**DOE/EM/PCP/QA-2010-1**

Revision 1

September, 2010

# Quality Assurance Guidance for Packaging of Radioactive and Fissile Materials

# DEPARTMENT OF ENERGY PACKAGING CERTIFICATION PROGRAM

**AVAILABLE ONLINE AT:**
http://rampac.energy.gov/PBoK.htm#DOE

**INITIATED BY:**
DOE PCP

EM Environmental Management
safety ❖ performance ❖ cleanup ❖ closure
DOE Packaging Certification Program

# Foreword

This Quality Assurance Guidance was developed by the Department of Energy Packaging Certification Program (DOE PCP) support organizations, including the Argonne National Laboratory (ANL), Lawrence Livermore National Laboratory (LLNL), Oak Ridge National Laboratory (ORNL), and Savannah River National Laboratory (SRNL).

"Quality Assurance" comprises all planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service.

The DOE employees and contractors are obligated to conduct business consistent with the requirements of the ten-point quality assurance (QA) program per DOE Order 414.1C, *Quality Assurance*, and Title 10 Code of Federal Regulations (CFR) Part 830, Subpart A, *Quality Assurance Requirements* (otherwise known as the "QA Rule").

Organizational elements involved in radioactive material (RAM) packaging and transportation (P&T) activities are also required to comply with the applicable portions of the 18-point QA program per Subpart H, *Quality Assurance*, of10 CFR Part 71, *Packaging and Transportation of Radioactive Material*. The DOE Safety Analysis Report for Packaging (SARP) must demonstrate this compliance.

The 18-point QA program has 18 QA criteria, each with several QA requirements. The 18 criteria are as follows.

Criterion I: Quality Assurance Organization
Criterion II: Quality Assurance Program
Criterion III: Package Design Control
Criterion IV: Procurement Document Control
Criterion V: Instructions, Procedures, & Drawings
Criterion VI: Document Control
Criterion VII: Control of Purchased Material, Equipment, & Services
Criterion VIII: Identification & Control of Materials, Parts, & Components
Criterion IX: Control of Special Processes
Criterion X: Internal Inspection
Criterion XI: Test Control
Criterion XII: Control of Measuring & Test Equipment
Criterion XIII: Handling, Storage, & Shipping Control
Criterion XIV: Inspection, Test, & Operating Status
Criterion XV: Nonconforming Materials, Parts, or Components
Criterion XVI: Corrective Action
Criterion XVII: Quality Assurance Records
Criterion XVIII: Audits

QA audits and SARP reviews by the DOE PCP over the last several years have demonstrated the need for consistent, systematic approaches for implementing QA

programs and meeting QA requirements. This QA guidance was prepared to meet this need. It summarizes the requirements of the 18 QA criteria, presents implementation strategies to meet these requirements, and describes lessons learned from past experiences. If the QA program description provided by the contractor is based solely on the DOE Order 414.1C/QA Rule, then the program must be supplemented. A comparison matrix between the 10- and 18-point programs with required supplementation is provided in Appendix A of this guidance.

The establishment of a QA program during the conceptual design process enables a uniform, consistent application of QA requirements during fabrication, use, and maintenance of packaging. Design efforts and requirements for a QA program are interrelated and should be developed simultaneously. Addressing them as independent functions may result in an overly stringent QA program or an inadequate QA program.

A user who leases certified packagings to transport radioactive and fissile material can be overwhelmed with all the information in this guidance. A user with a limited scope of work does not have to comply with all 18 QA criteria listed. To simplify and implement a focused QA program, the applicability of the QA criteria is discussed in a special subsection under each criterion.

Revision 1 of this guidance includes: the update from DOE Order 460.1B to 460.1C (460.1C was Issued/Effective May 14, 2010), a method for use in preparing and submitting QA program descriptions for review by the staff of the DOE Packaging Certification Program (PCP) and approval by the DOE Headquarters Certifying Official, and correction of minor typos. Revision 1 changes are indicated by revision bars in the side margins.

# Table of Contents

# Acronyms

| | |
|---|---|
| ANSI | American National Standard Institute |
| ASME | American Society of Mechanical Engineers |
| CoC | Certificate of Compliance |
| CFR | Code of Federal Regulations |
| CGD | Commercial Grade Dedication |
| DC | Document Control |
| DOE | Department of Energy |
| HMR | Hazardous Material Regulations, 49 CFR Parts 100 through 185 |
| IAEA | International Atomic Energy Agency |
| ISO | International Organization for Standardization |
| NDE | Nondestructive Examination |
| NCR | Non-Conformance Report |
| NRC | Nuclear Regulatory Commission |
| QA | Quality Assurance |
| QC | Quality Control |
| P&T | Packaging & Transportation |
| PCP | DOE Packaging Certification Program |
| RAM | Radioactive Material |
| RAMPAC | Radioactive Material Packaging |
| RG | Regulatory Guide |
| SARP | Safety Analysis Report for Packaging |
| SSC | Structures, Systems, and Components |

# 1.0 Part 1: Introduction

In accordance with DOE O 460.1C, Section 4.a.(3)(a), each DOE entity that participates in the design, fabrication, procurement, use, modification or maintenance of a Type B or fissile radioactive materials packaging must have a QA program that complies with 10 CFR Part 71, Subpart H, and is approved by the DOE Headquarters Certifying Official (HCO). The basis for use of Subpart H of 10 CFR 71 is 49 CFR 173.7(d) that states the following:

> "Packagings made by or under the direction of the U.S. Department of Energy may be used for the transportation of Class 7 materials when evaluated, approved, and certified by the Department of Energy against packaging standards equivalent to those specified in 10 CFR Part 71."

Guidance for the development of a QA program description in accordance with 10 CFR 71, Subpart H, is contained in Nuclear Regulatory Commission (NRC) Regulatory Guide (RG) 7.10, *Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material*. The guidance provided herein describes a method for use in preparing and submitting QA program descriptions for review by the staff of the DOE Packaging Certification Program (PCP) and approved by the HCO. Specifically, 10 CFR 71.37(a) requires that the applicant for a Certificate of Compliance (CoC) must describe the quality assurance program for design, fabrication, assembly, testing, maintenance, repair, modification, and use of the packaging. Subpart H of 10 CFR 71, specifies that QA programs of licensees, certificate holders, applicants for a CoC, and packaging users must satisfy each of the applicable criteria specified in 10 CFR 71.101 – 71.137 to an extent that is consistent with their importance to safety.

Subpart H of 10 CFR 71 establishes QA requirements for design, procurement, fabrication, inspection, testing, assembly, handling, storing, maintenance, repair, and modifying packaging components that are important to safety. In order to satisfy requirements for the above activities, the licensee, certificate holder, applicant for a CoC, or user should control the quality of each of the above activities using a graded approach. The QA effort expended should be consistent with the importance to safety for structures, systems, and components. A method for developing a graded approach is contained in Appendix A of RG 7.10. In addition, NUREG/CR-6407, *Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety*, provides additional guidance for application of the graded approach. Each DOE entity must submit a description of its QA program for packaging with an explanation of which Subpart H requirements apply and how those requirements will be satisfied. The user of the QA program should address the regulations delineated in Subpart H to the extent applicable to their respective operations. The types of activities that a DOE entity engages will determine which sections of Subpart H apply to their QA program.

The quality assurance (QA) requirements in this guidance are applicable to all activities associated with packaging and transportation (P&T) of radioactive and fissile materials. These activities can be performed, in whole or part, by a licensee; certificate holder; certified packaging user; QA program approval holder; applicant (for a license, certificate or QA program approval); or their contractors, subcontractors, or employees. For the sake of simplicity in this Guidance, any of these entities is referred to as "QA program user", matching the terminology of the RG 7.10.

Among all the QA program users, the end user of a certified packaging is of particular interest. This user performs no design, fabrication, testing, modification, or maintenance work, but rather the packaging is leased to transport radioactive and fissile materials. The QA program of such a user should be simple and easy to implement because it does not have to meet all 18 QA Criteria due to the limited scope of work. In Part 2 of this Guidance, a particular focus on this user is provided to outline the simple QA program.

The 18 QA Criteria of 10 CFR Part 71, Subpart H, are presented in Part 2. The requirements of each QA criterion are summarized, and implementation strategies to meet the requirements are outlined. The objective is to provide practical means to meet these requirements and satisfy the need for consistent, systematic implementation of QA programs. For the user who leases a packaging, applicability of the requirements is discussed to help outline a simplified QA program. In addition, lessons learned from recent QA audits and certification processes are listed under each criterion.

QA program users should be aware the QA regulations in 10 CFR Part 71, subpart H, include requirements not fully addressed by other standards and regulations. In general, programs based on or 10 CFR Part 830, *Nuclear Safety Management, Quality Management System-Requirements*, will require supplementation to address all Subpart H regulations. Appendix A of this Guidance provides a matrix of comparison and gap analysis between the two sets of QA criteria. The matrix can be used as a tool in determining the supplementation required.

A similar statement can be made regarding QA programs based on the International Organization for Standardization (ISO) 9001, *Quality Management System (QMS) - Requirements*. NRC SECY-03-0117 provides comparison and gap analysis between the two programs (the 18-criteria program and ISO-9001 program). The attachment to SECY-03-0117 is included in Appendix B of this Guidance to help the reader determine the supplementation required.

In general, programs based on the American Society of Mechanical Engineers (ASME) NQA-1, *Quality Assurance Requirements for Nuclear Facility Applications*, may require supplementation in order to address all Subpart H regulations. The only exception is the 1983 revision of NQA-1, endorsed by the NRC in its entirety per RG 1.28, *Quality Assurance Program Requirements (Design and Construction)*.

For the interested reader, ASME NQA-1-2008, Subpart 4.3, *Guide to Modification of an ISO 9001-2000 Quality Program to Meet NQA-1–2000 Requirements*, provides a

detailed comparison of the ISO-9001-2000 and NQA-1 and a gap analysis to determine the extent of required supplementation.

# 2.0 Part 2: Requirements, Implementation Strategies, and Lessons-Learned

The contents of Part 2 of this guidance follow the outlines of NRC Regulatory Guide (RG) 7.10 that discuss the 18-point QA program. The18 QA Criteria are presented in discrete sections. Each section has four subsections: *Requirements, Applicability to Packaging User, Implementation Strategies, and Lessons-Learned*. The *Requirements* subsection is per 10 CFR Part 71, Subpart H, and RG 7.10, and it is applicable to the general QA program user. The *Applicability to Packaging User* focuses on a user who leases a certified packaging and who performs no design, fabrication, modification, or maintenance work. The *Implementation Strategies* provide the reader with practical, non-mandatory means on how to meet these requirements. The readers may choose any of these means or develop others that meet their needs while still complying with the requirements. The *Lessons-Learned* are from relevant experiences in preparing Chapter 9 of SARPs and auditing QA programs.

The general QA program user may perform P&T activities such as design, procurement, fabrication, assembly, testing, modifications, and use of materials and components of packaging. These activities should follow a graded approach using quality categories and realistic quality requirements. A logical sequence leading to identifying realistic requirements would involve (1) classifying each structure, system, and component (SSC) as “important to safety” or “not important to safety” (“Q” or “non-Q”); (2) grouping items classified as important to safety into quality categories A, B, or C; and (3) specifying the applicable level of QA effort for each category in accordance with NRC Reg. Guide 7.10 and NUREG 6407. Typical Level of QA Effort for the three categories is presented under *Implementation Strategies* in each of the 18 sections of this part.

The categories A, B, and C are based on the impact to safety if the component were to fail or perform outside of its design basis conditions.

Category A Items and services are critical to safe operation and include SSCs whose single point failure could directly result in a condition adversely affecting public health and safety. The failure of a single item could cause loss of primary containment leading to a release of radioactive material beyond regulatory requirements, loss of shielding beyond regulatory requirements, or unsafe geometry compromising criticality control.

Category B Items and services have a major impact on safety and include SSCs whose failure or malfunction could indirectly result in a condition adversely affecting public health and safety. The failure of two Category B items could cause the loss of primary containment leading to a release of radioactive material beyond regulatory requirements, loss of shielding beyond regulatory requirements, or an unsafe geometry compromising criticality control

Category C Items and services have a minor impact on safety and include SSCs whose failure or malfunction would not significantly reduce the packaging effectiveness and would not be likely to create a situation adversely affecting public health and safety.

## 2.1. Criterion I: *Quality Assurance Organization*

## Source: Title 10 CFR 71.103

The organizational structure for executing the quality assurance program may take various forms, provided the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom.

### Requirements

1. Document a formal structure of the organization using organization charts that identify each organizational element that functions under the QA program. Ensure adequate resources are provided to obtain desired results.
2. Specify authorities and responsibilities. For the elements performing QA functions, ensure organizational freedom and sufficient independence from influences of cost and schedule.
3. Establish and document the required duties and qualifications for individuals performing QA functions, and obtain a written endorsement of top management for these individuals.
4. Establish a written corporate policy, endorsed by president or chief executive officer, stating that work on items important to safety must be performed in accordance with the requirements described in the QA program plan and its implementation documents.
5. Identify the functions and positions who have delegated authority for implementing and revising the provisions of the QA program and regularly assessing the scope, status, implementation, and effectiveness of the program.
6. Establish measures to provide adequate control over activities important to safety (e.g. inspecting, cleaning, and preparing the packaging for delivery).
7. Use individuals and groups that are not directly responsible for performing the work to verify conformance to established requirements.

### Applicability to Packaging User

The user of a certified packaging must comply with the requirements of this section and establish a QA organization in accordance with these requirements. The QA organization can take on various forms and can be reduced to a part-time-person as long as independence, organizational freedom, and personnel qualification are ensured.

### Implementation Strategy

The persons and groups assigned QA functions must have the authority, freedom, and independence required to perform their functions. They must also have management

support and the needed skills, resources, and tools. Various degree of independence can be achieved based on the type of the QA activity and the size of the organization. If staffing limitations force a few individuals to perform multiple functions, including QA, the following conditions must be met.

- The designated individuals are qualified and have the responsibility and authority to stop unsatisfactory work, delivery, and/or installation of nonconforming material.
- The individuals have direct access to management levels that can ensure that QA procedures important to safety are completed.
- The individuals' management documents and approves, in advance, the need to perform multiple functions.
- The QA audits cover the effectiveness of the use of these individuals to perform QA functions.
- The individuals must be independent of the work being evaluated.

An organization chart, such as the one shown in Figure 2.1-1, should be provided to depict the responsible QA groups and/or functions and their relationship with the packaging designer. Figure 2.1-1, as an example, shows Engineering, Procurement, and Operations organizations. Each of the three organizations has a QA group that is shown to be independent from the P&T Engineering. The P&T activities of these groups may include audits, surveillance, inspection, and review and approval of documentation. In addition, the user's organization may be the packaging "Design Authority". It is essential that the roles, responsibilities, and required qualification of each group be specified in order to avoid conflict, duplication of effort and ineffective use of resources.

Figure 2.1-2 is another example of an organization chart showing a QA Group that is independent from the designer in the Engineering organization.

QA program users should be aware the QA regulations in 10 CFR Part 71 include requirements not fully addressed by other standards. For this reason, a table comparing the user's QA program to the 10 CFR Part 71, Subpart H, program elements can be beneficial in demonstrating compliance with the requirements of the 18-point QA program. The table must address all 18 points of Subpart H individually.

A written corporate policy, signed by the company president, should be issued to all groups. The policy should emphasize the company commitment to the QA program and stress the need for complying with the program requirements.

The periodic assessments of the QA program status and effectiveness can be performed by an independent group from within the company or outside consultants. The group authority required to perform the assessment and implement revisions to the program should be specified and made known to all concerned parties. The period and scope of the assessment should also be specified.

Controls over activities important to safety can be provided by a set of procedures and a clearly defined process to develop, revise and implement the procedures. Each procedure should identify the responsible groups and persons, by functions and positions, and should specify their roles and responsibilities.

