Quality Assurance Program for 10CFR71, Appendix E Requirements for Procurement, Maintenance, Repair, and Use of Transportation Packages for Radioactive Materials

National Bureau of Standards
Washington, DC 20234

Approval _____

Date _____

Introduction

This document describes the quality assurance (QA) program of the National Bureau of Standards (NBS) for containers used for shipping certain radioactive materials (RAM). The program described is intended to meet the requirements of Title 10, Code of Federal Regulations, Part 71, Appendix E, when those requirements are applied in a graded approach, i.e., applied to the extent consistent with their importance to safety.

Quality can be defined as conformance with requirements. For the purposes of this program, QA is the assuring of regulatory compliance, and quality control (QC) is the set of mechanisms for implementing QA. The entire NBS organization: management, the designated QA/QC staff, and the operating units who are involved in shipping RAM, are dedicated to seeing that RAM shipments are made safe.

The degree of control on a RAM shipment is governed by the activity and form of the RAM involved. Control categories are: exempt, Type A, Type B and large quantity. This program does not concern shipments of RAM in the exempt or the Type A categories.

The categories that are covered by this program, listed in order of increasing QA requirements, are:

(a) such RAM as radiography-type sources and fresh fuel;

(b) miscellaneous shipments, including plutonium standard reference materials (SRM) up to twenty (20) curies per package; and

(c) large activities such as spent fuel and high-level radioactive wastes.

This program concerns itself with new and used containers for shipping RAM, from acquisition through use to disposition, either finally or to be returned for reuse. For containers not owned by NBS but for which NBS is a registered user, this QA program will apply. For any specific container or type of container, the graded approach will be applied at the time container use is required through special procedures, instructions, checklists, or documents to the degree necessary to assure safe transportion of RAM.

1. Organization

The NBS retains and exercises responsibility for the QA program, under which design services, purchasing, handling, shipping, storing, cleaning, assembling, inspecting, testing, operating, maintaining, repairing, and modifying of certain RAM shipping containers will be controlled.

Figure 1 shows the NBS QA organization. The Health Physics Chief or his designated representative retains overall authority and responsibility for the QA program as QA Program Manager (QAPM). The Health Physics chief is required to have a college degree or equivalent experience and at least five years of experience in the field of radiation safety. The QAPM is required to have at least five years of experience in a field that includes oversight of RAM shipments. The Chief of the Occupational Health and Safety Division, who must have a college degree or equivalent experience and five years of experience in a safety-related field, establishes QA policies, goals and objectives and maintains a continuing involvement in QA matters.

QA and QC functions are performed by designated Health Physics staff members. These individuals have the authority and responsibility to stop unsatisfactory work and control further processing, delivery, or installation of nonconforming materials.

2. Quality Assurance Program

The Chief, Occupational Health and Safety Division, will regularly assess the scope, status, implementation and effectiveness of the QA program to assure that the program is adequate and meets regulatory requirements. The QAPM will control distribution of QA manuals and revisions. Disputes between QA/QC personnel and operating units performing quality-affecting work will be brought to the attention of the Health Physics chief, who will resolve the issue.

The QA plan will be periodically reviewed for overall effectiveness. Minor changes may be made and documented by the QAPM. Other modifications that do not affect the purpose of the plan or reduce the extent or degree of safety considerations require the approval of the Health Physics chief.

An indoctrination and training program will be established for personnel involved in quality-affecting activities. The program will include instruction on the purpose, scope and implementation of quality-related manuals, instructions and procedures and training and qualification in the principles and techniques of the activity to be performed. A requalifying program will be established for regularly involved personnel. The scope, objective and the method for implementing these programs will be documented.

The graded approach to quality assurance will be applied at such time as containers are required for a RAM shipping activity. The extent of applied safety considerations will be based on their importance to safety as determined by the RAM involved. For example, more restrictive considerations would apply

for spent fuel or high-level wastes than for plutonium SRM's and these, in turn, would require more restrictions than unirradiated fuel or radiography-type sources.

As NBS will not normally engage in container design activities, those portions of this plan relating to design provide a contingency to be implemented at the time design functions are necessary.

3. Design Control

Procedures will be established at the time design services are required to carry out design activities in a planned, controlled and orderly manner, and to insure correct translation of applicable regulatory requirements and design bases into specifications, drawings, written procedures and instructions.

