Quality Assurance Requirements for Nuclear Facility Applications

August 2021 Draft
TENTATIVE
SUBJECT TO REVISION OR WITHDRAWAL
Specific Authorization Required for Reproduction or Quotation
ASME Standards and Certification
**PART I**

**INTRODUCTION**

200 APPLICABILITY

Part I is to be applied using a graded approach to any structure, system, component, activity, or organization that is essential to the safe, reliable, and efficient performance of a nuclear facility and to any activities independent of a facility that may affect performance (e.g., transportation of nuclear materials) of those activities. It is also to be applied using a graded approach to all phases of a nuclear facility life cycle (e.g., siting, design, construction, operation, and decommissioning) and to all types of activities (e.g., training, testing, software development and use). A Quality Assurance Program developed in accordance with Part I is to be applied when implementing Part II requirements.

300 RESPONSIBILITY

The user or implementing organization invoking this standard shall specify, determine, and document applicable Subparts Part I Requirements and appropriately relate them to specific items, activities, and services. The organization implementing this Part and applicable Part II requirements as determined by scope of work, contract, legal, and regulatory requirements, shall be responsible for complying with the specific requirements to achieve quality results in compliance with this Standard.

**PART II**

**INTRODUCTION**

200 APPLICABILITY

Subparts of Part II are to be applied using a graded approach to any structure, system, component, activity, or organization that is essential to the safe, reliable, and efficient performance of a nuclear facility and any activities independent of a facility that may affect performance (e.g., transportation of nuclear materials) of those activities. The determination as to which Subparts are applicable shall be determined and documented. It is also to be applied to all phases of a nuclear facility life cycle (e.g., siting, design, construction, operation, and decommissioning) and related activities (e.g., training, testing, software development or use). The Quality Assurance Program developed in accordance with Part I is to be applied to the implementation of Part II requirements.

300 RESPONSIBILITY

The user or implementing organization invoking this standard shall determine and document applicable Subparts as determined by based on the scope of the work, contract, rules, and regulatory requirements as they relate to specific items, activities, and services. Implementation of applicable Parts I and II requirements is necessary for the Quality Assurance Program to be in compliance comply with this Standard.
**Proposed Revision to NQA-1-2019**  
**(with line through / strikeout and replacement)**

<table>
<thead>
<tr>
<th>NQA-1-2019 Part I, Requirement 6 Revision</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>100 GENERAL</strong></td>
</tr>
<tr>
<td>The preparation, issuance, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings shall be controlled to ensure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy by a cognizant individual other than the originator, and approved for release by authorized personnel.</td>
</tr>
</tbody>
</table>

| **200 DOCUMENT CONTROL** |
| The following controls shall be applied to documents and changes thereto: |
| (a) the unique identification of the controlled documents, including a revision control identifier. |
| (b) the specified distribution of controlled documents for use at the appropriate location |
| (c) the identification of the individual roles responsible for the preparation, review, approval, and distribution of controlled documents |
| (d) the review of controlled documents for adequacy and completeness, and prior to approval, prior to distribution or processing |
| (e) a method to ensure the correct documents document and revision are being used |

| **300 DOCUMENT CHANGES** |
| **301 Major Changes** |
| Changes to documents, other than those defined as minor changes, are considered major changes and shall be reviewed and approved by the same organizations that performed the original review and approval unless other organizations are specifically designated. The reviewing organization shall have access to pertinent background data or information upon which to base their approval. |

| **302 Minor Changes** |
| Minor changes to documents, that do not change its applicability, meaning, intent or technical content, (such as inconsequential editorial corrections), shall not require that the revised documents receive the same review and approval as the original documents. To avoid a possible omission of a required review, the type of minor changes that do not require such a review and approval and the persons who can authorize such a decision shall be clearly delineated. The types of changes to be considered “Minor” shall be specified. |
Published 2019 Version – Part II, Subpart 2.7

DEFINITIONS

software tool: a computer program used in the development, testing, analysis, or maintenance of a program or its documentation.

Additional proposed Changes to be considered on this ballot are highlighted in yellow.

Published 2019 Version – Part III, Subpart 3.2-2.7.1

DEFINITIONS

reusable code: A computer program unit that can be used in more than one computer program to provide the same functionality.

software library: A collection of computer program units, data, and related documentation that may be used in software development, use, or maintenance to provide functionality. These may include configuration data, help data, message templates, libraries, functions, subroutines and data values or type specifications.
| **Published 2019 Edition**  
<table>
<thead>
<tr>
<th>[Subpart 2.7]</th>
<th><strong>Proposed Changes</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>302</strong> Otherwise Acquired Software</td>
<td><strong>302</strong> Otherwise Acquired Software</td>
</tr>
</tbody>
</table>
| Part I, Requirement 7, and Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services, shall be applied to acquired software that has not been previously approved under a program consistent with Part I of this Standard for use in its intended application. This includes computer programs not obtained using the procurement requirements of Part I, such as freeware, shareware, and computer programs from corporate repositories.  
Otherwise acquired computer programs whose results are verified with the design analysis for each application as specified in Part I, Requirement 3, para. 401 are excluded from the requirements of Part II, Subpart 2.14.  
Otherwise acquired computer programs shall be identified and controlled during the dedication process. The dedication process shall be documented and include the following:  
(a) identification of the capabilities and limitations for intended use as critical characteristics  
(b) utilization of test plans and test cases as the method of acceptance to demonstrate the capabilities within the limitations  
(c) instructions for use (e.g., user manual) within the limits of the dedicated capabilities  
The dedication process documentation and associated computer program(s) shall establish the current baseline.  
Subsequent revisions of the software shall be dedicated in accordance with this section. | Part I, Requirement 7, and Part II, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services, shall be applied to the acquisition of otherwise acquired software that has not been previously approved under a program consistent with Part I of this Standard for use in its intended application. This includes computer programs not obtained using the procurement requirements of Part I, such as freeware, shareware, provided commercial off-the-shelf, or otherwise acquired software, and computer programs from corporate repositories.  
Part I, Requirement 7 and Part II, Subpart 2.14, and paragraph 302.1 of this Subpart shall apply to otherwise acquired computer programs that perform a safety function. Otherwise acquired computer programs that do not perform a safety function, but perform a function related to quality, shall be evaluated in accordance with paragraph 302.2 of this Subpart.  
Otherwise acquired computer programs whose results are verified with the design analysis for each application as specified in Part I, Requirement 3, para. 401 are excluded from the requirements of this Subpart. |

| **302.1 Dedication process** | |
|-----------------------------||
| Otherwise acquired computer programs that perform a safety function shall be identified and controlled during the dedication process.  
The dedication process shall be documented and include the following:  
(a) identification of the capabilities and limitations for intended use as critical characteristics  
(b) utilization of test plans and test cases as the method of acceptance to demonstrate the capabilities within the limitations  
(c) instructions for use (e.g., user manual) within the limits of the dedicated capabilities |
### Proposed Changes

**The dedication process shall be documented** results of the above dedication and the performance of the actions necessary to accept the software shall be reviewed and approved. The resulting dedication process documentation and associated computer program(s) shall establish the current baseline. Subsequent revisions of accepted software received from organizations not required to follow this Subpart otherwise acquired computer programs that have not been previously approved under a program consistent with this Standard shall be dedicated in accordance with this section.

### Evaluation process

Otherwise acquired computer programs that do not perform a safety function but perform a function related to quality shall be identified and controlled during the evaluation process. The evaluation specified by this section shall be performed and documented for otherwise acquired computer programs that perform a function related to quality. The evaluation shall determine adequacy to support operation and maintenance and identify the activities to be performed and the documentation that is needed. This evaluation shall be documented and shall identify as a minimum:

- **(a)** capabilities and limitations for intended use;
- **(b)** testing used to demonstrate the capabilities within the limitations;
- **(c)** instructions for use within the limits of the specified capabilities;
- **(d)** exceptions to the documentation requirements of this Subpart; and
- **(e)** justification for accepting the software.

