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Quality Assurance Inspections for Shipping and Storage Containers

Prepared by
H. M. Stromberg, G. D. Roberts, J. H. Bryce

Idaho National Engineering Laboratory

Lockheed Idaho Technologies Company

Prepared for
U.S. Nuclear Regulatory Commission

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Prepared by
H. M. Stromberg, G. D. Roberts, J. H. Bryce

Idaho National Engineering Laboratory
Lockheed Idaho Technologies Company
Idaho Falls, ID 83415

D. G. Reid, NRC Technical Monitor

Prepared for
Spent Fuel Project Office
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
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ABSTRACT

This document is a guide for conducting quality assurance inspections of transportation packaging and dry spent fuel storage system suppliers. Suppliers are defined as designers, fabricators, distributors, users, or owners of transportation packagings and dry storage systems for radioactive materials. This document may be used during an inspection to determine regulatory compliance with Title 10 of the Code of Federal Regulations, Part 71, Subpart H; Title 10 of the Code of Federal Regulations, Part 72, Subpart G; Title 10 of the Code of Federal Regulations, Part 21; and supplier's quality assurance program commitments. This guide was developed to provide a structured and consistent approach to inspections. The guidance described in this document provides a framework for the evaluation of transportation packaging and dry spent fuel storage systems quality assurance programs. Inspectors are provided with the flexibility to adapt the methods and concepts to meet the inspection requirements for the particular facility. The method used in this document treats each activity at a facility as a separate performance element, and combines the activities within the framework of an "inspection tree." The method separates each performance element into several areas for inspection and identifies guidelines, based on regulatory requirements, to qualitatively evaluate each area. This document also serves as a field manual to facilitate the quality assurance inspection activities. This document replaces an earlier document, NUREG/CR-5717 *Packaging Supplier Inspection Guide*. NUREG-/CR-5717 contains a methodology for the quality assurance inspection activities of transportation packagings. This replacement document enhances the inspection activities for transportation packagings, and adds the dry spent fuel storage system quality assurance inspection activities.

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EXECUTIVE SUMMARY

This document outlines a standardized method for inspections conducted by the U.S. Nuclear Regulatory Commission's (NRC's) Office of Nuclear Materials Safety and Safeguards. Such inspections evaluate the quality assurance (QA) activities of transportation packaging and dry spent fuel storage system suppliers. Suppliers are defined as designers, fabricators, distributors, users, or owners of transportation and dry spent fuel storage system containers for radioactive materials. The guidelines are designed to facilitate the work of inspectors in assessing the licensee's level of compliance with regulatory requirements and QA program commitments.

The term licensee is used in this guide to include all entities for whom the NRC QA requirements apply, for example: designers, fabricators, and users of transportation packagings, fabricators, and operators of dry spent fuel storage systems approved by NRC through the issuance of a certificate of compliance.

The evaluation method presented in this document (a) uses an analytical tree to standardize inspections, (b) provides a basic structured evaluation technique, and (c) establishes a method for the overall evaluation of a licensee's compliance with regulatory requirements and QA Program commitments. The evaluation method addresses the regulatory requirements and QA Program commitments in four performance elements: management controls, design controls, fabrication controls, and maintenance controls.

This document presents the regulatory requirements and licensee commitments for inspection in a format that is suitable for use in the field. It presents each performance element and lists the applicable inspection elements that should be used to evaluate them. The performance elements are connected and structured through the use of an "inspection tree." Each element is evaluated and results are summarized using a color coding scheme.

QUALITY ASSURANCE INSPECTIONS FOR SHIPPING AND STORAGE CONTAINERS

1. INTRODUCTION

This inspection guide was developed as an aid for performing quality assurance (QA) inspections of fabricators of transportation packaging or dry spent fuel storage systems for the Nuclear Regulatory Commission's (NRC's) Office of Nuclear Material Safety and Safeguards. In earlier efforts, Reference 1 was the method used for inspecting and documenting transportation packagings vendor inspections. This report enhances the original report and adds the inspection of dry spent fuel storage systems.

The term licensee as used in this guide includes all entities for whom the NRC QA requirements apply, for example: holders of NRC approved QA programs for transportation packagings and dry spent fuel storage systems.

The regulatory requirements specified in this document are identified in Title 10 of the Code of Federal Regulations (10 CFR) or are commitments specified in licensees' QA programs. The requirements are specified in 10 CFR, Part 71, Subpart H, and 10 CFR, Part 72, Subpart G. The requirements from these two subparts of the code are similar with the exception of the period of record retention. 10 CFR, Part 71 requires that QA records be retained for the entire time that a licensee engages in the activity for which a license was obtained plus three years. 10 CFR, Part 72 requires that QA records be maintained until the NRC terminates the license. In addition to the requirements specified in the QA portions of the code referenced above, 10 CFR, Part 21 specifies requirements for reporting defective materials.

This inspection guide uses a Management Oversight Risk Tree (MORT), Reference 2. The MORT methodology provides an effective approach to perform QA inspections, and provides a means for systematically presenting the inspection findings by displaying the effectiveness of the licensees' QA practices.

Use of the systematic methodology establishes an overall summary of compliance with regulatory requirements and a licensee's QA program commitments. These summaries are obtained by examining all of the inspection elements (the bulleted criteria under each block in Figure 3) pertaining to a licensee's QA process. An assessment of each inspection element for adequacy is based on observations, inspection activities, inspection reports, past evaluations, and documentation in areas specific for each element. Once each inspection element is assessed, the results are summarized for the subtier performance elements (the blocked criteria numbered 1.1 through 4.2). The summaries for the subtier performance elements are used to summarize the major performance elements (the blocks numbered 1., 2., 3., and 4.). Using the summaries of the major performance elements, the QA Program assessment is then summarized.

For example, if an inspector assesses the effectiveness of the fabrication processes, an evaluation would be performed by examining the subtier performance elements of cleaning, special processes, machining, and assembly and determine which elements are applicable based on the licensee's activities. For the applicable subtier performance elements, the inspection elements listed below those blocks are assessed. Expanding the above example, when assessing the subtier performance element for cleaning, it is summarized by evaluating fluid controls, cleaning guidelines, and cleaning processes. Using the summaries from the assessment of these inspection elements, the effectiveness of the licensee meeting the regulatory requirements and licensee QA Program commitments for cleaning is assessed and summarized. Following this method, the inspection elements for each subtier element are assessed and summarized.

From an assessment of the inspection elements, all applicable subtier elements are summarized.

Once applicable elements below a major performance elements are assessed, the summaries for the subtier performance elements are used to assess the adequacy of the major performance elements.

The inspection guide presents the inspection process in three sections: Inspection and Evaluation Methodology, Use of the Quality Assurance Inspection Tree, and Inspection Evaluation Guidelines. Inspection Elements 1 through 4, in the appendices, contain the guidelines in checklist form. The checklists are provided in a format such that they can be removed from the document and be used during an inspection.

2. INSPECTION AND EVALUATION METHODOLOGY

The inspection and evaluation methodology requires that three tasks be performed: (a) information collection, (b) tailoring the guide to match the licensee, and (c) evaluation of inspection results. Each effort is discussed separately.

2.1 Information Collection

The inspection begins with information collection. Examples of a number of available sources that may be utilized are:

- Certificates of Compliance
- Previous Inspection Reports
- Previous Evaluations
- Safety Evaluation Reports (SERs)
- Quality Assurance Program Applications to NRC
- Safety Analysis Reports (SARs)
- U.S. NRC Enforcement Actions
- Organization Charts
- General Correspondence
- Procedures
- Quality Assurance Plan
- Quality Assurance Records

  * Procurement documents
  * Test Reports
  * Analysis Reports
  * Audit Reports
  * Inspection Reports
  * etc.

The inspectors examine the information collected and analyze it against the applicable inspection elements. Due to the large quantity of documents at a facility, it is sometimes difficult to examine all of them and identify all inspection elements to which each piece of information is applicable. Because of this, an inspector may inspect by sample and by researching noteworthy areas.

There are times when information for a performance element does not exist, the quantity of data is insufficient for an evaluation, or the data are inconclusive and an adequate evaluation cannot be performed. When this situation occurs, the significance of the performance element or inspection element should be evaluated and the possibility of special data collection pursued. When the quantity of data are determined to be adequate for evaluation, the guidelines outlined in Section 3 are used.

2.2 Tailoring the Guide to Match the Licensee

Licensees differ in activity, size, and organization. Many component suppliers, contractors, and vendors have a major role in the production or distribution of the containers. When contractors or vendors are used to perform any of the major or subtier performance elements presented in this guide, they may be inspected for compliance with the regulatory requirements and QA Program commitments as detailed for their specific elements (i.e., management, design, fabrication, or maintenance controls).

When inspecting a licensee with a small organization, this guide may still be used. However, in small organizations, many elements may be performed by one individual. In these cases, the inspection tree and guide are used to aid the inspector in asking the appropriate questions to ensure full coverage of all applicable performance elements and their associated inspection elements.

This guide is intended to provide a framework for QA inspections. Inspectors have the flexibility to adapt the methods and concepts presented in this guide to meet the needs of the particular licensee being inspected. It is up to the individual inspector to use his/her own judgement to properly apply the guidelines to the situation.

2.3 Evaluation of Results

During the inspection, the inspectors determine the adequacy of each applicable element based on the regulatory requirements and an assessment of compliance to these requirements. After the major performance elements have been evaluated within the framework of the guidelines, an overall assessment of the licensee's QA program performance is made. A further description of the method for determining the adequacy and assessment of the QA Program is provided in Section 3.

3. USE OF THE QUALITY ASSURANCE INSPECTION TREE

QA inspections are performed to determine compliance with NRC regulatory requirements and QA Program commitments. In the process, an assessment is made of each applicable element of the Quality Assurance Inspection Tree. The results of these assessments are used to determine a licensee's compliance with applicable regulatory requirements and QA Program commitments.

Use of standardized inspection methods permit objective comparison of observations made by different inspectors. A summary of the licensee's QA Program is developed by combining and assessing performance element findings, which are obtained using inspection elements. The inspection elements are listed in Section 4 (Inspection Evaluation Guidelines), on the inspection tree diagram, and in the appendices.

3.1 General Description

A MORT based inspection tree was developed to organize the inspection process. The inspection tree graphically depicts basic licensee activities and the way they are examined during an inspection. Figure 1, Inspection tree major elements, provides a presentation of the major performance elements. Subtier performance elements are presented in Figure 2.

From Figure 1, it can be seen that there are four major performance elements: Management Controls, Design Controls, Fabrication Controls, and Maintenance Controls. As can be seen in Figure 2, each major performance element is divided into subtier performance elements. Below the subtier performance elements are additional subtier performance elements or inspection elements. The inspection elements listed below each subtier performance element are used to assess the subtier performance element. The inspection elements are listed in Figure 3, Quality assurance inspection tree. Figure 3 provides a complete graphical depiction of a QA Program. Figure 4 (Quality assurance performance inspection summary tree) is a performance summary of the inspection showing the inspection tree through the major performance elements. The summary tree is used for presenting overall inspection findings. Figures 3 and 4 are attached at the end of this document so they can be separated during the inspection.

It is proposed that one of two methods be utilized for applying the inspection tree. The first method begins once information collection has been initiated. As information is collected and reviewed, applicable performance elements of the tree are identified. The information is compared to the inspection element criteria. Each subtier performance element is evaluated for compliance with the applicable codes, standards, regulatory requirements, and QA program commitments.

The second method for entering the inspection tree is to select a performance element and then locate information applicable to that element. The information is then used to determine the adequacy of performance element documentation and implementation.

3.2 Color Coding

During the inspection process, all major performance elements, their associated subtier performance elements, and inspection elements are reviewed for adequacy based on their significance to safety. Data selected during the information collection process are assessed against the inspection elements for each applicable performance and inspection element. Following that review, a color code is assigned that indicates the level of performance found by the inspectors.

