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Quality-System Management of Nuclear-Material Storage Containers

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Abstract

Quality-system management of nuclear-material (NM) storage containers remains the foundation for successfully procuring, designing, testing, and manufacturing NM storage containers for use at United States Department of Energy (DOE) national laboratories. The DOE, Los Alamos National Laboratory (LANL), and the American Society of Mechanical Engineers (ASME) specifically define quality-system requirements for NM storage containers. Quality-system management addresses the inherent risks and hazards associated with project activities. Implementation of project quality assurance (QA) minimizes environmental, safety, health, and security risks and any additional impacts associated with work processes, while maximizing reliability and performance of the NM storage container. To optimize worker safety, the management of quality-system requirements ensures the control of hazards and associated risks imposed by the work and by the functions required of the NM storage containers. Project QA also provides senior management a level of confidence that both business management and technical processes remain effective and efficient. My presentation will address the importance of quality-system management when procuring, designing, and testing NM storage containers to ensure worker safety and the minimization of environmental, health, and security risks.

Introduction

Quality-system management of nuclear-material (NM) storage containers remains the foundation for successfully procuring, designing, testing, and manufacturing NM storage containers for use at United States, Department of Energy (DOE) national laboratories. DOE Orders and Manuals and the American Society of Mechanical Engineers (ASME), NQA-1 national standard specifically define quality-system management requirements for NM storage containers.

The quality of a product or service equals the extent to which that product or service satisfies the requirements, needs, and expectations of the customer. Quality assurance (QA) represents all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component performs satisfactorily in service while minimizing and controlling risks and hazards to the worker.

Quality-system management addresses the inherent risks and hazards associated with project activities. Implementation of project QA minimizes environmental, safety, health, and security risks and any additional impacts associated with work processes, while maximizing reliability and performance of the NM storage container. To optimize worker safety, the management of quality-system requirements ensures the control of hazards and associated risks imposed by the work and by the functions required of the NM storage containers. Project QA also provides senior management a level of confidence that both business management and technical processes remain effective and efficient.

This paper addresses the importance of quality-system management when procuring, designing, testing, and manufacturing NM storage containers to ensure worker safety and the minimization of environmental, health, and security risks.

The SAVY-4000 NM Storage Container

The SAVY-4000 represents a new NM container developed for the safe and effective storage of NM outside of engineered barriers (e.g., glovebox line, hood, tank, or liquid-transfer line).

Design Features

The picture below depicts an eight-quart SAVY-4000. This container comes in 1-, 3-, 5-, 8-, 12-qt. and 5- and 10-gal. sizes. The following list identifies some unique design features:

- Bayonet style lock—no tools required
- Corrosion resistant 316L stainless steel
- Ceramic-filtered lid that allows container to "breath"
- Soft durometer, Viton O-ring seal

Figure 1. SAVY-4000 NM Storage Container

History

- Procurement: June 2007
- Contract Award: December 2008
- Phase I, R&D Closeout: November 2010
- Phase II, Final Design Approval: June 2011
- Phase III, Production: July 2011

Procurement Quality Assurance

The initial procurement specification for the SAVY-4000 NM storage container required the supplier to comply with the following QA requirements:

- DOE-O-414.1C (the Order)
- 10 CFR 830.122 (the Rule)
- NQA-1 2004, Part I (the National Standard)

This meant that all project Phases (i.e., Phase I, Research and Development; Phase II, Design; and Phase III, Production) must comply with these requirements. To date, since 2008, project quality performed 17 surveillances/assessments to ensure Supplier compliance. The project successfully worked as a team with the Supplier, a small business, to align the Supplier's Quality Assurance Project Plan (QAPP) and implementing procedures with these QA requirements.

Quality-System Requirements

- DOE Manual 441.1-1, *Nuclear Material Packaging Manual*: This Manual provides detailed packaging requirements for protecting workers from internal exposure to nuclear material stored outside of an approved engineered contamination barrier (e.g., outside of glovebox line, hood, tank, or liquid-transfer line). The nuclear materials of concern in the Manual are those whose composition and quantity create the potential for an airborne contamination hazard that could result in a facility worker receiving an internal radiation dose in excess of 5 rem Committed Effective Dose Equivalent (CEDE).