The results of the above evaluation and the performance of the actions necessary to accept the software shall be reviewed and approved. The resulting documentation and associated computer program(s) shall establish the current baseline. Subsequent revisions of otherwise acquired computer programs shall be evaluated in accordance with this section.
<table>
<thead>
<tr>
<th>Published 2019 Edition [Subpart 3.2-2.7.1]</th>
<th>Proposed Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>300</strong> SOFTWARE ACQUISITION</td>
<td><strong>300</strong> SOFTWARE ACQUISITION</td>
</tr>
<tr>
<td>Software developed not using Part II, Subpart 2.7 may require full or partial application of Part II, Subpart 2.7. For example, software design and software design implementation are not applicable for acquired software. The following is guidance to assist in this activity. This application guide serves to recognize the need for a consistent approach to bringing software that has been developed outside the control of Part II, Subpart 2.7 under configuration control and into compliance with the Subpart.</td>
<td>Software developed not using Part II, Subpart 2.7 may require full or partial application of Part II, Subpart 2.7. For example, software design and software design implementation are not applicable for acquired software. The following is guidance to assist in this activity. This application guide serves to recognize the need for a consistent approach to bringing software that has been developed outside the control of Part II, Subpart 2.7 under configuration control and into compliance with the Subpart. Software acquisition includes the subcontracting of software development to the purchaser’s design, purchase of commercial off the shelf software, and acquisition of software through other methods (e.g., code centers, company repositories, user groups, etc.). This section provides guidance for software acquired in accordance with Part I and otherwise acquired software that was not developed in accordance with Part I.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>301 Procured Software and Software Services</th>
<th>301 Procured Software and Software Services</th>
</tr>
</thead>
</table>
| See Part II, Subpart 2.7. | See Part II, Subpart 2.7. The development of software for the Purchaser by a Supplier should include detailed specifications in the Purchase Order that identify the software lifecycle documentation required to be submitted to the Purchaser for approval. Requirements for the content of the Purchase Order and the process for evaluating, selecting and approving the software product or service provided as defined in Part I Requirement 7 specifies methods for acceptance that are not always readily applied for software. For example, PO specifications should define Purchaser approved methods of accepting software including software design reviews, factory (supplier) testing (e.g., source verification), and Acceptance Testing (e.g., post installation tests). Acceptable methods for Suppliers’ reporting of errors include but are not limited to:  
(a) email direct to the Purchaser’s point of contact,  
(b) posting on the Supplier’s web site, |
<table>
<thead>
<tr>
<th>Proposed Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>302 Otherwise Acquired Software</td>
</tr>
<tr>
<td>See Part II, Subpart 2.7.</td>
</tr>
<tr>
<td>(c) other documented communication methods that have been agreed upon with the Purchaser.</td>
</tr>
<tr>
<td>302 Otherwise Acquired Software</td>
</tr>
<tr>
<td>See Part II, Subpart 2.7.</td>
</tr>
<tr>
<td>Otherwise acquired software includes computer programs that perform a safety function and computer programs that perform a function related to quality. Commercial Grade Dedication is required in accordance with Part II, Subpart 2.14, for otherwise acquired computer programs that perform a safety function. Otherwise Acquired Computer Programs that do not perform a safety function, but that perform a function related to quality should be evaluated to assure that the product meets its intended use as described in 302.2.</td>
</tr>
<tr>
<td>302.1 Dedication process</td>
</tr>
</tbody>
</table>
| Subpart 3.2-2.14 provides guidance on performing commercial grade dedication of software in accordance with Part II Subpart 2.14. Computer programs that perform a safety function includes but is not limited to the following:  
(a) software that is used to design basic components in a nuclear facility  
(b) software that is used to perform safety analysis  
(c) software that is used to test or operate basic components in a nuclear facility.                                                                                                                                                       |
| 302.2 Evaluation process                                                                                                                                                                                                                                                                                                                                               |
| This evaluation process applies to computer programs used to design or control systems, structures and components whose failure would not create a situation adversely affecting public health and safety, but performs (or are used for) functions related to quality. For example, this could include computer programs used for design of chemical and volume control system, normal residual heat removal system, and the startup (backup) feedwater system.  
As per Part II Subpart 2.7 para. 302.2, software and software services that have not been previously approved under a program consistent with the requirements of this Standard and that do not meet the
<table>
<thead>
<tr>
<th>Published 2019 Edition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subpart 3.2-2.7.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Proposed Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>criteria of para. 302.1 are evaluated to assure the software or software service is acceptable for its application. The capabilities of the software may be found in system or facility operation process descriptions, interviews with expected software users, supplier product descriptions, and the user’s manual. Limitations for use of the software should consider any restrictions associated with the computer hardware or operating environment, current known software errors, application to the domain of interest, cyber security, and user access. Identifying the technical requirements, and documenting test plans, test cases, and installation test results may be sufficient, provided that the rigor of the evaluation is commensurate with the computer program’s effect on quality. However, if access to the Supplier is limited and documentation is not available for the acquired software, computer program testing activities may be the primary method to evaluate the computer program.</td>
</tr>
</tbody>
</table>
100 GENERAL

This Subpart provides amplified requirements for a Purchaser to accept supplier accreditation for calibration or testing services as an alternative to supplier evaluation and selection requirements. It supplements the requirements of Part I and shall be used in conjunction with applicable requirements of Part I when and to the extent specified by the organization invoking this Subpart.

In this Subpart, the user shall apply the applicable edition of ISO / IEC 17025 is 2017, to which the applicable supplier’s program was accredited. For the purpose of this Subpart, either the 2005 or the 2017 edition of ISO/IEC 17025 is acceptable.
## Implementing Guidance for Part I, Requirement 1: Organization

### Proposed Revision to NQA-1-2017
(with line through / strikeout and replacement)

### 100 GENERAL
This Subpart provides nonmandatory guidance on organization as specified in Requirement 1 of Part I.

### 200 ORGANIZATIONAL STRUCTURE
In structuring the organization and assigning responsibility, quality assurance should be recognized as an interdisciplinary function involving many organizational components and, therefore, should not be regarded as the sole domain of a single quality assurance group. The quality assurance group (or groups), however, should be designated to describe, integrate, and monitor the agreed-upon quality assurance activities of the various disciplines and functions.

Quality assurance encompasses many functions and should extend to all levels that perform activities affecting quality from senior management down, including, but not limited to the following: extends to various levels in all participating organizations, from the top executive to workers, such as designers, computer programmers, welders, inspectors, facility operators, craftsmen, and Auditors, who perform activities affecting quality.

Different organizational structures may be effective, depending on the portion of the project or job in which the implementing organization is involved.

The organization’s members should know, understand, and work to the documented quality assurance program and its interfaces.

### 300 BASIC PRINCIPLES

#### 301 Management Functions
Designated management should have the authority and responsibility to identify or approve:
(a) quality assurance program scope and appropriate quality levels
(b) characteristics to be verified and acceptance criteria
(c) actions to resolve quality problems
(d) determination of the validity and disposition of nonconforming items and services

#### 302 Quality Achievement Functions
Those performing quality achievement functions should have:
(a) means or information, or both, to monitor or check the quality of their work.
(b) authority and responsibility to identify and control defective work products
(c) responsibility to correct quality problems in their area of responsibility, whether self-identified or reported to them by others
(d) freedom to provide or recommend solutions to quality problems outside their area of responsibility
<table>
<thead>
<tr>
<th><strong>ASME Record No:</strong> 19-17</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NQA Part and Document:</strong> Part III SP 3.1-2.1</td>
</tr>
<tr>
<td>Implementing Guidance for Part I, Requirement 2: Quality Assurance Programs</td>
</tr>
<tr>
<td><strong>Proposed Revision to NQA-1-2017</strong></td>
</tr>
<tr>
<td>(with line through / strikeout and replacement)</td>
</tr>
<tr>
<td>NQA-1-2017 Part III SP 3.1-2.1</td>
</tr>
</tbody>
</table>

### 100 GENERAL
This Subpart provides nonmandatory guidance on Requirement 2 of Part I, Quality Assurance Program.
200 PROGRAM FORMAT
The format of NQA-1 has retained the original eighteen criteria. Other recently developed quality assurance requirements documents use different formats.

One such format example is:
(a) management,
(b) performance, and
(c) assessment.

Another format example is:
(a) program
(b) personnel training and qualification
(c) quality improvement
(d) documents and records
(e) work processes
(f) design
(g) procurement
(h) inspection and acceptance testing
(i) management assessment
(j) independent assessment

Still another format uses twenty elements to describe a quality assurance program. Regardless of how the requirements are grouped and formatted, the important success factor is to adequately address all imposed requirements.

This Standard does not restrict the development of quality assurance programs to the format of requirements specified herein, provided the technical contents of the requirements imposed by the organization invoking this Standard are met. An adequate review to determine if all requirements have been identified is through tracking of “shall” statements throughout the standard. Each “shall” statement within a sentence identifies 1 or more requirements.

Frequently, one quality assurance program can be adapted to satisfy the needs of more than one standard, or customer. Because of its broad base of requirements, NQA-1 provides a core program that can be related to other standards and customer specifications. A relationship matrix can be used to demonstrate programmatic comparability with other source requirement documents.

The following are good examples of other source documents relationship matrices:
-Subpart 4.1.2 Guidance on the Use of NQA-1–2008/1a–2009 for Compliance With Department of Energy Quality Assurance Requirements 10 CFR 830, Subpart A and DOE O 414.1
-Subpart 4.1.4 Guidance to Modification of an IAEA GS-R-3 Quality Program to Meet NQA-1a–2009 Requirements and Modification of an NQA-1a–2009 Quality Program to Meet IAEA GS-R-3 Requirements

Accommodating multiple customer needs with one quality assurance program has several benefits: consistency of application to minimize performance errors, minimization of training, and process cost effectiveness.
300 PROGRAM DEVELOPMENT
301 Purpose and Scope
The quality assurance program should be developed to meet customer requirements and user needs. Application of management controls and the degree of program formality should be graded to satisfy criteria based on the defined risks associated with meeting specified requirements.

Most quality assurance applications will have multiple customers and users (stake-holders), and to meet the intended purpose of the quality assurance program, customer needs should be viewed individually and then collectively. Customers can be internal or external to the quality assurance program applied to the work process. Internal users of the quality assurance program will have different needs (i.e., performance) than external customers, who are recipients of the products (i.e., items or services) of the work process to which the quality assurance program applies. A regulator should be viewed as a customer with a defined set of requirements and expectations to be met.

The quality assurance program should describe the organizational structure, functional responsibilities, authority levels and relationships, and communication interfaces needed to accomplish the work and quality objectives.

Generally, functional interfaces should be identified to link with key customer communication points. This will promote performance-based operations and reporting if used effectively to communicate performance status and resolution of issues.

302 Timing
The primary reason for establishing a quality assurance program is to ensure that items and services are developed and provided for use in compliance with specified requirements. To achieve this objective, control and verification measures should be planned, documented, and implemented at predetermined points throughout the life cycle of the work process. The program should provide control from initiation of activities through their completion.

The quality assurance program should specify an orderly and timely sequence for the implementation of applicable requirements and standards; for example, as a nuclear project moves through its various stages, activities affecting quality will change as the type of work dictates.

400 WORK REQUIREMENTS AND PERFORMANCE
401 Basis and Structure
The structure, graded content, and application of a quality assurance program should be based on a defined baseline of requirements to accomplish performance objectives. Tasks derived as the step-wise methods to achieve performance objectives can be logically collected into a work process to form the basis for defining work functions. These functions are the building blocks of an organization framework. Work task relationships are frequently described in work breakdown structure that relates process requirements, tasks, and work products and provides the basis for work scheduling, cost control, and performance measurement.

Each work requirement should be related to a—a customer, an end product, a work task, and a work process—and a customer. Progress toward achieving a work product should be measurable to determine how effectively work objectives are met.
### 402 Planning
Work activities should be planned to ensure a systematic approach. Planning should result in the documented identification of methods and functional responsibilities. Planning should determine what is to be accomplished, who is to accomplish it, how it is to be accomplished, when it is to be accomplished, and how to measure performance and progress. Planning should be performed as early as practicable and prior to the start of the activities to be controlled to ensure functional interface compatibility and satisfactory coverage of governing requirements. Planning for a quality assurance program should take into consideration:

1. Applicable quality and technical requirements, including governing specifications, codes, standards, and practices.
2. The need for special procedures, work instructions, controls, processes, equipment, qualifications, or certifications required to achieve quality requirements.
3. The documentation needed to demonstrate the quality of the work performed and the items and services provided for use.
4. The assignment of task and performance responsibilities.
5. The methods to be used to verify conformance with quality and technical requirements, and program effectiveness for their equivalency should be documented.