The blocks on the inspection tree are separated diagonally into two parts. The part above the diagonal line shows the adequacy with which the performance area is documented procedurally. The part below the diagonal line shows the adequacy of licensee's implementation of the approved procedures. The color coding system consists of coloring the upper and lower areas of the boxes either green, yellow, red, or blue. Each block's coding can be a combination of any two of those colors, depending on the adequacy of established procedures and their implementation. As an example, green/green shows that a performance element has excellent procedural control and excellent implementation of the proce-

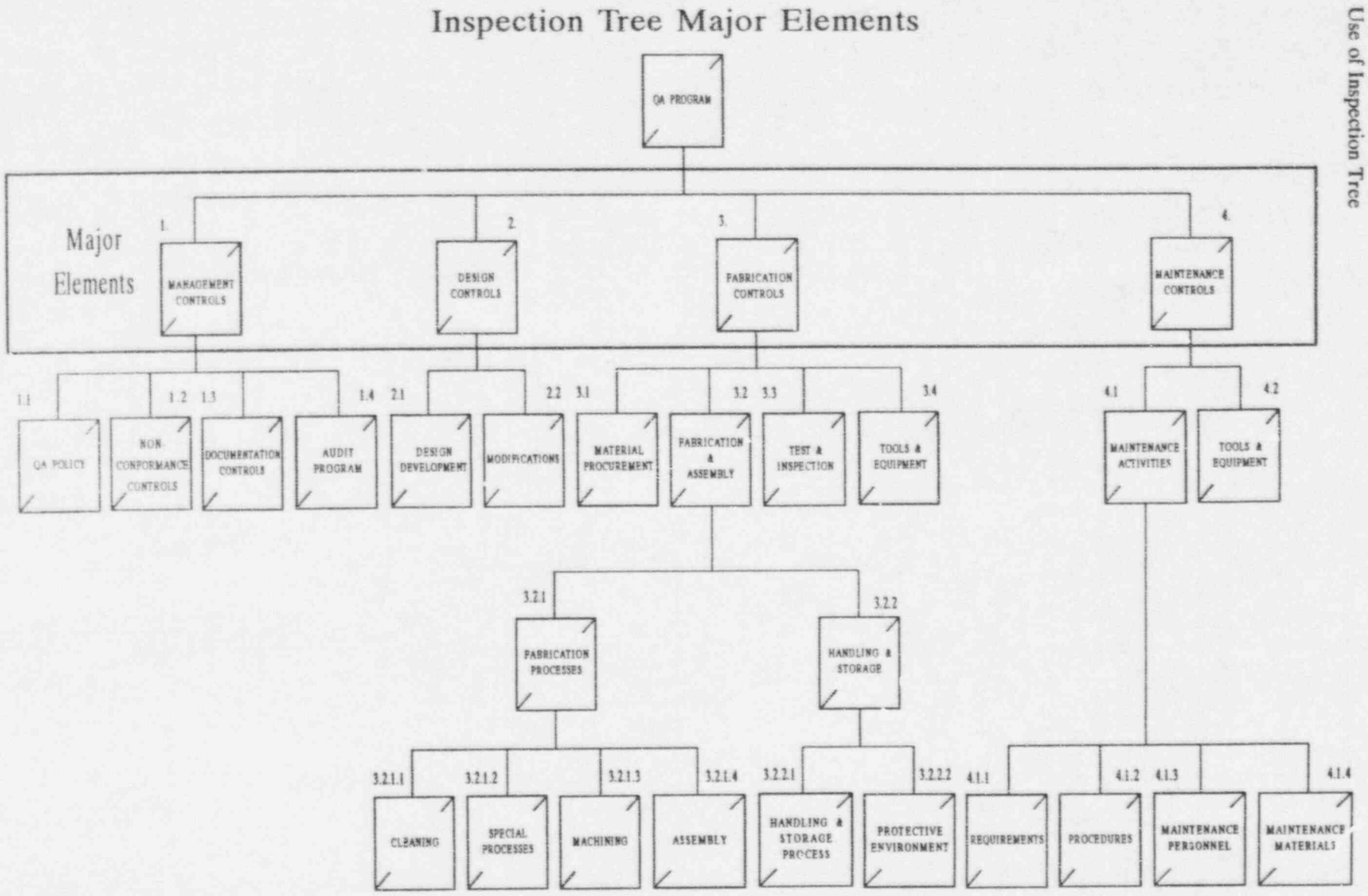


Figure 1. Inspection tree major elements.

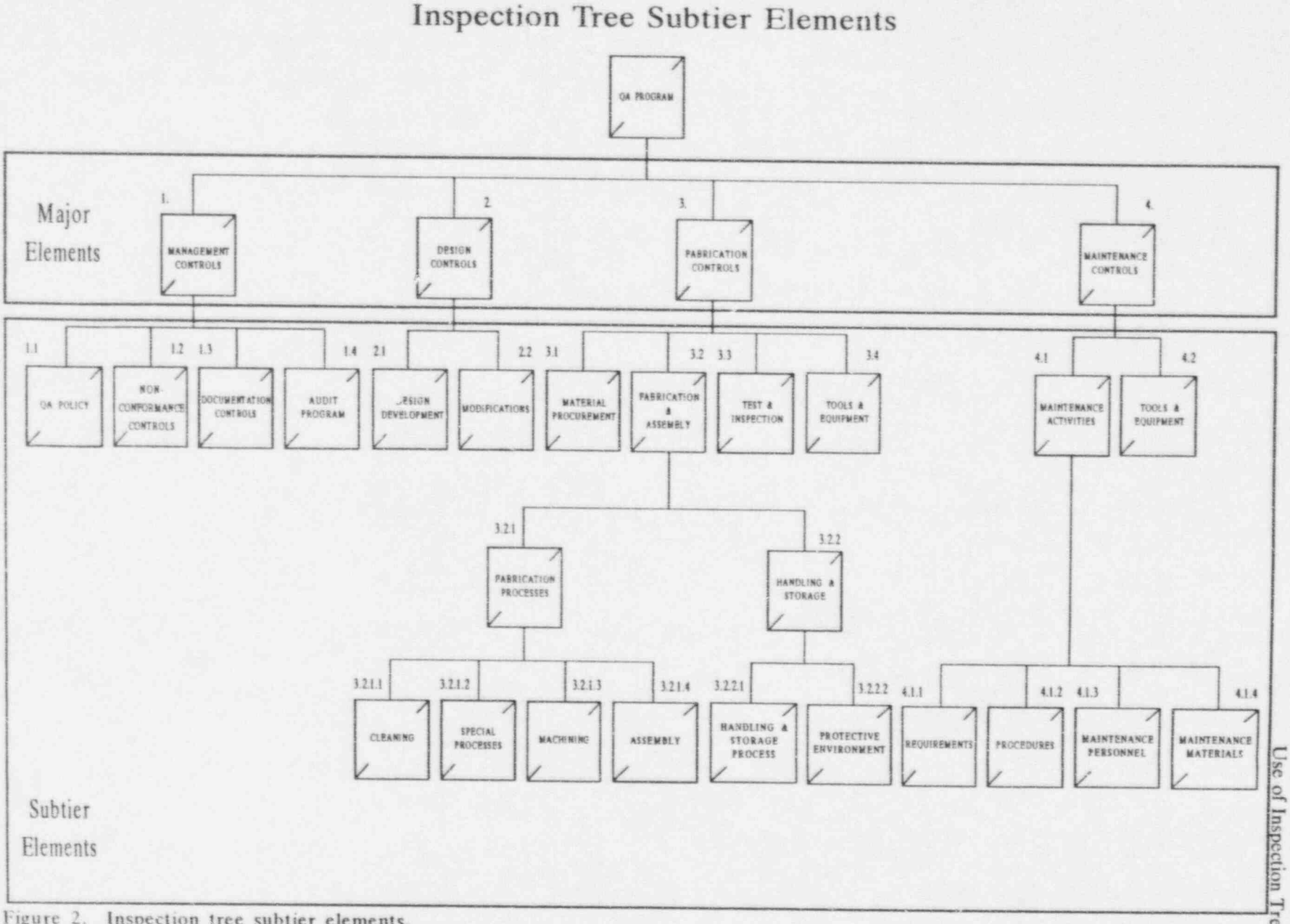


Figure 2. Inspection tree subtier elements.

dures, while red/red indicates that the element has inadequate procedures and unsatisfactory implementation. Table 1 below, lists the colors used for coding and the assessment criteria.

Each major performance element on the summary tree is coded accordingly, based on the assessments of the subtier performance and inspection elements. After all major performance elements are evaluated, the overall QA program performance is summarized and color coded based on an assessment of its major performance elements.

3.3 Assessment Process

The inspection assessment is summarized using the following steps.

1. Evaluate the information gathered during the inspection against the applicable inspection elements (the items that have bullets on Figure 3) for all subtier performance elements (shown as enclosed blocks on Figure 2). This is done for each inspection element identified in Section 4 and as presented in the appendices.

2. Consider the criteria that are used to assess the subtier performance elements. Consider documentation and implementation where appropriate. The working copy of the inspection tree, Figure 3, is used during the inspection as a worksheet to document and display the findings. Following an evaluation of the data, each subtier element is assessed and color coded.

3. Consider the assessment criteria for each major performance element (Figure 1). Combine the assessment for all subtier elements into a single decision for the major performance element.

Table 1. Performance Color Code

Colors	Assessment Criteria
Green	Indicates that overall performance is EXCELLENT. Overall performance surpasses regulatory requirements and applicable commitments. Guidelines are fully documented and implemented.
Yellow	Indicates that overall performance is SATISFACTORY. Applicable elements of this program have been developed, documented, and implemented so that the regulatory requirements and applicable commitments are met. Some areas may require improvement.
Red	Indicates that overall performance is UNSATISFACTORY. Inadequate or no effort has been made in this specific area, and does not meet regulatory requirements or applicable commitments. Documentation or implementation is missing or inadequate.
Blue	Indicates that the element was not inspected, data are insufficient for evaluation, or the element is not applicable.

4. After each major performance element has been evaluated, the process of assessing the performance elements is repeated for each level of the tree until the top element is determined. It should be noted that some major performance elements may be considered more important than others based on their importance to safety and the licensee's operation. In the analysis, these elements may be considered and weighted more heavily. The color coding of the top element is a measure of compliance of the licensee's overall QA Program with regulatory requirements and QA Program commitments.

5. The results of the assessment are transferred from the Quality Assurance Inspection Tree to the Quality Assurance Performance Inspection Summary Tree. The Quality Assurance Performance Inspection Summary Tree (Figure 4) is used for the presentation of the inspection findings.

4. INSPECTION EVALUATION GUIDELINES

The Quality Assurance Inspection Tree provides a means to systematically assess a licensee's compliance with regulatory requirements and licensee QA Program commitments. To provide a correlation between the text and the numbering scheme on the Quality Assurance Inspection Tree, the numbers shown in the parentheses behind the section titles below correspond to the inspection element numbers in the Quality Assurance Inspection Tree. Also included at the end of each inspection element description is a reference to the applicable section of the 10 CFR, Part 21, Part 71, or Part 72.

4.1 Management Controls (1.)

Evaluation of management controls covers the QA policy, nonconformance controls, documentation controls, and audit program. QA policy effectiveness is verified through personnel interviews, review of control documents, working document reviews (including procedures, purchase orders, specifications, drawings, manuals, etc.), and a review of QA inspections and audit reports and findings.

The guidelines provided below are used to evaluate the adequacy of management controls. The inspection checklist is provided in Appendix A.

4.1.1 Quality Assurance Policy (1.1)

The QA policy consists of the philosophies and procedures that are established to ensure effective QA Program implementation.