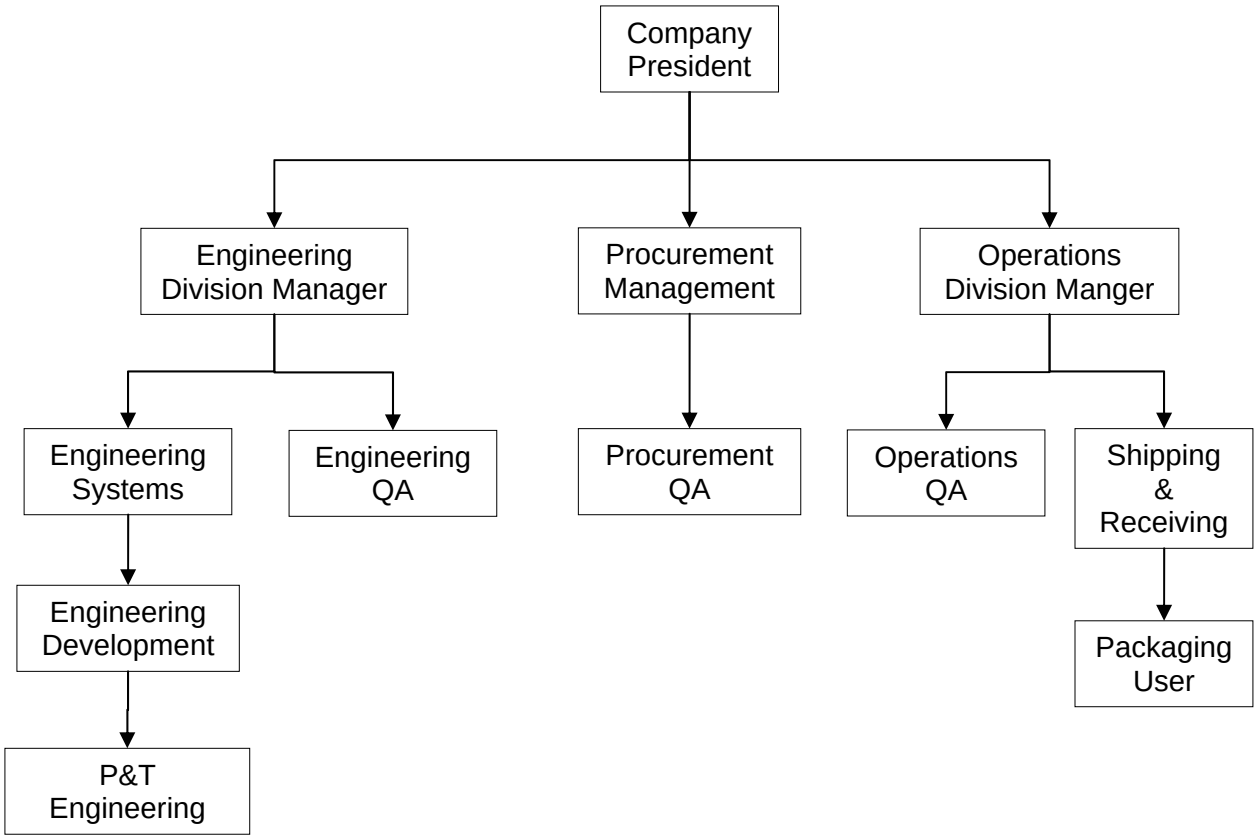


**Figure 2.1-1 Quality Assurance Organization (typical)**

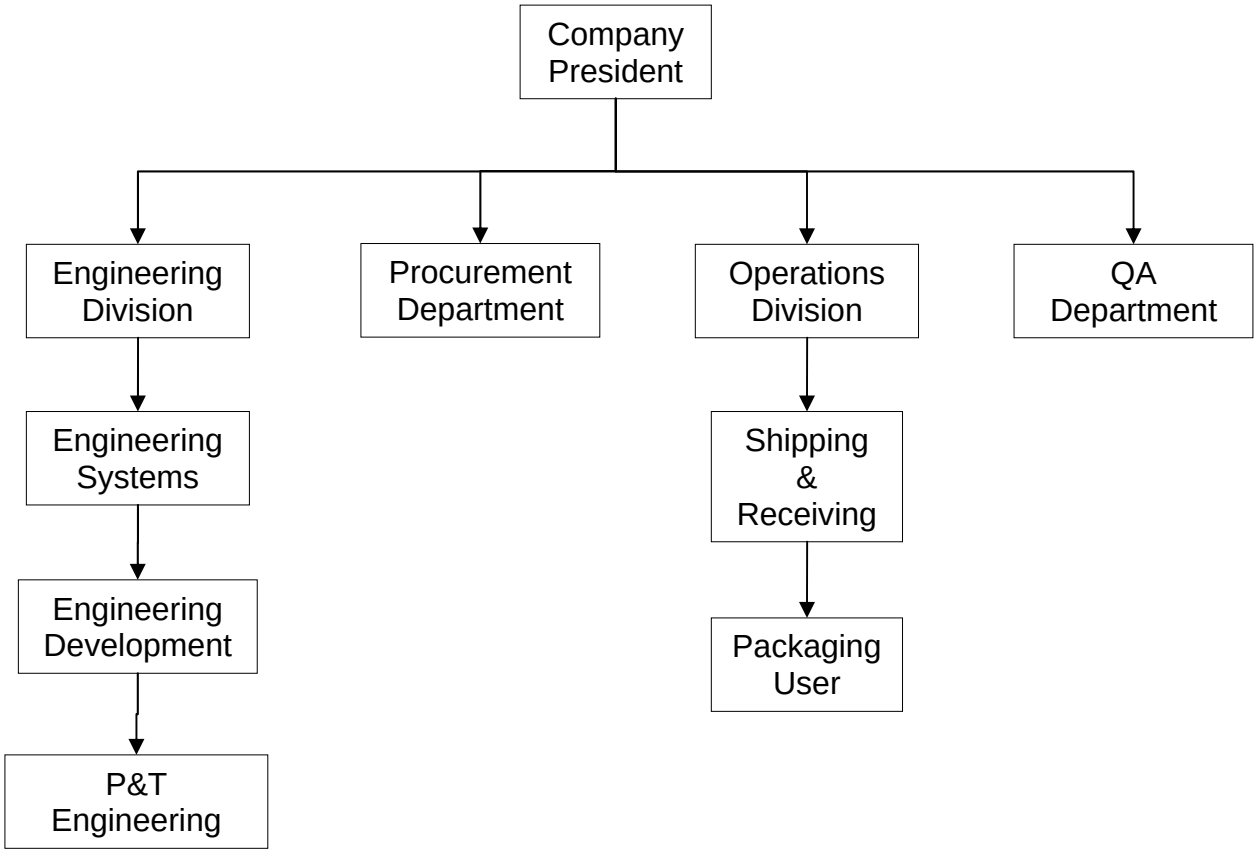


**Figure 2.1-2 Quality Assurance Function in One Department (typical)**

Conformance to established requirements can be achieved by formal reviews of related documents. The persons conducting the reviews must have no involvement in performing the work under review.

Packaging items important-to-safety are classified as Category A, B, or C. The level of effort listed in Table 2.1-1 should be commensurate with each category importance to safety.

**Table 2.1-1 QA Categories and Applicable QA Elements for Criterion I**

| QA Element/Level of Effort | Category A | Category B | Category C |
|---|---|---|---|
| I. QA Organization | | | |
| Responsibility established | X | X | X |
| Authority and duties written | X | X | X |
| QA functions executed | X | X | X |
| Reporting levels clearly defined | X | X | X |
| Independence from cost and schedule assured | X | X | X |
| Independence of quality achievers vs. verifiers | X | X | X |
| Management Endorsement | X | X | X |

## Lessons-Learned

- ✓ Any organization may delegate to others, such as subcontractors, the work of establishing QA plans, but the organization must retain responsibility for the plans.
- ✓ The persons and organizations performing QA functions should report to a management level ensuring the required authority and organizational freedom is provided. By reporting to a level of management that is higher than the management of the entity performing the work, freedom and independence can be assured.

## 2.2. Criterion II: *Quality Assurance Program*

## Source: Title 10 CFR 71.105

The QA program description should identify how each criterion in 10 CFR Part 71, Subpart H, applies to a particular organization and how those regulations will be satisfied. The individual QA program description will vary depending on the activities for the responsible organizations. For example, an organization that only leases a packaging will only address a limited number of criteria in Subpart H. On the other hand, an organization that is responsible for design, fabrication, assembly, testing, repair, and modification will be required to address each of the 18 criteria in Subpart H.

The QA program description should not contain either too little or excessive information. Relative to providing too little information, the QA program description should not merely restate the applicable criteria from Subpart H. However, the QA program description should not be excessively detailed as to include implementing procedures.

In general, the criteria common to most QA program descriptions for packaging users includes: Organization, QA program, procurement activities, control of nonconforming items, corrective actions, QA records, and audits. In some cases, a packaging user may procure a packaging for a single shipment. Should the DOE entity's QA program description not encompass the single shipment, the packaging user will be required to submit a QA program description for this single shipment. Typically, a licensee, certificate holder, or an applicant for a CoC is required to provide a QA program description that includes all 18 criteria from Subpart H of 10 CFR 71. In most cases the QA program description will include all Type B and fissile material packaging for a particular DOE entity.

The inclusion of excessive detail will result in less flexibility and additional submittals to DOE PCP for approval. As an example for developing the QA program description for the Measuring & Test Equipment criterion, the program description should typically include the following requirements for calibration of Measuring & Test Equipment (M&TE) as follows:

- Label or tag M&TE to indicate the new planned calibration date.
- Identify, maintain, and store calibration records as QA records.
- Establish measures to ensure that in-house reference or transfer standards used in calibrating M&TE are traceable to nationally recognized standards. If no known recognized standard exists, document basis for calibration.
- Validate previous inspection and test results up to the time of previous calibration when M&TE is found to be out of calibration. Repair or replace any measuring equipment that is consistently out of calibration.

Any changes to the DOE PCP approved QA program description must be submitted to the DOE PCP for review and approval by the DOE Headquarters Certifying Official prior to implementation.

Information for submitting QA Program Descriptions for review by the DOE PCP and approval by the HCO is available on the RAMPAC website (http://rampac.energy.gov/hco_qap.htm)

## Requirements

1. Establish rational to identify items and activities that are classified as important to safety and subject to the user's QA program.
2. Implement each of the applicable Subpart H regulations in a graded approach to an extent that is consistent with its importance to safety.
3. Establish measures for identifying (1) the SSC to be covered by the QA program, and (2) the approach for verifying that these SSC meet design objectives.
4. Establish measures to ensure that (1) activities important to safety are performed using specified equipment and under suitable environmental conditions, (2) QA/QC manuals specify the designated QA and QC responsibilities for performing these activities, and (3) indoctrination and training programs are established to qualify personnel and maintain proficiency to perform these activities.
5. Written procedures and instructions must describe all activities that are important to safety and are applicable to the design, procurement, fabrication, and testing of packaging. The procedures and instructions must be in place before engaging in those activities.
6. Establish measures to address the use, management, and storage of electronic records and data.
7. Establish intervals/frequency to review the status and adequacy of the QA program.

## Applicability to Packaging User

The end user does not perform any design, procurement, fabrication, modifications, or maintenance activities but rather operates the packaging. The user performs activities important to safety such as unloading, loading, leak testing, and handling the package. To this extent, the user must have a QA program that complies with the requirements of this section, except for Requirement No. 3. Also, portions of Requirement 5 associated with design, procurement and fabrication do not apply to this user. If the user replaces packaging gaskets, then requirements associated to procurement may apply. In either case, the user is expected to develop a QA management plan and personnel qualification program.

## Implementation Strategy

The key points of a QA program are to plan what must be accomplished, outline a process on how to accomplish it, develop written procedures to ensure personnel follow the plan and complete the work as intended, and train and qualify these personnel prior to performing any QA-related work.

A company-level (or program-level), QA management plan that is, at a minimum, based on the requirements of DOE Order 414.1C and 10 CFR Part 830 is essential to any QA program. A company-level (or program-level) QA manual would describe the QA program and demonstrate that it complies (or contains supplemental controls that maintain compliance) with Subpart H of 10 CFR Part 71. The Manual should outline a process and provide procedures to be used by line organizations to develop implementation procedures. The interrelationship among these documents can be best illustrated by a figure, such as Figure 2.2-1.

The QA management plan should declare that an assessment of the proper implementation, adequacy and effectiveness of the QA program will be performed at least annually, and the results will be reported to management.

The creation of a master index of QA procedures related to all activities important to safety as well as a matrix of the QA procedures that implement each section of Subpart H should be developed and would greatly facilitate the review and approval of the QA program. The procedures should be identified by title and procedure number, and brief descriptions of their contents should be provided.

Personnel who perform P&T activities important to safety, such as inspections, tests and examinations, must be qualified in accordance with applicable requirements, including specific provisions for education and/or experience.

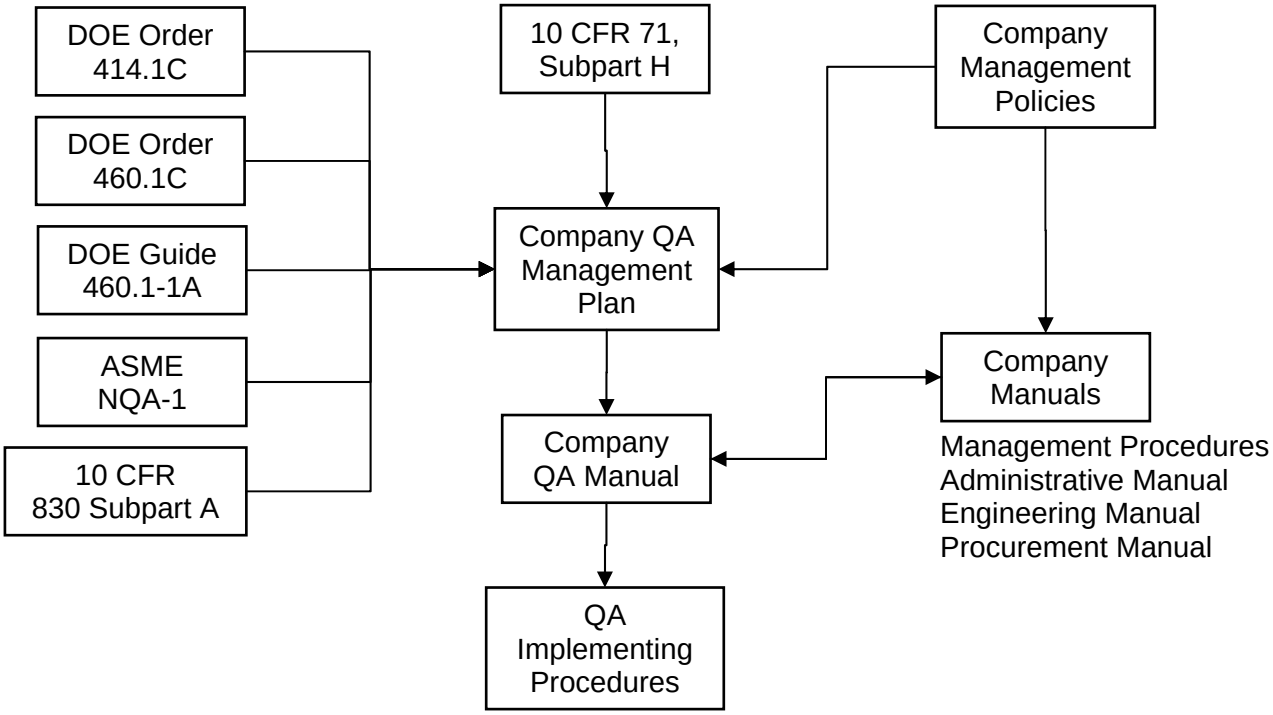


**Figure 2.2-1 Quality Assurance Program Document Hierarchy (typical)**

The QA program should implement a graded approach per 10 CFR Part 71, Subpart H, using quality categories in order to identify realistic quality requirements for each P&T activity. Each item and service should be classified as "important to safety" or "not important to safety" ("Q" or "non-Q" item). The Q Items would be subject to the formal QA program requirements, while the Non-Q Items would be subject to "best management practices". This classification can be accomplished by following a documented process and written procedures that provide basis and rational for the classification. Then based on their relative significance to safety, the Q-items and services should be grouped into quality categories (A, B, and C) that can be used to implement the graded approach. The basis and rational behind this grouping should be documented as well. The level of effort listed in Table 2.2-1 should be commensurate with the impact to safety of each category.