### 500 WORK PROCESSES
#### 501 Process Management
The input to a work process consists of requirements and the output is a product that meets those requirements. Quality assurance is the discipline for ensuring that a product meets specified requirements. Thus, quality assurance is designed into all aspects of work planning, management, performance, validation, verification, documentation, close-out, and product delivery. The quality assurance discipline provides a dedicated approach for achieving performance objectives. The quality assurance program should describe the scope (i.e., breadth and depth) of its application, including coverage of administrative services, if that is what is needed to meet customer performance expectations.

### 502 Graded Approach
Items and services may require varying degrees of control and verification to ensure compliance with requirements. Factors that should be considered in determining appropriate levels of control and verification include:

1. The hazards associated with doing the work or using the results of the work.
2. The consequences of malfunction or failure of the item, or inappropriate use of the results of services provided.
3. The probability of the occurrence of the postulated consequences.
4. The design and fabrication complexity or uniqueness of the item, or difficulty to perform services.
5. The degree to which functional compliance can be demonstrated by inspection, test, or performance verification.
6. The quality history and degree of standardization of items and services.
7. The difficulty of repair, replacement, or replication of the items and services.
600 TRAINING AND QUALIFICATION
The definition of work requirements, individual work tasks, and their collection into a work process should be used to determine the individual and collective training and qualification needs.

The accumulation of knowledge and skills through experience is an effective way of becoming proficient in a work activity. On-the-job training (including mentoring) is an effective training method and should be documented as well as classroom training.

Demonstrated proficiency and consistent performance are two primary measures of good training and qualification practices. Controlling process variability may be a good indication that the training and qualification practices are adequate to reach performance objectives.

Requirements for Qualification Records are found in Part I, Requirements 2, Paragraph 400.

700 ASSESSMENT OF PERFORMANCE
Work task objectives should be clearly established with in-process and final acceptance criteria. Progress toward meeting objectives should be measured against parameters that are meaningful to the work process. If work task and performance objectives, and work responsibilities have been defined, performance measurement should automatically follow.

Those doing the work should have first-line responsibility for the acceptability of their work. Their managers should regularly assess work performance.

Management assessments can be continuous measurements of performance or periodic efforts, depending on the scope of the work and process complexity as well as risk management considerations.

A clear understanding of hazards and risks of achieving or not achieving work objectives should be used as the basis for establishing a management assessment process, and the nature of that process.

Frequently, a well-developed (and well-coordinated) management assessment process can be linked to customer reporting needs to avoid duplicate performance measurement programs.

Management may choose to use individuals who have no direct responsibility for accomplishing work tasks or objectives to assist in the management assessment.
SUBPART 3.1-2.4
Implementing Guidance for Part I, Requirement 2: Quality Assurance Programs, Management Assessment of the QA Program

100 GENERAL

This Subpart establishes nonmandatory guidance for performing the QA Program management assessment required by Part I, Requirement 2, Section 100(c) to assess the adequacy and effectiveness of the QA Program. Additionally, this Subpart provides guidance on other types of management assessments that some organizations find useful to supplement the required QA Program Management Assessment or to satisfy regulatory commitments. These include: Individual Assessments, Management “Walk-Around” Assessments, and Functional Area Assessments. [1]

This Subpart does not apply to internal or external audits performed per Part I, Requirement 18. However, the QA Program Management Assessments should include an evaluation of previously completed audit results.

200 TYPES OF MANAGEMENT ASSESSMENT

201 QA Program Management Assessment

The assessment is performed periodically to assess the adequacy and effectiveness of the overall QA Program. This should include a review and assessment of some of the following inputs: internal audits and assessments, customer audits, supplier performance, corrective action results, and trend analysis. This type of assessment may be performed by an individual or team with subject matter expertise to determine the adequacy and effectiveness of the program element(s) being assessed.

The emphasis of a Management Assessment is on processes that affect the performance of an activity or process, or personnel qualification and training, staffing and skills mix, communication, organizational interfaces, completion of mission objectives or other topics.

202 Supplemental Management Assessments

The following assessment types may be used to supplement to the QA Program Management Assessment or to satisfy other regulatory commitments.

1. Individual Assessments
   This type of assessment is when an individual performs an assessment. This is a quick-hit assessment, usually directed by management and focused on a limited area or process. It can be used to gather information or data for additional evaluation or to determine the status of an activity.

   This type of assessment is similar to individual assessments but does not need a specific plan or schedule. It is predominately a visual assessment used to determine the status or implementation of management direction or requirements.

3. Functional Area Assessments
   This type of assessment is used for the review of a limited process or a functional area. For example, the implementation of the work package process or the review of selected training and qualifications. This type of assessment should consist of an individual or team with subject matter expertise to help determine the adequacy and effectiveness of the program or process being assessed.
300 SCHEDULING AND PLANNING

301 Scheduling

Management should identify the focus area and performance period (i.e. schedule) of Functional and Program type assessments so that adequate time is available to select an appropriate team or individual and to develop an effective assessment plan.

Management should establish expectations for type, length and periodicity of the assessments. The Assessment Team Leader or responsible individual should coordinate with the Management of the assessed organization to agree on a timeframe for the assessment.

Some assessments may be in response to events or situations and may be scheduled to support management direction.

302 Planning Assessments

The extent and scope of the assessment is determined by management and is based upon the assessment type and the importance of the activity being assessed.

Management Assessments should be planned to the depth, breadth and rigor necessary, with emphasis on adequacy and effectiveness. Management Assessments may require the development of objective criteria to determine if Management’s goals are being achieved.

Assessment planning should ensure that actions for the assessment cover the depth, breath and scope of the assessment as determined by management. Aspects of the program or activity to be assessed may include and are not limited to:

- Determining how systems, processes and procedures effectively meet stated requirements and accomplish work
- Describing the clarity of the organizational mission, goals and objectives
- Identifying and correcting problems that hinder the organization from achieving its objectives
- Determining the adequacy of procedural processes and assessing their ability to meet management objectives
- Determining the adequacy of training and qualification programs for personnel
- Assessing the implementation and effectiveness of planning processes and communication systems, including communication and coordination with external organizations
- Determining compliance and adequacy of scheduling processes to assure project goals are met
- Determining the adequacy of support processes and systems such as equipment maintenance, security, operations, etc.
- Evaluating an organizations capabilities to accomplish objectives
- Evaluating leadership capabilities to enable the organization to meet internal or external objectives, requirements and expectations
- If applicable, use a prior Management Assessment’s criterion, information and/or results from that
Table 301

<table>
<thead>
<tr>
<th>Type of Assessment</th>
<th>Recommended</th>
<th>Documents Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Schedule</td>
<td>Plan</td>
</tr>
<tr>
<td></td>
<td>Note 4</td>
<td></td>
</tr>
<tr>
<td>QA Program Management Assessments</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Individual Self-Assessments</td>
<td>Yes – see note 1</td>
<td>Yes – see note 1</td>
</tr>
<tr>
<td>Manager Assessments (walk around assessment)</td>
<td>Yes – see note 1</td>
<td>Yes – see note 1</td>
</tr>
<tr>
<td>Functional Area Assessments</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Note 1 – this should be a simple plan or schedule – document – what will be reviewed, when it will be reviewed.
Note 2 – the individual performing the assessment assumes the role of the team leader
Note 3 – if performed by an individual, the individual is the team leader
Note 4 – schedule does not imply a periodic activity: one time assessments should have a projected completion date

400 ASSESSMENT PERFORMANCE

401 Assessment Team Responsibilities

Assessment Team Leaders or designated individual should perform the following:
  a. Select Assessment Team Members, for the assessment type being performed. Selection of Team Members should be based upon experience related to work scope, and should possess technical familiarity with the activities being assessed while not having direct responsibility for activity performance.
  b. Acquire the resources required.
  c. Acquire any other pertinent information that needs to be communicated to the team and Organization being assessed.
  d. Notify the Manager(s) of the Assessed Organization(s) of the Management Assessment schedule.
  e. Notify personnel, coordinate meeting locations and scheduling of the assessment.
  f. Utilize, as necessary, Subject Matter Experts Process or Activity Owners to help determine the status of the criterion being assessed. Knowledgeable persons can be utilized for interviews or help during document reviews.
  g. Keep affected managers (of both the assessed organization and requesting organization, as applicable) apprised of the status of assessment efforts and results.
h. Immediately notify management of conditions requiring prompt corrective action.

The Assessment Team Members should collect objective evidence within the limits imposed by the purpose and scope to address each assessment criterion.

402 Assessment Methodologies

The assessment team may use one or more of the following methodologies to evaluate the criteria established in the assessment plan:

a. Work Observation—Provides direct observation of work (both physical and/or process) when it is practical and available. This method is considered the most effective technique for determining whether performance is adequate. Assessors should understand the effect their presence has on the person being observed and convey an attitude that is helpful, constructive, positive, and unbiased. The primary goal of work observation is to obtain the most complete picture possible of the performance, which should then be put into perspective relative to the overall program, system, or process. Before drawing final conclusions, the assessor should verify the results through at least one other technique, if possible.

b. Document Reviews - Provides the objective evidence to substantiate compliance with applicable requirements. This technique should be combined with interviews, work observation and/or field observation to complete the performance picture. Records and documents should be selected carefully to ensure they adequately characterize the program, system, or process being assessed.

c. Interviews – Provides the means of verifying the results of work observation, document review and/or field observation. Interviews allow the responsible person to explain and clarify those results, help to eliminate misunderstandings about program implementation and provide a venue where apparent conflicts or recent changes can be discussed, and organization and program expectations can be described.

500 REPORTING

Summarize assessment results, including a statement on the adequacy and effectiveness of the areas assessed. The report should be signed by the Assessment Team Leader or designated individual and issued to the manager responsible for the area assessed, and other management personnel as deemed appropriate. The contents of the report should include the following as appropriate: (a) describe the assessment scope (b) identify assessment team members and persons contacted, documents reviewed, and activities observed (c) summarize assessment results, including a statement on the effectiveness of the areas assessed and (d) describe each issue (strength, deficiency or weakness) identified during the assessment.