The QA policy is assessed based on the emphasis and controls it places on ensuring that the highest level of QA standards are met. QA policy is used to verify whether all aspects of the QA system are verifiable and traceable while being applied to the design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection. testing, operation, maintenance, repair, modification of structures, systems, and components, and decommissioning of packaging and dry storage systems that are important to safety. The following guidelines are used to assess QA Policy:

1. Ensure QA policies have been documented, approved, and implemented. (71.101[c] and 71.103), (72.140[c] and 72.142)

2. Ensure that QA program authorities and responsibilities have been clearly defined and documented. (71.103), (72.142)

3. Ensure the QA organization functions as an independent group. (71.103), (72.142)

4. Ensure the organizational charts indicate QA organization independence from cost and schedule influences. (71.103), (72.142)

5. Ensure a graded approach to QA is applied consistent with importance to safety. Ensure controls are placed on identified materials, structures, systems, and components. Consider the following: (71.101[b], 71.103, and 72.105[a]), (72.140[b], 72.142, and 72.144[a])

   a. The impact of malfunction or failure of the item to safety;

   b. The design and fabrication complexity or uniqueness of the item;

   c. The need for special controls and surveillance applications to processes and equipment;

   d. The degree to which functional compliance can be demonstrated by inspection or test; and

   e. The quality history and degree of standardization of the item.

6. Ensure QA personnel have sufficient freedom and authority to identify and resolve quality problems. (71.103), (72.142)

7. Ensure the materials, structure, systems, and components covered by the QA Program have been identified and documented. (71.105[a]), 72.144[a])

8. In cases where a parts dedication program is used, ensure that the following are documented and implemented. (21.3[c])

    a. A safety-related component identification program. Included are the following:

        1 Component safety-related levels documented and implemented;
        2 Safety-related components for each container documented and evaluated; and
        3 An inspection program that meets the requirements of the safety-related level ratings.

    b. Material specification identification program for safety-related components is identified, documented, and implemented.

    c. Sources for safety-related equipment, materials, and commercial grade alternates are identified and placed on approved vendor lists.

    d. A program for identifying and ensuring that commercial grade alternates meet or exceed the specifications for the safety-related components has been developed, documented, and implemented. This program should include the following:

        1 Sample testing methods; and
        2 Substituted materials are traceable to technical justifications in program documents and specific containers having substitutions are identified.

4.1.2 Nonconformance Controls (1.2)

Control of materials, parts, or components that do not conform to requirements is verified using the following guidelines.

1. Ensure that a nonconformance control program identifies, tracks, and resolves major quality discrepancies. Ensure the nonconformance control programs and procedures are documented, controlled, periodically reviewed, and updated. (71.131 and 71.133), (72.170 and 72.172)

    a. Ensure that nonconformances are identifiable and traceable.

    b. Ensure that nonconforming materials are adequately identified and segregated to prevent inadvertent use.

    c. Ensure nonconformances are dispositioned in accordance with documented procedures.

    d. Ensure nonconformance dispositions are appropriately reviewed and approved.

    e. Ensure safety-related nonconformances are reported to appropriate management levels.

2. Ensure the deficiency and deviation control program identifies, tracks, and resolves minor quality discrepancies. The deficiency and deviation control program is documented, controlled, reviewed, and updated. (71.133), (72.172)

3. Ensure the corrective action tracking programs have been developed, documented, and implemented to follow deficiencies, deviations, nonconformances, and audit and inspection findings. (71.131, 71.133, and 71.137), (72.170, 72.172, and 72.176)

4. Ensure a root cause analysis program has been developed and implemented for determining the root causes of failures or rework events. (71.133), (72.172)

5. Ensure the provisions of Part 21 are identified on procurement documents for safety-related components purchased after January 6, 1978. (21.31)

6. Ensure that the required Part 21 documents are posted conspicuously. (21.6)

    a. 10 CFR, Part 21,

    b. Section 206 of Energy Reorganization Act of 1974, and

c. Procedures adopted pursuant to 10 CFR, Part 21.

7. In the cases of failures to comply with the license or the existence of a defect, the following criteria must be addressed to be in compliance with Part 21 (21.21):

   a. Ensure appropriate procedures have been documented and implemented to accomplish the following:

      1- Evaluation of deviations and failures to comply with the license, and identify defects associated with substantial safety hazards as soon as practicable.

      2- Ensure that if an evaluation of a deviation or failure to comply can not be completed within 60 days, an interim report is prepared and submitted to NRC within 60 days of discovery.

      3- Ensure that the responsible licensee officer is informed within five working days after completion of the evaluation if the component fails to comply with the Atomic Energy Act, or any applicable rule, regulation order, or NRC license.

   b. When there are cases of failure to comply with the license or the existence of a defect, appropriate procedures have been developed, reviewed, and approved to ensure NRC reporting requirements are met. (21.21)

   c. Records that document accomplishing Part 21 are prepared and maintained. (21.51)

4.1.3 Documentation Controls (1.3)

The documentation controls are evaluated based on the ability of the QA Program to control its quality documentation. During the inspection, the instructions, procedures, and drawings, including changes are reviewed for adequacy, released by authorized personnel, and available at locations where the prescribed activities are performed. The following are used to assess the adequacy of documentation controls:

1. Ensure documentation controlling the fabrication, maintenance, and procurement processes is approved, with provisions in place for periodic review and updates. (71.111, 71.115[a], and 71.135), (72.150, 72.154[a], and 72.174)

2. Ensure a procedure development program is established and documented. This program specifies the various reviews and approvals required during procedure development, with provisions in place for periodic reviews and updates. (71.111 and 71.113), (72.150 and 72.152)

3. Ensure the contractor control program is documented and all materials and services supplied by contractors are covered by adequate QA procedures. This includes specification of appropriate inspections and audits. (71.109 and 71.115[a]), (72.148 and 72.154[a])

4. Ensure the quality records are identified, retrievable, controlled, stored, and periodically reviewed and updated. Ensure quality records are retrievable for the life of the packaging and three years after ceasing activities for packagings licensed under Part 71. Ensure quality records are retrievable until the NRC terminates a license for dry storage systems licensed under Part 72. (71.135), (72.174)

5. Ensure a completed document close-out review program is documented and implemented. (71.123 and 71.135), (72.162 and 72.174)

6. Ensure the appropriate procedures are available at job locations. (71.113), (72.152)

7. Ensure changes to controlled documents are reviewed and approved. (71.113), (72.152)

8. Ensure measures are established for the issuance of controlled documentation. Control documentation should ensure that only the most current documents are used. (71.113), (72.152)

4.1.4 Audit Program (1.4)

The QA audit program examines the policies, procedures, and historical documentation demonstrating that high QA standards are implemented and practiced. When inspecting the audit program, consider whether the following attributes are addressed:

1. The audit program covers all applicable aspects of the QA Program. (71.137), (72.176)

2. Audits are scheduled and conducted periodically. Included are audits to ensure conformance with documented instructions, procedures, and drawings for accomplishing the activity. (71.121 and 71.137), (72.160 and 72.176)

3. Audits are performed in accordance with approved procedures or checklists. (71.137), (72.176)

4. Audit personnel are appropriately trained to perform audits. (71.137), (72.176)

5. Audit personnel do not have direct responsibility in the areas being audited. (71.137), (72.176)

6. Audit results are documented. (71.137), (72.176)

7. Audit records are reviewed and approved by the appropriate levels of management. (71.137), (72.176)

8. Appropriate follow-up actions are taken for deficient areas. (71.137), (72.176)

9. An audit discrepancy resolution program has been developed, documented, and implemented. Resolutions are implemented in a timely manner. (71.137), (72.176)

10. Corrective action follow-up programs have been identified and implemented. (71.133), (72.172)

11. Audits are performed on the following, as appropriate, based on importance to safety, complexity, and quantity of product: (71.137), (72.176):

    a. Internal operations;
    b. Contractors;
    c. Vendors; and
    d. Suppliers.

12. Contractors, vendors, or suppliers if used are, approved, and that an approved vendor list is maintained and complied with. (71.115 [a]), (72.154[a])

13. Contractors or vendors, if used, adhere to a vendor control program that is in place. The program should ensure that all materials and services supplied by contractors or vendors are covered by adequate QA programs as verified through appropriate inspections and audits. (71.109 and 71.115[a]), (72.148 and 72.154[a])

4.2 Design Controls (2.)

All phases of the design processes are required to be controlled and traceable from the onset of design through the completion of testing and delivery. A review of this area ensures that the design and any changes have been given adequate consideration in accordance with certificates of compliance. Specific areas to be considered during the design are: criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; features to facilitate decontamination; and delineation of acceptance criteria for inspections and tests.

The types of documents reviewed include design documents, procurement documents, procedures, test documents, nondestructive examination (NDE) records, and management control documents. Inspect a sample of several fabrication and modification activities to ensure adequate design review has been completed, particularly in the areas of design basis calculations, criticality control, and thermal design. The areas considered are discussed in greater detail below. The design control checklists are presented in Appendix B.

4.2.1 Design Development (2.1)

The design development program consists of measures established to ensure that high standards of design control are implemented and practiced. When inspecting and evaluating the design development, consider the following:

1. Ensure the measures that control the design process are documented and implemented. (71.107[a] and 71.111), (72.146[a] and 72.150)

2. Ensure that the regulatory and license application requirements are reflected in the specifications, drawings, procedures, and instructions. (71.107[a]), (72.146[a])

3. Ensure that the appropriate quality standards are specified and included in the design. (71.107[a]), (72.146[a])

4. Ensure that any deviations from standards are adequately controlled. (71.107[a]), (72.146[a])

5. Ensure measures have been established to determine the suitability of materials, parts, equipment, and processes that are important to safety. (71.107[a]), (72.146[a])

6. Ensure that the design control interfaces are established and implemented. (71.107[b]), (72.146[b])

7. Ensure interface activities between participating organizations are controlled by approved and documented procedures. (71.107[b]), (72.146[b])

8. Ensure that design control measures provide independent verification of design accuracies, (eg., design review, calculations, prototype testing, etc.). (71.107[b]), (72.146[b])

9. Ensure that design changes receive similar design controls as the original design. (71.107[c]), (72.146[c])

10. Ensure design changes have NRC approval. (71.107[c]), (72.146[c])

4.2.2 Modifications (2.2)

Examine the controls for the design modification process that ensure any changes made to the design are reflected in the design documents. Consider the following:

1. Weight and center of gravity are changed to support any modifications. (71.33 and 71.107[c]) (72.24[b] and 72.146[c])

2. Material property changes are reflected in design documents. (71.33 and 71.107[c]), (72.24[b] and 72.146[c])

3. Galvanic and chemical property changes are reflected in the design documents. (71.43[d] and 71.107[c]), (72.24[b] and 72.146[c])

4. Modifications to closure devices are reflected in the design documents. (71.43[c] and 71.107[c]), (72.24[b] and 72.146[c])

5. Modifications to lifting devices are reflected in the design documents. (71.45[a] and 71.107[c]), (72.24[b] and 72.146[c])

6. Modifications to tie-down devices are reflected in the design documents.(71.45[b] and 71.107[c]), (72.24[b] and 72.146[c])

7. Type B packaging items (load resistance and external pressure) and potential changes in environmental conditions are given adequate consideration during the design and modification process. Consider the following: (71.71, 71.73, and 71.107[c])

   - temperature
   - immersion
   - vibration
   - water spray
   - drops
   - internal pressure
   - compression
   - load resistance
   - percussion
   - fire
   - external pressure
   - penetration pressure.

8. Evaluate the document review process used during the development, modification, and closeout of procedures and documents. Ensure the review process is documented and imple-

mented. Ensure that any changes to procedures and control documents are implemented into the design. Consider the following: (71.107[c]), (72.146[c])

a. Drawing changes
b. Fabrication and manufacturing procedures.

9. Evaluate the engineering change notice (ECN) control process. Ensure the ECN process is proceduralized, approved, and traceable. (71.107[c]), (72.146[c])

10. Evaluate the drawing change control process. Ensure the drawing control process is proceduralized, approved, and traceable. (71.107[c]), (72.146[c])

11. Assess the design modification review process. Ensure the design modification review process is documented, proceduralized, approved, and traceable. Ensure the design modification review is as comprehensive as the original design review. (71.107[c]), (72.146[c])

4.3 Fabrication Controls (3.)

The inspection and evaluation of this performance element verifies that all phases of the fabrication process are properly controlled and implemented. The fabrication process is required to be controlled and verifiable from the onset of design through the completion of the manufacturing process. The areas include material procurement, fabrication and assembly, test and inspection, and equipment. Inhouse, contractor, or vendor supplied fabrication controls are evaluated using identical criteria.