  The Safety Analysis Report (SAR) for the LANL SAVY-4000, NM storage container, documents in detail how the SAVY-4000 meets all Manual requirements. All DOE sites across the country must comply with the Manual when storing NM in containers outside of engineered barriers. Many sites across the DOE complex will use the SAVY-4000, especially those who possess small quantities of NM.

- Title 10, Code of Federal Regulation (CFR), Part 830, *Nuclear Safety Management*, Section 830.122, *Quality Assurance Requirements*: This rule governs the conduct of DOE contractors, DOE personnel, and other persons conducting activities (i.e., including providing items and services) that affect, or may affect, the safety of DOE nuclear facilities.

  At LANL, we define a "facility" as follows: Land, buildings, and other structures; their functional systems and equipment; and other fixed systems and equipment installed herein; including site development features outside the plant, such as landscaping, roads, walks, parking areas, outside lighting and communication systems, central utility plants, utilities supply and distribution systems, and other physical plant features. As used at LANL, "facility" may refer to a specific building or structure, a set of buildings and related systems, or LANL as a whole.

- DOE Order 414.1C, *Quality Assurance*: DOE wrote the Order to achieve QA for all work based upon the following principles:

  1. Quality assured and maintained through a single, integrated, effective QA program (i.e., management system)
  2. Management support for planning, organization, resources, direction, and control remains essential to QA

3. Performance and quality improvement require thorough, rigorous assessment, and corrective action
4. Workers remain responsible for achieving and maintaining quality
5. Environmental, safety, and health risks and impacts associated with work processes are minimized while maximizing reliability and performance of work products

- American National Standard, NQA-1, *Quality Assurance Requirements for Nuclear Facility Applications*: This national Standard reflects industry experience and current understanding of the QA requirements necessary to achieve safe, reliable, and efficient utilization of nuclear energy, and management and processing of radioactive materials. This Standard focuses on the achievement of results, emphasizes the role of the individual and line management in the achievement of quality, and fosters the application of these requirements in a manner consistent with the relative importance of the item or activity.

SAVY-4000 Quality Assurance Plan

The following figure pictorially represents the requirements' hierarchy for the SAVY-4000 Quality Assurance Plan (QAP).

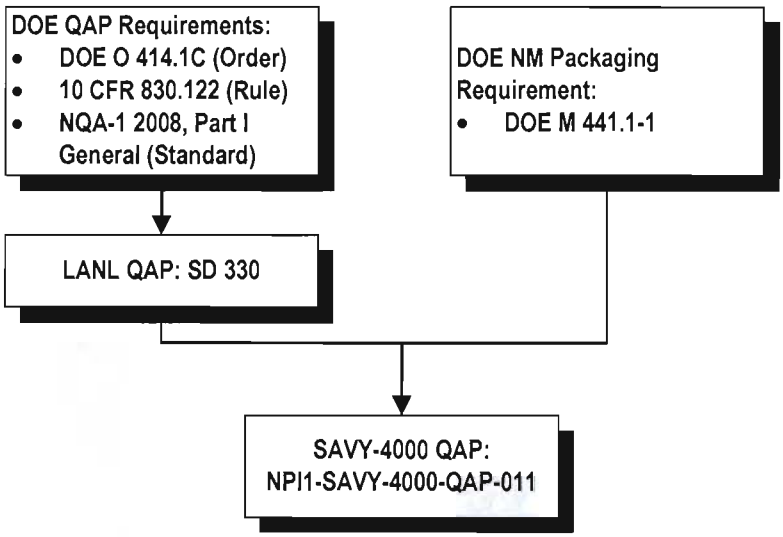

Figure 2. SAVY-4000 QAP Requirements' Hierarchy

Quality Assurance Program Development

Each DOE organization must develop and implement a Quality Assurance Program that performs the following[1]:

1. Implements DOE-O-414.1C, *Quality Assurance* (Order)
2. Implements 10 CFR 830.122, *Quality Assurance Requirements* (Rule)
3. Uses national or international consensus standards where practicable and consistent with contractual or regulatory standards including ASME NQA-1-2008, *Quality Assurance*

Requirements for Nuclear Facility Applications (i.e., for nuclear-related activities) (National Standard)

4. Applies additional standards, where practicable and consistent with contractual or regulatory requirements (e.g., DOE M 414.1-1, for NM storage containers used outside engineered barriers) and as necessary, to address unique/specific work activities (e.g., development and use of safety software or establishing the competence of a testing and calibration laboratory).