Typical classification of assessment issue includes:

- **Strength**—Fully meets and exceeds the related performance criteria.
- **Acceptable**—Performing acceptably (or prepared to perform acceptably) and personnel in this area are capable of meeting project mission goals and objectives. Procedures, processes, and staffing are adequate and meet program or contract requirements.
- **Deficiency**—Condition adverse to quality as described in Part 1 Requirement 16 Corrective Action. The expectation is that conditions adverse will be entered into the appropriate corrective action program.
- **Weakness**—Marginal, underperforming or some elements are missing to be successful.
Subpart 3.1-18.3
Implementing Guidance for Part I, Requirement 18: Audits, Use of Surveillance

SUBPART 3.1-18.3

100 GENERAL
This Appendix provides nonmandatory guidance on the use of Surveillance as a means to ensure the effective implementation of the quality assurance program. There are organizations that use “surveillances” to complement their audit program under Part 1, Requirement 18. This subpart can be used to complement that process as long as the personnel used to accomplish surveillances under this subpart are trained and qualified in accordance with Requirement 2. This Subpart provides nonmandatory guidance for one method that may be used as an element in meeting the audit program requirement.

Surveillance as used in this subpart is an assessment technique that uses observation or monitoring to provide confidence that ongoing processes and activities are adequately documented and effectively performed. Surveillance can be used effectively to complement the audit, review, inspection, and test functions.

In addition to supporting Requirement 18, Surveillance may be used by managers and supervisors as part of their routine assessment activities as noted in Part 1, Requirement 2 to provide timely data on performance and to identify quality issues before they have a significant impact on safety and reliability.

Surveillance has the following advantages:
(a) It is flexible, adaptable, and easy to use.
(b) It may be implemented quickly.
(c) It may be applied by line personnel, management as well as independent personnel.
(d) It is adaptable to a broad range of assessments including item acceptance and diagnostics for determination of extent and cause of nonconforming issues.

Examples of processes and activities suitable for surveillance include research and development, design, internal procurement process, manufacturing, plant operations, modifications and maintenance, radiological and industrial safety, safeguards and security, sampling, laboratory, inspection, testing, calibration, hazardous waste management, materials management, and environmental management.

200 PLANNING AND SCHEDULING
Planning and scheduling should be used to determine those processes and activities that would most benefit from surveillance, when and how frequently it should be performed, as well as who should perform or lead it. Surveillance plans may be integrated into the overall assessment program complementing other evaluation techniques as deemed useful and appropriate for the process or activity being covered.
201 Planning
Planning efforts should precede scheduling arrangements to determine what processes, activities, or conditions are important and which prerequisites are needed to be completed prior to performing a surveillance. Planning should consider aspects such as regulatory impact, safety and reliability significance, experience and previous history, follow-up of previous concerns, management commitments, line supervisory concerns, and related industry experience. Industry experience may be derived from inspection results, industry standards and information networks. Selection of personnel to perform a surveillance should also be considered. Directly related experience is a desirable attribute for surveillance personnel. Consideration of other scheduled assessments also should be made to avoid duplication and to optimize timing of the surveillance.

202 Scheduling
Scheduling may be flexible and informal to implement the surveillance plans to coincide with ongoing activities. When used, schedules may be informally controlled, but detailed to the extent that opportunities are not missed and priorities are satisfied. Control of scheduling may be accomplished by simply indicating the month in which the surveillance is to be performed, who is assigned to perform the surveillance, and the need for additional technical expertise.

300 PREPARATION
A surveillance plan should include a purpose or objective of what will be observed or monitored and actions or attributes to be assessed. The amount of detail in the surveillance plan should be commensurate with aspects such as the knowledge and experience of the personnel performing the surveillance and the complexity or uniqueness of the process or activity. The surveillance plan should be used as a tool to guide personnel through the surveillance and to ensure that the purpose or objectives are accomplished. The extent of the surveillance and related preparation should be consistent with its purpose and the importance of the processes and activities being observed.

Familiarization with management expectations, governing procedures, specifications and other policy documents is desirable. The governing resource documents may include drawings, procedures, supplier manuals, system descriptions, license commitments, codes and standards, controls, research and experiment guidelines, as well as industry publications. Reports from previous or other assessments, both internal and industrywide, should be considered. Additionally, reports that provide performance indicators, status, trends, and histories may also be useful.

Methods of surveillance should also be considered with preference given to direct observation of performance. Direct observation may be augmented by discussions with personnel, observation of results, and review of documents.

Other preparation considerations may include the following:

(a) surveillance date(s) to coincide with performance of the process or activity
(b) need for additional assistance to include subject matter experts or other experienced personnel who can make accurate and meaningful assessments of performance
(c) orientation of surveillance personnel not yet familiar with the performance of surveillances by clarifying the reporting processes and the need to pursue identified concerns
(d) the need for observing processes and activities of groups performing the activity during all work periods
(e) generic attributes that apply to many or all surveillances but that are not specifically outlined in each plan

400 PERFORMANCE
401 Notification
Cognizant management or area supervision should be given sufficient notification prior to the surveillance being performed so that they can be adequately prepared. Ideally the surveillance plan would be included in this notification.

402 Conduct of Surveillance
402.1 Surveillance personnel should use the following guidelines, as appropriate:
(a) Prior to starting the surveillance:
   (1) Develop a clear understanding of the scope of the surveillance, the safety and reliability aspects of the work scope, the requirements and rules applicable to the facility and to the work to be observed, and the communication and reporting agreements made with the organization responsible for performing the work.
   (2) Inform personnel responsible for the activity or process, why the surveillance is being conducted, the scope of the surveillance, communication and reporting agreements, the authority of the person performing the surveillance (particularly in the area of Stop Work).
   (3) Allow activities to continue without interference unless it is apparent that immediate corrective or preventive action is necessary in accordance with governing procedures, or if a safety hazard is present. This provides the opportunity to confirm that all personnel involved understand the work, their roles, the risks, interfaces, and preparedness by having the correct tools, apparatus, and documentation required to accomplish the work.
(b) Using checklists will enhance the documentation of the surveillance effort. However, a checklist should not preclude the opportunity to observe an unanticipated or unexpected event that may have the potential to yield additional performance data. Nor should the checklist prevent the immediate follow-up of an important or significant observation or concern.
(c) Record observations on the checklist for reference and follow-up.
(d) Pursue concerns and deficiencies sufficiently to characterize the nature and extent of each.
(e) Exercise care in keeping facts separated from opinions or judgments. Where possible, confirmation of observations or perceptions should be sought prior to forming conclusions. This may be achieved through non-disruptive inquiries of personnel involved in the activity or by review of results.
(f) Offer to review observations with the personnel involved at the end of the surveillance, noting the observed strengths, weaknesses, and recommendations for improvements. Indicate if formal corrective action is being considered and invite comments and questions.
(g) Finally, express appreciation for cooperation demonstrated during the surveillance.

402.2 Surveillances should consider the following, as appropriate:
(a) Upon arrival at the workplace note:
   (1) the existence of any apparent hazards, such as radiation, chemicals, toxins, spills, electricity, leaks, tripping, combustibles and flammables, noise, overhead work, unsecured ladders or scaffolding, dangerous apparatus or
tools, hot or cold surfaces or liquids, compressed gases, unguarded rotating equipment, and general housekeeping.

(2) the application of barriers, such as isolations, tags, clearances, warning signs, locked or roped-off areas, and segregation of nonconforming materials.

(3) the condition of facilities, such as cleanliness, ventilation, temperature, area alarms, public-address system, availability of protective and emergency equipment, and current status of testing for fire protection and lifting equipment.

(4) the availability and use of appropriate equipment and materials, such as apparatus and tools, calibrated tools and measuring and test equipment and instruments, shelf life, labeling and traceability of raw materials and samples.

(5) the availability and use of documentation, such as current reference documents, instructions, procedures, drawings, specifications and documentation required to authorize work or to record key results or data.

(6) if not evaluated earlier under para. 402.1(d) of this Subpart, note such things as
  (a) supervisory involvement
  (b) worker preparedness and understanding of assigned tasks and associated risks
  (c) skills and expertise available
  (d) communications

(b) As the surveillance progresses;

(1) the performance of the personnel conducting work and inspection should be observed. Some aspects that may be evaluated include
  (a) communications with supervision and supporting organizations
  (b) how accountability is established
  (c) adherence to rules and procedures
  (d) use of tools, apparatus, and equipment
  (e) handling of problems or unexpected events
  (f) inspection activities performed to verify that materials, parts, and components meet specifications

(2) the adequacy of procedures, specifications, and work instructions should be assessed.

(3) the adequacy of process controls used for activities that cannot be clearly delineated in procedures should be assessed. Controls for tests and experiments should support and validate the results and conclusions and provide sufficient data for replication and peer reviews when required. Controls during development, which are applied to the fabrication, construction, test, and operation of prototypes and test rigs, should support and validate the results and provide reliable data for subsequent production-line activities.

(c) On completion of the surveillance;

(1) the observations should be evaluated by the individual who performed the surveillance with the assistance of cognizant personnel if necessary to assess their validity, importance and significance, and impact on quality, safety, and reliability both individually and collectively.

(2) care should be taken to identify trends and isolated incidents that may have generic implications so that they may be appropriately followed up.

(3) consideration should also be given to reviewing other surveillances of similar work activities for identification of trends. This evaluation may identify conditions adverse to quality, nonconforming items, and quality program
inadequacies. These should be processed in accordance with applicable corrective action procedures.

(4) observed strengths and positive trends should also be identified.
(5) issues not included in the above considerations, such as industrial safety, cost effectiveness, and process efficiency, should also be identified.

500 REPORTING AND COMMUNICATION
Reporting and communication may take many forms within the organization. The following elements should be considered:

(a) reaching agreement on communicating results during the surveillance
(b) providing immediate verbal feedback concerning strengths and weaknesses to first-line supervisors, managers, and workers, as appropriate
(c) notifying appropriate personnel of conditions adverse to quality in accordance with governing procedures
(d) consider giving the surveilled organization the opportunity to review and discuss the surveillance report for factual accuracy, prior to report finalization.
(e) report details should be sufficient for a knowledgeable individual to understand without recourse to the person who conducted the surveillance

600 RESOLUTION OF ISSUES
601 Response to Surveillance Reports
Issues that constitute or may constitute a condition adverse to quality should be entered into the corrective action system.

Issues should be resolved at the lowest level that has the authority to effectively resolve the issue.

Responses to identified issue should be made in a timely manner, with consideration given to the importance of the issues. Should there be a disagreement; resolution should be in accordance with governing procedures.