The types of documents to be reviewed include design documents, procurement documents, fabrication documents (e.g., travelers), process documents (e.g., machining and welding), procedures, test documents, NDE records, and management control documents. The fabrication controls checklists are provided in Appendix C.

4.3.1 Material Procurement (3.1)

Materials are to be controlled, verifiable, and traceable from the time of purchase through the life of the packaging or dry storage system. Specific areas are discussed below.

1. Ensure measures that control material procurement are documented and implemented. (71.109 and 71.135), (72.148 and 72.174)

2. Ensure procurement documents are controlled and retrievable. Also ensure that the applicable codes, standards, and regulations are referenced. (71.109, 71.115[b], and 71.135), (72.148, 72.154[b], and 72.174)

3. Ensure material traceability documentation is available and auditable. (71.115[b] and 71.117), (72.154[b] and 72.156)

4. Ensure drawings and procedures used for procurement are identified and consistent with specifications. Ensure procurement is made in accordance with approved specification changes. Ensure any changes made to specifications and design basis analyses are incorporated in these documents. (71.111), (72.150)

5. Ensure suitable materials are specified and used in accordance with design specifications, calculations, and models. Ensure substituted materials are as good or better than the original. Consider the following specifically but others may be considered: (71.115[a]), (72.154[a])

- seals
- gaskets
- foam.

6. Ensure material shelf life for safety-related components has been considered. (71.117), (72.156)

7. Ensure there is a receipt inspection program to address compliance with procurement documents. Also ensure that the results of the receipt inspections are documented and retrievable. (71.115[b]), (72.154[b])

8. Ensure measures have been established that assure each item is identified by heat number, part number, or other appropriate means, either on the item or on records traceable to the item. The measures are required throughout fabrication, installation, and use of the item. (71.117), (72.156)

4.3.2 Fabrication and Assembly (3.2)

The fabrication and assembly performance element consists of procedures that ensure high standards of fabrication and assembly controls are implemented and practiced.

The fabrication and assembly process controls are inspected through personnel interviews, reviews of control documents (including purchase orders, specifications, drawings, manuals, etc.) review of work control documents (design, procurement, procedures, test records, NDE records, and management control documents), and a review of QA inspections and audits.

4.3.2.1 Fabrication Processes (3.2.1). The fabrication process is separated into four areas during an inspection. These areas, discussed separately below, are examples of major processes that may be applicable to a particular facility.

Some areas may not be applicable, the nonapplicable areas may be dropped from the evaluation. The inspector has the flexibility to inspect the fabrication process as it is performed at each facility. When inspecting fabrication activities, as appropriate, consider the following:

1. Ensure the fabrication procedures are documented, approved, and implemented for each applicable step of a process. Ensure the following are addressed where appropriate: (71.111), (72.150)

    a. Appropriate codes, standards, and drawings are identified and implemented. (71.105[b] and 71.119), (72.144[b] and 72.158)

    b. Specifications are identified and compliance ensured. (71.105[b] and 71.119), (72.144[b] and 72.158)

    c. Applicable drawings are identified and referenced. (71.111), (72.150)

    d. Are hold points identified?

    e. Are hold points appropriately released?

2. Ensure process control measures for QA inspections, hold points, program reviews, documentation reviews, and onsite controls for contractor work performed onsite are established and functional. Consider the following questions: (71.111, 71.113, and 71.121), (72.150, 72.152, and 72.160)

    a. Were the control measures performed when required?

    b. Were the operational steps signed off when performed?

    c. Were obsersations of the control measures within the specifications?

    d. Were noncompliances handled in accordance with the noncompliance control program?

3. Ensure the tools, equipment, and measurement instruments required by each procedure are identified in fabrication control documents. Verify that calibration requirements and sensitivity ranges are adhered to during use. (71.125), (72.164)

4.3.2.1.1 Cleaning (3.2.1.1). Ensure that procedures controlling the cleaning processes have been documented and implemented. Observe the cleaning process and review completed documents to ensure that: (71.119), (72.158)

1. Appropriate cleaning fluids are identified and specified, along with any cleanliness and/or chemistry controls. (71.111 and 71.127), (72.150 and 72.166)

2. Guidelines for any cleaning process are specified. (71.111 and 71.127), (72.150 and 72.166)

3. That the exact cleaning process to be used is specified. Consider the following: (71.111 and 71.127), (72.150 and 72.166):

   - NDE processes
   - acid baths
   - solvents.

4.3.2.1.2 Special Processes (3.2.1.2). Ensure procedures involving special processes are documented, approved, and implemented. Special processes include welding, NDE, brazing, lead pour, foam pour, heat treating, stress relieving, forging, casting, roiling, and others. Ensure the controls that have been established are documented, implemented, and approved by appropriate personnel.

1. Ensure procedures for controlling and performing special processes have been documented, approved, and implemented. Also ensure that the procedures are in compliance with the applicable codes, standards, specifications, criteria, and other special requirements. (71.119), (72.158)

2. Ensure acceptance criteria and hold points for special processes and inspections are documented and implemented. (71.121), (72.160)

3. Ensure special process personnel controls have been documented and implemented. Ensure training requirements and qualifications are reviewed and documented. Ensure special process procedures are qualified prior to use. (71.119), (72.158)

4. For shielding, consider: (71.111), (72.150)

   a. Lead shield processes:

      - ambient temperature
      - pour
      - heating and cooling
      - support
      - wall thickness guidelines
      - acceptance criteria.

   b. Uranium shield processes:

      - oxidizing and hydriding controls
      - heat treatment guidelines
      - welding criteria and procedures
      - cladding procedures
      - stainless steel sensitizing controls
      - personnel requirements.

5. Ensure the controls implemented for NDE including radiography, ultrasonic inspection, penetrant inspection, and magnetic particle inspection are documented, approved, and implemented. Ensure the following: (71.119), (72.158)

   a. The personnel that perform NDE activities are qualified and certified per procedures.

   b. The equipment used in NDE activities are suitable for the application.

   c. The NDE activities are performed satisfactorily and per a written procedure. This should include:

      1 Through observations ensure that NDE activities are performed satisfactorily.
      2 Second person verification of NDE activities are performed by qualified and certified individuals.
      3 The personnel used in NDE activities are qualified and certified.
      4 The equipment used in NDE activities are suitable for the application.
      5 The personnel testing requirements are current.

6. Ensure the controls implemented on welding activities are documented, approved, and implemented. Ensure the following: (71.119), (72.158)

   a. Personnel used in welding activities are qualified and certified.

   b. Equipment used in welding activities are suitable for the application.

   c. Personnel testing requirements are current.

d. Welding materials are adequately controlled to prevent unauthorized use. Also welding materials are stored appropriately.

4.3.2.1.3 Machining (3.2.1.3). Ensure procedures controlling the machining processes have been documented, approved, and implemented. Machining controls should be verified by observation of the machining processes or by reviewing completed documents. Consider: (71.111), (72.150)

- feed rates
- cutting rates
- hold points
- personnel
- cutting depths
- cooling fluids
- surface finish criteria
- acceptance criteria.

4.3.2.1.4 Assembly (3.2.1.4). Ensure measures have been implemented for controlling the assembly process. The measures should insure the assembly is controlled and traceable.

1. Ensure procedures have been documented, approved, and implemented. (71.111), (72.150)

2. Ensure preparations for assembly have been identified and completed prior to commencing assembly. (71.111), (72.150)

3. Ensure that the finished packagings and dry storage containers have been assembled per certified drawings. (71.111), (72.150)

4.3.2.2 Handling and Storage (3.2.2). The inspection ensures that adequate controls are implemented so that the handling and storage processes are controlled, and traceable from the start of the packaging and dry storage container assembly process through following fabrication, testing, inspection, and final acceptance. The types of documents reviewed include procedures, storage records, and traceability documents. The areas considered include the handling and storage, and protective environment. These areas are discussed in greater detail below.

4.3.2.2.1 Handling and Storage Process (3.2.2.1). The handling and storage process consists of procedures that ensure high standards of storage and handling are implemented and practiced. Completed documents and stored products are reviewed to ensure acceptance criteria are met, steps are performed in the proper order, the correct revision of the procedure has been used, spare parts and materials are controlled, and packagings and dry storage container systems are traceable to QA standards. (71.111 and 71.127), (72.150 and 72.166)

1. Ensure measures that control the handling and storage process are documented and implemented. (71.111), (72.150)

2. Ensure spare part inventories are identified in the procurement documents. (71.117), (72.156)

3. Ensure the spare part procurement and inventories are controlled by the QA Program. (71.109 and 71.117), (72.148 and 72.156)

4. Ensure material issuance and storage are documented, approved, and implemented. (71.117), (72.156)

5. Ensure the safety-related component shelf life has been assessed. Also ensure the shelf life is controlled so that material is not used after the shelf life is exceeded. (71.117), (72.156)

4.3.2.2.2 Protective Environment (3.2.2.2). If a protective environment is required, ensure any protective environmental controls required to protect the product have been documented and implemented. Consider the following: (71.127), (72.166)

- inert gas
- humidity
- moisture content
- temperature.

4.3.3 Test and Inspection (3.3).

Ensure tests and inspections are controlled, verifiable, and traceable, from the design phase through testing and inspections up to and including the review of closed-out procedures and inspection reports. Documents considered for review should include design documents, procedures, test documents, NDE records, and management control documents.

Inspection Guidelines

The testing and inspection program ensures the procedures controlling testing and inspections are documented, approved, and implemented. When inspecting this element, consider both the controls placed on the testing and inspection program and the controls placed on the analysis of the results. Testing and inspection effectiveness is verified by personnel interviews, review of control documents, working document reviews (including procedures, purchase orders, specifications, drawings, manuals, etc.), and a review of QA inspections and hold points. Documents that should be considered for review include design documents, procedures, test documents, NDE records, and management control documents.

Consider the following attributes:

1. Ensure testing and inspection requirements, when appropriate, are identified for: hydrostatic/leak tests, shielding, thermal loads, heavy lifts, and NDE. Ensure measures have been established so that prerequisites are met prior to initiating a test. (71.123), (72.162)

   - Are tests performed using written and approved procedures?

   - Are the test procedures reviewed an approved by appropriate personnel?

   - Are measures established that ensure prerequisites are met prior to beginning the testing?

2. Ensure acceptance criteria are identified and compliance ensured. (71.123), (72.162)

3. Ensure test conditions are suitable. (71.123) (72.162)

   - Were tests performed to the appropriate procedure revision?

4. Ensure a completed document close-out review program has been implemented, documented, and approved. Ensure the acceptance criteria are met, all steps were completed, and the procedures are acceptable. (71.123), (72.162)

5. Ensure the controls implemented for NDE activities (including radiography, ultrasonic, penetrant, and magnetic particle) are documented, approved, and implemented. (71.119 and 71.123) (72.158 and 72.162)

6. Ensure controls placed on the tools and equipment required for implementation of the testing and inspection processes are documented and implemented. Consider: (71.125), (72.164)

   a. Tools and equipment are identified and controlled. Items to be considered include meters, gauges, calipers, micrometers, torque wrenches, relief valves, dial indicators, cranes, etc. (71.125), (72.164)

   b. Tool and equipment calibration requirements are identified and controlled. (71.125), (72.164)

   c. Tool and equipment rated measurement capacities and sensitivities are identified, and actions taken to ensure they are complied with. (71.125), (72.164)

   d. Tools and equipment used in test and inspections can be identified by test. Also ensure that the tools and equipment are compatible with the test and inspection needs (i.e., instrument ranges are compatible with the test acceptance criteria). (71.123), (72.162)

7. Ensure measures for specifying quality control hold points have been documented and implemented, with provisions in place for periodic reviews and updates. (71.111 and 71.121), (72.150 and 72.160)

8. Ensure that a procedure controlling the operation of packaging and dry storage systems has been documented and implemented. The procedure should consider the status of inspections or tests. (71.129), (72.168)

9. Ensure measures have been established and implemented to control the operating status of packagings and dry storage systems. The mea-

sures should prevent inadvertent operations. (71.129), (72.168)

10. Ensure inspections are performed by individuals other than those who performed the activity. (71.121), (72.160)

4.3.4 Tools and Equipment (3.4).

Ensure procedure controls have been documented, approved, and implemented for the tools and equipment. The types of equipment of concern are meters, gauges, regulators, transmitters, sensors, torque wrenches, relief valves, cranes, etc.

