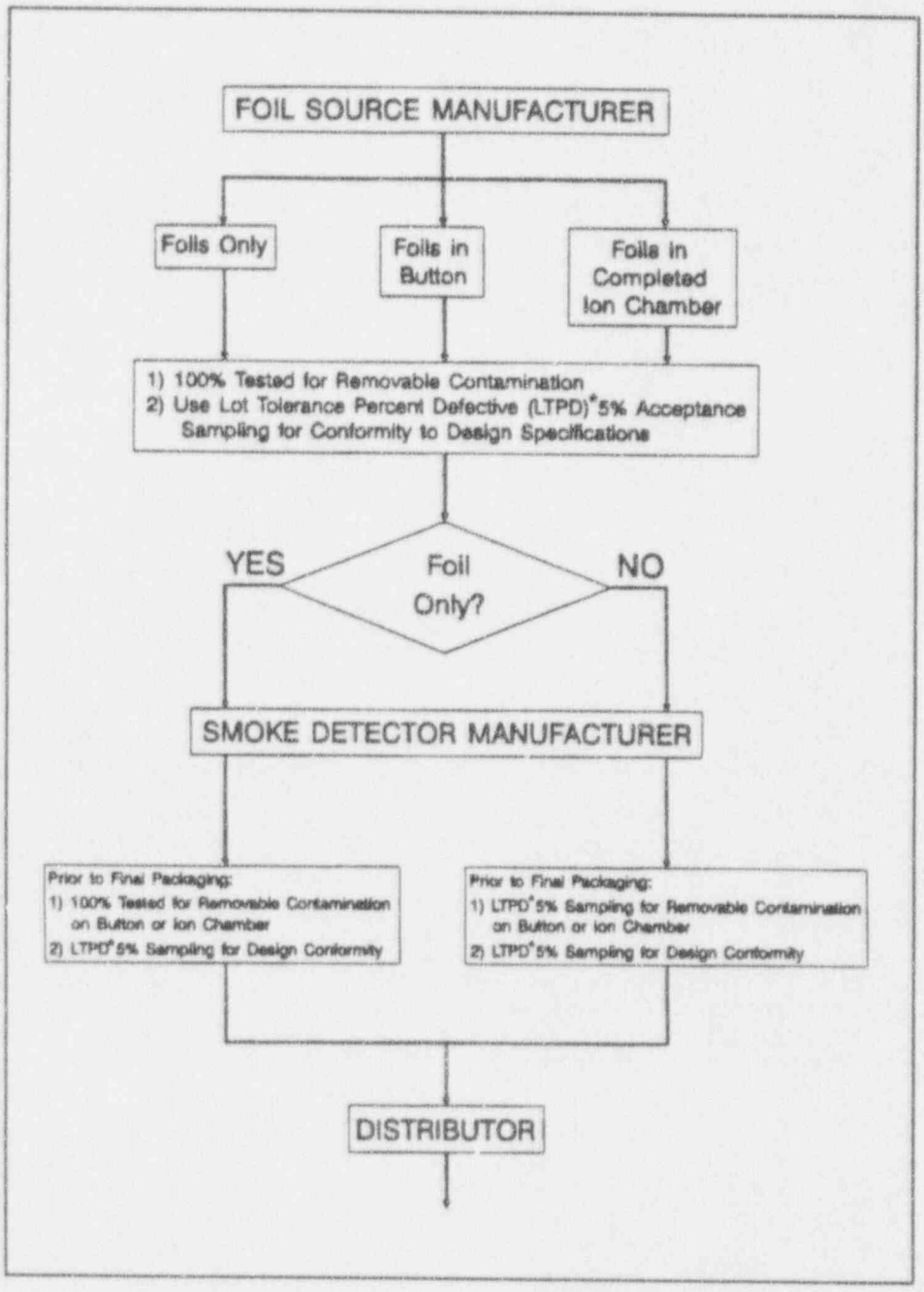
The attached document details the QC specifications for the manufacture and distribution of smoke detectors. The same specifications should be incorporated for the manufacture and distribution of all devices containing byproduct material that are distributed to persons exempt from licensing.

QC Program Specifications for the Manufacture and Distribution of Smoke Detectors

10 CFR 32.29 requires an applicant to provide information on an adequate QC program to ensure that each production lot meets the design standards approved by the U.S. Nuclear Regulatory Commission.