602 Follow-Up
Follow-up of important issues should be initiated as necessary to confirm there satisfactory resolution. Results from surveillances should be provided as inputs to existing corrective action, trending, or quality improvement programs in accordance with governing procedures.
<table>
<thead>
<tr>
<th>ASME Record No: 20-844</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Proposed Revision to NQA-1-2021</strong></td>
</tr>
<tr>
<td>(with line through / strikeout and replacement)</td>
</tr>
<tr>
<td><strong>NQA-1-2019 Part III, Subpart 3.2-2.15</strong></td>
</tr>
<tr>
<td><strong>Revision</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>100 GENERAL</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>This Subpart provides guidance on the design and use of hoisting, rigging, and transporting equipment to maintain the quality of designated nuclear power plant items that require special handling, from the time these designated items are delivered at the point of receipt for the plant until the operating phase of the plant. The guidelines of this Subpart may also be extended to other appropriate parts of nuclear power plants when specified in contract documents.</td>
</tr>
</tbody>
</table>

Subpart 3.2-2.15 has been deleted. Subpart 3.2-2.15 and Subpart 2.15 have been replaced with HRT-1-2016, Rules For Hoisting, Rigging, and Transporting Equipment for Nuclear Facilities. Copies of this standard can be obtained from the American Society of Mechanical Engineers (ASME), Two Park Avenue, New York, NY, 10016.

<table>
<thead>
<tr>
<th><strong>200 RECOMMENDED DESIGN CRITERIA</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>This section describes specific design criteria that are appropriate for most applications and that are recommended for general use. If it can be shown that these criteria are not appropriate for a specific application, the engineer responsible shall select compatible criteria and document the justification.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>201 Structural</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommended safety factors for guyed systems are 3 to 1 (breaking strength to working load) for strength of guys, and 2 to 1 based on anchorage pullout.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>202 Mechanical</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydraulic circuits may require design features, such as pressure-operated check valves, to minimize possibilities of unexpected lowering of loads.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>300 RECOMMENDED CONTROL OF THE USE OF HANDLING EQUIPMENT</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Where applicable, soils tests should be made and the results analyzed by an individual qualified in soils engineering to determine the stability of ground areas in the vicinity of lifting equipment or along the route of transport equipment. Requirements for the use of soil compaction, timber mats, concrete pads, or other methods of reinforcement should be based on these tests and their evaluation. Tests may be waived when a history of previous use with equal or greater weight is available for the same area under similar conditions, including any reinforcement if previously used.</td>
</tr>
</tbody>
</table>
# 100 PURPOSE AND SCOPE

This Subpart provides guidance to organizations that have established a quality management system in accordance with ISO 9001 and additionally need to meet the requirements of NQA-1. This Subpart compares the requirements of NQA-1—2015, Part I, and of ISO 9001:2015. The purpose of this comparison is to identify equivalences and differences between those two standards. The guidance comprises practical recommendations on how to reconcile differing requirements when both standards are to be simultaneously implemented in an organization.

The comparison table was prepared using NQA-1-2015 and is valid through the 2019 edition of NQA-1. No changes were required to the existing table to make it current to the 2019 edition.

---

### 200 BACKGROUND

No changes

### 300 TERMS AND DEFINITIONS

It should be noted that terms and definitions may differ between NQA-1—2015, in particular Part I, Introduction, section 400, and ISO 9000:2015, Quality Management Systems—Fundamentals and Vocabulary. While this Subpart contains only guidance, the word “shall” is used to denote that full implementation of the requirements of Part I is mandatory to comply with this Standard.

---

### 400 COMPARISON TABLES

No changes
SUBPART 4.1.5

100 INTRODUCTION
The purpose of this Subpart is to compare the requirements of ANSI/ANS-15.8–1995 (R2005; R2013) (ANSI/ANS-15.8) and NQA-1 and to identify where actions may be needed to address the differences. The comparison table was prepared using NQA-1–2012 and is valid through the current published 2019 edition of NQA-1 (Parts I and II), and to identify where actions may be needed to address the differences.

Table 200-3 Corresponding NQA Sections (Requirement 2) to ANSI/ANS-15.8

<table>
<thead>
<tr>
<th>NQA-1, Part I, Requirement 2: Quality Assurance Program</th>
<th>ANSI/ANS-15.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 General</td>
<td>2.2 Quality Assurance Program</td>
</tr>
<tr>
<td></td>
<td>3.2 Performance Monitoring [Note (1)]</td>
</tr>
<tr>
<td>200 Indoctrination and Training</td>
<td>2.2 Quality Assurance Program</td>
</tr>
<tr>
<td>201 Indoctrination</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>202 Training</td>
<td>2.2 Quality Assurance Program</td>
</tr>
<tr>
<td></td>
<td>3.3 Operator Experience [Note (1)]</td>
</tr>
<tr>
<td></td>
<td>2.10 Inspections [Note (2)]</td>
</tr>
<tr>
<td>300 Qualification Requirements</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>301 Nondestructive Examination</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>302 Inspection and Test</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>303 Lead Auditor</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>303.1 Communication Skills</td>
<td>2.18 Assessments</td>
</tr>
<tr>
<td>303.2 Training</td>
<td>2.18 Assessments</td>
</tr>
<tr>
<td>303.3 Audit Participation</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>303.4 Examination</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>303.5 Maintenance of Proficiency</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>303.6 Requalification</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>304 Auditors</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>305 Technical Specialists</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>400 Records of Qualification</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>500 Records</td>
<td>No corresponding requirement</td>
</tr>
</tbody>
</table>

NOTES:
(1) ANSI/ANS-15.8 also applies this Requirement to Facility Operations.
(2) ANSI/ANS-15.8 is more prescriptive in inspection training requirements (see Table 200-11).

RECOMMENDATIONS: There are several areas that need more detail for an ANSI/ANS-15.8 quality program organization to meet this NQA-1 Requirement.

(a) The ANSI/ANS-15.8 documented quality assurance program does not include the planning, implementation, and maintenance requirements for the documented quality assurance program described in NQA-1, Part I, Requirement 2, section 100. NQA-1 is more prescriptive in the specific recognition, where necessary, of “Controlled Conditions” as it relates to the use of appropriate equipment or processes, suitable environmental conditions, and satisfaction of activity prerequisites in NQA-1, Part I, Requirement 2, section 100.

(b) NQA-1 is more prescriptive in the requirements of Indoctrination and Training.

1. It requires documented indoctrination for personnel performing or managing quality-affecting activities to include job responsibilities and authority and general criteria, including applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements by NQA-1, Part I, Requirement 2, sections 201 and 202.

2. The training requirements of NQA-1 are more explicit and include determining the need for formal training for personnel performing or managing quality-affecting activities. This training may include achieving and maintaining proficiency and/or changes to technology, methods,
or job responsibilities by NQA-1, Part I, Requirement 2, section 202.

(c) NQA-1 is more prescriptive in explicit qualification requirements for personnel performing activities determined to need qualified personnel. Specific qualification requirements for personnel performing nondestructive examination, inspection, tests to verify quality and auditing, and qualification records shall be in accordance with NQA-1, Part I, Requirement 2, sections 300 and 400 (including sections 401 and 402 for NQA-1-2015 through current the 2019 edition of NQA-1).

(d) The records requirements for training in NQA-1 are more explicit for formal training of personnel performing or managing quality-affecting activities per NQA-1, Part I, Requirement 2, section 500.
Table 200-4 Corresponding NQA Sections (Requirement 3) to ANSI/ANS-15.8

<table>
<thead>
<tr>
<th>NQA-1, Part I, Requirement 3: Design Control</th>
<th>ANSI/ANS-15.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 General</td>
<td>2.3 Design Control</td>
</tr>
<tr>
<td>200 Design Input</td>
<td>2.3.2 Design Processes</td>
</tr>
<tr>
<td>300 Design Process</td>
<td>2.3.1 Design Requirements</td>
</tr>
<tr>
<td>400 Design Analysis</td>
<td>2.3.2 Design Process</td>
</tr>
<tr>
<td>401 Use of Computer Programs</td>
<td>2.3.5 Commercial Grade Items</td>
</tr>
<tr>
<td>402 Documentation of Design Analysis</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>500 Design Verification</td>
<td>2.3.3 Design Verification</td>
</tr>
<tr>
<td>501 Methods</td>
<td>2.3.3 Design Verification</td>
</tr>
<tr>
<td>Design Reviews</td>
<td>2.3.3 Design Verification</td>
</tr>
<tr>
<td>Alternate Calculations</td>
<td>2.3.3 Design Verification</td>
</tr>
<tr>
<td>Qualification Tests</td>
<td>2.3.3 Design Verification</td>
</tr>
<tr>
<td>600 Change Control</td>
<td>3.10 Configuration Control [Note (1)]</td>
</tr>
<tr>
<td>601 Configuration Management of Operating Facilities</td>
<td>2.3.6 Change Control</td>
</tr>
<tr>
<td>700 Interface Control</td>
<td>2.3.2 Design Process</td>
</tr>
<tr>
<td>800 Software Design Control</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>801 Software Design Process</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>Identification of Software Design Requirements</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>Software Design</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>Implementation of the Software Design</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>Software Design Verification</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>Computer Program Testing</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>802 Software Configuration Management</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>Configuration Identification</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>Configuration Change Control</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>Configuration Status Control</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>900 Documentation and Records</td>
<td>No corresponding requirement</td>
</tr>
</tbody>
</table>

NOTE:
(1) ANSI/ANS-15.8 also applies this Requirement to Facility Operations.

RECOMMENDATIONS: NQA-1 contains substantially more scope and detailed requirements for the design process. An ANSI/ANS-15.8 design process must be carefully compared with NQA-1 to establish compliance.

There are several areas that may need more detail for an ANSI/ANS-15.8 quality program organization to meet this NQA-1 Requirement.

(a) NQA-1 requires sufficient documented detail of design input to perform the design process in a correct and consistent manner for making design decisions and accomplishing design verification. Design changes shall have at least the same level of control as applied to the original design and shall be incorporated into the appropriate documents in a timely manner. Those approving design changes shall have demonstrated competence in the specific design area of interest and have adequate understanding of the requirements and intent of the original design by NQA-1, Part I, Requirement 3, sections 200 and 600.

(b) The design process of NQA-1 requires approval of design inputs, quality standards, and interface control documents. NQA-1 requires the final design to specify required inspections and tests and include or reference appropriate acceptance criteria by NQA-1, Part I, Requirement 3, section 300.

(c) Formalize and document in detail design analysis, design verification processes, and interface control. The requirements for these design functions are in NQA-1, Part I, Requirement 3, sections 400, 500, and 700.