Quality-System Management

Minimizes Risks and Hazards

Quality-system management addresses the inherent risks and hazards associated with project activities. Implementation of project QA minimizes environmental, safety, health, and security risks and any additional impacts associated with work processes, while maximizing reliability and performance of the NM storage container.

To optimize worker safety, the management of the following quality-system requirements ensures the minimization and control of hazards and associated risks imposed by the work and by the functions required of the NM storage containers[2]:

1. **Program Development:** The intent of program development is to assure effective accomplishment of missions through clear assignment and effective communication of roles, responsibilities, and authorities for program and process development, execution, and maintenance. Contract and mission are communicated to workers through management-approved documents that are supplemented with implementation procedures and tools. Procedures stipulate process ownership and establish measures to assess for accountability the processes directly coupled to an organization's success.
2. **Personnel Training and Qualification:** Personnel performing or managing activities affecting quality receive training in job responsibilities and authorities that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, institutional procedures, and QAP requirements.
3. **Quality Improvement:** The intent of quality improvement is to establish an appropriate process for the identification of problems/issues, causes and corrective actions, and reporting of issues that result from defects, noncompliances, or inefficient practices. Implementation of a corrective-action program ensures the prompt identification and correction of quality problems (i.e., conditions adverse to quality) as soon as practicable. In the case of a significant condition adverse to quality, the cause of the condition is determined and corrective actions taken to preclude recurrence. Completion of corrective actions requires verification. Responsible management must encourage all workers to pursue quality improvement in every aspect of work by applying lessons learned; analyzing work for unacceptable risk; and continuously reporting, preventing, or mitigating problems that may affect the quality of the work performed.
4. **Document Control and Records Management:** A quality problem or condition adverse to quality is a collective term that may mean one of the following:

- A failure, malfunction, defect, or deficiency in an activity, product, service, item characteristic
- Process parameter
- A noncompliance to a requirement
- An indeterminate/substandard condition
- A suspect/counterfeit item

Project personnel must promptly identify conditions adverse to quality and require the implementation of timely corrective action. When a quality problem is detected, risks and hazards occur less often because established procedures are followed to report, analyze, and acceptably mitigate the problem and improve the process. If conditions adverse to quality are not corrected expeditiously, project personnel must implement compensatory measures pending completion of corrective actions. For significant conditions adverse to quality, the cause(s) of the condition is determined and corrective action(s) taken to preclude recurrence.

Workers remain responsible for identifying quality problems and for reporting potential or existing conditions adverse to quality. Inspection, testing, acceptance, occurrence reporting, surveillance, self-assessments, management assessments, and independent oversight activities are designed to identify, document, evaluate, and correct quality concerns, deficiencies, and nonconformances. Quality problems must be documented; cause(s) of the deficiencies determined; and corresponding corrective actions determined, corrected, verified, and closed out in accordance with a formal corrective action management system.

5. **Work Processes:** Work-process control assures the planning and performance of work activities using approved policies, procedures, instructions, etc., under controlled conditions. When items and materials are required to accomplish specified functions, work controls that include maintaining and controlling items and equipment to prevent damage, loss, or deterioration, to ensure proper use, and to ensure equipment calibration and maintenance reduce risks and hazards for the worker.