**Table 2.2-1 QA Categories and Applicable QA Elements for Criterion II**

| QA Element/Level of Effort | Category A | Category B | Category C |
|---|---|---|---|
| II. QA Program | | | |
| Procedures written | X | X | X |
| Activities affecting quality controlled | X | X | X |
| Graded approach established | X | X | X |
| Indoctrination and training provided | X | X | X |

## Lessons-Learned

- ✓ Personnel qualification programs should include documentation of personnel capabilities as well as evidence of maintenance of proficiency based on retraining and continued satisfactory performance. Operator's training in the use of packagings should be documented and maintained in the operators' training files. The conduct of the training and contents of the files should be monitored and reviewed by qualified, independent personnel, at least annually, who will report to management that is independent of the operation being monitored.
- ✓ The required personnel training should be accomplished before the personnel engage in functions affecting important-to-safety items and activities.

## 2.3. Criterion III: *Package Design Control*

## Source: Title 10 CFR 71.107

The implementation of QA requirements to packaging SSC should be commensurate with their safety significance. It is essential that engineering personnel perform a systematic analysis of these SSC to assess the consequences to the health and safety of the public and the environment that would result from malfunction or failure of such items. This engineering assessment and development of the QA program should be initiated as early in the design process as practicable and should be in accordance with approved procedures.

Essential elements of adequate design control are (1) effective relationships among those responsible for preparing design disclosures, (2) independent design reviews and analyses, (3) Efficient interface coordination, and (4) effective lines of communication. The packaging design should be supported with adequate tests and analysis, and the design should be challenged by qualified independent reviewers.

The requirements of this section are not applicable to end users of packaging who do not perform design activities. However, such users should establish and verify that the packaging was designed under the control of an approved QA program.

### Requirements

1. Establish QA procedures to address the control of electronic data in design applications and ensure authenticity and technical accuracy.
2. Establish measures to ensure that packaging designs are reviewed to emphasize critical parameters that can be controlled by inspections or tests and to identify test and inspection criteria and quality standards.
3. Establish measures for the identification and control of interfaces and for coordination among participating design organizations.
4. Implement recognized engineering practices, such as prescribing drafting room standards, checking methods, establishing review/approval and issuance/distribution requirements (including revisions to them), maintaining current “as-built” configurations, and storing and controlling original and master copies.
5. Ensure that appropriate codes and standards are used in the design of the packaging.
6. Establish measures to ensure that (1) the responsible design organization has properly considered, reviewed, and approved all design parameters (e.g., criticality safety, cooling, and decontamination of an item); (2) the parameters are in accordance with the applicable performance codes, standards, and regulatory

requirements; and (3) design documents specify the related maintenance, repair, in-service inspection, handling, storage, and cleaning requirements.

7. Establish methods for use in verifying the adequacy of the design (e.g., qualification testing, design review, or alternative calculations, including use of computer programs). The verification must be done by individuals or groups other than those who performed the design work.
8. Drawing and specification changes must be reviewed and approved by the same individuals or organizations that reviewed and approved the original documents.
9. Ensure that design verification be satisfactorily completed prior to (1) release for procurement or fabrication and (2) release to other organizations for use in other design activities. If this timing cannot be met for portion of the design, verification may be deferred, provided that the justification for this action is documented and the unverified portion of the design output documents are appropriately identified and controlled.

## Applicability to Packaging User

None of the "design control" requirements is applicable to the packaging end user because this user does not perform any design work but rather leases an already certified packaging.

## Implementation Strategy

The implementation strategy must ensure that (1) the packaging design is defined and controlled, and its adequacy is verified; (2) design inputs are specified and documented; (3) design interfaces are identified and controlled; and (4) design changes are controlled and approved in accordance with established configuration management process.

Different organization may be involved in the packaging design process. The design roles and responsibilities of each organization should be clearly specified. A process should be outlined, and written procedures should be developed and applied to identify and control interfaces and coordinated work among these organizations. One of these organizations should be designated as the "Design Agency" and be assigned the responsibility of controlling the design in order to prevent any unauthorized, unanalyzed, or untested changes to the design inputs or outputs. Similar control should be specified for computer software and electronic data used in the packaging design.

The written procedures should establish requirements for the review, approval, release, distribution, and revision of design documents. They should also ensure that these documents specify required maintenance, repair, in-service inspection, handling, storage, and cleaning of packaging components important to safety. Requirements for maintaining as-built documents and for storing and controlling original copies should also be specified.

Design review and verification should be performed in accordance with clearly defined processes and written procedures. Verification methods should include alternate calculations, benchmark testing and independent reviews. The processes should require verification be completed prior to release and should outline a path with appropriate conditions for any exception. If verification involves inspection and testing, acceptance criteria and quality standards should be specified and used. The groups of individuals conducting the reviews and verifications should be identified, and their independence from those who performed the design work should be demonstrated, especially for Category A and B.

The designer's immediate supervisor may perform the verification provided that the supervisor is the only technically-qualified individual, the supervisor does not participate in the design work, the supervisor's management documents and approves this action in advance, and the QA audits cover the effectiveness of this action.

The application of Quality Assurance Controls on the Design phase of a radioactive material (RAM) packaging is a multi-level effort. The initial phase establishes the Quality Assurance Categories for the various components and leads to the three failure based designators of A, B or C in accordance with NRC Reg. Guide 7.10, *Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material*, and NUREG 6407, *Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety*.

The set of codes and standards used in the design of packaging components important to safety (mainly, category A and B) should be specified, and details of the design, fabrication and testing criteria should be provided. The versions of these codes and standards should also be defined. The design analysis, fabrication, inspection and testing should be based on the same set and versions. In the absence of such codes and standards, alternative approaches should be identified. Note that guidance has been provided in NRC Reg. Guide 7.11 and NUREG CR-3854 regarding applicability of the Sections of the ASME Code to design aspects such as containment, criticality control, and other safety related systems. The QA program user should be aware of the variations in bases between the ASME Section III and Section VIII. One is based on design by analysis while the other relies on design by rule.

The designer should have provisions within their QA program which addresses commercial grade dedication (CGD). CGD is process whereby a commercially available part or component undergoes evaluation and verification such that it is deemed appropriate for a safety grade application.

The designer needs to address auxiliary equipment such as overpacks and impact limiters which may not be addressed by a national standard comparable to the ASME code for pressure vessels.

The application of computer software in the development of the package should be addressed in the QA program. This would include the maturity and techniques for software used for analysis/design. The QA program user should provide for the use of

industry recognized software with well documented verification/validation documentation as appropriate. The user should consider any limitations associated with the software including the appropriateness of modules for discrete analysis.

As part of the graded approach, Table 2.3-1 illustrates typical Level of QA Effort by Quality Category for the *Packaging Design Control*.

**Table 2.3-1 QA Categories and Applicable QA Elements for Criterion III**

| QA Element/Level of Effort | Category A | Category B | Category C |
|---|---|---|---|
| III. Packaging Design Control | | | |
| Most stringent codes and standards | X | | |
| Codes and standards | | X | |
| Prototype test and/or analysis | X | X | |
| Formal design review (Independent for Cat A&B) | X | X | |
| Internal peer review | X | X | |
| Software QA | X | X | |
| Off-the-shelf items | | | X |
| Conditions of approval controlled | X | X | X |

## Lessons-Learned

- ✓ The type, quantity, or configuration of materials to be shipped may require a packaging that is different from what the user already has. Designing a new packaging is not likely to be the user's preferred option due to the cost and schedule required to perform the design and certify a new packaging. Rather, the user may search the RAMPAC database for a packaging currently certified for the exact materials and configurations. If unsuccessful, then perhaps a packaging certified for similar material type, quantity and configuration could be found. In this case, an addendum or amendment to the packaging SARP and CoC may be necessary. If all fail, the user may be forced to design a new packaging in accordance with the requirements of 10 CFR Part 71.
- ✓ When a test program is used to verify the adequacy of a design, the prototype should be subjected to the most adverse design conditions coupled with the most adverse loading. A test plan should be written and approved. The tests to be performed should be identified, and the test configuration should be described

explicitly. Test results should be documented, reviewed, and approved to ensure that the test requirements have been met.

- ✓ The Design Team should be involved in the testing to ensure the test packaging configuration is adequately represented in their computer models.
- ✓ Nondestructive examination (NDE) may be required on materials of construction of packaging components. The ASME Section III may require NDE on the base material which may exceed and therefore be considered as supplemental requirements to those specified in ASME Section II. Furthermore, materials acceptable for an ASME Section VIII application may not be permitted in a comparable Section III safety application.
- ✓ The appropriateness of welding, including joint configuration, should be considered, and the related inspection criteria, including NDE if applicable, should be specified. The need for appropriately trained and certified NDE personnel should be defined. The inspections and tests required during fabrication should be specified including provisions for independent personnel to witness these activities. The sequence of testing should be defined in appropriate design documents, (drawings, specifications etc.).
- ✓ The QA program user should flow down applicable QA requirements to the supplier and subtler suppliers.

## 2.4. Criterion IV: *Procurement Document Control*

## Source: Title 10 CFR 71.109

The preparation, review, concurrence, and approval of all procurement documents must be controlled per established processes and procedures. These documents must specify necessary and sufficient items and services that are needed for the task and the requirements that each item or service must satisfy.

### Requirements

1. Ensure that procurement documents include the following information (as applicable):
   - 1.1 The scope of work to be performed by the prospective supplier.
   - 1.2 The design-basis technical requirements, including applicable regulatory requirements, material and component identification requirements, drawings, specifications, codes and standards, special process instructions, and test and inspection requirements and acceptance criteria.
   - 1.3 Applicable QA requirements that should be complied with and described in the supplier's QA program. The extent of these requirements depends on the particular item or service being procured.
   - 1.4 Permission to gain access to the supplier's and sub-tier supplier's plant facilities and records for inspection and audit purposes.
   - 1.5 Identification of the documentation (e.g., drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, personnel and procedure qualifications, results of chemical and physical tests on material) that the supplier(s) must prepare, maintain, and submit to the purchaser for approval.
   - 1.6 Requirements for reporting and approving disposition of non-conformance items.
   - 1.7 Identification of records that the supplier must retain, control, and maintain, as well as those records that the supplier must deliver to the purchaser prior to installation of hardware.
2. The procurement of replacement parts important to safety must be reviewed by QA personnel to ensure that appropriate technical and QA requirements are included in purchase orders.
3. Ensure that review and approval of procurement documents are recorded prior to release, and that changes and revisions to those documents are subject to at least the same review and approval as the original documents.

## Applicability to Packaging User

The applicability of the requirements of this section to the end user is limited to preparing and maintaining specifications describing the rented/leased packaging. In this regards, Requirements No. 1 and 3 are applicable. Specifications should be used as part of the requisition to identify the user's requirements including codes and standards and any special conditions. The specifications should prescribe necessary requirements for inspections, testing, shipping and handling, and any other related QA requirements. If the user purchases consumable items such as packaging gaskets, then gasket procurement document must comply with the requirements of this section.

## Implementation Strategy

A company-level (or program-level) procurement manual can be used to outline a process and identify written procedures that can be used in the procurement of items and services important to safety. A graded approach can be implemented based on the QA category (A, B, or C). Items and services that are critical to safe operation must be subject to the most stringent quality requirements and controls.

The procurement process and written procedures should direct the company/program to evaluate suppliers, including sub-tier suppliers, and assess their ability to meet the QA program requirements specified in the purchase requisition. As part of the graded approach, the extent of assessment against the QA requirements depends on the particular item or service being procured.

Procurement specifications should be used as part of purchase requisitions to identify applicable requirements including codes and standards, any special conditions and the use of off-the-shelf items. The specifications should prescribe necessary requirements for inspections, testing, shipping and handling and any other related QA requirements. Prior to fabrication of any item or delivery of any service, the supplier must have in place a QA program that includes the elements specified in the purchase requisition. The requisition should be reviewed and approved by the Design Authority, the end user, and independent QA group.

The QA program should have provisions to reconcile differences between specified items and those fabricated in accordance with different standards.

Typical Level of QA Effort by Quality Category for the subject QA element is shown in Table 2.4-1.

**Table 2.4-1 QA Categories and Applicable QA Elements for Criterion IV**

| QA Element/Level of Effort | Category A | Category B | Category C |
|---|---|---|---|
| IV. Procurement Document Control | | | |
| Traceability | X | X | |
| Qualified vendor lists | X | | |
| Suppliers required to meet Subpart H | X | X | |
| Off-the-shelf items | | | X |

## Lessons-Learned

- ✓ Procurement documents should identify the type of verification activities required of any sub-tier suppliers for supplied materials (e.g. validation of sub-tier supplier certificate of conformance), as well as for any design, fabrication, assembly, testing, maintenance, and repair services or activities supplied.
- ✓ Suppliers' records should include the pertinent documentation to be furnished with the procured materials or services such as certificates of conformance, as-built drawings, photographs, sketches, and user and maintenance manuals. These records should be easily retrievable for review. If the pertinent documentation is in an electronic format, the user should specify the software system that must be used to prepare and deliver the documentation.
- ✓ Purchase requisitions of replacement parts important to safety should be placed with suppliers previously qualified during fabrication of the packaging. If replacement parts are purchased from suppliers not previously identified as qualified sources, the user must ensure that the replacement parts meet requirements at least as stringent as the original criteria.
- ✓ In case the same exact part cannot be found, the Design Authority, with help from QA personnel, must select another part that is equivalent, (i.e. capable of performing the same functions and meeting the same requirements), or document the differences and justify the new part's acceptability. For items important to safety, the DOE Headquarters Certifying Official must authorize substitute, equivalent parts prior to use.

## 2.5. Criterion V: *Instructions, Procedures, & Drawings*

## Source: Title 10 CFR 71.111

Activities important to safety must be prescribed and accomplished in accordance with current documented instructions, procedures, or drawings that have been approved by appropriate levels of management.

### Requirements

1. Specify in instructions, procedures, and drawings the methods for complying with each of the applicable QA requirements.
2. Coordinate with QA personnel to ensure that the work controlling documents incorporate appropriate inspection and hold points to verify that initial work, planned work, effective repairs, or rework have been performed satisfactorily.
3. Include quantitative acceptance criteria (e.g., dimensions, tolerances, and operating limits) and qualitative acceptance criteria (e.g., workmanship samples) in instructions, procedures, and drawings to verify that activities important to safety have been satisfactorily accomplished.
4. Address the use, management, storage, and protection of electronic records and data in written procedures. Also, information on the specific software applications and storage or computing hardware must be properly maintained.
5. Establish measures to ensure that the QA organization reviews and concurs in inspection plans, test and calibration procedures, special process procedures and specifications as well as any changes thereto.

### Applicability to Packaging User

The packaging end user typically performs activities important to safety such as unloading, loading, closing, leak testing, and handling the package. These activities must be performed per written instructions and procedures as Requirement No. 1 of this section specifies. The instructions and procedures must include acceptance criteria, such as operating limits, in accordance with Requirement No. 3. Inspection plans and test and calibration procedures must be reviewed and accepted in accordance with Requirement No. 5. Electronic records of these operations must be used, managed and stored per Requirement No. 4. Requirement No. 2 of this section is not applicable.

### Implementation Strategy

Written operating procedures or instructions should be developed and used by the packaging user for activities important to safety such as package unloading and loading, leak rate testing and shipping. The procedures should specify requirements on sequential setups, technical constraints, acceptance criteria and references. Specific

information governing acceptance tests and inspections and maintenance activities associated with each package should also be included.

Written procedures or instructions should also be prepared for repair, rework, modification, and maintenance of each packaging and its components and for obtaining approvals prior to their use. Inspection, testing and independent verification, whenever required, should also be included in the procedures.