Consider the following:

1. Ensure the tools and equipment are identified, specified, and controlled. (71.125), (72.164)

2. Ensure that a testing and calibration program has been documented, approved, and implemented. Ensure calibration and testing standards are traceable to national standards. (71.125), (72.164)

3. Ensure the tool and equipment measurement ranges and sensitivities have been identified, the equipment used accordingly, and actions taken to ensure the ranges and sensitivities are met. (71.125), (72.164)

4. Ensure the tools and equipment are traceable to specific jobs and date of use. Traceability should include documentation showing where and when used. (71.123), (72.162)

5. Ensure that in cases where instruments are found to be out of calibration, there is a procedure for justifying product quality for the tests or inspections performed using the out of calibration instruments. (71.123), (72.162)

4.4 Maintenance Controls (4.)

The goals of the maintenance process are to identify and perform maintenance on the packagings and dry storage systems to ensure each will meet its design task, ensure suitable spare parts are used, and ensure that adequate tool and equipment controls are established. To expedite the effort, the maintenance program has been separated into two areas (maintenance activities and tools and equipment), each of which is discussed below. The maintenance inspection checklist is presented in Appendix D.

Maintenance controls are verified through personnel interviews, document reviews, and observations. The types of documents that should be reviewed include: vendor manuals, operating manuals, procurement documents, reports, test documents, letters of correspondence, procedures, and maintenance orders.

4.4.1 Maintenance Activities (4.1).

Maintenance activities consist of procedures and programs established to ensure that maintenance requirements are identified and performed properly. When inspecting and evaluating this element, four areas are addressed: requirements, procedures, maintenance personnel, and maintenance materials.

4.4.1.1 Requirements (4.1.1). The maintenance requirements section assesses the controls and guidelines that ensure applicable maintenance is identified, performed, and documented. The following are used to evaluate maintenance requirement identification.

1. Ensure a program for the identification of required maintenance has been developed and implemented. (71.105[b] and 71.127), (72.144[b] and 72.166)

2. Ensure acceptance criteria governing maintenance activities are identified. These include tolerances, frequency of replacements, and frequency of performance. (71.111), (72.150)

3. Ensure a trending program for component failures and maintenance has been developed and implemented. (71.105[b] and 71.133), (72.144[b] and 72.172)

4. Ensure hold points for maintenance inspections and verifications are identified and follow specified guidelines. (71.121), (72.160)

4.4.1.2 Procedures (4.1.2). Procedures are established to control required maintenance. Consider the following during the inspection:

1. Ensure procedures have been documented, approved, and implemented for the performance of all maintenance activities. Include consideration for the manufacturers and suppliers providing any changes to the maintenance program when deemed necessary. (71.111), (72.150)

2. Ensure a root cause analysis program has been developed and implemented for determining the root causes of failures or rework events. (71.133), (72.172)

3. Ensure the adequate maintenance requirements are provided. (71.105[b]), (72.144[b])

4.4.1.3 Maintenance Personnel (4.1.3). Evaluate maintenance personnel, taking into account management controls. The guidelines for inspecting maintenance personnel are discussed below.

1. Ensure personnel qualification requirements are identified and compliance assured. Ensure qualification exams and/or required educational and experience levels are appropriate. (71.105[d]), (72.144[d])

2. Ensure training requirements for personnel are identified for staff in quality control, shipping and receiving, and maintenance activities. (71.105[d]), (72.144[d])

4.4.1.4 Maintenance Materials (4.1.4). The inspection assesses the materials control process, including the effectiveness of identifying materials, materials receipt inspections, controls for storage and handling before use, and materials traceability. Consider whether the following areas are addressed:

1. Documentation necessary to demonstrate appropriate materials have been used and is available for maintenance is available and traceable. Consider procurement documents, specifications, design documents, tests, and past maintenance actions. (71.109, 71.111, and 71.115[a]), (72.148, 72.150, and 72.154[a])

2. Shipping, handling, and receiving requirements are identified and compliance ensured. (71.105[b] and 71.115[b]), (72.144[b] and 72.154[b])

3. Material specifications, part substitutions, and shelf life requirements for degradable materials are identified. (71.109, 71.115[b], and 71.135), (72.148, 72.154[b], and 72.174)

4. Spare parts inventories have been addressed where appropriate. (71.105[b]), (72.144[b])

5. The material procurement process is adequately controlled and documented. Consider the following:

   a. Procedures for control of materials have been documented, approved, and implemented. (71.111), (72.150)

   b. Material traceability has been assured. (71.115[b], 71.117, and 71.135), (72.154[b], 72.156, and 72.174)

   c. Material storage, handling, and issuing have been addressed. (71.115[b], 71.117, and 71.127), (72.154[b], 72.156, and 72.166)

4.4.2 Tools and Equipment (4.2).

The tool and equipment area is established for the identification of tools and equipment necessary for packaging and dry storage system maintenance. The types of equipment that should be considered

include meters, gauges, calipers, regulators, transmitters, sensors, micrometers, torque wrenches, relief valves, dial indicators, cranes, etc.

Verify tool and equipment controls through personnel interviews, reviews of control procedures, review of work control documents, calibration sheets, calibrations records, etc.

The review should consider the following areas:

1. Ensure tools and equipment necessary for safe and controlled maintenance are identified and specified. (71.125), (72.164)

2. Ensure tools and equipment for calibration and testing requirements are identified and controlled. Ensure a testing and calibration program has been documented, approved, and implemented. Ensure traceability of the calibration and testing standards to national standards. (71.125), (72.164)

3. Ensure the tools and equipment rated measuring ranges and sensitivities are identified and actions taken to ensure compliance. (71.125), (72.164)

4. Ensure the tools and equipment are traceable to specific jobs and date of each use. Traceability should include documentation showing where and when used. (71.123), (72.162)

5. Ensure that when instruments are found to be out of calibration, there is a procedure for justifying product quality for the tests or inspections performed using the out of calibration instruments. (71.123), (72.162)

5. REFERENCES

1. U.S. Nuclear Regulatory Commission, *Packaging Supplier Inspection Guide*, NUREG/CR-5717, April 1991.

2. W. G. (Bill) Johnson, *MORT - The Management Oversight and Risk Tree*, SAN 821-2, February 12, 1973.

APPENDIX A
INSPECTION ELEMENT 1 - MANAGEMENT CONTROLS

Element	Inspection Criteria	Acceptable	Remarks and Observations
1.	Management Controls Verify that adequate measures have been implemented to ensure that all aspects of the facility are adequately controlled to ensure compliance with regulatory requirements and QA program commitments. Management controls include a quality assurance policy, nonconformance controls, documentation controls, and an audit program.		
1.1	Quality Assurance Policy Verify that all aspects of quality assurance are controlled and traceable while being applied to the design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, modification of structures, systems, and components, and decommissioning of packaging and dry storage systems that are important to safety.		
	Verify QA policies are documented, approved, and implemented. (71.101[c] and 71.103) (72.140[c] and 72.142)		
	Verify that QA program authorities and responsibilities are clearly defined and documented. (71.103) (72.142)		
	Verify that the QA organization functions as an independent group. (71.103) (72.142)		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
1.1 (cont.)	Verify that the organizational charts demonstrate QA organization independence from cost and schedule influences. (71.103) (72.142)		
	Verify that a graded approach to QA is applied consistent with importance to safety. Verify controls are placed on identified materials, structures, systems, and components commensurate with their importance to safety. Consider the following: (71.101[b], 71.103, and 71.105[a]) (72.140[b], 72.142, and 72.144[a]) The impact of malfunction or failure of the item to safety. The design and fabrication complexity or uniqueness of the item. The need for special controls and surveillance application to processes and equipment. The degree to which functional compliance can be demonstrated by inspection or test. The quality history and degree of standardization of the item.		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
1.1 (cont.)	Verify that the QA personnel have sufficient freedom and authority to identify and resolve quality problems. (71.103) (72.142)		
	Verify that the materials, structure, systems, and components covered by the QA Program have been identified and documented. (71.105[a]) (72.144[a])		
	Verify that when a parts dedication programs is used, the following are documented and implemented. (21.3[c]) A safety-related component identification program has been developed, documented, and implemented. Verify that the program includes the following: a. Component safety-related levels identified, documented, and implemented. b. Safety-related components for each container identified, documented, and evaluated. c. Inspection program meets the requirements of the safety-related level ratings. Material specification identification program for safety-related components identified, documented, and implemented.		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
1.1 (cont.)	Sources for safety-related equipment materials and commercial grade alternates identified and placed on approved vendor lists. Verify that a program for identifying and ensuring commercial grade alternates meets or exceeds the specifications for the applicable safety-related components has been developed, documented, and implemented. Verify the following: a. Sample testing methods are appropriate. b. Substituted materials are traceable to technical justifications in program documents and packaging or dry storage systems having substitutions are identifiable.		
1.2	Nonconformance Controls Verify all nonconformances are identifiable, traceable, and the disposition of nonconformances are clear.		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
1.2 (cont.)	Verify that the nonconformance control program is documented, controlled, periodically reviewed, and updated. Also verify the nonconformance control program considers the following (71.131 and 71.133) (72.170 and 72.172): Verify nonconformances are identifiable and traceable. Are nonconforming materials adequately identified and segregated to prevent inadvertent use? Are nonconformances dispositioned in accordance with documented procedures? Are dispositions appropriately reviewed and approved? Are safety-related nonconformances reported to appropriate management levels?		
	Verify that the deficiency and deviation control program identifies, tracks, and resolves minor quality discrepancies. Also verify that the deficiency and deviation control program is documented, controlled, periodically reviewed, and updated. (71.133) (72.172)		
	Verify corrective action tracking programs have been developed, documented, and implemented to follow deficiencies, deviations, nonconformances, and audit and inspection findings. (71.131, 71.133, and 71.137) (72.170, 72.172, and 72.176)		
	Verify that a root cause analysis program has been developed and implemented for determining the root causes of failures or rework events. (71.133) (72.172)		
	Verify the provisions of Part 21 are identified on procurement documents for safety-related components purchased after January 6, 1978. (21.31)		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
1.2 (cont.)	Verify that the following 10 CFR Part 21 documents are posted conspicuously. (21.6) 10 CFR Part 21, Section 206 of Energy Reorganization Act of 1974, and Procedures adopted pursuant to 10 CFR Part 21.		
	In the cases of failures to comply with the license or the existence of a defect, verify the following for compliance: (21.21) The appropriate procedures have been documented and implemented to accomplish the following: a. Evaluate deviations and failures to comply, and identify defects associated with substantial safety hazards as soon as practicable. b. Ensure that if evaluation of a deviation or failure to comply can not be completed within 60 days, an interim report is prepared and submitted to the NRC within 60 days of discovery. c. Ensure the responsible licensee officer is informed within 5 working days after completion of the evaluation if the component fails to comply with the Atomic Energy Act, or any applicable rule, regulation order, or NRC license, or contains a defect.		
	In cases of failures to comply with the license or the existence of a defect, appropriate procedures have been developed and approved to ensure NRC reporting requirements are met. (21.21)		
	Records that document accomplishing 10 CFR 21 are prepared and maintained. (21.51)		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
1.3	Documentation Controls Verify that all aspects of the document controls are verifiable, controlled, and traceable. Verify instructions, procedures, and drawings, including changes are reviewed for adequacy. Verify instructions, procedures, and drawings are released by authorized personnel. Verify instructions, procedures, and drawings are used at locations where prescribed activities are performed.		
	Verify the fabrication plans, maintenance, and procurement documents are approved. Are they reviewed and updated periodically? (71.111, 71.115[a], and 71.135) (72.150, 72.154[a], and 72.174)		
	Verify a procedure development program is established and documented. Also verify that this program specifies the various reviews and approvals required during procedure development, with provisions in place for periodic reviews and updates. (71.111 and 71.113) (72.150 and 72.152)		
	Verify that a contractor control program is documented and ensures that all materials and services supplied by contractors are covered by an adequate QA Program. This includes specification of appropriate inspections and audits. (71.109 and 71.115[a]) (72.148 and 72.154[a])		
	Verify that quality records are identified, retrievable, controlled, stored, and periodically reviewed and updated. Verify that the quality records are retrievable for the life of the packaging and three years after ceasing activities for packagings licensed under Part 71. Ensure quality records are retrievable until the NRC terminates a license for dry storage systems licensed under Part 72. (71.135) (72.174)		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
1.3 (cont.)	Verify that a completed document close-out review program is documented and implemented. (71.123 and 71.135) (72.162 and 72.174)		
	Verify that appropriate procedures are available at job locations. (71.113) (72.152)		
	Verify that changes to controlled documents are reviewed and approved. (71.113) (72.152)		
	Verify that measures have been established that control the issuance of controlled documentation. Verify that the measures ensure only the most current documents are used. (71.113) (72.152)		
1.4	Audit Program Verify that all aspects of the QA audit program are verifiable, controlled, and traceable.		
	Verify that the audit program covers all applicable aspects of the QA Program. (71.137) (72.176)		
	Verify that audits are scheduled and conducted periodically. Verify audits to ensure conformance with documented instructions, procedures, and drawings. (71.121 and 71.137) (72.160 and 72.176)		
	Verify that audits are performed in accordance with approved procedures or checklists. (71.137) (72.176)		
	Verify that audit personnel are appropriately trained to perform audits. (71.137) (72.176)		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
1.4 (cont.)	Verify that audit personnel do not have direct responsibility in the areas being audited. (71.137) (72.176)		
	Verify that audit results are documented. (71.137) (72.176)		
	Verify that audit records are reviewed and approved by appropriate levels of management. (71.137) (72.176)		
	Verify appropriate follow-up actions are taken for deficient areas. (71.137) (72.176)		
	Verify an audit discrepancy resolution program has been developed, documented, and implemented. Verify that resolutions are implemented in a timely manner. (71.137) (72.176)		
	Verify corrective action follow-up programs have been identified and implemented. (71.133) (72.172)		
	Verify that the following areas are audited as appropriate, based on importance to safety, complexity, and quantity of product. (71.137) (72.176): a. Internal operations; b. Contractors; c. Vendors; and d. Suppliers.		
	Contractors, vendors, and suppliers, if used are approved and an approved vendor list is maintained and compliance ensured. (71.115[a]) (72.154[a])		
	Contractor or vendor if used adhere to a vendor control program that ensures all materials and services supplied by contractors or vendors are covered by adequate QA Programs as demonstrated through appropriate inspections and audits. (71.109 and 71.115[a]) (72.148 and 72.154[a])		
Comments:			