6. **Design:** Design control also reduces risks and hazards by performing the following:

   - Item and process design developed using engineering principles and appropriate technical and industrial standards
   - Identification and control of design interfaces, including organizational and design-product interfaces
   - Verification of design adequacy by independent, multi-discipline reviews before implementation, where appropriate
   - Review and approval of changes comparable to the reviews and approvals of the original design

7. **Procurement:** The procurement process also assures the following:

   - Functional and operational requirements, including QA requirements, are appropriately translated to specifications and contractual documents
   - Suppliers evaluated and monitored to ensure the provision of items and services that meet established requirements
   - Test and inspection requirements identified and documented to mitigate risks

- Material packaging, handling, shipping, and storage requirements communicated to the supplier through contractual requirements
- Purchased items, services, and pedigrees verified to assure they meet established requirements and performance expectations.
- Procurement specifications and inspection plans developed to identify technical and QA requirements, to prevent the introduction of suspect /counterfeit items , and to enable inspection to verify that items meet established requirements

8. **Inspection and Acceptance Testing:** Inspections and tests build confidence that risks/hazards remain mitigated through performing the following:

   - Verification that physical and functional aspects of items, services, and processes meet requirements and are fit for acceptance and use
   - Tests collect data for siting and design input
   - Performance expectations, inspections, and tests identified/considered early in the design process and/or specified in the design output and procurement documents
   - Required inspections verify conformance of an item or activity to specified requirements or continued acceptability of items in service
   - The status identification of inspections and tests either on items or in documents traceable to the items, where necessary, to ensure that required inspections and tests performed and items that did not pass the required inspections and tests are not inadvertently installed, used, or operated
   - Status maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means
   - Markings transferred to each part on an unidentified item when the item is subdivided, and not obliterated or hidden by surface or coating unless other means of identification substituted
   - The authority for application and removal of tags, markings, labels, and stamps specified.
   - Status indicators, such as tags, show the operating status of systems and components, such as valves and switches, to prevent inadvertent operation

9. **Management Assessment:** Management assessment, which includes the following, provides the means for a responsible manager to evaluate an organization's safety, security, and quality programs and processes and correct any identified problems:

   - Effectiveness of management controls
   - Adequacy of resources and workers assigned to perform work
   - Technical and programmatic verifications to support project missions
   - Compliance with requirements

10. **Independent Assessment:** Independent assessment, which includes the following, also affects the confidence in identified and lowered risks/hazards:

    - Evaluation of the acceptability of work performance and products
    - Performance of independent assessments by technically qualified and knowledgeable personnel with sufficient authority and freedom from the assessed organization
    - Feedback and continuous improvement processes, which include trend analysis, where appropriate data provided

The activities addressed above (i.e., project QA) also provides senior management a level of confidence that both business management and technical processes remain effective and efficient. When quality-system management succeeds, then senior management becomes confident in all project activities and processes.

Conclusion

Quality-system management addresses the inherent risks and hazards associated with project activities/processes, which include procurement, design, and production activities associated with the development of the SAVY-4000, NM storage container. Implementation of project QA minimizes environmental, safety, health, and security risks and any additional impacts associated with work processes, while maximizing reliability and performance of the SAVY-4000, NM storage container. To optimize worker safety, the management of quality-system requirements ensures the control of hazards and associated risks imposed by the work and by the functions required of the NM storage container. Project QA also provides senior management a level of confidence that both business management and technical processes remain effective and efficient. Project QA also provides senior management a level of confidence that both business management and technical processes remain effective and efficient.

References

1. American Society of Mechanical Engineers, NQA-1—2008, *Quality Assurance Requirements for Nuclear Facility Applications,* Part I: Requirements for Quality Assurance Programs for Nuclear Facilities, Subpart 4.5, *Application Guide on the Use of NQA-1—2008/1a-2009 for Compliance with Department of Energy Quality Assurance Requirements 10 CFR 8230 Subpart A and DOE O 414.1*, p. 205
2. a. SD 330, Revision 1, *Los Alamos National Laboratory Quality Assurance Program*
   b. DOE Order 414.1C, *Quality Assurance*, 07-07-05
   c. Title 10, Code of Federal Regulation (CFR), Part 830, *Nuclear Safety Management,* Section 830.122, *Quality Assurance Requirements*, 1–1–06 Edition