Quality standards will be specified in the design documents, and significant deviations and changes from these standards will be controlled. Design controls will be applied as necessary to such activities as reactor physics; seismic, stress, thermal, hydraulic, radiation and accident analyses; material compatibility; and accessibility for inservice inspection, maintenance and repair.

Designs will be reviewed to assure that (1) design characteristics are controlled, inspected and tested and (2) inspection and test criteria are identified. Design verification or checking processes such as by design reviews, alternate calculations or qualification testing will be selected and accomplished to assure quality. These processes will be performed by groups or individuals other than the original designer and the designer's immediate supervisor. Design adequacy will be verified by testing a prototype unit with marginally acceptable characteristics that are related to the safety consideration in question.

The same individual or group responsible for original design controls and approvals, or an equivalent individual or group authorized by the QAPM, will be used for design and specifications changes, including field changes. Procedures will be developed as necessary for identifying and controlling the authority and responsibility of individuals or groups responsible for design reviews and other design verification activities.

Documentation will be generated for errors and deficiencies in the design, including the design process, that could adversely affect safety-related structures, systems, and components; the documentation will include corrective actions for preventing recurrence.

Procedures will be developed as necessary for selecting suitable materials, parts, equipment and processes for safety-related structures, systems and components which include valid industry standards and specifications. Those materials, parts and equipment items which are standard, commercial (off-the-shelf) or which have been previously approved for a different application will be reviewed for suitability prior to selection.

4. Procurement Document Control

Procedures will be established to delineate the sequence of actions for preparation, review, approval and control of procurement documerts (PD), including review and concurrence on the adequacy of quality requirements by the QAPM in order to assure that QA requirements are correctly stated, inspectable and controllable; that there are adequate acceptance and rejection criteria; and that the PD has been prepared, reviewed and approved in accordance with QA program requirements. Review and approval of PD's will be documented prior to release and the documents will be available for verification. Significant changes and revisions to PD's will be subject to at least the same review and approval as the original document.

PD's will require a signed certificate from the supplier that the QA containers have been manufactured and treated according to a QA plan approved by the NRC, or will contain the following information:

(a) Identification of the applicable 10CFR71, Appendix E requirements which must be complied with and described in the supplier's QA program. This QA program or portions of it will be reviewed and concurred with by the NBS QAPM prior to initiation of the procurement actions.

(b) Design basis technical requirements, including the applicable regulatory requirements, material and component identification requirements, drawings, specifications, codes and industrial standards test and inspection requirements, and special process instructions.

(c) Identification of documentation to be prepared, maintained and submitted by the supplier to NBS for review and approval.

(d) Identification of records to be retained, controlled and maintained by the supplier, and those to be delivered to NBS prior to use or installation of the hardware.

(e) A statement on the right of NBS to have access to the supplier's facilities and records for inspection and audit.

5. Instructions, Procedures and Drawings

Documented instructions, procedures and drawings will be developed for prescribing and accomplishing activities affecting quality. Procedures will exist for this development process, describing the sequence of actions to be accomplished in the preparation, review, approval and control of the instructions, procedures and drawings.

The QAPM will provide for QA review and concurrence with inspection plans; test, calibration, and special process procedures; drawings and specifications; and changes to or acceptable alternatives for these.

6. Document Control

Procedures will exist for review, approval and issue of QA affecting documents to assure adequacy and conformance with QA requirements. The procedures will assure that the same individual or group or an equally qualified individual or group designated by the QAPM will review and approve significant changes to these documents. Such changes will be included in instructions, procedures, drawings or other documents prior to implementation of the change. Documents will be available at the work location prior to commencing the work.

The QAPM will establish a master list or equivalent which identifies the current revision number of instructions, procedures, specifications, drawings and procurement documents. This list will be updated and distributed to predetermined, responsible personnel to preclude use of superseded documents.

7. Control of purchased material, equipment or services is not applicable to this program.

8. Identification and control of materials, parts and components is not applicable to this program.

9. Control of Special Processes

Procedures will be developed as necessary for special processes such as welding, heat treating, nondestructive testing and cleaning.

10. Inspection

Written, controlled procedures will be developed to establish, document and accomplish an inspection program which verifies conformance of quality-affecting activities with requirements. The inspection personnel will be independent from the individuals performing the activity being inspected.