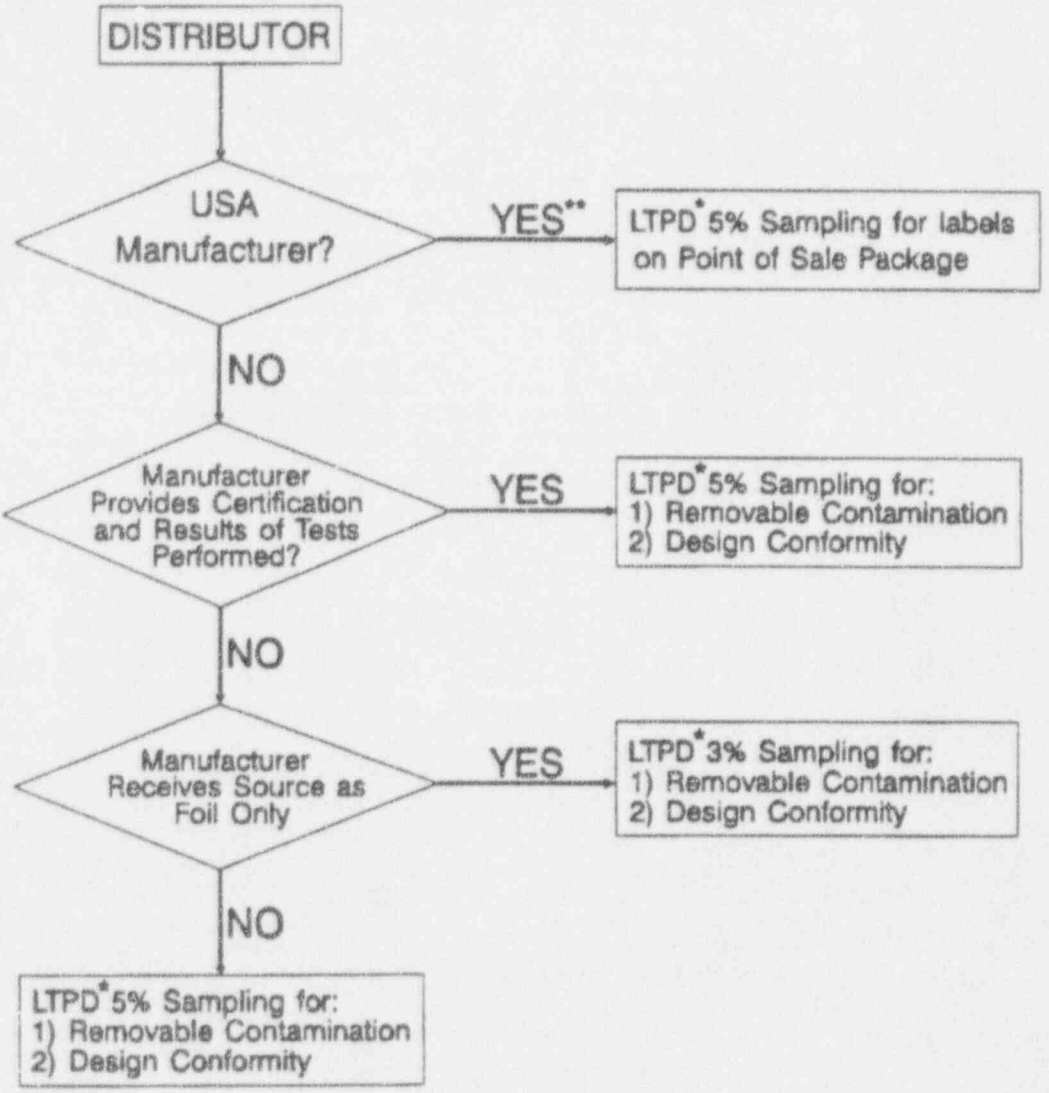
The following flowchart and text represent the specifications that have been deemed appropriate for such a program. Applicants are encouraged to use this approach or submit, in detail, an equivalent alternative program.

QC Program Specifications for the Manufacture and Distribution of Smoke Detectors (Cont'd)



* LTPD acceptance sampling is based on the attached charts.

QC Program Specifications for the Manufacture and Distribution of Smoke Detectors (Cont'd)



* LTPD acceptance sampling is based on the attached charts.

** Based on reliability/inspectability of USA fabrication records and facilities.

Definitions:

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

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

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

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

5. **Design Conformance** means a complete unit that has been inspected and has been shown to meet the design specifications that were submitted to and approved by NRC. Design specifications include detailed information about labeling, point of sale packaging, and detector construction.

6. **Disposition of Lot:** If any units within a sample are observed to be defective, the entire lot must either be rejected or inspected. All failed units must pass the test criterion before release.

7. **Final Packaging** is the packaging in which the unit is contained for sale to the end user. Also known as market package.

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

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

10. **Quality Characteristics** are the test criteria. The devices must have less than 185 becquerels (0.005 microcurie) of removable contamination and conform to the manufacturer's design specifications (e.g., labeling, packaging, construction, etc.). Up to 75 units may be tested for removable contamination, using one swipe. The trigger level for multiple units using one swipe is 185 becquerels (0.005 microcurie).