The QA program description should include requirements on the packaging design drawings. The "Design Agency" is typically responsible for the preparation of these drawings and their subsequent revisions. There may be two sets of drawings: drawings included in the SARP and fabrication drawings. Typically, the SARP drawings present details that are necessary and sufficient to demonstrate compliance with the requirements of 10 CFR Part 71. Fabrication drawings include additional details necessary to make the parts, such as surface finish, assembly details, and weld details.

Approved procedures, instructions, or drawings should be distributed as controlled documents. Changes to these approved documents require the same level of approval as the initial issue.

Typical Level of QA Effort by Quality Category for the subject QA element is shown in Table 2.5-1.

**Table 2.5-1 QA Categories and Applicable QA Elements for Criterion V**

| QA Element/Level of Effort | Category A | Category B | Category C |
|---|---|---|---|
| V. Instructions, Procedures, and Drawings | | | |
| Written and documented | X | X | |
| Qualitative or quantitative acceptance criteria | X | X | |
| Changes to conditions of approval listed in certificate controlled | X | X | X |

## Lessons-Learned

- ✓ Ensure the flow down of information from the SARP drawings and notes to the procurement specifications and fabrication drawings is complete and accurate.
- ✓ Prior to fabrication of an item, the QA organization should review and concur in the related manufacturing plans, including scheduled witness and hold points during fabrication.

- ✓ Ensure supplier, or sub-tier supplier, generated shop drawings are reviewed by the Design Authority for consistency with the approved fabrication and/or SARP drawings.

## 2.6. Criterion VI: *Document Control*

## Source: Title 10 CFR 71.113

Each of the documents under the QA program should be maintained and controlled to reflect the current status and ensure correct documents are used. As a minimum, the following documents should be included:

- design documents (e.g., drawings, specifications, and computer codes)
- procurement documents
- QA and QC manuals
- operating, maintenance, and modification procedures
- inspection and test plan and procedures
- Test reports/records
- nonconformance reports
- design change requests
- Fabrication records
- Drawings of packages and components
- Shipment documentation
- Certificate of Compliance
- corrective action reports

### Requirements

1. Identify (by function or position) the individuals or groups responsible for reviewing, approving, and issuing documents under the control of the QA program and revisions thereto.
2. Establish controls over documents under the QA program to ensure that each document and revisions are adequately reviewed and approved prior to their issuance.
3. Ensure revisions to documents are reviewed and approved by the same organization that performed the original review and approval and that every change is in accordance with established configuration control procedures.
4. Access to electronic documents must be controlled to ensure that the latest versions of the documents are available and revisions to documents are properly authorized and implemented.

### Applicability to Packaging User

A packaging end user is required to have available prior to use of a certified package current copies of applicable chapters of the SARP (e.g. Chapter 1, 7, 8, and 9), applicable drawings, and DOE or NRC CoC. Also the availability of operating instructions and procedures is required. In this regard, compliance with the four

requirements stated in this section is necessary to ensure availability and use of current approved revisions of these documents.

## Implementation Strategy

As a minimum, the implementation strategy must satisfy the following two requirements: (1) Documents that specify QA requirements must be controlled, and (2) Changes to these documents must be reviewed and approved in accordance with established configuration management process.

A company-level (or program-level) manual should identify the level of organizational elements, such as the department, that has responsibility for the establishment, development, review, approval, distribution, revision and retention of its documents. The defined responsibility should cover documents associated with items or activities affecting quality. Then, departmental procedures should specify the level of control on these documents and personnel responsibilities and qualification requirements, including training. In addition, revisions to these documents must be handled in a manner as the original issue in accordance with established document control procedures. The procedures should include control measures, such as the creation of a master document list, and requirements to ensure that only current approved revisions are available for use at location where the activity is being performed to preclude use of obsolete or superseded documents.

As part of the graded approach, typical Level of QA Effort by Quality Category for the subject QA element is shown in Table 2.6-1.

**Table 2.6-1 QA Categories and Applicable QA Elements for Criterion VI**

| QA Element/Level of Effort | Category A | Category B | Category C |
|---|---|---|---|
| VI. Document Control | | | |
| Controlled issue | X | X | |
| Controlled changes | X | X | |

## Lessons-Learned

- ✓ The QA program user should check every packaging affected by design changes to verify that it is in accordance with the appropriate revision.
- ✓ The software and hardware systems used to store electronic information should be reliable to avoid alteration or corruption of the information.
- ✓ The user should validate and verify that the latest revisions of documents are used, especially for tasks requiring extended period of execution.

- ✓ The Nuclear Information and Records Management Association (NIRMA), American National Standards Institute (ANSI), and the Electric Power Research Institute (EPRI) provide guidance for use in developing QA programs for managing electronic data. In addition, NRC Generic Letter 88-18, *Plant Record Storage on Optical Disks*, and Regulatory Information Summary 00-18, *Guidance on Managing Quality Assurance Records in Electronic Media*, provides guidance on the use of optical disc document imaging systems for retrieving copies of QA records.

## 2.7. Criterion VII: *Control of Purchased Material, Equipment, & Services*

## Source: Title 10 CFR 71.115

The requirements presented in this section ensure that received materials, equipment, and services conform to procurement documents. Only necessary and sufficient QA requirements should be included in these documents.

### Requirements

1. Define pre- and post-award activities, such as meetings and other communications means, to ensure that the supplier understands procurement requirements, including, if applicable, “hold and/or witness points” during manufacturing and testing before shipment.
2. Define the extent to which source surveillance will be performed to ensure conformance with the purchase order requirements.
3. Perform audits of records (along with source surveillance) to ensure that the supplier performed the design and fabrication of packaging under the control of the approved QA program.
4. Define the extent to which inspection will be performed upon receipt of supplier-furnished hardware to ensure that the received items are properly identified and correspond with procurement documentation.
5. The procurement of replacement parts must be done under a QA program that meets the requirements of 10 CFR Part 71, Subpart H. Procurement of non-Q Items can be done under a 10-point QA program (the QA Rule).
6. Establish and implement a process and procedures to ensure the proper disposition of items or services that do not meet procurement requirements. The process should include evaluation of nonconforming items categorized by the supplier, along with technical justification and recommended disposition (e.g., “use as is” or “repair”).
7. Ensure that the supplier furnishes to the purchaser a complete set of records, such as documents required by the SARP or referenced in the CoC, and documents related to the use and maintenance of the packaging.
8. Retain and have available procurement documentation for the life of the packaging plus 3 years.

### Applicability to Packaging User

These requirements may only apply to end users who purchase consumable replacement parts, lease packaging, or contract for services (e.g., leakage testing). Hence, Requirements No. 2 and 5 of this section are not applicable while Requirements

No. 3, 4 and 6 are applicable. Also, this user must have a complete set of records and must retain these documents in accordance with Requirement No. 7 and 8. In addition, compliance with Requirement No. 1 can help the supplier better understands the user's requirements and avoid future pitfalls.

Should this user replace the packaging gaskets, then Requirements 5 would be applicable.

## Implementation Strategy

The implementation strategy focus should be on the control of procured items and services to ensure conformance with specified requirements and on source selection and supplier evaluation to ensure that only approved suppliers are used for Category A items.

Company-level (or program-level) procurement process and procedures should be established and should ensure that purchase requisitions and procurement specifications are complete and accurate and that purchased items and services satisfy the requirements included in these documents. Each procurement step leading to contract award for these items and services should be described, and the organization responsible for that step should be identified. In addition, the procurement process for packaging should incorporate a graded approach based on the Q-categories A, B, and C as outlined in Table 2.7-1.

**Table 2.7-1 QA Categories and Applicable QA Elements for Criterion VII**

| QA Element/Level of Effort | Category A | Category B | Category C |
|---|---|---|---|
| VII. Control of Purchased Material, Equipment, and Services | | | |
| Source evaluation and selection | X | | |
| Inspection at contractor | X | | |
| Formal receiving inspection | X | X | |
| Audits or surveillance at vendor plants | X | | |
| Evidence of QA at contractor | X | X | |
| Objective proof that all specifications are met | X | X | |
| Commercial grade item/services dedication | X | X | |
| Incoming inspection for damage only | | | X |

The procurement process should include provisions for the evaluation and selection of suppliers based on technical considerations, conformance to QA requirements of

10 CFR Part 71, production capability, and past performance. The extent of involvement in this evaluation of the Design Authority and QA personnel should also be defined. Only evaluated and approved suppliers should be allowed to provide Category A items and services.

The procurement process and procedures should require the Design Agency to establish witness and hold points during fabrication. This may include audits and source surveillance to ensure that the supplier is operating under the control of the approved QA program. The hold points, audits, and surveillance should be included in the procurement specifications.

Procurement specifications should include codes and standards requirements and any special conditions requirements. They should also prescribe necessary requirements for packaging inspections, tests, handling, and shipping.

Procurement specifications should identify the set of records to be furnished by the supplier, including the following items, as applicable.

- Welding procedure specifications and welding qualification records (process and personnel)
- Types of inspections and tests to be performed during manufacturing
- Nondestructive examination (NDE) procedures and records as well as personnel qualification records
- Procedures for the control and disposition of nonconformance items

## Lessons-Learned

- ✓ Prior to contract award, the QA program user should resolve (if possible) all unacceptable conditions identified during the bid evaluation. If any unacceptable conditions cannot be resolved prior to contract award, the user should obtain the supplier's commitment that the conditions will be resolved at a mutually agreeable date during the contract period. The user must then follow up to ensure the unacceptable conditions have been resolved as agreed to.
- ✓ Inspection points in the manufacturing process should be defined. They require inspection approval and release by the specifying QA organization prior to further processing.
- ✓ Source surveillance should be performed during fabrication, assembly, maintenance, modification, repair, inspection, testing, and shipment to ensure conformance with the purchase order requirements. The surveillance requirements should specify (1) characteristics or processes to be witnessed, inspected, or verified, (2) documentation required to ensure conformance, and (3) personnel responsible for performing the surveillance and meeting the requirements.
- ✓ When acceptance of a purchased item is contingent on tests after installation in the packaging, the QA program user and item supplier should mutually establish the

relevant acceptance criteria and documentation. Note that this is acceptance testing and is not meant for commercial grade dedication.

- ✓ The use of suppliers with ISO 9001-2000 certification would be appropriate for replacement parts purchased as commercial-grade items. For items important to safety, commercial-grade dedication must be performed under an approved, 18-point QA program.
- ✓ The supplier's records should be retained at the facility and/or site where the material or equipment is used. The set of records should, as a minimum, include:
  - → documentation that identifies material or equipment and the specific procurement requirements (e.g., codes, standards, and specifications met by the items),
  - → documentation that identifies any procurement requirements that have not been met, along with a description of nonconformance items designated "use as is" or "repair",
  - → documentation that the supplied material and equipment meets the applicable procurement requirements prior to installation or use, and
  - → fabrication records that accompanies the packaging during delivery and is received at the destination by the user.

## 2.8. Criterion VIII: *Identification & Control of Materials, Parts, & Components*

## Source: Title 10 CFR 71.117

Measures for the identification and control of materials, parts, and components should provide the means for physical identification (e.g., stamping, tags, labels, or lot-follower cards) and traceability to appropriate documentation (e.g., mill reports, drawings, or specifications) throughout the packaging fabrication, assembly, and use.

### Requirements

1. Establish measures to ensure that materials, parts, and components, including partially fabricated assemblies, are adequately identified to preclude the use of incorrect or defective items.
2. Preclude the use of items for which the shelf life or prescribed operation time has expired (e.g., limited-life items).
3. Establish a process and procedures to facilitate continued processing when required inspections or tests have not been completed in order to maintain physical identity and control over affected materials.

### Applicability to Packaging User

This type of user can rent or lease packagings and is not involved in any fabrication, modification, maintenance or part replacement processes. Hence, the requirements of this section are not applicable to this user. However should this user replace the packaging gaskets, Requirements 1 and 2 would be applicable.

### Implementation Strategy

The implementation strategy should focus on the identification, traceability and control of certain items throughout fabrication, assembly and storage in order to ensure that correct and acceptable items are used as intended. Each QA program user is responsible for identifying these items and the level of control to be maintained. The implementation can follow the graded approach depicted in Table 2.8-1.

**Table 2.8-1 QA Categories and Applicable QA Elements for Criterion VIII**

| QA Element/Level of Effort | Category A | Category B | Category C |
|---|---|---|---|
| VIII. Identification and Control of Materials, Parts, and Components | | | |
| Positive identification and traceability | X | | |
| Identification and traceability to heats, lots, or other groupings | X | X | |
| Identification to end use drawings | | | X |

Containment vessels (both primary and secondary) are Category A items. Each should be identified with a drawing number, revision number and individual serial number. The serial number should be permanently marked onto the vessel surface.

For any packaging component that does not meet specified requirements, a non-conformance report (NCR) must be prepared and issued, and the item must be appropriately tagged and segregated until disposition. Replacement parts must be identified in a similar manner as the original component to ensure correct usage.

## Lessons-Learned

- ✓ Means of marking should not be detrimental to the component being marked.
- ✓ Actions should be taken to ensure that identification of stored items is not lost as a result of handling, aging, corrosion, or mildew of either markings or records.
- ✓ Fabrication markings should be reviewed and approved by the Design Authority, with respect to the type of marking (e.g., vibroetch, ink, etc.) and location on the component, to ensure the marking type is chemically and mechanically compatible with the component material and the marking location does not interfere with the function of the packaging.

## 2.9. Criterion IX: *Control of Special Processes*

## Source: Title 10 CFR 71.119

Special processes (e.g., welding, heat treating or nondestructive testing) are performed during fabrication and occasionally during maintenance. These processes must be controlled in accordance with the following requirements:

### Requirements

1. Procedures, equipment, and personnel must be qualified in accordance with applicable codes, standards, and specifications.
2. The operations must be performed by qualified personnel and accomplished in accordance with written process or procedure sheets that direct the recording of evidence of verification.
3. Qualification records of procedures, equipment, and personnel must be created, filed, and kept current.

### Applicability to Packaging User

These requirements may only apply to an end user when a packaging has a welded closure (e.g., disposable packaging).

### Implementation Strategy

The implementation strategy must ensure that special processes are performed by qualified personnel using approved, written procedures to meet specified requirements.

During fabrication, welding, Weld radiography, and examination of the weld area and heat-affected zone are examples of these special processes. Independent inspectors can be contracted to verify, during fabrication at the vendor, the dimensions of the welded components, the welding process (i.e., welder qualification records, weld procedure qualifications, inspection of the welds and review of the weld records, including any repairs), and other activities as required by the procurement documents. Acceptance criteria are needed by the inspectors in order to determine that the specified requirements are met. Such verification can be performed in accordance with the graded approach of the Table 2.9-1.

**Table 2.9-1 QA Categories and Applicable QA Elements for Criterion IX**

| QA Element/Level of Effort | Category A | Category B | Category C |
|---|---|---|---|
| IX. Control of Special Processes | | | |
| Welding, heat treating, and NDE performed with qualified/certified personnel and procedures | X | X | |
| Qualification records and training of personnel | X | X | |
| Only specified critical operations by qualified personnel | | X | |
| No special processes | | | X |

## Lessons-Learned

- ✓ It may be necessary for the Design Authority to review and approve written procedures as well as personnel qualification for special processes.
- ✓ When a weld is ground to remove excess material from the weldment, ensure the weld is not ground below the base metal surface and the weldment meets the minimum wall thickness required.

## 2.10. Criterion X: *Internal Inspection*

## Source: Title 10 CFR 71.121

A program for inspection of activities affecting quality must be established and executed to verify conformance with specified requirements and documented instructions, procedures, and drawings. Individuals and groups performing these inspections must be qualified and independent from individuals performing the activities.