11. Test control conditions are not applicable to this program.

12. Control of Measuring and Test Equipment

Measuring and test equipment will be identified and traceable to calibration test data. The instruments used will be calibrated at specified intervals based on the required accuracy, purpose, degree of usage, stability characteristics and other conditions affecting the measurement. Standards will be traceable to nationally recognized standards or, where national standards do not exist, provisions will be established to document the calibration basis.

Measures will be taken and documented to determine the validity of previous inspections performed when measuring and test equipment is found to be out of calibration.

13. Handling, Storage, and Shipping

Special handling, preservation, storage, cleaning, packaging and shipping requirements will be established and accomplished by qualified individuals in accordance with predetermined work and inspection instructions. Applicable conditions of NRC package approval and DOT shipping requirements will be satisfied prior to shipment. All necessary shipping papers will be prepared as required. Where necessary, departure and arrival times and the destination of a package will be established and monitored to a degree consistent with the safe transportation of the package.

14. Inspection, Test and Operating Status

Procedures will be established to control application and removal of inspection and welding stamps and status indicators such as tags, markings, labels and stamps used to provide identification of inspection, test and operating status of structures, systems and components throughout manufacturing and installation.

The QAPM will develop procedures as necessary for bypassing normally required inspections, tests and other critical operations. Nonconforming, inoperative or malfunctioning structures, systems or components will be identified to prevent inadvertent use.

15. Nonconforming Materials, Parts or Components

Procedures will be developed as necessary for the identification, documentation, segregation, review, disposition and notification to affected organizations of nonconforming materials, parts, components or services.

16. No corrective actions are required in this program.

17. Quality Assurance Records

Identifiable and retrievable QA records shall be kept to provide sufficient documentary evidence of the quality of items and quality-affecting activities. The records shall include, as necessary, operating logs; results of reviews, inspections, tests, audits and material analyses; monitoring of work performance; qualification of personnel, procedures and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports; and nonconformance reports.

18. Audits

Audits of the QA program will be performed at least annually, at intervals not to exceed fifteen months, based on safety significance of the activity being audited. Written procedures or checklists will be established to assure that audits are performed and conducted by trained personnel not having direct responsibilities in the area being audited. The audit results will be documented and reviewed by management having responsibilities in the area audited, upon which the responsible management will take the necessary actions to correct deficiencies revealed by the audit. Reaudits of deficient areas will be performed on a timely basis to verify implementation of corrective actions to minimize recurrence of deficiencies.

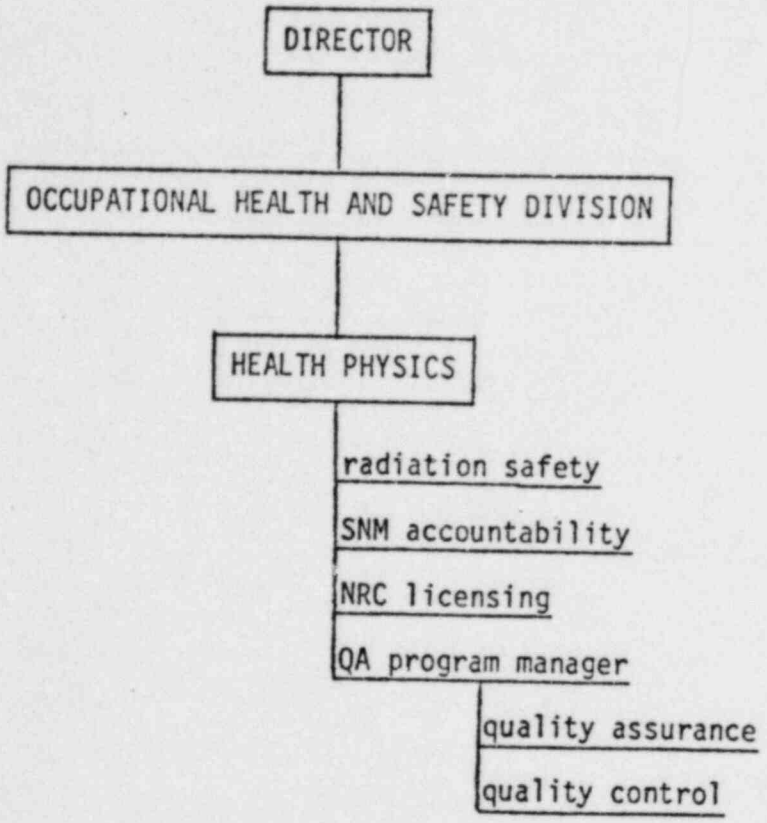
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FIGURE 1