11. **Sample (*n*)** means, in acceptance sampling, one or more units of product (where *n* is the number of units) drawn from a lot, for purposes of inspection, to reach a decision regarding acceptance of the lot.

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

For our purposes, the LTPD tables found in 10 CFR 32.110 and Regulatory Guide 6.6 have been modified, whereby the acceptance number for all lot sizes is zero (0). The reasoning behind this change is that from a health and safety standpoint, no defects in these devices are acceptable. If defective units are found within the sample, the entire lot shall either be rejected, or inspected for conformance to the quality characteristic(s) in which the sample units were found to be defective. All units that are found to be defective must conform to the quality characteristic(s) before release, or be rejected entirely. It is recommended that the choice of samples be as random as possible, to provide the maximum probability that a defect will be detected.

The following are the modified 3% LTPD and 5% LTPD tables:

LTPD = 3%

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

LTPD = 5%

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

Rationale for Specifications.

Foil source suppliers can be divided into three general categories: 1) manufacturers who supply only foil sources; 2) manufacturers who supply foil sources installed in button holders; 3) manufacturers who supply foil sources installed in complete ion chambers. All source manufacturers are required to ensure that each source is tested and meets the requirements for removable contamination, before delivery to the smoke detector manufacturer. Foils installed in buttons and/or completed ion chambers tend to be better protected from abrasion or mishandling. Accordingly, these sources have a lesser chance than unprotected foil sources of being damaged during installation into a smoke detector. Therefore, smoke detector manufacturers who receive foil sources, only, must additionally test each smoke detector or ion chamber assembled for removable contamination, before the final packaging of the device. Conversely, smoke detectors that are manufactured using a foil source received in a button or a completed ion chamber need only be tested for removable contamination, according to the LTPD=5% table. All smoke detectors, regardless of manufacturer, must be tested for conformance to design specifications, according to the LTPD=5% table. This yields a 95 percent confidence level that the devices meet design specifications.

Before a smoke detector is distributed in the United States, the foil source, button, or ion chamber used in the device must be registered with NRC, according to Regulatory Guide 10.10 or 10.11. Smoke detector manufacturers can be located inside or outside the United States. NRC cannot always have access to the records of foreign manufacturers, since inspection of the manufacturers is not always possible. The records and facilities of manufacturers and distributors located within the United States are always available for inspection by NRC. Therefore, distributors who receive complete devices from a U.S. manufacturer need not conduct further testing for removable contamination and/or design conformity. This testing is conducted by the manufacturer and can easily be verified. Accordingly, distributors who receive devices from U.S. manufacturers need only check the devices for the appropriate labeling on the point-of-sale packaging, according to the LTPD=5% table.

Since foreign manufacturers cannot easily be inspected, tests for removable contamination and design conformity performed by these manufacturers cannot easily be verified. The distributor must provide assurance that devices received from a foreign manufacturer have been tested for these criteria. This is accomplished by the distributor conducting lot sampling of the devices. If the foreign manufacturer provides a written certification that these tests were performed, as well as providing the results of these tests, then the distributor need only perform lot sampling for these criteria according to the LTPD=5% table. However, if the foreign manufacturer does not provide a certification and the test results, and if the manufacturer received the source in foil form only, then the distributor must perform lot sampling for these criteria, according to the LTPD=3% table. This yields a 97 percent confidence level that the devices are within removable contamination limits and meet design specifications. The reason the additional level of confidence is needed goes back to the fact of unprotected foil sources being more susceptible to damage during shipment and installation. If, however, the foreign manufacturer receives the source in a button or a completed ion chamber, from a U.S. manufacturer, then the distributor need only test the devices for removable contamination and design conformance, according to the LTPD=5% table, even if the manufacturer does not provide a certification and test results.

DRAFT VALUE/IMPACT STATEMENT

1. BACKGROUND

It is essential that the Commission have assurance that sealed sources and devices containing byproduct material meet the product specifications that were submitted to the Commission as part of the application for registration of the product. These specifications are the basis on which use of the sealed sources and devices is approved.

To provide this assurance to the Commission, Paragraph 32.210(c) would require the applicant to submit information about the QC program that the device will be manufactured under, and Paragraph 32.210(f) would require the registrant to manufacture and distribute the product in accordance with the statements and representations about the QC program. However, Section 32.210 does not provide specific guidance on what is an acceptable QC program.

In addition to Section 32.210, other sections of the regulations, specifically Sections 32.25 and 32.29, require applicants to manufacture and distribute products in accordance with QC standards approved by the Commission. Again, no specific guidance on acceptable standards is provided.

In developing this regulatory guide, the NRC staff reviewed exisiting QA guidance and the programs of manufacturers and distributors of sealed sources and devices. This draft guide proposes a QA program for the safe use of the sealed sources and devices.