(d) Establish and document the configuration management for the operating facility prior to facility operation. The requirements for the configuration management of the operating facilities are found in NQA-1, Part I, Requirement 3, section 600.
Table 200-4  Corresponding NQA Sections (Requirement 3) to ANSI/ANS-15.8 (Cont’d)

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>Controls are required for computer software design using the requirements found in NQA-1, Part I, Requirement 3, section 800, including NQA-1 Subpart 2.7 Quality Assurance Requirements for Computer Software for Nuclear Facility Applications for NQA-1-2015 through the 2019 edition of NQA-1. NQA-1 is more prescriptive for software design control in specifying the steps of the software design process, acceptance testing, verification activities, and validation of results for the intended purpose. ANSI/ANS-15.8 does not distinguish design control requirements between software and hardware except for the added requirement that verification of design-unique computer programs shall include benchmark testing.</td>
</tr>
<tr>
<td>(b)</td>
<td>Include in documentation and records of the design not only final design documents, such as drawings and specifications, and revisions to those documents but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design by NQA-1, Part I, Requirement 3, section 900.</td>
</tr>
<tr>
<td>(c)</td>
<td>NQA-1 defines commercial grade dedication (CGD), prescribes the development of critical characteristics and acceptance criteria, and refers the implementer to specific requirements in a separate Part II, Subpart of NQA-1, for CGD requirements by NQA-1, Part I, Requirement 3, section 300.</td>
</tr>
<tr>
<td>(d)</td>
<td>NQA-1 requires design verification prior to procurement, manufacture, construction, or use, and if this condition cannot be met, then the unverified portion of the design must be identified and controlled by NQA-1, Part I, Requirement 3, section 500.</td>
</tr>
<tr>
<td>(e)</td>
<td>NQA-1 is more prescriptive for design verification, design reviews, alternate calculations and qualification tests, configuration management of operating facilities, and design documentation and records by NQA-1, Part I, Requirement 3, section 601.</td>
</tr>
</tbody>
</table>
Table 200-12 Corresponding NQA Sections (Requirement 11) to ANSI/ANS-15.8

<table>
<thead>
<tr>
<th>NQA-1, Part I, Requirement 11: Test Control</th>
<th>ANSI/ANS-15.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 General</td>
<td>2.11 Test Control</td>
</tr>
<tr>
<td>200 Test Requirements</td>
<td>2.11 Test Control</td>
</tr>
<tr>
<td>300 Test Procedures (Other Than for Computer Programs)</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>400 Computer Program Test Procedures</td>
<td>2.11 Test Control</td>
</tr>
<tr>
<td>500 Test Results</td>
<td>2.11 Test Control</td>
</tr>
<tr>
<td>600 Test Records</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>601 Test Records</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>602 Computer Program Test Records</td>
<td>No corresponding requirement</td>
</tr>
</tbody>
</table>

RECOMMENDATIONS: There are major additions that need to be included in an existing ANSI/ANS-15.8 quality program to meet this NQA-1 Requirement.

(a) NQA-1 is more prescriptive in defining and requiring the use of acceptance criteria, obtaining accurate results, and performing verification and validation activities of computer programs for design, operation, and in-use according to NQA-1, Requirement 11, sections 200 and 400 (including NQA-1 Subpart 2.7 Quality Assurance Requirements for Computer Software for Nuclear Facility Applications for NQA-1-2015 through current the 2019 edition of NQA-1).

(b) NQA-1 is more prescriptive in defining and requiring test procedures for items and services other than computer programs per NQA-1, Requirement 11, sections 300 and 400 (including NQA-1 Subpart 2.7 Quality Assurance Requirements for Computer Software for Nuclear Facility Applications for NQA-1-2015 through current the 2019 edition of NQA-1).

(c) NQA-1 is more prescriptive in test records for items, services, and in-computer programs per NQA-1, Requirement 11, sections 600 through 602 (including NQA-1 Subpart 2.7 Quality Assurance Requirements for Computer Software for Nuclear Facility Applications for NQA-1-2015 through current the 2019 edition of NQA-1).
Table 200-19 Corresponding NQA Sections
(Requirement 18) to ANSI/ANS-15.8

<table>
<thead>
<tr>
<th>NQA-1, Part I, Requirement 18: Audits</th>
<th>ANSI/ANS-15.8</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 General</td>
<td>2.18 Assessments</td>
</tr>
<tr>
<td>200 Scheduling</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>300 Preparation</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>301 Audit Plan</td>
<td>2.18 Assessments</td>
</tr>
<tr>
<td>302 Personnel</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>303 Selection of Audit Team</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>400 Performance</td>
<td>2.18 Assessments</td>
</tr>
<tr>
<td>500 Reporting</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>600 Response</td>
<td>2.18 Assessments</td>
</tr>
<tr>
<td>700 Follow-up Actions</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>800 Records</td>
<td>2.18 Assessments</td>
</tr>
</tbody>
</table>

RECOMMENDATIONS: There are major additions that need to be included in an existing ANSI/ANS-15.8 quality program to meet this NQA-1 Requirement.

(a) NQA-1 is more prescriptive in specifying the requirements for audit planning and performance according to NQA-1, Requirement 18, sections 301 and 400.

(b) NQA-1 defines the requirements for the scheduling of audits, authority of audit personnel, audit team composition, audit reporting, and follow-up action per NQA-1, Requirement 18, sections 200 (including sections 201 through 202 for NQA-1-2015 through current the 2019 edition of NQA-1), 302, 303, 500, and 700.
SUBPART 4.1.X

100 PURPOSE AND SCOPE
This Subpart provides guidance to organizations involved in the nuclear industry that currently have established a quality assurance program in accordance with NQA-1 and are required to additionally comply with the requirements of the IAEA Safety Standard No. GSR Part 2, Leadership and Management for Safety. It compares the requirements of NQA-1-2019, Part I (NQA-1), to the requirements of GSR Part 2 (2016). The purpose of this comparison is to identify equivalences and differences between these two standards. The guidance comprises practical recommendations on how to reconcile differing requirements when both standards are to be simultaneously implemented.

200 APPLICABILITY
The guidance is intended for all parties involved in the nuclear industry that are currently applying/implementing NQA-1 requirements and are required to comply with GSR Part 2 requirements.

300 BACKGROUND
301 Global Uses of NQA-1 and GSR Part 2
Governments are adopting or applying GSR Part 2 requirements through regulations. Organizations providing nuclear items or products and services around the globe may be compelled to comply with the GSR Part 2 management system requirements while maintaining certification or compliance of their activities, items, products, and services to an NQA-1 quality assurance program. Consequently, many organizations will need to adopt both GSR Part 2 and NQA-1 as the basis of their QA program. GSR Part 2 requires both sets of requirements to be integrated within one management system.

302 Conceptual Approaches to the Development of NQA-1 and GSR Part 2
GSR Part 2 and NQA-1 apply to the life cycle of nuclear facilities and activities, including siting, design, construction, commissioning, operation, and decommissioning. GSR Part 2 and NQA-1 foster the application of requirements in a manner that is consistent with the relative importance of the item or activity. Both GSR Part 2 and NQA-1 can be invoked by contract, adopted voluntarily, or used as the basis for assessing a management system or quality assurance program.

NQA-1 defines requirements for an organization to establish, implement, and assess a Quality Assurance (QA) Program to achieve nuclear safety. NQA-1 reflects industry experience and
current understanding of QA requirements for the safe, reliable, and efficient utilization of nuclear energy and management and processing of radioactive materials.

The NQA-1 approach applies quality assurance requirements to activities that could affect the quality of nuclear material applications, structures, systems, and components of nuclear facilities. Quality assurance requirements are used to develop a Quality Assurance Program necessary to achieve safe, reliable, and efficient utilization of nuclear energy and management and processing of radioactive material.

Both GSR Part 2 and NQA-1 provide high level requirements; however, NQA-1 also provides additional lower level implementing requirements for many of the individual QA requirements. GSR Part 2 is focused on establishing, assessing, and maintaining formal management and leadership controls for controlling radiation safety related items and activities, which is broader than the QA program. Existing QA program Policy statements may already mention nuclear safety culture and other integrated management systems.

400 HOW TO USE THIS GUIDE TO ACHIEVE COMPLIANCE WITH NQA-1

Table 1 lists all 14 requirements of GSR Part 2, plus the sub-tier requirement of each. In the right column, where a requirement of NQA-1 meets the specific GSR Part 2 requirement, it is so stated. Where there is no corresponding NQA-1 requirement that meets the GSR Part 2, a recommendation is provided as to how the GSR Part 2 requirement should be met.
### Table I
The Extent to Which NQA-1 Addresses GSR Part 2 Requirements

<table>
<thead>
<tr>
<th>GSR Part 2 Requirement</th>
<th>Recommendations for NQA-1 Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1 – Provisions to achieve the fundamental safety objective of protecting people and the environment</td>
<td>NQA-1 Part I, Introduction and by the standard’s Foreword and Introduction</td>
</tr>
<tr>
<td>2.2 (a) – Senior management actions for: Safe siting, design, construction, commissioning, operation, and decommissioning of facilities</td>
<td>NQA-1 Part I, Introduction&lt;br&gt;Recommendation: NQA-1 users should address senior management involvement, not just line management and individuals.</td>
</tr>
<tr>
<td>2.2 (b) – Safety, quality, and management standards</td>
<td>NQA-1 Part I, Introduction&lt;br&gt;Recommendation: Since NQA-1 is a quality standard, NQA-1 users should also address applicable safety and management standards.</td>
</tr>
<tr>
<td>2.2 (c) – Radioactive material and radiation sources management and control</td>
<td>NQA-1 Part I, Introduction</td>
</tr>
<tr>
<td>2.2 (d) – Understanding of radiation risks and how to manage</td>
<td>No corresponding requirement&lt;br&gt;Recommendation: NQA-1 users should address applicable radiation protection standards.</td>
</tr>
<tr>
<td>2.2 (e) – Adequate resources and funding, including long term management and disposal of radioactive waste</td>
<td>No corresponding requirement&lt;br&gt;Recommendation: NQA-1 users should address requirements for resources and funding.</td>
</tr>
<tr>
<td>2.2 (f) – Preparedness and response for a nuclear or radiological emergency</td>
<td>No corresponding requirement&lt;br&gt;Recommendation: NQA-1 users should address requirements for emergency preparedness and response.</td>
</tr>
<tr>
<td>Part 4, Subpart 4.1.x</td>
<td>ASME NQA-1-2019</td>
</tr>
<tr>
<td>-----------------------</td>
<td>-----------------</td>
</tr>
<tr>
<td><strong>SECTION 4 – MANAGEMENT FOR SAFETY</strong></td>
<td></td>
</tr>
</tbody>
</table>
### Requirement 3: Responsibility of Senior Management for the Management System