APPENDIX B
INSPECTION ELEMENT 2 - DESIGN CONTROLS

Element	Inspection Criteria	Acceptable	Remarks and Observations
2.	Design Controls Verify that all phases of the design processes are controlled, retrievable, and traceable from the onset of design through the completion of testing and delivery. Specific areas to be considered during the design are: criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; features to facilitate decontamination; and delineation of acceptance criteria for inspections and tests.		
2.1	Design Development Verify that all aspects of the design development process are verifiable, controlled, and traceable from the onset of the design through the completion of testing and delivery.		
	Verify measures that control the design process are properly documented and implemented. (71.107[a] and 71.111) (72.146[a] and 72.150)		
	Verify that regulatory and license application requirements are reflected in the specifications, drawings, procedures, and instructions. (71.107[a]) (72.146[a])		
	Verify appropriate quality standards are specified and included in the design. (71.107[a]) (72.146[a])		
	Verify that deviations from established standards are adequately controlled. (71.107[a]) (72.146[a])		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
2.1 (cont.)	Verify that measures have been established to determine the suitability of materials, parts, equipment, and processes that are important to safety. (71.107[a]) (72.146[a])		
	Verify that design control interfaces are established and implemented. (71.107[b]) (72.146[b])		
	Verify that interface activities between participating organizations are controlled by approved and documented procedures. (71.107[b]) (72.146[b])		
	Verify that design control measures provide independent verification of design accuracies (eg., design reviews, calculations, prototype testing, etc.). (71.107[b]) (72.146[b])		
	Verify that design changes are subjected to similar design control measures as the original design. (71.107[c]) (72.146[c])		
	Verify that design changes have received NRC approval. (71.107[c]) (72.146[c])		
2.2	Modifications Verify that all aspects of the design modification process are controlled and traceable.		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
2.2 (cont.)	Verify whether weight and center of gravity changes have been accounted for in any modifications. (71.33 and 71.107[c]) (72.24[b] and 72.146[c])		
	Verify that material property changes are reflected in design documents. (71.33 and 71.107[c]) (72.24[b] and 72.146[c])		
	Verify that galvanic and chemical property changes are reflected into the design documents. (71.43[d] and 71.107[c]) (72.24[b] and 72.146[c])		
	Verify whether modifications to closure devices are reflected into the design documents. (71.43[c] and 71.107[c]) (72.24[a] and 72.146[c])		
	Determine whether modifications to lifting devices are reflected into the design documents. (71.45[a] and 71.107[c]) (72.24[a] and 72.146[c])		
	Determine whether modifications to tie-down devices are reflected into the design documents. (71.45[b] and 71.107[c]) (72.24[a] and 72.146[c])		
	Type B items (load resistance and external pressure) and potential changes in environmental conditions are given adequate consideration during the design and modification process. Consider the following items (71.71, 71.73 and 71.107[c]): - temperature - immersion - vibration - water spray - drops - internal pressure - compression - load resistance - percussion - fire - external pressure - penetration pressure.		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
2.2 (cont.)	Verify that a document review process for use during the development, modification, and closeout of procedures and documents has been documented and implemented. Verify that all changes to procedures and control documents are implemented in the design. Consider drawings and fabrication and manufacturing procedures. (71.107[c]) (72.146[c])		
	Verify the engineering change notice (ECN) control process. Verify that the ECN process is proceduralized, approved, and traceable. (71.107[c]) (72.146[c])		
	Verify that the drawing control process is proceduralized, approved, and traceable. (71.107[c]) (72.146[c])		
	Verify that the design modification review process is documented, proceduralized, approved, and traceable. Verify that the design modification review process is as comprehensive as the original design review. (71.107[c]) (72.146[c])		
Comments:			