2. PROPOSED ACTION

2.1 Description

The proposed action would provide guidance on formulating a QA program applicable to the design, inspection, testing, manufacture, and distribution of sealed sources or devices to persons who have registered sealed sources or devices. The QA program should include the planned and systematic actions that provide confidence that the firm or product will meet the required specifications. The QA program must include the QC standards that are referenced in the regulations.

The NRC plans to revise the references to QC standards in the regulations and include a statement that the registrants are required to implement an approved QA program. Therefore, this proposed action is necessary to provide the registrants with guidance on what the NRC staff considers an acceptable program.

All persons licensed to manufacture, distribute, or redistribute sealed sources and devices containing byproduct material would implement and maintain a QA program. The QA program should cover all persons, materials, processes, or services related to the manufacture, distribution, or redistribution of the sealed sources or devices.

2.2 Need

According to the proposed Paragraph 32.210(c), an applicant for registration of a source or a device containing byproduct material would submit information pertaining to its QC program and should manufacture and distribute the source or device in accordance with the QC program. In addition, 10 CFR 32.25 and 32.29 require applicants to manufacture and distribute products in accordance with QC standards approved by the Commission.

Guidance is needed to establish and maintain QA programs that encompass the QC requirements of 10 CFR Part 32. The NRC staff also needs guidance to develop review and inspection plans and procedures.

Furthermore, because there are disparities among types of sources and devices, specific guidance concerning particular QA programs and their impact on safety is needed.

2.3 Value/Impact Assessment

2.3.1 NRC

Staff time for evaluation and inspection should be reduced, because standardized QA programs should allow the use of standard review plans and uniform inspection plans and procedures.

Other than the allocation of staff resources to developing, reviewing, and issuing this guide, no impact on the NRC is anticipated.

2.3.2 Other Government Agencies

Impact on other government agencies would be essentially the same as that on industry, to the extent that these agencies are regulated by NRC.

2.3.3 Industry

Specific guidance on QA criteria applicable to the manufacture and distribution of sources and devices should aid in developing, establishing, and maintaining a QA program that meets the spirit and intent of Sections 32.25, 32.29, and 32.210. Formulating a program in which the QA effort expended on an activity is consistent with its importance to safety can be interpreted quite differently by different licensees. Spelling out only the applicable criteria, as well as the specific applicable safety elements, will result in an approach of custom programs being developed for each type of industry. Proliferation of documentation, which is prevalent in industry, should be reduced.

2.3.4 Public

No impact on the public is foreseen.

2.3.5 Worker

No impact on the worker is foreseen.

2.4 Decision

The proposed action, developing and issuing a revised regulatory guide, should be completed because of the benefits previously discussed.

3. PROCEDURAL APPROACH

3.1 Alternatives

No meaningful alternative exists. Using the general descriptions of QA criteria found in many industrial standards, without further amplification, would make licensees overly responsible for judging what constitutes an acceptable program.

3.2 Discussion

A regulatory guide is the most efficient way to transmit information about the subject QA programs that would be acceptable to the NRC. In addition to providing guidance to licensees, it allows the licensees an additional opportunity to provide input into future rulemaking concerning QA programs.

4. STATUTORY CONSIDERATIONS

4.1 NRC Authority

The proposed guide would provide guidance for the implementation of regulations promulgated in 10 CFR Part 32. Authority for the proposed action is derived from the Atomic Energy Act of 1954, as amended, and from the Energy Reorganization Act of 1974, as amended, and implemented through 10 CFR Part 32.

4.2 Need for National Environmental Protection Act Assessment

Issuance or amendment of guides for the implementation of regulations in Title 10, Chapter I, of the U.S. Code of Federal Regulations is a categorical exclusion under paragraph 51.22(c)(16) of 10 CFR Part 51. Thus, an environmental impact statement or assessment is not required for this action.

5. RELATIONSHIP TO OTHER EXISTING OR PROPOSED REGULATIONS OR POLICIES

The structure of this guide is similar to the requirements in Subpart H to 10 CFR Part 71 and Appendix B to 10 CFR Part 50, which describe QA criteria now in effect for manufacturers and users of packages for transporting radioactive material and for nuclear power plants and certain fuel cycle facilities. Changes were made to the guide so it could be more easily understood by the diverse group of manufacturers and distributors of sealed sources and devices.

6. SUMMARY AND CONCLUSIONS

The proposed action will provide persons involved in activities related to the manufacture and distribution of sealed sources and devices with much needed information on the essential elements of QA programs that are acceptable to the NRC. Therefore, the regulatory guide discussed here should be prepared and issued.

Federal Recycling Program

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, $300

FIRST CLASS MAIL
POSTAGE AND FEES PAID
USNRC
PERMIT NO. G-67

120555064215 2 1S61SA1SB
US NRC-OIRM
DOCUMENT CONTROL DESK
P1-124D
WASHINGTON DC 20555