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
<th>Reference/Recommendation</th>
</tr>
</thead>
</table>
| 4.1         | Senior management accountable for management system even if responsibilities are delegated | NQA-1 Requirement 1, Section 202  
Recommendation: NQA-1 users should also address senior management involvement. |
| 4.2         | Senior management ensures safety policy                                      | No corresponding requirement  
Recommendation: NQA-1 users should address safety policy. |

### Requirement 4: Goals, Strategies, Plan, and Objectives

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
<th>Reference/Recommendation</th>
</tr>
</thead>
</table>
| 4.3         | Goals, strategies, plans, and objectives should not conflict with meeting safety requirements | NQA-1 Requirement 1, Section 201  
Recommendation: NQA-1 users should also address the Part 2 requirement for goals, strategies, and objectives. |
| 4.4         | Measurable safety goals are established at various levels in the organization | No corresponding requirement  
Recommendations: NQA-1 users should develop policies and/or procedures to address. |
| 4.5         | Senior management periodically reviews goals, strategies, and plans against safety objectives. Actions are taken for deviations | No corresponding requirement  
Recommendations: NQA-1 users should develop policies and/or procedures to address. |

### Requirement 5: Interaction with Interested Parties

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Description</th>
<th>Reference/Recommendation</th>
</tr>
</thead>
</table>
| 4.6         | Interested parties are identified. Strategies for interaction are defined.    | No corresponding requirement  
Recommendations: NQA-1 users should address in the appropriate implementing document. It is noted that NQA-1 Requirement 1, Section 300 does contain requirements for interactions with various design organizations only. |
| 4.7 (a)     | Processes and plans regarding interested parties ensure routine and effective communications concerning radiation risks. | No corresponding requirement  
Recommendations: NQA-1 users should address in the appropriate implementing document. It is noted that NQA-1 Requirement 1, Section 300 does contain requirements for interactions with various design organizations only. |
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.7 (b)</td>
<td>Processes and plans regarding interested parties ensure timely and effective communication.</td>
<td>No corresponding requirement. Recommendations: NQA-1 users should address in the appropriate implementing document. It is noted that NQA-1 Requirement 1, Section 300 does contain requirements for interactions with various design organizations only.</td>
</tr>
<tr>
<td>4.7 (c)</td>
<td>Process and plans regarding interested parties ensure dissemination of information relevant to safety.</td>
<td>No corresponding requirement. Recommendation: NQA-1 users should address in the appropriate implementing document. It is noted that NQA-1 Requirement 1, Section 300 does contain requirements for interactions with various design organizations only.</td>
</tr>
<tr>
<td>4.7 (d)</td>
<td>Processes and plans regarding interested parties ensure concerns and expectations of interested parties are considered.</td>
<td>No corresponding requirement. Recommendation: NQA-1 users should address in the appropriate implementing document. It is noted that NQA-1 Requirement 1, Section 300 does contain requirements for interactions with various design organizations only.</td>
</tr>
</tbody>
</table>

**Requirement 6: Integration of the Management System** – The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised.

Note: Since NQA-1 is only a quality management standard, the NQA-1 user should address all these other elements listed here as they implement the requirements in Requirement 6 below.

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.8</td>
<td>Management system shall be developed, applied and continuously improved, and aligned with safety goals.</td>
<td>NQA-1 Requirement 2, Section 100. Recommendation: NQA-1 users should also address alignment with safety goals. Also see Note above.</td>
</tr>
<tr>
<td>4.9 (a)</td>
<td>Management system addresses all necessary elements for safely managing the organization.</td>
<td>NQA-No corresponding requirement. Recommendation: Also see Note above.</td>
</tr>
<tr>
<td>4.9 (b)</td>
<td>Management system describes management of the organization.</td>
<td>NQA-1 Requirement 1, Sections 100 and 201. Recommendation: Also see Note above.</td>
</tr>
<tr>
<td>4.9 (c)</td>
<td>Management system describes planned and systemic actions to ensure all requirements are met.</td>
<td>NQA-1 Requirement 2, Section 100. Recommendation: Also see Note above.</td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
<td>Requirement</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
<td>-------------</td>
</tr>
<tr>
<td>4.9 (d)</td>
<td>Management system ensures that safety is considered in decision making.</td>
<td>NQA-1 Part I Requirements (all)</td>
</tr>
<tr>
<td>4.10</td>
<td>Management system includes conflict resolution processes. Security impacts of safety and safety impacts on security shall be considered.</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>4.11</td>
<td>Management system includes organizational structures, responsibilities, accountabilities, and interfaces.</td>
<td>NQA-1, Requirement 1 (all)</td>
</tr>
<tr>
<td>4.12</td>
<td>Regulatory requirements are included in the management system.</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td>4.13</td>
<td>Management system changes are appropriately analyzed.</td>
<td>NQA-1 Requirement 6 (all)</td>
</tr>
<tr>
<td>4.14</td>
<td>Significant safety decisions require independent reviews. Reviewer competence is specified.</td>
<td>NQA-1 Requirements 2 (Sections 200, 300, and 400) and 3 (Sections 100 and 500)</td>
</tr>
<tr>
<td><strong>Requirement 7: Application of the graded approach to the management system</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.15</td>
<td>Development of a graded approach</td>
<td>NQA-1 Part I, Introduction Sections 200 and 400; Requirement 2 Section 100(a)</td>
</tr>
<tr>
<td><strong>Requirement 8: Documentation of the management system</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.16</td>
<td>Minimum management system documentation, such as policy statements, organization structure and description, and safety objectives</td>
<td>NQA-1 Requirements 1, Organization; Requirement 2, Quality Assurance Program</td>
</tr>
<tr>
<td>Section</td>
<td>Description</td>
<td>Recommendation</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
<td>----------------</td>
</tr>
<tr>
<td>4.17. Control of documents</td>
<td>NQA-1 Requirement 2, Sections 200 through 400; and Requirement 6, Document Control</td>
<td>Recommendation: NQA-1 user should also address access to appropriate information in the appropriate implementing document.</td>
</tr>
<tr>
<td>4.18. Control of revisions to documents</td>
<td>NQA-1 Requirement 6, Section 300</td>
<td>Recommendations: NQA-1 user should also address same level of approval as the initial document even for minor changes.</td>
</tr>
<tr>
<td>4.19. Control of records</td>
<td>NQA-1 Requirement 17</td>
<td></td>
</tr>
<tr>
<td>4.20. Retention of records</td>
<td>NQA-1 Requirement 17, Section 700</td>
<td>Recommendation. NQA-1 users should also address records retention for test materials or specimens and assuring that if media used for records will be readable for the retention time in the appropriate implementing documents.</td>
</tr>
</tbody>
</table>

**Requirement 9: Provision of resources**

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.21. Competences and resources for necessary activities</td>
<td>NQA-1 Requirement 2, Sections 200, 300, and 400</td>
<td>Recommendations: NQA-1 users should address resources per GSR Part 2 (note 10) under requirement 4.21. NQA-1 users should also address resources for emergency response activities in the appropriate implementing document.</td>
</tr>
<tr>
<td>4.22. Retention and development of competences and resources</td>
<td>No corresponding requirement</td>
<td>Recommendation: NQA-1 users should address which resources are required and retained internally and which resources are obtained externally in the appropriate implementing document.</td>
</tr>
<tr>
<td>4.23. Training and evaluation</td>
<td>NQA-1 Requirement 2, Section 200</td>
<td></td>
</tr>
</tbody>
</table>
### Part IV, Subpart 4.1.3 ASME NQA-1-2019

<table>
<thead>
<tr>
<th>No.</th>
<th>Section</th>
<th>Description</th>
<th>Requirement</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.24</td>
<td>Competences for leadership and safety culture</td>
<td></td>
<td>No corresponding requirement</td>
<td>Recommendation: NQA-1 users should address competency for leadership and safety culture in the appropriate implementing document.</td>
</tr>
<tr>
<td>4.25</td>
<td>Competence for assigned tasks and to work safely</td>
<td>NQA-1 Requirement 2, Sections 200, 300, and 400</td>
<td></td>
<td>Recommendation: NQA-1 users should address how to evaluate the effectiveness of training.</td>
</tr>
<tr>
<td>4.26</td>
<td>Management system training</td>
<td>NQA-1 Requirement 2, Sections 200, 300, and 400</td>
<td></td>
<td>Recommendation: NQA-1 users should also address how training material is tied to the organization’s goals.</td>
</tr>
<tr>
<td>4.27</td>
<td>Knowledge and information management</td>
<td></td>
<td>No corresponding requirement</td>
<td>Recommendation: NQA-1 user should address management of knowledge and the information of the organization in the appropriate implementing document.</td>
</tr>
</tbody>
</table>

**Requirement 10, Management of processes and activities**

<table>
<thead>
<tr>
<th>No.</th>
<th>Section</th>
<th>Requirement</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.28</td>
<td>Maintain documents and records</td>
<td>NQA-1 Requirement 5 (all); Requirement 6 Section 100; and Requirement 17, Sections 100 and 200</td>
<td></td>
</tr>
<tr>
<td>4.29</td>
<td>Interface with inside and outside organizations</td>
<td>NQA-1 Requirement 1, Section 300; and Requirement 3, Section 700</td>
<td></td>
</tr>
<tr>
<td>4.30</td>
<td>Processes, goals and objectives</td>
<td>NQA-1 Requirement 5; and Requirement 6, Section 300</td>
<td>Recommendation: NQA-1 users should address ensuring that processes including modifications, are aligned with the goals, strategies and objectives of the organization.</td>
</tr>
<tr>
<td>4.31</td>
<td>Inspection and testing activities</td>
<td>NQA-1 Requirements 10 (all) and 11 (all)</td>
<td></td>
</tr>
<tr>
<td>4.32</td>
<td>Procedures, instructions and drawings</td>
<td>NQA-1 Requirement 5</td>
<td>Recommendation 1: NQA-1 users should address validation and periodic reviews of instructions, procedures, and drawings.</td>
</tr>
</tbody>
</table>
### Requirement 11, Management of Supply Chain