APPENDIX C
INSPECTION ELEMENT 3 - FABRICATION CONTROLS

Element	Inspection Criteria	Acceptable	Remarks and Observations
3.	Fabrication Controls Verify that the fabrication process is controlled and verifiable from the onset of design through the completion of the assembly process. Inhouse, contractor, or vendor supplied transportation packaging fabrication controls should be evaluated using identical criteria.		
3.1	Material Procurement Verify that all aspects of the materials procurement are controlled, verifiable, and traceable from the time of purchase through the life of the packaging or dry storage system.		
	Verify that the measures that control material procurement are documented and implemented. (71.109 and 71.135)(72.143 and 72.174)		
	Verify that procurement documents are controlled and retrievable. Also verify that applicable codes, standards, and regulations are referenced. (71.109, 71.115[b], and 71.135) (72.148, 72.154[b], and 72.174)		
	Verify that material traceability documentation is available and auditable. (71.115[b] and 71.117) (72.154[b] and 72.156)		
	Verify that drawings and procedures used for procurement are identified and consistent with specification. Verify that any changes made to specifications are incorporated into these documents. (71.111) (72.150)		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
3.1 (cont.)	Verify that procurments are made in accordance with these latest approved specification changes? (71.111) (72.150)		
	Verify that suitable materials are specified and used in accordance with design specifications, calculations, and models. Verify that if materials are substituted, the new material is as meet the same or higher quality requirements than the original material. Consider the following specifically but other components may be considered: (71.115[a]) (72.154[a]) - seals - gaskets - foam.		
	Verify that material shelf life for safety related components has been considered. (71.117) (72.156)		
	Verify that there is a receipt inspection program to ensure compliance with procurement documents. Also ensure that the results of the receipt inspections are documented and retrievable. (71.115[b]) (72.154[b])		
	Verify that measures have been established that assure each item is identified by heat number, part number, or other appropriate means, either on the item or on records traceable to the item. Verify the measures are required throughout fabrication, installation, and use of the item.(71.117)(72.156)		
3.2	Fabrication and Assembly Verify that the fabrication and assembly process consists of procedures that ensure high standards of fabrication and assembly are implemented and practiced.		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
3.2.1	Fabrication Processes The fabrication process is separated into four areas, some of which may not be applicable to a particular facility. Inspect only the areas that are applicable.		
	Verify that fabrication and assembly procedures are documented, approved, and implemented. Consider the following: (71.111) (72.150)		
	a. Verify that the appropriate codes, standards, and drawings, are identified and implemented. (71.105[b] and 71.119) (72.144[b] and 72.158)		
	b. Verify that the appropriate specifications are identified and compliance ensured. (71.105[b] and 71.119) (72.144[b] and 72.158)		
	c. Verify that the applicable drawings are identified and referenced. (71.111) (72.150)		
	d. Are hold points instituted?		
	e. Are hold points appropriately released?		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
3.2.1 (cont.)	Verify that process control measures for QA inspections and hold points, program reviews, documentation reviews, and onsite controls for contractor work performed onsite are established and functional. Consider the following: (71.111, 71.113, and 71.121) (72.150, 72.152, and 72.160) a. Were the control measures performed when required? b. Were the operational steps signed off when performed? c. Were the observations of the control measures within the specifications? d. Were noncompliances handled in accordance with the noncompliance control program?		
	Verify that the tools, equipment, and measurement instruments required by each procedure are identified in fabrication control documents. Verify that calibration requirements and sensitivity ranges were adhered to at the time of each use. (71.125) (72.164)		
3.2.1.1	Cleaning Verify that procedures involving cleaning processes are documented, approved, and implemented. Verify that controls are documented and implemented for the following: (71.119) (72.158)		
	Verify that appropriate cleaning fluids are identified and specified, along with any cleanliness and/or chemistry controls. (71.111 and 71.127) (72.150 and 72.166)		
	Verify that guidelines for any cleaning process are specified. (71.111 and 71.127) (72.150 and 72.166)		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
3.2.1.1 (cont.)	Verify the appropriate cleaning process is specified. Consider the following cleaning processes: (71.111 and 71.127) (72.150 and 72.166): - NDE type processes - acid baths - solvents.		
3.2.1.2	Special Processes Verify that the special process controls have been documented, approved, and implemented. Special processes include welding, NDE, brazing, lead pour, foam pour, heat treating, stress relieving, forging, casting, rolling, and others. Verify that all procedures relating to special processes are reviewed and approved by the appropriate personnel.		
	Verify that procedures for controlling and performing special processes are documented, approved, and implemented. Also verify that the procedures are in compliance with the applicable codes, standards, specifications, criteria, and other special requirements. (71.119) (72.153)		
	Verify that acceptance criteria and hold points for special processes and inspections are documented, approved, and implemented. (71.121) (72.160)		
	Verify that special process personnel controls have been documented and implemented. Verify training requirements and qualifications are reviewed and documented. Determine if special process procedures are qualified prior to first use. (71.119) (72.158)		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
3.2.1.2 (cont.)	For shielding processes, consider the following items: (71.111) (72.150) a. For lead shield processes: - ambient temperature - pour - heating and cooling - support - wall thickness guidelines - acceptance criteria. b. For uranium shield processes: - oxidizing and hydriding controls - heat treatment guidelines - welding criteria and procedures - cladding procedures - stainless steel sensitizing controls - personnel requirements.		
	Verify that the controls implemented for NDE including radiography, ultrasonic inspection, penetrant inspection, and magnetic particle inspection are documented, approved, and implemented. Verify the following: (71.119) (72.158) The personnel used in NDE activities are qualified and certified per written procedures. The equipment used in NDE activities are suitable for the application. The NDE activities are performed satisfactorily and per written procedures. The following are included: - Through observations ensure NDE activities are performed satisfactorily.		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
3.2.1.2 (cont.)	- Second person verification of NDE activities are performed by qualified and certified individuals. - The personnel used in NDE activities are qualified and certifed. - The personnel testing requirements are current		
	Verify that the controls implemented on welding activities are documented, approved, and implemented. Verify the following: (71.119) (72.158) The personnel used in welding activities are qualified and certified. The equipment used in welding activities are suitable for the application. The personnel testing requirements are current. The welding materials are adequately controlled so as to prevent unauthorized use. Also the welding materials are stored in compliance with storage requirements.		
3.2.1.3	Machining Verify that procedures involving machining processes are documented and implemented.		
	Consider the following areas that may need to be addressed in the machining procedures: (71.111) (72.150) - feed rates - cutting depths - cutting rates - cooling fluids - hold points - surface finish criteria - personnel - acceptance criteria.		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
3.2.1.4	Assembly Verify the controls implemented for the assembly process. Consider the following items.		
	Verify that assembly procedures have been documented, approved, and implemented. (71.111) (72.150)		
	Verify preparations for assembly are identified and completed prior to commencing assembly. (71.111) (72.150)		
	Verify that the finished packagings and dry storage systems were assembled per the certified drawings. (71.111) (72.150)		
3.2.2	Handling and Storage Verify that adequate controls have been implemented to ensure handling and storage processes are controlled, and traceable from the start of the packaging and dry storage assembly processes to storage.		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
3.2.2.1	Handling and Storage Process Review completed documents to verify whether acceptance criteria are met, steps are performed in the proper order, correct revisions of procedures were used, spare parts and materials are controlled, and packagings and dry storage container systems are traceable to the QA standards. (71.111 and 71.127) (72.150 and 72.166)		
	Determine whether the measures controlling the handling and storage process are documented and implemented. (71.111) (72.150)		
	Are the spare part inventories are identified in the procurement documents? (71.117) (72.156)		
	Are the spare part procurement and inventories controlled by the QA Program? (71.109 and 71.117) (72.148 and 72.156)		
	Verify that material issuance and storage measures are documented, approved, and implemented. (71.117) (72.156)		
	Verify that the material shelf life for safety-related components has been assessed. Verify whether material shelf life is controlled so that material is not used after shelf life is exceeded. (71.117) (72.156)		
3.2.2.2	Protective Environment Verify that the controls established to protect the product have been documented and implemented.		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
3.2.2.2 (cont.)	Consider the following environmental areas and their controls: (71.127) (72.166) - inert gas - moisture content - humidity - temperature.		
3.3	Test and Inspection Verify that the tests and inspections are controlled and traceable, from the design basis events through testing and inspections up to and including the review of closed-out procedures and inspection reports.		
	Verify that testing and inspection requirements are identified, as appropriate, for hydrostatic/leak tests, shielding, criticality, thermal loads, heavy lifts, and NDE. Consider the following: (71.123) (72.162) - Are tests performed using written and approved procedures? - Are the test procedures reviewed an approved by appropriate personnel? - Are measures established that ensure prerequisites are met prior to beginning the testing?		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
3.3 (cont.)	Verify that acceptance criteria are defined and compliance ensured. (71.123) (72.162)		
	Verify the suitability of test conditions. (71.123) (72.162) - Were tests performed to the appropriate procedure revision?		
	Verify that a completed document close-out review program has been documented, approved, and implemented. Verify that acceptance criteria are met, the steps were completed satisfactorily, and procedures are acceptable. (71.123) (72.162)		
	Verify that NDE procedures are appropriately reviewed, approved, and controlled. Consider radiography, ultrasonic inspection, penetrant inspection, and magnetic particle inspection. (71.119 and 71.123) (72.158 and 72.162)		
	Verify that the controls placed on the tools and equipment calibration required for implementation of the testing and inspection process are documented and implemented. Consider the following: (71.125) (72.164)		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
3.3 (cont.)	a. Verify whether tools and equipment are identified and controlled. Items to be considered include meters, gauges, calipers, micrometers, torque wrenches, relief valves, dial indicators, cranes, etc. (71.125) (72.164)		
	b. Verify if tool and equipment calibration requirements are identified and controlled. (71.125) (72.164)		
	c. Verify that tool and equipment rated capacities and sensitivities are identified, and actions taken to ensure compliance. (71.125) (72.164)		
	d. Verify that tools and equipment used in test and inspections can be identified by test. Also verify that the tools and equipment are compatible with the test and inspection needs (i.e., instrument ranges are compatible with the test acceptance criteria). (71.123) (72.162)		
	Verify that established quality control hold points were appropriately released. (71.111 and 71.121) (72.150 and 72.160)		
	Verify that a procedure controlling the operation of packaging and dry storage systems has been documented and implemented. The procedure should consider the status of inspections or tests. (71.129) (72.168)		
	Verify that the measures to control the operating status of packagings and dry storage systems have been documented and implemented. The measures should prevent inadvertent operations. (71.129) (72.168)		
	Ensure inspections are performed by individuals other than those who performed the activity. (71.121) (72.160)		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
3.4	Tools and Equipment Verify that procedures have been documented, approved, and implemented for tool and equipment controls. Verify that the tools and equipment are controlled and traceable. The types of equipment of concern are meters, gauges, regulators, transmitters, sensors, torque wrenches, relief valves, cranes, etc. When inspecting and assessing this area, consider controls placed on the tools and equipment storage and handling, controls (procedures, acceptance criteria, use tracking, qualifications of personnel, etc.) placed on the their use, and the controls placed on ensuring they are ready for use (calibration records and deficiency control).		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
3.4 (cont.)	Verify that the tools and equipment are identified, specified, and controlled. (71.125) (72.164)		
	Verify that a testing and calibration program has been documented, approved, and implemented. Verify that calibration and testing standards are traceable to national standards. (71.125) (72.164)		
	Verify that tool and equipment rated capacities and sensitivities have been identified and actions taken to ensure the ranges and sensitivities are met. (71.125) (72.164)		
	Verify that tools and equipment uses are documented and traceable to where and when used. (71.123) (72.162)		
	Verify that when instruments are found to be out of calibration, there is a procedure for justifying product quality for the tests or inspections performed using the out of calibration instruments. (71.123) (72.162)		
Comments:			

APPENDIX D
INSPECTION ELEMENT 4 - MAINTENANCE CONTROLS

Element	Inspection Criteria	Acceptable	Remarks and Observations
4.	Maintenance Controls The maintenance process identifies and performs maintenance on the packagings and dry storage systems to ensure each will meet its design task.		
4.1	Maintenance Activities Verify that maintenance activities consist of procedures and programs established to ensure that maintenance requirements are identified and performed so that the packagings and dry storage systems are capable of performing their designed tasks.		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
4.1.1	Requirements Verify that controls and guidelines are in place that ensure maintenance is identified and documented as required. Use the following to inspect maintenance requirement identification.		
	Verify that a program for the identification of required maintenance has been developed and implemented. (71.105[b] and 71.127) (72.144[b] and 72.166)		
	Verify that acceptance criteria governing maintenance activities are identified. These include tolerances, frequency of replacements, and frequency of performance. (71.111) (72.150)		
	Verify that a trending program for component failures and maintenance has been developed and implemented. (71.105[b] and 71.133) (72.144[b] and 72.172)		
	Verify whether maintenance QA hold points and verifications are identified and follow specified guidelines. (71.121) (72.160)		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
4.1.2	Procedures Verify that documentation and controls are established to control maintenance adequately. Consider the following:		
	Verify that procedures have been documented, approved, and implemented for the performance of all maintenance activities. Include consideration for the manufacturers and suppliers providing any changes to the maintenance program when deemed necessary. (71.111), (72.150)		
	Verify that a root cause analysis program is in placed for determining the root causes of failures. (71.133) (72.172)		
	Verify that adequate maintenance requirements are provided. (71.105[b]) (72.144[b])		
4.1.3	Maintenance Personnei Verify maintenance personnel controls are documented and implemented, consider management controls. The inspection criteria are listed below.		
	Verify personnel qualification requirements are identified and met. Verify qualification exams and/or required educational and experience levels are appropriate as required. (71.105[d]) (72.144[d])		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
4.1.3 (cont.)	Verify that appropriate levels of personnel training are provided for staff in quality control, shipping and receiving, and maintenance activities as applicable. (71.105[d]) (72.144[d])		
4.1.4	Maintenance Materials Verify that the materials control process, including the effectiveness of identifying materials, materials receipt inspections, controls for storage and handling before use, and materials traceability.		
	Verify if appropriate materials have been used and are available when maintenance is performed. Verify the materials are traceable. Consider procurement documents, specifications, design documents, test procedures, and past maintenance actions. (71.109, 71.111, and 71.115[a]) (72.148, 72.150, and 72.154[a])		
	Verify that shipping, handling, and receiving requirements are identified and followed if required. (71.105[b] and 71.115[b]) (72.144[b] and 72.154[b])		
	Verify material specifications and part substitutions. Determine if shelf life requirements for degradable materials are applicable. (71.109, 71.115[b], and 71.135) (72.148, 72.154[b], and 72.174)		
	Has a spare parts inventories have been addressed where appropriate? (71.105[b]) (72.144[b])		
	Verify that the material procurement process is adequately controlled and documented. Consider the following: a. Verify procedures for control of materials have been documented, approved, and implemented. (71.111) (72.150)		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
4.1.4 (cont.)	b. Verify that material traceability has been assured. (71.115[b], 71.117, and 71.135) (72.154[b], 72.156, 72.174) c. Verify that material storage, handling, and issuing have been addressed. (71.115[b], 71.117, and 71.127) (72.154[b], 72.156, and 72.166)		
4.2	Tools and Equipment Verify that controls that have been established and implemented for the identification and control of tools and equipment necessary for packaging maintenance. Consider meters, gauges, calipers, regulators, transmitters, sensors, micrometers, torque wrenches, relief valves, dial indicators, cranes, etc.		
	Verify that the tools and equipment necessary for safe and controlled maintenance are identified and specified. (71.125) (72.164)		
	Verify that the tools and equipment for calibration and testing requirements are identified and controlled. Verify that a testing and calibration program has been documented, approved, and implemented. Verify that the calibration and testing standards are traceable to national standards. (71.125) (72.164)		
Comments:			

Element	Inspection Criteria	Acceptable	Remarks and Observations
4.2 (cont.)	Verify that tool and equipment are appropriately used within their rated capacities and sensitivities. (71.125) (72.164)		
	Verify that tool and equipment uses are documented and traceable to where and when used. (71.123) (72.162)		
	Verify that when instruments are found to be out of calibration, there is a procedure for justifying product quality for the tests or inspections performed using the out of calibration instruments. (71.123) (72.162)		
Comments:			