### Requirements

1. Ensure that inspection procedures, instructions, or checklists are available for each work operation, where necessary to ensure quality.
2. Ensure that inspectors are qualified in accordance with applicable codes, standards, and company training programs and their qualifications are kept current.
3. Ensure inspection personnel are independent from all individuals performing the activity being inspected.
4. Assign appropriate personnel to approve data and ensure that all inspection requirements are satisfied.
5. Identify hold or witness points.
6. Objective evidence of inspection results must be recorded.
7. Outline an inspection program that ensures adequate maintenance of packaging. The program should identify the items to be maintained, criteria for acceptability or replacement, and the frequencies of inspection assigned to each item.
8. Identify prerequisites to be satisfied prior to inspection, including operator qualification and equipment calibration.
9. Identify the standard used as the basis for acceptance where sampling is used to verify acceptability of a group of items.
10. Establish measures to ensure that items important to safety meet the requirements specified on the purchase order when the items are received at the site.
11. Establish measures to ensure that process specifications and their supporting documentation provide for indirect control by monitoring processing methods, equipment, and personnel if direct inspection is impractical.
12. Final inspections must provide for resolution of nonconformance items identified in earlier inspections. The inspected item must be identifiable and traceable to specific records and be adequately protected from physical or environmental damage.
13. Maintain inspection records as QA records to document performance of inspection activities.

## Applicability to Packaging User

This type of user operates the packaging without getting involved in the design, fabrication, modification, or maintenance work. Operation activities include post loading inspection prior to shipment. In addition, Chapter 7 and 8 of the packaging SARP may contain additional inspection to be performed by the user. Therefore, the requirements of this section are applicable to the packaging operation, except Requirement No. 5, 9, 10, 11, and 12. However should this user replace packaging gaskets, then Requirement No. 10 and 12 would be applicable as well.

## Implementation Strategy

The main objective of internal inspection is to make sure that delivered items meet specified requirements before they are installed in the packaging. Fabrication inspections of these items should be conducted by the supplier, and independent inspections of the items should be performed by the Design Authority and/or QA program user. These inspections and associated results should be included in the package documentation record.

It may be necessary for the supplier to have manufacturing and inspection (M&I) plan approved by the Design Authority prior to the start of fabrication. The plan specifies the supplier inspections required to ensure accepted items conform to the design criteria. It provides details on how fabrications and inspections, including in-process inspections, are to be performed and describes the qualifications of involved personnel. Each inspection should be documented, including results of the inspection, and the documents should be delivered as QA records to the QA program user along with the packaging. The M&I plan can also be used as a tool for establishing witness and hold points.

Inspections by the QA program user must be performed upon receipt of the packaging, prior to first use, and annually. Furthermore, post loading inspection of the package must be performed prior to shipment. These inspections should be conducted in accordance with written procedures which have provisions to ensure:

- Inspectors have successfully completed the required training program,
- Inspectors are qualified in accordance with applicable codes and standards,
- Inspectors are independent from individuals performing the activity being inspected, and
- Inspectors' certifications are kept current.

Required inspections and examinations are also found in the SARP of the packaging (in Chapter 7, "Package Operations", and in Chapter 8, "Acceptance Testing and Maintenance Program"). These inspections and examinations should also be performed by qualified individuals in accordance with written procedures as described previously. These activities must include verification of conformance with acceptance/rejection criteria, completion of prerequisites, and equipment calibration.

A graded approach to these inspections can be implemented based on the Q-Category (A, B, and C) of the inspected items, as illustrated in Table 2.10-1.

**Table 2.10-1 QA Categories and Applicable QA Elements for Criterion X**

| QA Element/Level of Effort | Category A | Category B | Category C |
|---|---|---|---|
| X. Internal Inspection | | | |
| Documented inspection of all specifications | X | | |
| Process monitoring if required by quality | X | | |
| Examination, measurement, or test of material or processed product to assure quality | X | X | |
| Inspectors independent of those performing operations | X | X | |
| Qualified inspectors only | X | X | |
| Visual receiving inspection only | | | X |

Visual inspections should include the following features:

- surface conditions
- weld and structural integrity
- the condition of flange faces or sealing areas, gaskets, seals, gauges, rupture disks, valves, and pressure relief devices
- the condition of tie-down members (if applicable)
- labeling and marking
- leak-tightness of the packaging

## Lessons-Learned

- ✓ Develop documents outlining methods for identifying characteristics and activities to be inspected, acceptance and rejection criteria, and the individuals or groups responsible for performing the inspection
- ✓ Items important to safety must be placed under control of the QA program. Examples of such items are the structure, systems, or components necessary to ensure the integrity of the packaging and its capability to prevent or mitigate the consequences that could result from release of radioactive material.
- ✓ The criteria for acceptance of each of the inspection activities as well as the actions to be taken if noncompliance is encountered should be established.

- ✓ Provisions to control accepted items until they are placed in stock or released for use should be established. This should include provisions for the proper disposition of rejected items.
- ✓ Checklists should be developed and used to perform inspections and verify that:
  - → All components are present.
  - → Packages are properly assembled.
  - → Moderators and neutron absorbers are present, if applicable.
  - → Valves through which primary coolant flows are protected against tampering.
  - → Valves are set to specifications.
  - → All shipping papers are properly completed.
  - → Packages are conspicuously and durably marked as required by the regulations set forth by the U.S. Department of Transportation.
  - → Appropriate personnel designated by the package user sign the shipping tags or indicators prior to authorization for shipping.
- ✓ Inspection records should contain the following information:
  - → a description of the observation,
  - → evidence of completion of the inspection operation,
  - → results of inspections with appropriate data,
  - → conditions that are detrimental to quality,
  - → names of inspectors, and
  - → evidence of acceptability.
- ✓ Determine upfront if sampling is appropriate, and if it is determine the sample size.
- ✓ All maintenance and repair work performed on a packaging following the final inspection should be re-inspected to ensure that the items remain acceptable.

## 2.11. Criterion XI: *Test Control*

## Source: Title 10 CFR 71.123

All required testing must be performed in accordance with written test procedures. The testing is required to demonstrate that packaging components will perform satisfactorily in service. The test procedures must incorporate the requirements of 10 CFR Part 71, Subpart H, and the requirements and acceptance limits contained in the package approval.

### Requirements

1. Ensure applicable test programs, including prototype qualification tests, production tests, proof tests, and operational tests, are accomplished in accordance with written procedures.
2. The test procedures must outline test prerequisites and test requirements identified in the appropriate design disclosures.
3. Establish measures to ensure that acceptance tests are conducted prior to delivering packages for transport to a carrier. These measures should identify the basis for acceptance criteria.
4. The documented test results and their evaluations must be maintained as QA records. A qualified individual or group should determine the acceptability of these records.

### Applicability to Packaging User

The packaging user performs preshipment leakage rate tests and, hence, must comply with the requirements of this section, especially in the area of written procedures, acceptance criteria, equipment calibration and qualification, personnel qualification, and record maintenance.

### Implementation Strategy

Tests are conducted to ensure that each item (packaging and its components) will perform its intended function satisfactorily in service and will protect the workers, public and environment. Test records and qualification documents should be included in the package documentation record.

The QA program user's test program should specify training and qualification requirements for personnel conducting the tests and verifying the results. The training and qualification should be documented and kept current. The program should also establish requirements for equipment qualification and calibration with appropriate documentation.

A maintenance test program should be developed and implemented to ensure that packages remain usable and free of excessive radiation and contamination throughout their lifecycles. The program should require qualified individuals to evaluate, assess and document the acceptability of the test results.

Written test procedures should be used to conduct these tests. The procedures should require documentation of the test objectives, conditions, and results. Chapter 8 of the packaging SARP provides requirements for acceptance testing and maintenance testing that should be incorporated in the written procedures.

Acceptance tests performed by the supplier should be observed by the QA Program user, especially for items of Q-Category A.

Written procedures should be used to test computer software and demonstrate adherence to specified requirements. Alternative methods can be employed by these procedures to evaluate technical adequacy of the test results.

The test program and associated efforts can be accomplished in a graded approach, such as the one illustrated in Table 2.11-1.

**Table 2.11-1 QA Categories and Applicable QA Elements for Criterion XI**

| QA Element/Level of Effort | Category A | Category B | Category C |
|---|---|---|---|
| XI. Test Control | | | |
| Written test program | X | X | |
| Written test procedures | X | X | |
| Documentation of testing and evaluation | X | X | |
| Observation of supplier acceptance tests as appropriate | X | | |
| Validate computer programs, computer hardware, and operating system | X | X | |

## Lessons-Learned

- ✓ Test prerequisites identified in design disclosures include, but are not limited to, instrument calibrations, monitoring to be performed, mandatory hold points, suitable environmental conditions to be maintained, condition of the test equipment, methods for physical identification of test specimen, methods for documenting or recording test data, and criteria for acceptance.
- ✓ Acceptance tests should include the following considerations:
  - → structural integrity
  - → allowable leakage rate
  - → component performance for valves, gaskets, and fluid transport devices
  - → shielding integrity
  - → thermal integrity
- ✓ When performing leakage rate tests of the containment boundary, the components become unique to the qualified system (i.e., O-rings, gaskets, closure, and body) and must remain with the containment vessel.
- ✓ Test records should contain the following information:
  - → a description of the test,
  - → evidence of completion of the test operation,
  - → results of tests with appropriate data,
  - → conditions that are detrimental to quality,
  - → names of the testers and data recorders,
  - → acceptance criteria, and
  - → evidence of acceptability
- ✓ Modifications, repairs and replacements (e.g., repair to containment system) should be tested in accordance with the original design and testing requirements.

## 2.12. Criterion XII: *Control of Measuring & Test Equipment*

## Source: Title 10 CFR 71.125

Measurement and test equipment (M&TE) are used in tests and inspections (e.g., gauges, fixtures, reference standards, and devices used to measure product characteristics). This equipment must be calibrated, adjusted, and maintained at prescribed intervals or prior to use in order to ensure the validity and viability of the results.

### Requirements

1. Label or tag M&TE to indicate the planned date of its next calibration.
2. Identify the calibration records and maintain them as QA records.
3. Establish measures to ensure that in-house reference or transfer standards used in calibrating M&TE are traceable to nationally recognized standards. If no known recognized standard exists, document the basis for calibration.
4. Validate previous inspection and test results up to the time of previous calibration when M&TE is found to be out of calibration. Repair or replace any measuring equipment that is consistently out of calibration.

### Applicability to Packaging User

The end user typically performs post-loading leak tests that require the use of M&TE. Consequently, the requirements of this section are applicable to this user.

### Implementation Strategy

M&TE is devices used to control and validate acquired data and verify conformance to specified requirements. They must be calibrated at prescribed intervals or prior to use and be adjusted and maintained in accordance with defined accuracy limits. A formal calibration and maintenance program should be established, and a process should be in place to keep these devices under control and define their status at all times. Calibration procedures, as well as acquired vendor manuals, should provide detail requirements for calibration, including frequency, and the use of appropriate standards. Organizational responsibilities should be defined in order to establish and ensure effectiveness of the calibration program. The employed standards should be traceable to the U. S. National Institute of Standards and Technology.

M&TE procedures should include disposition and/or corrective measures when discrepancies are encountered. Damaged or inaccurate M&TE must be immediately removed from service until repaired, recalibrated or replaced. If M&TE is found to be out of calibration, the validity of previously performed inspections should be determined and documented. If previously performed inspections are found invalid, a

nonconformance report must be completed and dispositioned in accordance with established procedures. If the affected packaging has already been shipped, the end user must notify the receiving facility. Furthermore if the nonconformance item is safety related, the HCO must be notified.

The formal calibration and control program can be implemented in a graded approach such as the one illustrated in Table 2.12-1. Calibration records should be included in the package documentation record.

**Table 2.12-1 QA Categories and Applicable QA Elements for Criterion XII**

| QA Element/Level of Effort | Category A | Category B | Category C |
|---|---|---|---|
| XII. Control of Measuring and Test Equipment | | | |
| Tools, gauges, and instruments in formal calibration program | X | X | |

## Lessons-Learned

- ✓ Ensure that M&TE is of the type and range appropriate for the application. This includes uncertainty in the measurements (e.g., accuracy and resolution).

## 2.13. Criterion XIII: *Handling, Storage, & Shipping Control*

## Source: Title 10 CFR 71.127

Cleaning, handling, storage, and shipping of a packaging and its components must be accomplished in accordance with established requirements to preclude damage or deterioration by environmental conditions such as temperature and humidity.

### Requirements

1. Establish, whenever necessary, provisions for the use of special handling, lifting, or storage devices (e.g. cranes, shock absorbers, or special markings) to adequately identify and preserve packaging components or assemblies.
2. All conditions identified in the CoC must be adhered to when unloading the packaging.
3. Cavities within gas-cooled package containments must be adequately dried, and cavities within liquid-cooled packages must be drained to allow adequate void space.
4. Use marking or labeling to specify need for special environments or special controls.
5. Ensure that all conditions (including specified operations, inspections, and tests) are completed, and all applicable hazardous material regulations (HMR) are satisfied prior to delivery to a carrier.
6. All necessary shipping papers must be prepared as required and reviewed by qualified personnel to verify completeness and accuracy.

### Applicability to Packaging User

Handling, storage, & shipping control are a few of the activities performed by the packaging end user. Therefore, the requirements of this section are applicable to this user.

### Implementation Strategy

The objective of the implementation strategy should be the protection of the package from any damage that can be caused by environmental conditions or by handling, shipping, cleaning, or storage.

To address and control handling, storage and shipping, every package user should develop written operating procedures that satisfy the requirements presented in Chapter 7, *Package Operations*, of the SARP. This should include the following requirements.

- Limited-life components (e.g. the outer and inner O rings) must be replaced within the required period or prior to use.

- The shipper must verify that the requirements of Chapter 7 are met prior to shipping.
- The receiving organization must perform visual inspection of the package upon receipt.
- The need for special environment or special controls must be indicated using marking or labeling.
- Special equipment, materials (e.g. shock absorbers), and protective environment (e.g. inert gas) must be specified and verified.
- Operators of special handling equipment must be trained and qualified.
- The work accomplished and inspection performed must be documented.

This implementation strategy can be tailored based on the Q-category of the items (A, B, or C) as illustrated in 2.13-1.

**Table 2.13-1 QA Categories and Applicable QA Elements for Criterion XIII**

| QA Element/Level of Effort | Category A | Category B | Category C |
|---|---|---|---|
| XIII. Handling, Storage, and Shipping Control | | | |
| Written plans and procedures | X | X | |
| Routine handling | | | X |

## Lessons-Learned

✓ A final pre-release review must be completed to ensure that the package

→ is prepared for delivery to the purchaser in accordance with approved drawings, specifications, and government regulations;
→ has passed all applicable inspections and tests;
→ is properly identified by physical markings or tags; and
→ contains operating manuals, maintenance manuals, and generic procedures relating to its use (see Chapter 7, 8, and 9 of the SARP).

✓ Storage of packaging components should be in accordance with prescribed storage levels based on the item characteristics and importance to safety. The use of the four levels (A, B, C, and D) defined in Section 2.7 and 6 of American National Standard Institute (ANSI)/American Society of Mechanical Engineers (ASME) N45.2.2 – 1978, *Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants*, is recommended.

- ✓ Special handling tools and equipment should be inspected and tested periodically and operated only by qualified personnel as specified in written procedures.
- ✓ Failure to properly store the packaging has led to mold growth and insect infestation in fiberboard packaging.

## 2.14. Criterion XIV: *Inspection, Test, & Operating Status*

## Source: Title 10 CFR 71.129

The status of inspections and tests performed upon individual items of a packaging must be clearly indicated on the item or in a document traceable to the item in order to specify that the item was accepted and is operable. Items that have satisfactorily passed required inspections and tests must be identified in order to preclude inadvertent bypassing of the inspections and tests.

### Requirements

1. Ensure that the status of inspections, tests, and operating conditions (including maintenance of items) is known by responsible organizations, including the QA function.
2. Establish measures to control the use and removal of status indicators (e.g., tags, markings, stamps) and to ensure that bypassing a required inspection or test or any other required operation is procedurally controlled.

### Applicability to Packaging User

Inspection, test, & operating status are parts of operation activities performed by the packaging end user. Consequently, the requirements of this section are applicable to this user.