QUALITY ASSURANC

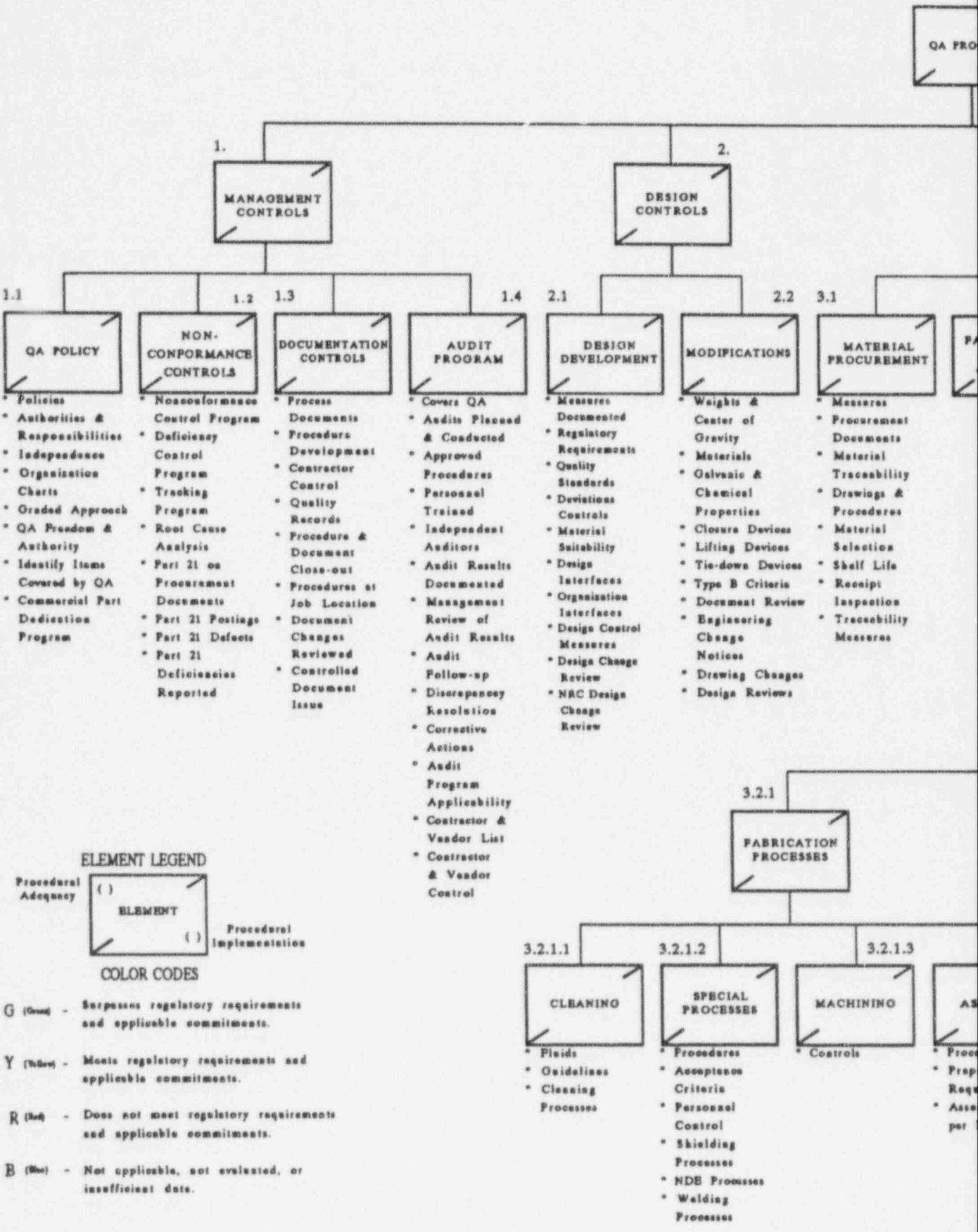
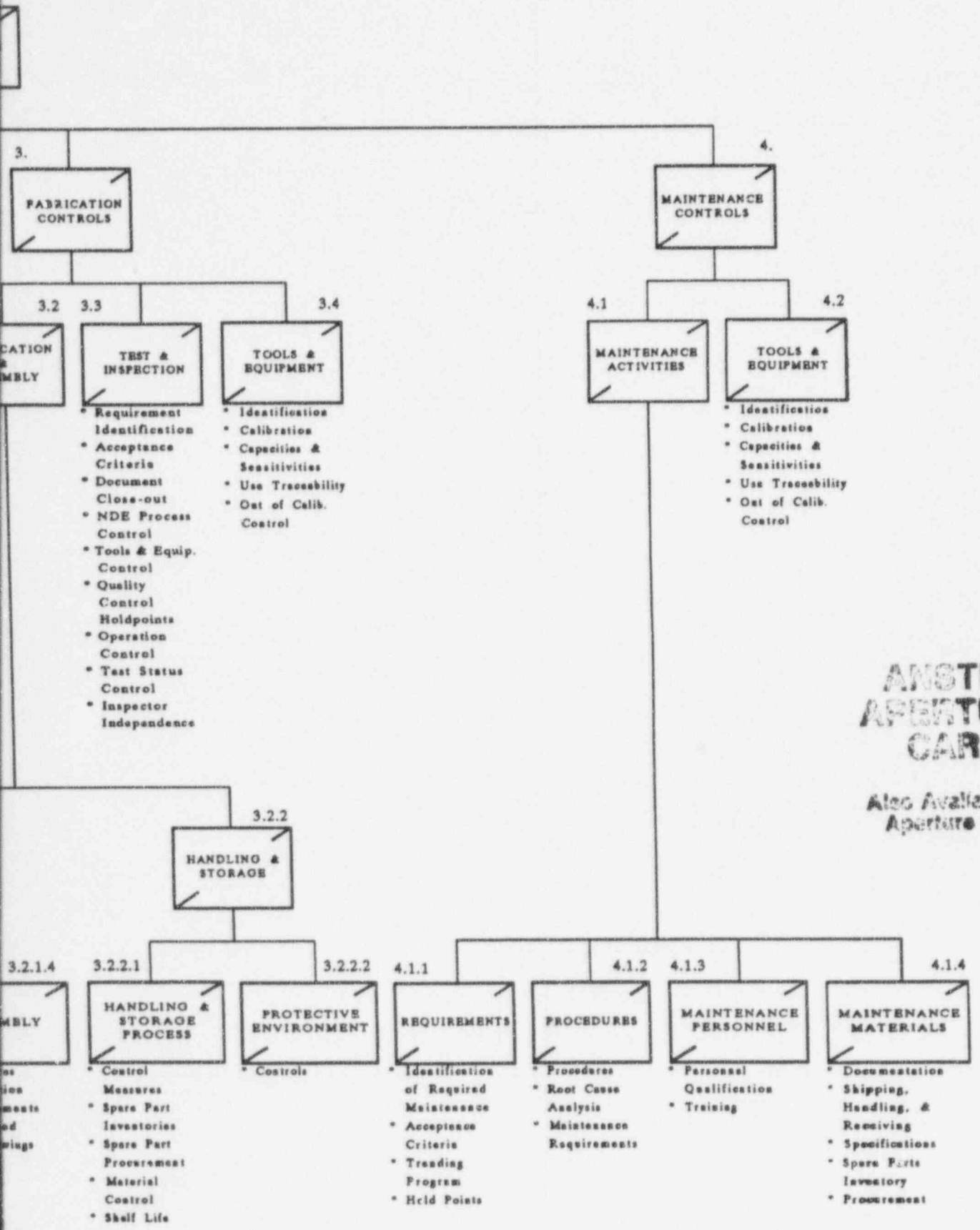


Figure 3. Quality ass

INSPECTION TREE



ance inspection tree.

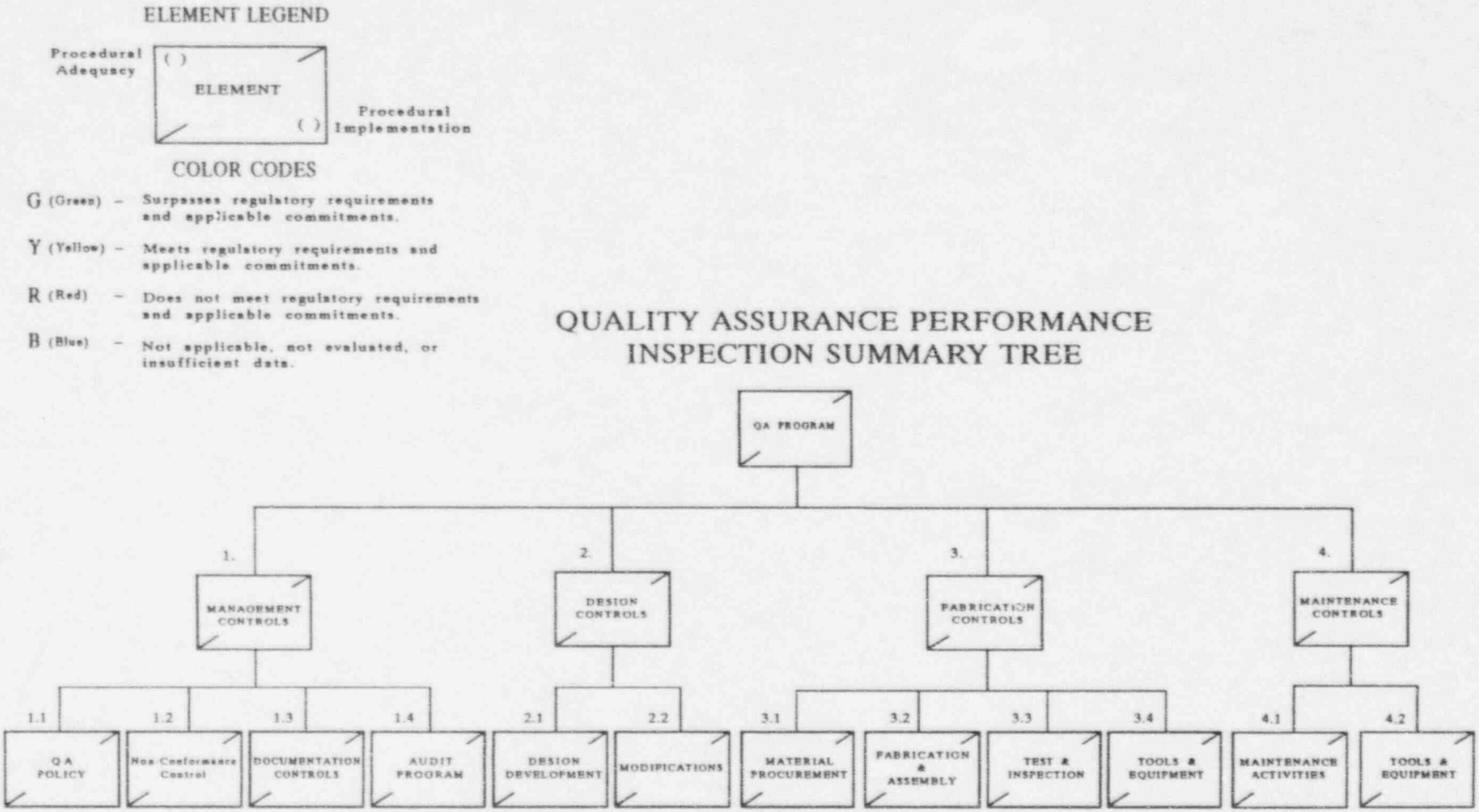


Figure 4. Quality assurance performance inspection summary tree.

NRC FORM 335 (2-89) NRCM 1102, 3201, 3202

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BIBLIOGRAPHIC DATA SHEET

(See instructions on the reverse)

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H. M. Stromberg, G. D. Roberts, and J. H. Bryce

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10. SUPPLEMENTARY NOTES

D. G. Reid, NRC Technical Monitor

11. ABSTRACT *(200 words or less)*

This document is a guide for conducting quality assurance inspections of transportation packaging and dry spent fuel storage system suppliers. This document is used during an inspection to determine regulatory compliance with Title 10 of the Code of Federal Regulations, Part 71, Subpart H; Title 10 of the Code of Federal Regulations, Part 72, Subpart G; and Title 10 of the Code of Federal Regulations, Part 21, and quality assurance program commitments. The guidance provides a framework for transportation packaging and dry spent fuel storage system inspections. Inspectors are provided with the flexibility to adapt the methods and concepts to meet the inspection requirements for the particular facility. This guide was developed to provide a structured and consistent approach for inspections. The method separates each performance element into several areas for inspection and identifies guidelines, based on regulatory requirements, to qualitatively evaluate each area. This document was also developed to serve as a field manual to facilitate the quality assurance inspection activities.

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