### Implementation Strategy

Every package user should develop written operating procedures that satisfy the requirements presented in Chapter 7, *Package Operations*, of the SARP. In addition, the procedures must have provisions that ensure clear identification of the status or condition of Category A and B components resulting from tests and inspections. Typical means used for this purpose include:

- Stamps,
- Tags,
- Labels, and
- routing cards.

Authority and responsibility for the applications and removals of tags and markings must also be specified. Furthermore, the procedures must outline and record each maintenance step performed on Category A and B components.

For Category C components, visual examination may be sufficient as indicated by Table 2.14-1.

**Table 2.14-1 QA Categories and Applicable QA Elements for Criterion XIV**

| QA Element/Level of Effort | Category A | Category B | Category C |
|---|---|---|---|
| XIV. Inspection, Test, and Operating Status | | | |
| Individual items identified as to status or condition | X | X | |
| Status indicated by stamps, tags, labels, etc. | X | X | |
| Visual examination only | | | X |

## Lessons-Learned

- ✓ In order to avoid expiration of the annual leakage tests for containment vessels, a label should be affixed to the outermost part of the packaging to alert operators of the status and due date of the test.
- ✓ QA hold tags should only be removed by authorized QA personnel.

## 2.15. Criterion XV: *Nonconforming Materials, Parts, or Components*

## Source: Title 10 CFR 71.131

Items not meeting the specified requirements must be identified, segregated and reviewed for disposition, and the selected disposition option with basis must be documented.

### Requirements

1. Establish a program for controlling nonconforming items to prevent their inadvertent use. The program should include the following principal elements:
   - 1.1 proper identification and documentation,
   - 1.2 segregation of discrepant or nonconforming items,
   - 1.3 evaluation of the nonconforming items,
   - 1.4 disposition of the nonconforming items,
   - 1.5 notification of affected organizations, and
   - 1.6 documentation of evaluation process and personnel and disposition activities.
2. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

### Applicability to Packaging User

The end user operates the packaging without getting involved in the design, fabrication, modification, or maintenance work and without having the need for any materials or replacement parts. However, this user may replace packaging gaskets. Also, this user may identify a nonconforming item for which an NCR must be generated. Consequently, the requirements of this section apply. In the evaluation and disposition of the nonconformance item (Requirement 1.3 and 1.4); an assistance from the Design Authority will be required.

### Implementation Strategy

The QA program user should develop and establish written procedures to identify, control, and document any nonconforming item or activity. These items must be marked, tagged, segregated and placed in controlled hold areas until disposition is complete in order to prevent inadvertent use. The procedures should include steps to evaluate the item functions, requirements and impact to safety, and recommend a disposition option such as “repair,” “rework,” “reject” or “use-as-is”. Prior to realization of the option, the user should obtain approvals of the Design Authority. If “repair” was

the selected option, an examination of the repaired items must be performed and documented prior to use.

The written procedures should also specify authority, responsibility and qualification of personnel involved in the evaluation and disposition of nonconforming items. The qualification of these personnel must be documented.

The final disposition of nonconformance items and activities must be documented, and the documentation must be maintained as a QA record. The extent of documentation can be based on the Q-category (A, B, or C) of the item as illustrated in Table 2.15-1.

**Table 2.15-1 QA Categories and Applicable QA Elements for Criterion XV**

| QA Element/Level of Effort | Category A | Category B | Category C |
|---|---|---|---|
| XV. Nonconforming Materials, Parts, or Components | | | |
| Written procedures to prevent inadvertent use | X | X | X |
| Nonconformance documented and closed | X | X | X |
| Disposal (scrap) without records | | | X |

## Lessons-Learned

- ✓ Label non-conforming items to provide positive identification without jeopardizing their eventual acceptability.
- ✓ Ensure acceptability of each item is verified by reinspecting and/or retesting the item against the original requirements after designated repair or rework.
- ✓ Any accepted deviation from the requirements should be identified on the as-built drawings.
- ✓ Final disposition of nonconforming items should be identified, justified, and documented by trained personnel who understand the requirements and have relevant support information available.
- ✓ Nonconformance reports should be analyzed by the QA function to determine quality trends for management review and assessment.
- ✓ The HCO must be notified when an NCR is for an item important to safety.
- ✓ The packaging identification plate must be removed and destroyed when a packaging is permanently removed from service.

## 2.16. Criterion XVI: *Corrective Action*

## Source: Title 10 CFR 71.133

The purpose of corrective actions is to fix the immediate problem as well as its causes in order to prevent recurrence.

### Requirements

1. Establish measures to ensure that the causes of conditions detrimental to quality (e.g., those resulting from failures, malfunctions, deficiencies, deviations, or defective material and equipment) are promptly identified and reported to appropriate levels of management.
2. Establish measures to obtain corrective actions from suppliers and ensure that follow-up actions are documented to verify that the corrective actions were implemented and effective.
3. Identify (by function or position) the individuals or organizations responsible for closing out corrective actions and documenting their resolution.

### Applicability to Packaging User

This packaging end user utilizes certified packagings to transport RAM and fissile materials. Corrective actions to fix operation problems can be encountered by such a user. As a result, the requirements of this section are applicable to this user.

### Implementation Strategy

The implementation strategy should provide means to identify and correct conditions adverse to quality, identify the cause and necessary corrective actions to eliminate the cause and prevent recurrence, and verify that these actions are implemented and effective.

A process and written procedures should be developed and established to assist personnel in identifying and documenting causes and conditions that can lead to failures, deficiencies, or deviations. The process and procedures should include steps where cognizant, qualified individuals review these causes and conditions, and develop corrective actions to prevent recurrence.

Procurement specifications should require suppliers to establish similar process and procedures to identify and correct/eliminate causes and conditions detrimental to quality. The specifications should also require follow-up actions to verify and document that the corrective actions were implemented and effective.

Authority and responsibility of groups or individuals for implementing and closing out corrective actions should be specified. The extent of documentation can be tailored

based on the Q-Category (A, B, or C) of the items involved as illustrated in Table 2.16-1.

**Table 2.16-1 QA Categories and Applicable QA Elements for Criterion XVI**

| QA Element/Level of Effort | Category A | Category B | Category C |
|---|---|---|---|
| XVI. Corrective Action | | | |
| Conditions adverse to quality identified and corrected | X | X | X |
| Cause and corrective action documented | X | X | |
| Safety significant events reported | X | X | X |

## Lessons-Learned

✓ The implementation of corrective actions should be verified and assessed to determine their effectiveness in preventing recurrence. Corrective action status should be monitored. Follow-up reviews, surveillance, or audits should be performed to determine whether the corrective actions have been and remain effective.

## 2.17. Criterion XVII: *Quality Assurance Records*

## Source: Title 10 CFR 71.135

QA records should furnish documentary evidence of the activities that affect quality and should provide sufficient information to allow each record to be identified with the items or activities to which it applies. QA records must be retrievable.

### Requirements

1. Ensure that, as a minimum, QA records include the following information:
   - 1.1 design, procurement, manufacturing, and installation records
   - 1.2 supplier evaluations
   - 1.3 nonconformance reports
   - 1.4 results of inspections and tests
   - 1.5 failure analysis
   - 1.6 as-built drawings and specifications
   - 1.7 qualification of personnel, procedures, and equipment
   - 1.8 calibration procedures
   - 1.9 training and retraining records
   - 1.10 corrective action reports
   - 1.11 records demonstrating evidence of operational capability
   - 1.12 records verifying repair, rework, and replacement
   - 1.13 audit plans, audit reports, and associated corrective actions
   - 1.14 records that are used as a baseline for maintenance
   - 1.15 lifetime records
2. Each QA record must be traceable to item or activity (i.e., traceable to packaging serial number).
3. Establish a record retention program, consistent with applicable regulations, that designates duration, location and responsibility.
4. QA records must reflect the work accomplished and be stored in a manner that avoids unnecessary delay when the record is needed (i.e., records are easily retrieved).
5. Records that are maintained in-house or at other locations must be identifiable and retrievable and must not be disposed of until prescribed conditions are satisfied.

6. Records pertaining to use of a package must be retained for a period of 3 years after the shipment.

## Applicability to Packaging User

Packaging operations always produce “QA Records”. The packaging end user must acquire/generate and maintain these records in accordance with the requirements of this section.

## Implementation Strategy

The implementation strategy should focus on the generation, maintenance and retention of packaging QA records. The storage location of these records should be designed to minimize the risk of damage or destruction from natural causes, such as water, extreme temperatures, high humidity, insects, mold, or fire.

Individual packaging QA records should be maintained by serial number. The retention periods for various types of these records should be established. Minimum retention periods must comply with 10 CFR 71.91 and 10 CFR Part 71, Subpart H.

The procurement specifications should define the QA records that suppliers have to generate and the time of submittal of these records. A receipt control system of QA records should be established. The system should identify individuals by functions or positions in each organization responsible for receiving records and assessing their status.

The storage, preservation, and safekeeping of QA records could be achieved through the use of a vault with fire protection or one-hour rated fire cabinets. Security systems and facility activity classifications should be established to prevent unauthorized access to these records.

QA records could be maintained as hard copies and/or in electronic format. In either case, the methods employed to manage these records must result in retrievable, intelligible, and reliable information. New hardware systems must reliably store and retrieve information from existing software systems, and existing software systems employed to image and store information must be compatible with new hardware as current technologies are implemented.

A graded approach, such as the one illustrated by Table 2.17-1, can be implemented for QA record generation and retention.

**Table 2.17-1 QA Categories and Applicable QA Elements for Criterion XVII**

| QA Element/Level of Effort | Category A | Category B | Category C |
|---|---|---|---|
| XVII. QA Records | | | |
| Design and use records | X | X | |
| Results of reviews, inspections, tests, audits, surveillances, and materials analysis | X | X | |
| Personnel qualifications | X | X | |
| Records of design, fabrication, acceptance testing, and maintenance retained for life of packaging plus 3 years | X | X | |
| Shipping records retained for 3 years after shipment | X | X | X |
| Records managed by a written procedure for retention and disposal | X | X | X |

## Lessons-Learned

- ✓ QA records should be classified as either "lifetime" or "nonpermanent":
  - → Lifetime records include those pertaining to package fabrication and those associated with a particular item while it is installed in the packaging or stored for future use. These records demonstrate the capability for safe operation; provide evidence of repair, rework, replacement, or modification; aid in determining the cause of an accident or malfunction of an item; and provide a baseline for in-service inspection.
  - → Nonpermanent records are those that show evidence that an activity has been performed but do not meet the criteria for lifetime records.
- ✓ Records should be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets.
- ✓ Electronic records should be maintained in facilities that minimize or eliminate the potential for destruction of information as a result of demagnetization.
- ✓ Electronic records should be backed up daily to eliminate the potential for loss of information as a result of equipment failure or human error.
- ✓ If dual storage facilities are used to ensure the record integrity, the storage facilities should be sufficiently remote from each other to preclude a single event (such as a fire or flood) from damaging both facilities.

- ✓ Special records (e.g., radiographs and microfilm) should be protected from excessive light, electromagnetic fields, and temperature.
- ✓ Electronic information storage systems should be accessible only through security measures such as passwords, and the number of personnel who have authorized access should be limited. Personnel who have authorized access should have identified privileges, such as “read only” or “read and add only”.
- ✓ Ensure prompt replacement of a record that is lost or damaged.

## 2.18. Criterion XVIII: *Audits*

## Source: Title 10 CFR 71.137

The frequency of audits should be based on each activity's importance to safety. However, each of the eighteen Quality Criteria of 10 CFR Part 71, as applicable, should be audited annually or at least once within the life of the activity, whichever is shorter.

### Requirements

1. A comprehensive audit program should include the following elements:
   - 1.1 assurance of the authority and organizational independence of the auditors,
   - 1.2 a commitment to adequate manpower, funding, and facilities to implement the audit,
   - 1.3 identification of audit personnel (by function or position) and their qualifications,
   - 1.4 provisions for reasonable and timely access of audit personnel to facilities, documents, and qualified personnel necessary for performing audits,
   - 1.5 use of established procedures and checklists,
   - 1.6 methods for reporting audit findings to responsible management of both the audited and auditing organizations,
   - 1.7 provisions for the audit team to gain access to levels of management that have responsibility and authority for corrective action, and
   - 1.8 methods for verifying that effective corrective actions have been accomplished on a timely basis.
2. Ensure that packaging suppliers are audited to assess the extent of their compliance with purchase orders and to verify that their work is controlled under an approved QA program.
3. The schedules for internal audits should ensure that applicable elements of the QA program are audited annually or at least once within the life of the activity, whichever is shorter.
4. The schedules for external audits should ensure that all elements of a major supplier's (or major contractor's) QA programs are audited on a triennial basis. The 3-year period should begin with performance of an audit when sufficient work is in progress to demonstrate implementation of a QA program that has the required scope for purchases placed during the 3-year period.
5. Management audits should be conducted annually.
6. The lead auditor and audit team members must have no direct responsibility in the areas being audited.

7. Establish the qualifications of the lead auditor and audit team members and specify their respective responsibilities with respect to evaluating and issuing audit reports.
8. Establish a schedule for issuing audit reports and for a corrective action response by the audited organization. The response should include corrective action to prevent recurrence of nonconformance items. The response should also include scheduled dates for initiation and completion of the corrective actions.
9. The audit team leader should verify that (1) the audited organization provides a timely response to the audit report, (2) the response is adequate, and (3) the corrective actions have been accomplished within the prescribed schedule.

## Applicability to Packaging User

Packaging operations include activities that are important to safety. They must be audited at least once every twelve months. Consequently, the requirements of this section apply to the packaging end user.

## Implementation Strategy

Audits are planned activities performed by qualified personnel, independent of the group or function being audited, using written procedures and/or checklists. The list presents activities important to safety that are to be audited and the frequency at which each quality criterion is to be audited. The list should reflect the current status of the activities.

Schedules for internal audits, external audits, and audits performed by management should be developed and distributed to the involved parties. Key activities, such as design and fabrication, and activities important to safety, such as procurement and personnel training, should receive priority consideration. The schedule for management audits should identify the level of management designated to assess the overall effectiveness of the QA program implementation.

A written report documenting the audit results should be prepared within 30 days, distributed to appropriate management personnel, and retained in accordance with applicable requirements. If the report includes corrective action, it should require the audited organization to reply, within a specified time, with a plan and schedule for implementation of the required actions.

It may be necessary to supplement regularly scheduled audits with additional audits of specific subjects to provide adequate coverage if quality or conformance to requirements are suspects. Also, unscheduled audits can be performed if, for some reason, the current status and/or critical information are required.

A training and qualification system for auditors should be established, and their training and qualification records should be maintained in accordance with established procedures.

The audit level of effort should be commensurate with the Q-Category of the audited item as illustrated by Table 2.18-1.

**Table 2.18-1 QA Categories and Applicable QA Elements for Criterion XVIII**

| QA Element/Level of Effort | Category A | Category B | Category C |
|---|---|---|---|
| XVIII. Audits | | | |
| Written plan of periodic audits | X | X | X |
| Implementation by written procedures | X | X | X |
| Lead auditor qualified | X | X | |
| All auditors qualified | X | | |

## Lessons-Learned

- ✓ Specific guidance for determining qualifications for the lead auditor and individual audit team members may be obtained from ANSI/ASME NQA-1, Requirement 2: *QA Program*, Paragraph 303: *Lead Auditor*.
- ✓ A pre-audit conference should be held between management of the organizations being audited and the team conducting the audit. The purpose of the conference is to meet counterparts, confirm the audit scope and dates, establish channels of communication, discuss the sequence and duration of the audit, prepare an agreed-upon agenda for the audit, and set the time for the post-audit conference.
- ✓ A post-audit conference should take place between management of the organizations being audited and the team conducting the audit to present the results and clarify any misunderstandings that may arise.
- ✓ A draft report should be provided by the audit team to the audited organization to check and confirm facts.
- ✓ The QA program user should identify (by function or position) the individuals or groups that have the responsibility and authority to ensure that corrective actions resulting from audit findings are accomplished on a timely basis. The user should re-audit deficient areas on a timely basis to verify implementation of corrective actions.
- ✓ Audit records should include audit plans and reports, written replies, and documentation that corrective actions were completed. Audit records should be considered “lifetime records”.

# 3.0 References

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3.2. DOE, 10 CFR Part 830, *Nuclear Safety Management*, Subpart A, *Quality Assurance Requirements* (the "QA Rule")

3.3. U.S. Nuclear Regulatory Commission, 10 CFR Part 71, *Packaging and Transportation of Radioactive Materials*, 01-01-2005 Edition.

3.4. U.S. Nuclear Regulatory Commission, *Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material*, Regulatory Guide 7.10, Revision 2, Washington, DC (March 2005)

3.5. Oak Ridge National Laboratory, M-5003, *The Radioactive Materials Packaging Handbook: Design, Operations, and Maintenance*, 1998

3.6. U.S. Nuclear Regulatory Commission, *Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety*, NUREG 6407, February 1996

3.7. U.S. Nuclear Regulatory Commission, *Fabrication Criteria for Shipping Containers*, NUREG/CR- 3854, March 1985

3.8. International Organization for Standardization quality standard ISO 9001-2000, "*Quality Management System (QMS) - Requirements*."

3.9. U.S. Nuclear Regulatory Commission Policy Issue Information, SECY-03-0117, *Approaches for Adopting More Widely Accepted International Quality Standards*, July 9, 2003

3.10. American Society of Mechanical Engineers NQA-1, 1983, *Quality Assurance Requirements for Nuclear Facility Applications*

3.11. U.S. Nuclear Regulatory Commission, *Quality Assurance Program Requirements (Design and Construction)*, Regulatory Guide 1.28, Revision 3, August 1985

3.12. U.S. Nuclear Regulatory Commission , *Plant Record Storage on Optical Discs*, Generic Letter 88-18, October 20, 1988

3.13. A.A. DiSabatino, et al., Packaging Review Guide for Reviewing Safety Analysis Reports for Packagings, UCID-21218, Revision 3, Lawrence Livermore National Laboratory (February 2008)

3.14. SARP Completeness Checklist for EM-60, Revision 1, March 2007

3.15. IAEA Safety Series 50-C/SG-Q, *Quality Assurance for Safety in Nuclear Power Plants and other Nuclear Installations*

3.16. American Society of Mechanical Engineers Boiler and Pressure Vessel Code, Section II, *Material Specifications*

3.17. American Society of Mechanical Engineers Boiler and Pressure Vessel Code, Section III, *Rules for Construction of Nuclear Facility Components*

3.18. American Society of Mechanical Engineers Boiler and Pressure Vessel Code, Section VIII, *Rules for Construction of Pressure Vessels*

3.19. ANSI/ASME N45.2.2 – 1978, *Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants*, 1978

# Appendix A: Comparison & Gap Analysis of 10- and 18-Point QA Programs

In general, the eighteen QA criteria of 10 CFR Part 71, Subpart H, are more prescriptive and rigorous than the ten criteria of 10 CFR Part 830, Subpart A (QA Rule), and DOE O 414.1C. Chapter 9 of the SARP (the QA Chapter) should be responsive to all eighteen criteria of 10 CFR Part 71. If the use's QA program is based solely on the 10 criteria of the QA Rule/DOE Order, then that QA program must be augmented and be included in Chapter 9. In order to help the QA program user determine the required QA supplementation, a comparison matrix with gap analysis is provided in this Appendix.

## Table A-1 Comparison of 10-Point- & 18-Point Programs with Gap Analysis

| 10 CFR 71 Subpart H Criteria | 10 CFR 830 Subpart A/ DOE O 414.1C Criteria | Comments/Gap Analysis |
|---|---|---|
| **71.103 – Criterion I – QA Organization**<br><br>(a) The licensee, certificate holder, and applicant for a CoC shall be responsible for the establishment and execution of the quality assurance program. The licensee, certificate holder, and applicant for a CoC may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.<br><br>(b) The quality assurance functions are--<br><br>(1) Assuring that an appropriate quality assurance program is established and effectively executed; and<br><br>(2) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.<br><br>(c) The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom to--<br><br>(1) Identify quality problems;<br><br>(2) Initiate, recommend, or provide solutions; and<br><br>(3) Verify implementation of solutions.<br><br>(d) The persons and organizations performing quality assurance functions shall report to a management level that assures that the required authority and organizational freedom, including sufficient independence | **1 – Management/ Program**<br><br>(1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.<br><br>**6 – Performance/ Design**<br><br>(4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.<br><br>**10 – Assessment/ Independent Assessment**<br><br>(1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.<br><br>(2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments.<br><br>**9 – Assessment/ Management Assessment**<br><br>Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives. | The QA program may need to be supplemented to ensure that the degree of independence, authority, and access to management is adequate for personnel performing QA functions in order to meet the requirements of this section of 10 CFR 71 Subpart H. |

| 10 CFR 71 Subpart H Criteria | 10 CFR 830 Subpart A/ DOE O 414.1C Criteria | Comments/Gap Analysis |
|---|---|---|
| from cost and schedule, when opposed to safety considerations, are provided.<br><br>(e) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom.<br><br>(f) Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform this function. | | |
| **71.105 – Criterion II – QA Program**<br><br>(a) The licensee, certificate holder, and applicant for a CoC shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of §§ 71.101 through 71.137. The licensee, certificate holder, and applicant for a CoC shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee, certificate holder, and applicant for a CoC shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.<br><br>(b) The licensee, certificate holder, and applicant for a CoC, through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package | **830.121 Quality Assurance Program**<br><br>(a) Contractors conducting activities, including providing items or services, that affect, or may affect, the nuclear safety of DOE nuclear facilities must conduct work in accordance with the Quality Assurance criteria in § 830.122.<br><br>(b) The contractor responsible for a DOE nuclear facility must:<br><br>(1) Submit a QAP to DOE for approval and regard the QAP as approved 90 days after submittal, unless it is approved or rejected by DOE at an earlier date.<br><br>(2) Modify the QAP as directed by DOE. | Essentially equivalent except that 10 CFR 71 Subpart H has additional specificity on the impact/risk of failure of materials and components on safety. This has been translated into the requirement for a Q-list of packaging structures, systems, and components; and the grading of QA effort as to the Q-category, as per NRC Reg Guide 7.10 [15] and Chapter 9 of the DOE Packaging and Review Guide [16]. |

| 10 CFR 71 Subpart H Criteria | 10 CFR 830 Subpart A/ DOE O 414.1C Criteria | Comments/Gap Analysis |
|---|---|---|
| used for the shipment of radioactive material. The licensee, certificate holder, and applicant for a CoC shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee, certificate holder, and applicant for a CoC shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.<br><br>(c) The licensee, certificate holder, and applicant for a CoC shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:<br><br>(1) The impact of malfunction or failure of the item to safety;<br><br>(2) The design and fabrication complexity or uniqueness of the item;<br><br>(3) The need for special controls and surveillance over processes and equipment;<br><br>(4) The degree to which functional compliance can be demonstrated by inspection or test; and<br><br>(5) The quality history and degree of standardization of the item.<br><br>(d) The licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee, certificate holder, and applicant for a CoC shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations | (3) Annually submit any changes to the DOE-approved QAP to DOE for approval. Justify in the submittal why the changes continue to satisfy the quality assurance requirements.<br><br>(4) Conduct work in accordance with the QAP.<br><br>(c) The QAP must:<br><br>(1) Describe how the quality assurance criteria of § 830.122 are satisfied.<br><br>(2) Integrate the quality assurance criteria with the Safety Management System, or describe how the quality assurance criteria apply to the Safety Management System.<br><br>(3) Use voluntary consensus standards in its development and implementation, where practicable and consistent with contractual and regulatory requirements, and identify the standards used.<br><br>(4) Describe how the contractor responsible for the nuclear facility ensures that subcontractors and suppliers satisfy the criteria of § 830.122.<br><br>2 – Management/Personnel Training and Qualification | |

| 10 CFR 71 Subpart H Criteria | 10 CFR 830 Subpart A/ DOE O 414.1C Criteria | Comments/Gap Analysis |
|---|---|---|
| participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing. | (1) Train and qualify personnel to be capable of performing their assigned work.<br><br>(2) Provide continuing training to personnel to maintain their job proficiency.<br><br>**9 – Assessment/ Management Assessment**<br><br>Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.<br><br>**10 – Assessment/ Independent Assessment**<br><br>(1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.<br><br>(2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments.<br><br>(3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed. | |
| **71.107 – Criterion III – Package Design Control**<br><br>(a) The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that applicable regulatory requirements and | **6 – Performance/Design**<br><br>(1) Design items and processes using sound engineering/scientific principles and | Generally equivalent. 10 CFR 71 Subpart H includes additional requirements for design control/verification. |

| 10 CFR 71 Subpart H Criteria | 10 CFR 830 Subpart A/ DOE O 414.1C Criteria | Comments/Gap Analysis |
|---|---|---|
| the package design, as specified in the license or CoC for those materials and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the materials, parts, and components of the packaging that are important to safety.<br><br>(b) The licensee, certificate holder, and applicant for a CoC shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures, among participating design organizations, for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design, by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee shall designate individuals or groups other than those who were responsible for the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, the licensee, certificate holder, and applicant for a CoC shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. The licensee, certificate holder, and applicant for a CoC shall apply design control measures to the following:<br><br>(1) Criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses;<br><br>(2) Compatibility of materials;<br><br>(3) Accessibility for inservice inspection, maintenance, and repair; | appropriate standards.<br><br>(2) Incorporate applicable requirements and design bases in design work and design changes.<br><br>(3) Identify and control design interfaces.<br><br>(4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.<br><br>(5) Verify or validate work before approval and implementation of the design. | |

| 10 CFR 71 Subpart H Criteria | 10 CFR 830 Subpart A/ DOE O 414.1C Criteria | Comments/Gap Analysis |
|---|---|---|
| (4) Features to facilitate decontamination; and<br><br>(5) Delineation of acceptance criteria for inspections and tests.<br><br>(c) The licensee, certificate holder, and applicant for a CoC shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the CoC require prior NRC approval. | | |
| **71.109 – Criterion IV – Procurement Document Control**<br><br>The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that adequate quality is required in the documents for procurement of material, equipment, and services, whether purchased by the licensee, certificate holder, and applicant for a CoC or by its contractors or subcontractors. To the extent necessary, the licensee, certificate holder, and applicant for a CoC shall require contractors or subcontractors to provide a quality assurance program consistent with the applicable provisions of this part. | 831.121 (4) Describe how the contractor responsible for the nuclear facility ensures that subcontractors and suppliers satisfy the criteria of § 830.122. | Generally equivalent. |
| **71.111 – Criterion V – Instructions, Procedures, and Drawings**<br><br>The licensee, certificate holder, and applicant for a CoC shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished. | **5 – Performance/Work Processes**<br><br>(1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.<br><br>**4 – Management/ Documents and Records**<br><br>(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. | Generally equivalent. In addition, 10 CFR 71 Subpart H requires that acceptance criteria be included in instructions, procedures, and drawings. |

| 10 CFR 71 Subpart H Criteria | 10 CFR 830 Subpart A/ DOE O 414.1C Criteria | Comments/Gap Analysis |
|---|---|---|
| **71.113 – Criterion VI – Document Control**<br><br>The licensee, certificate holder, and applicant for a CoC shall establish measures to control the issuance of documents such as instructions, procedures, and drawings, including changes that prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed. | **4 – Management/ Documents and Records**<br><br>(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. | In general, Criterion IV is applicable to all sections of 10 CFR 71 Subpart H that require written documents. |
| **71.115 – Criterion VII – Control of Purchased Material, Equipment, and Services**<br><br>(a) The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products on delivery.<br><br>(b) The licensee, certificate holder, and applicant for a CoC shall have available documentary evidence that material and equipment conform to the procurement specifications before installation or use of the material and equipment. The licensee, certificate holder, and applicant for a CoC shall retain, or have available, this documentary evidence for the life of the package to which it applies. The licensee, certificate holder, and applicant for a CoC shall assure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment.<br><br>(c) The licensee, certificate holder, and applicant for a CoC shall assess the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or services. | **7 – Performance/ Procurement**<br><br>(1) Procure items and services that meet established requirements and perform as specified.<br><br>(2) Evaluate and select prospective suppliers on the basis of specified criteria.<br><br>(3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services. | Generally equivalent. Additional specificity in 10 CFR 71 Subpart H for procurement records. |
| **71.117 – Criterion VIII – Identification and Control of Materials,** | **5 – Performance/Work Processes** | Supplementation is needed to |

| 10 CFR 71 Subpart H Criteria | 10 CFR 830 Subpart A/ DOE O 414.1C Criteria | Comments/Gap Analysis |
|---|---|---|
| **Parts, and Components**<br><br>The licensee, certificate holder, and applicant for a CoC shall establish measures for the identification and control of materials, parts, and components. These measures must assure that identification of the item is maintained by heat number, part number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, installation, and use of the item. These identification and control measures must be designed to prevent the use of incorrect or defective materials, parts, and components. | (2) Identify and control items to ensure their proper use. | comply with the traceability requirements of this section of 10 CFR 71 Subpart H. |
| **71.119 – Criterion IX – Control of Special Processes**<br><br>The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that special processes, including welding, heat treating, and nondestructive testing are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements. | **2 – Management/Personnel Training and Qualification**<br><br>(1) Train and qualify personnel to be capable of performing their assigned work.<br><br>(2) Provide continuing training to personnel to maintain their job proficiency. | No specific requirement in 10 CFR 830/A and DOE O 414.1C, however Criterion II is generally applicable. Supplementation is needed, in order to comply with 10 CFR 71 Subpart H, on special processes and qualification of personnel and procedures. |
| **71.121 – Criterion X – Internal Inspection**<br><br>The licensee, certificate holder, and applicant for a CoC shall establish and execute a program for inspection of activities affecting quality by or for the organization performing the activity, to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. The inspection must be performed by individuals other than those who performed the activity being inspected. Examination, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If direct inspection of processed material or products is not carried out, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when quality control is inadequate without both. If mandatory inspection hold points, which require witnessing or inspecting by the licensee's designated representative and beyond which work should not | **8 – Performance/ Inspection and Acceptance Testing**<br><br>(1) Inspect and test specified items, services, and processes using established acceptance and performance criteria. | No specific requirement for independence of inspectors, although 10 CFR 830 Subpart A/ DOE O 414.1C generally requires independence (e.g., for independent assessments, design verification). Supplementation may be needed.<br><br>Additional specificity in 10 CFR 71 Subpart H for process monitoring vs. direct inspection, and hold points. |

| 10 CFR 71 Subpart H Criteria | 10 CFR 830 Subpart A/ DOE O 414.1C Criteria | Comments/Gap Analysis |
|---|---|---|
| proceed without the consent of its designated representative, are required, the specific hold points must be indicated in appropriate documents. | | |
| **71.123 – Criterion XI – Test Control**<br><br>The licensee, certificate holder, and applicant for a CoC shall establish a test program to assure that all testing required demonstrating that the packaging components will perform satisfactorily in service is identified and performed in accordance with written test procedures that incorporate the requirements of this part and the requirements and acceptance limits contained in the package approval. The test procedures must include provisions for assuring that all prerequisites for the given test are met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. The licensee, certificate holder, and applicant for a CoC shall document and evaluate the test results to assure that test requirements have been satisfied. | **8 – Performance/ Inspection and Acceptance Testing**<br><br>(1) Inspect and test specified items, services, and processes using established acceptance and performance criteria. | Generally equivalent, but 10 CFR 71 Subpart H has additional specificity for the content of test procedures, instrumentation, and environmental conditions. |
| **71.125 – Criterion XII – Control of Measuring and Test Equipment**<br><br>The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified times to maintain accuracy within necessary limits. | **5 – Performance/Work Processes**<br><br>(4) Calibrate and maintain equipment used for process monitoring or data collection.<br><br>8 – Performance/ Inspection and Acceptance Testing<br><br>(2) Calibrate and maintain equipment used for inspections and tests. | Generally equivalent. |
| **71.127 – Criterion XIII – Handling, Storage, and Shipping Control**<br><br>The licensee, certificate holder, and applicant for a CoC shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and | **5 – Performance/Work Processes**<br><br>(3) Maintain items to prevent their damage, loss, or deterioration. | Generally equivalent. Additional specificity is provided in 10 CFR 71 Subpart H for protective environments. |

| 10 CFR 71 Subpart H Criteria | 10 CFR 830 Subpart A/ DOE O 414.1C Criteria | Comments/Gap Analysis |
|---|---|---|
| temperature levels must be specified and provided. | | |
| **71.129 – Criterion XIV – Inspection, Test, and Operating Status**<br><br>(a) The licensee, certificate holder, and applicant for a CoC shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of the inspections and tests.<br><br>(b) The licensee shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation. | **5 – Performance/Work Processes**<br><br>(2) Identify and control items to ensure their proper use. | Generally equivalent except that supplementation is needed to meet the additional specificity of 10 CFR 71 Subpart H with regards to identification/labeling of items as to their inspection and test status, and prevent the inadvertent operation of packaging components. |
| **71.131 – Criterion XV – Nonconforming Materials, Parts, or Components**<br><br>The licensee, certificate holder, and applicant for a CoC shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures. | **3 – Management/Quality Improvement**<br><br>(1) Establish and implement processes to detect and prevent quality problems.<br><br>(2) Identify, control, and correct items, services, and processes that do not meet established requirements. | Generally equivalent. 10 CFR 71 Subpart H provides additional specificity regarding the control of nonconforming items and materials. |
| **71.133 – Criterion XVI – Corrective Action**<br><br>The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse | **3 – Management/Quality Improvement**<br><br>(1) Establish and implement processes to detect and prevent quality problems.<br><br>(3) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem. | Generally equivalent. |

| 10 CFR 71 Subpart H Criteria | 10 CFR 830 Subpart A/ DOE O 414.1C Criteria | Comments/Gap Analysis |
|---|---|---|
| to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management. | (4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement. | |
| **71.135 – Criterion XVII – Quality Assurance Records**<br><br>The licensee, certificate holder, and applicant for a CoC shall maintain sufficient written records to describe the activities affecting quality. The records must include the instructions, procedures, and drawings required by § 71.111 to prescribe quality assurance activities and must include closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures which establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee, certificate holder, and applicant for a CoC shall retain these records for 3 years beyond the date when the licensee, certificate holder, and applicant for a CoC last engage in the activity for which the quality assurance program was developed. If any portion of the written procedures or instructions is superseded, the licensee, certificate holder, and applicant for a CoC shall retain the superseded material for 3 years after it is superseded. | **4 – Management/ Documents and Records**<br><br>(2) Specify, prepare, review, approve, and maintain records. | Supplementation is needed to comply with the detailed requirements on documents and records of this section of 10 CFR 71 Subpart H. |
| **71.137 – Criterion XVIII – Audits**<br><br>The licensee, certificate holder, and applicant for a CoC shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, must be taken where indicated. | **9 – Assessment/ Management Assessment**<br><br>Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.<br><br>**10 – Assessment/ Independent Assessment**<br><br>(1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work | Management assessments are not directly required by 10 CFR 71 Subpart H.<br><br>Specific requirements of 10 CFR 71 Subpart H related to audits need to be included in the QA program. |

| 10 CFR 71 Subpart H Criteria | 10 CFR 830 Subpart A/ DOE O 414.1C Criteria | Comments/Gap Analysis |
|---|---|---|
| | performance, and to promote improvement.<br><br>(2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments.<br><br>(3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed. | |

# Appendix B: Comparison & Gap Analysis of 10 CFR 71 and ISO-9001 QA Programs

The NRC staff reviewed ISO 9001-2000, "Quality Management System (QMS) - Requirements," and performed a comparison to 10 CFR Part 50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*. The results were reported in an attachment to NRC SECY-03-0117, *Approaches for Adopting More Widely Accepted International Quality Standards,* July 9, 2003. The content of this attachment is included in this appendix. Based on this review, the NRC staff concluded that "supplemental quality requirements would need to be applied when implementing ISO 9001 within the existing regulatory framework".

Although 10 CFR Part 50 is for *Domestic Licensing of Production and Utilization Facilities*, the QA criteria presented in Appendix B are equivalent to those in 10 CFR Part 71 Subpart H. Consequently, the table presented in this appendix can be used to compare 10 CFR Part 71 Subpart H to the ISO-9001 QA requirements and determine the required QA supplementation for P&T of RAM and fissile materials.

The major differences as stated in SECY 0117 are summarized as follows.

- Independence in the area of design control: Appendix B, Criterion III, requires measures for independently verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculations, or by a suitable testing program; ISO 9001 does not.
- Passing QA requirements to sub-suppliers: Appendix B, Criterion VII, requires suppliers to pass requirements consistent with Appendix B to sub-suppliers; ISO 9001 does not.
- Independence of inspections: Appendix B, Criterion X, requires that inspections be performed by individuals other than those who performed an activity; ISO 9001 does not.
- Independent audits: Appendix B suppliers are audited independently by licensees, who bear the ultimate liability for the safety of procured items; ISO programs are reviewed and audited by auditors under a commercial contract to the supplier.

**Table B-1 Comparison of 10 CFR Part 50, Appendix B, to ISO 9001-2000**

| 10 CFR Part 50, Appendix B | ISO 9001-2000 | Regulatory Impact/Compliance |
|---|---|---|
| **Criterion I: Organization** | | |
| I - Responsibility for establishing and executing of a quality assurance program | | |
| Allows delegation of responsibility for establishing and executing of the QA program to others as long as responsibility is retained by the applicant. | Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. (4.1) | Does not specify that responsibility is retained by the applicant. |
| **Criterion II: Quality Assurance Program** | | |
| II - Determination of appropriate quality requirements | | |
| Requires identification of items controlled by the program and control only to a degree consistent with the item's importance to safety. | Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. (5.4.1) | No direct link to safety |
| II - Controlled conditions for activities affecting quality | | |
| Requires activities affecting quality to be accomplished under controlled conditions. | The organization shall determine and manage the work environment needed to achieve conformity to product requirements. (6.4) | No direct link to safety |

| 10 CFR Part 50, Appendix B | ISO 9001-2000 | Regulatory Impact/Compliance |
|---|---|---|
| Requires control of prerequisites. | The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. (8.2.3) | No direct requirement for the control of prerequisites. |
| II - Indoctrination and training of personnel | | |
| Specifies extent as...suitable proficiency is achieved and maintained. (Implicitly requires a program for retraining or proficiency maintenance). | The organization shall<br>e) maintain appropriate records of education, training, skills, and experience. (6.2.2) | Does not address proficiency achievement and retraining. |
| II - Management review of quality assurance program status and adequacy | | |
| **Criterion III: Design Control** | | |
| III - Review of materials and processes for suitability | | |
| Limits the materials, parts, equipment, and processes selected for review to those that are essential to the safety-related function. | Does not imply that the review is limited to elements essential to the safety-related function. | Does not imply that the review is limited to elements essential to the safety-related function. |
| III - Control of design documents | | |

| 10 CFR Part 50, Appendix B | ISO 9001-2000 | Regulatory Impact/Compliance |
|---|---|---|
| Requires participating design organizations to have procedures. | During the design and development planning, the organization shall determine<br>b) the review, verification, and validation that are appropriate to each design and development stage<br>c) the responsibilities and authorities for design and development. (7.3.1) | Does not directly state the requirement for procedures among participating design organizations. |
| III - Independent verification of design adequacy | | |
| Requires verification and checking to be performed by individuals or groups other than those who performed the design. | Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met design and development input requirements. (7.3.5) | Does not include requirement for independent design verification. |
| Requires qualification testing of specific design features to be performed under the most adverse design conditions. | In planning product realization, the organization shall determine the following, as appropriate:<br>c) required...testing activities specific to the product and the criteria for product acceptance. (7.1) | Does not require testing under the most adverse design conditions. |
| **Criterion IV: Procurement Document Control** | | |
| IV - Inclusion of all applicable requirements in procurement documents | | |

| 10 CFR Part 50, Appendix B | ISO 9001-2000 | Regulatory Impact/Compliance |
|---|---|---|
| Provides examples of regulatory and design bases requirements. | The type and extent of control applied to the ...purchase product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. (7.4.1) | No direct examples of regulatory and design bases requirements. |
| **Criterion VI: Document Control** | | |
| VI - Control of review and approval of changes to documents | | |
| Requires changes to be reviewed and approved by the same organizations that performed the original review and approval. | No direction given on who shall review documents. | No direction given on who shall review documents. |
| Allows designation of another organization for the review and approval. | No direction given on who shall review documents. | No direction given on who shall review documents. |
| **Criterion VII: Control of Purchased Material, Equipment, and Services** | | |
| VII - Documented evidence of conformance prior to installation | | |
| Requires evidence of conformance to be at the site prior to the product being installed and used. | No direction given on having evidence of conformance to be at the site prior to installation. | No direction given on having evidence of conformance at the site prior to installation. However, all documentation pertinent to the product is given over to the licensee. |
| VII - Documented evidence of conformance after installation | | |

| 10 CFR Part 50, Appendix B | ISO 9001-2000 | Regulatory Impact/Compliance |
|---|---|---|
| Requires retention of evidence at the site. | No direction given for retention of evidence at the site. | No direction given for retention of evidence at the site. |
| **Criterion VIII: Identification and Control of Materials, Parts, and Components** | | |
| VIII - Lineage traceability and duration of identification control | | |
| Requires identification maintenance to continue throughout fabrication, erection, installation, and use of the item. | No direction requiring identification maintenance throughout fabrication, erection, installation, and use of the item. | No direction requiring identification maintenance throughout fabrication, erection, installation, and use of the item. |
| VIII - Prevention of use of incorrect items | | |
| **Criterion X: Inspection** | | |
| X - Independence of inspection personnel | | |
| Requires inspection personnel to be independent of the performance of the activity being inspected. | No direction that inspection personnel be independent of the performance of the activity being inspected. | No direction that inspection personnel be independent of the performance of the activity being inspected. |
| X - Indirect inspection by monitoring | | |

| 10 CFR Part 50, Appendix B | ISO 9001-2000 | Regulatory Impact/Compliance |
|---|---|---|
| Specifies monitoring of processing methods, equipment, and personnel. | The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. (8.2.4) | There is no direct requirement to monitor personnel. |
| X - Recognition of hold points | | |
| Defines hold points as points beyond which work may not proceed until inspections are completed. | No direction for hold points beyond which work may not proceed until inspections are completed. | No direction for hold points beyond which work may not proceed until inspections are completed. |
| Requires indication of hold points in appropriate documents if hold points are used. | No direction for hold points in appropriate documents if hold points are used. | No direction for hold points in appropriate documents if hold points are used. |
| **Criterion XI: Test Control** | | |
| XI - Establishment and execution of test program | | |

| 10 CFR Part 50, Appendix B | ISO 9001-2000 | Regulatory Impact/Compliance |
|---|---|---|
| Requires establishment of a test program. | The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system [including].<br>c) required inspection and test activities specific to the product and the criteria for product acceptance. (7.1) | No direct requirement to establish a test program, only to establish test requirements needed for the product. |
| Requires assurance that structures, systems, and components (SSCs) will perform satisfactorily in service. | The organization shall validate any process for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use... (7.5.2) | No direct requirement to validate those SSCs will perform satisfactorily in service. |
| Requires test procedures to incorporate requirements and acceptance limits contained in design documents. | In planning product realization, the organization shall determine the following, as appropriate:<br>b) the need to establish processes, documents...<br>c) required...inspection and test activities specific to the product and the criteria for product acceptance. (7.1) | No direct requirement to incorporate requirements and acceptance limits contained in design documents. |
| XI - Inclusion of test parameters in test documents | | |

| 10 CFR Part 50, Appendix B | ISO 9001-2000 | Regulatory Impact/Compliance |
|---|---|---|
| Requires test procedures to assure completion of test prerequisites. | In planning product realization, the organization shall determine the following, as appropriate:<br>b) the need to establish processes, documents...<br>c) required...inspection and test activities specific to the product and the criteria for product acceptance. (7.1) | No requirement for the documentation or completion of test prerequisites. |
| Requires testing to be performed under suitable environmental conditions. | In planning product realization, the organization shall determine the following, as appropriate:<br>b) the need to establish processes, documents...<br>c) required...inspection and test activities specific to the product and the criteria for product acceptance. (7.1) | No direct requirement that testing to be performed under suitable environmental conditions. |
| **Criterion XIII: Handling, Storage and Shipping** | | |
| XIII - Controls for handling, storage, shipping, cleaning, and preservation | | |
| Requires control in accordance with work and inspection instructions. | No direct requirements to have controls in accordance with work and inspection instructions. | No direct requirements to have controls in accordance with work and inspection instructions. |
| Defines the purpose of controls as prevention of damage or deterioration. | No definition of the purpose of controls as prevention of damage or deterioration. | No definition of the purpose of controls as prevention of damage or deterioration. |
| XIII - Provisions for special product requirements | | |

| 10 CFR Part 50, Appendix B | ISO 9001-2000 | Regulatory Impact/Compliance |
|---|---|---|
| Provides examples of types of protective environments. | No examples given of types of protective environments. | No examples given of types of protective environments. |
| **Criterion XV: Nonconforming Materials, Parts, and Components** | | |
| XV - Identification, documentation, segregation, and notification | | |
| Requires notification to affected organizations. | When nonconforming product is detected after delivery or after use has started, the organization shall take action as appropriate to the effects, or potential effects, of the nonconformity. (8.3) | No requirement to inform licensees of potential deficiencies in defective equipment. |
| **Criterion XVI: Corrective Action** | | |
| XVI - Identification and corrections of condition adverse to quality | | |
| Provides examples of applicable conditions, (e.g., failures, malfunction, deficiencies, deviations, defective material, and nonconformances). | No examples are given of applicable conditions, (e.g., failures, malfunction, deficiencies, deviations, defective material, and nonconformances). | No examples are given of applicable conditions, (e.g., failures, malfunction, deficiencies, deviations, defective material, and nonconformances). |
| XVI - Determination of causes and preclusion of repetition of adverse quality conditions | | |
| Requires determination of the cause of significant conditions adverse to quality. | A documented procedure shall be established to define requirements for<br>d) determining and implementing action needed. (8.5.2) | Does not segregate “significant conditions adverse to quality.” |

| 10 CFR Part 50, Appendix B | ISO 9001-2000 | Regulatory Impact/Compliance |
|---|---|---|
| XVI - Documentation and reporting of corrective action | | |
| Requires that the cause and the corrective action taken be reported to appropriate management levels. | No discussion on reporting cause and corrective action to appropriate management levels. | No discussion on reporting cause and corrective action to appropriate management levels. |
| **Criterion XVII: Quality Assurance Records** | | |
| XVII - Identification of record types | | |
| Lists the minimum types of records to be maintained. | A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention, time, and disposition of records. (4.2.4) | Does not list the minimum types of records to be maintained. |
| XVII - Special requirements for inspection and test records | | |
| Requires identification of the inspector, type of observation, inspection results, and acceptability. | No direct requirement to identify the inspector or type of observations. In planning product realization, the organization shall determine the following, as appropriate:<br>c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance. (7.1) | No direct requirement to identify the inspector or type of observations. |

| 10 CFR Part 50, Appendix B | ISO 9001-2000 | Regulatory Impact/Compliance |
|---|---|---|
| XVII - Retention and retrievability of records | | |
| **Criterion XVIII: Audits** | | |
| XVIII - Audit performance, documentation, and review | | |
| Requires trained auditors who are independent of the activity being audited. | No requirement for trained auditors who are independent of the activity being audited. | No requirement for trained auditors who are independent of the activity being audited. |
| XVIII - Audit follow-up requirements | | |
| Includes re-audit of deficient areas in followup actions. | No direction for re-audit of deficient areas. | No direction for re-audit of deficient areas. |