<table>
<thead>
<tr>
<th>Requirement 11, Management of Supply Chain</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>4.33 Subcontracting processes and receiving items, products, and services</td>
<td>NQA-1 Requirement 4, Section 200; and Requirement 7, Sections 100, 500, 600, and 700</td>
</tr>
<tr>
<td>4.34 Scope and specification requirements</td>
<td>NQA-1 Requirement 4, Sections 100, 200; and Requirement 7, Sections 100, 500, 600, and 700,</td>
</tr>
<tr>
<td>4.35 Qualification of supply chain</td>
<td>NQA-1 Requirement 7, Section 200</td>
</tr>
<tr>
<td>4.36 Ensuring supplies meet expectations</td>
<td>NQA-1 Requirement 4 (all) and Requirement 7, Sections 100, 500, 600, and 700.</td>
</tr>
</tbody>
</table>

### SECTION 5 – CULTURE FOR SAFETY

**Requirement 12: Fostering a culture for safety**

<table>
<thead>
<tr>
<th>5.1 Contribution by all individuals</th>
<th>No corresponding requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommendation:</strong> NQA-1 users should address how to foster and sustain a strong safety culture.</td>
<td></td>
</tr>
<tr>
<td>5.2 Key elements (understanding, acceptance, organizational culture, reporting, attitude, enhancement, decision-making, exchange)</td>
<td>No corresponding requirement</td>
</tr>
<tr>
<td><strong>Recommendation:</strong> NQA-1 users should address how senior managers and all other supervisors advocate and support safety culture in the appropriate implementing document.</td>
<td></td>
</tr>
</tbody>
</table>

### SECTION 6 – MEASUREMENT, ASSESSMENT AND IMPROVEMENT

**Requirement 13: Measurement, assessment and improvement of the management system**

<table>
<thead>
<tr>
<th>6.1 Effectiveness of management system</th>
<th>NQA-1 Requirement 18(all)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.2 Effectiveness of processes</td>
<td>NQA-1 Requirement 18 (all)</td>
</tr>
<tr>
<td>6.3 Causes of nonconformances and events</td>
<td>NQA-1 Requirement 16 (all)</td>
</tr>
<tr>
<td>6.4 Independent assessments and self-assessments</td>
<td>NQA-1 Requirement 18 (all)</td>
</tr>
<tr>
<td><strong>Recommendation:</strong> NQA-1 users should address self-assessments and analysis of lessons learned from assessments.</td>
<td></td>
</tr>
<tr>
<td>Section</td>
<td>Requirement</td>
</tr>
<tr>
<td>---------</td>
<td>-------------</td>
</tr>
<tr>
<td>6.5</td>
<td>Responsibility for independent assessments</td>
</tr>
<tr>
<td>6.6</td>
<td>Senior management review</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>6.7</td>
<td>Learning from experience, events and good practices</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>6.8</td>
<td>Learning from strengths</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>6.9</td>
<td>Self-assessment</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>6.10</td>
<td>Independent assessment</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>6.11</td>
<td>Communication of results</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
100 GENERAL

This Subpart provides non-mandatory guidance on managing the transition from construction to operation for nuclear facilities.

200 APPLICABILITY

The recommendations of this Subpart apply to any organization or individual participating in work related to activities commencing with turnover from construction to testing, continuing through turnover to operations, and ending with the completion of the startup test program. Proper transition is attained by controlling the following activities:

(a) turnover from construction to testing
(b) testing of plant-facility systems and components
(c) turnover to operations
(d) preparation for operation
(e) startup test program

201 Regulatory

In addition, regulatory commitments made during the transition process should be integrated into turnover and testing activities on an ongoing basis. Specific attention should be given to Safety Analysis Report, Safety Basis, or similar safety documents used to authorize design, construction and operations, and technical specification reviews including licensee’s responses to the Regulatory Authority NRC questions, regulatory and non-regulatory agency requirements, local and state government interfaces, and final certification of readiness for operation. Commitments should be tracked using the licensee’s / owner’s / operator’s commitment tracking system.

300 TRANSITION RECOMMENDATIONS

301 Turnover From Construction to Testing

Responsibility for components, systems, and areas should be specified and transferred from the construction organization to the testing organization in a controlled manner. Controls should provide for:

(a) establishing the status of construction phase completion,
(b) identifying construction phase testing activities,
(c) identifying and establishing system / facility boundaries and identities,
(d) developing interface responsibilities,
(e) developing open item and deficiency tracking system(s),
(f) maintaining configuration control,
(g) establishing rework and repair turn-back procedures to include the process of returning systems / facilities from the testing organization, and,
(h) evaluating readiness for turnover.

301.1 Construction Phase Testing and service Activities

The status of construction phase testing and vendor/contractor service activities should be identified, tracked and reviewed for completeness. These activities include, but are not limited to:

(a) hydrostatic testing
(b) pneumatic testing
(c) flushing and cleaning
(d) calibration, alignment, and testing of mechanical, electrical, and instrumentation and control
equipment and systems
(e) initial component/equipment operation
(f) crane/hoist load testing
(g) nondestructive testing
(h) vendor equipment testing
(i) review of systems to support testing, such as hangars, snubbers, supports, insulation, etc.
j) maintenance activities
(k) preservice inspection

301.2 Boundary Identification

When transferring responsibility, boundaries should be clearly identified and delineated. Particular
attention should be given to personnel and equipment protection and safety programs, test status,
testability, operability, shared system or facility interfaces, custody identification, and access control.

301.3 Interface

Organizations should clearly understand the transition process in order to ensure that interfaces are
coordinated and controlled. Activities to be considered should include, but not be limited to, the following:
(a) maintenance of equipment/components
(b) operation of components and systems
(c) physical identification and jurisdictional controls
(d) plant/facility chemistry
(e) vendor-supplier services
(f) testing
(g) system/facility walk-downs
(h) spare and replacement parts procurement and storage

Responsibilities for these activities should be clearly defined and maintained throughout the turnover from
construction to testing. When interfaces change during the transition, new interfaces should be
established and understood with the effective time of transition communicated and documented.
Particular attention should be given to the interaction of systems and components that are common to
multiple facilities. Controls should be established to document and track open items and deficiencies
throughout the transition. Deficiencies should be identified and the responsibility for corrective action
clearly defined and assigned.

301.4 Configuration Control

The management of configuration control is an ongoing process. During the turnover process,
configuration status should be reviewed to ensure that the configuration is maintained and controlled
during the testing phase. Specific areas of concern during the testing phase include, but are not limited to:
(a) document control
(b) design changes
(c) as-built condition
(d) as-built test documentation
(e) temporary modifications and alterations and subsequent restoration

301.5 Turnback/Rework/Repair Activities

During the testing phase turnback for rework or repair (as appropriate to each individual deviation) of
components, systems and areas by the responsible work organization should be controlled. Elements of
this control include:
(a) delineation of organizational responsibilities
(b) identification of system boundaries and system interfaces
(c) development of a work plan that provides for reentry control, cleanliness and chemistry controls, and
detailed work controls
(d) requirements for retest, evaluation, and approval
(e) inspection, documentation control, and review

301.6 Readiness for System/Area Turnover

The status of system/area readiness for turnover should be evaluated at designated intervals prior to turnover for test. Walk-downs should be performed by knowledgeable personnel in the areas of design, construction, test, operations, and maintenance because they are an important element in determining readiness. In addition to planned inspections, walk-downs support the test schedule and determine the completeness and acceptability of a system or area.

302 Testing of Plant-Facility Systems and Components

An organization(s) with clearly defined responsibilities and organizational interfaces should be established to control testing activities. Specifically, this organization should ensure the adequacy of training and qualification requirements, test program requirements, preparation of test procedures, and the conduct of testing.

302.1 Training and Qualification

Personnel performing testing activities should receive training in the following areas, as applicable:
(a) test program elements as defined in para. 302.2 of this Subpart
(b) modification and temporary alteration process
(c) procedures for handling non-conformances, deficiencies, and engineering evaluation requests
(d) plant-facility tagging system
(e) control and use of test and measuring equipment
(f) document control
(g) set-point requirements
(h) maintenance procedures
(i) work control procedures
(j) environmental controls
(k) chemistry control procedures
(l) vendor-supplier services control
(m) regulatory requirements
(n) Safety Analysis Report
(o) plant-facility technical specifications
(p) state and local regulations
(q) regulatory and industry standards
(r) vendor-supplier technical manuals
(s) special test requirements
(t) component and integrated system requirements

302.2 Test Program

A test program should be developed that delineates the following requirements:
(a) test scope
(b) form and content of test procedures
(c) review and approval methods
(d) conduct of test
(e) evaluation and verification methods
The test program should utilize plant-facility operations personnel to the degree practical to enhance their knowledge and plant-facility experience.

302.3 Test Procedure

Test procedures and test documents should be prepared in accordance with industry standards and the plant-facility design, safety, administrative and operating requirements. Further guidance regarding
procedural requirements is contained in ANSI/ANS-3.2-1988 (R2017), Managerial, Administrative Controls and Quality Assurance Controls for the Operational Phase of Nuclear Power Plants.

302.4 Conduct of Testing

Testing should be conducted by qualified test personnel in accordance with approved test procedures.

303 Turnover to Operations

Turnover of components, systems, and areas to operations should be accomplished in a controlled manner similar to those elements in section 301. This activity should define organizational interfaces, identify turnover package items, track open items and deficiencies, and define jurisdictional controls.

303.1 Organizational Interfaces

Organizational interfaces should be clearly defined and documented to afford an orderly turnover of components, systems, and areas from construction to operations.

303.2 Turnover Package

The scope and status of those items that are to be contained in the turnover package should be identified. These items include, but are not limited to:

(a) documentation of component and system tests, the test results, and the status of testing completeness
(b) system cleanliness and chemistry controls that are in effect
(c) an open items list (punch-list that identifies open work, commitments, and incomplete documentation)
(d) outstanding deficiencies
(e) equipment maintenance history records (including preventive maintenance)
(f) available vendor-supplier-provided spare parts
(g) special tools and test equipment

A document review should be completed on the turnover package prior to turnover acceptance. Additionally, vendor and contractor services provided by existing contracts should be identified to the operations personnel.

303.3 Tracking Systems

Open items, deficiencies, commitments, and work items identified in the turnover package should be tracked for resolution and completion.

303.4 Jurisdictional Controls

During the turnover process, the jurisdictional responsibility for components, systems, and areas should be clearly defined. The organization with jurisdictional responsibility should ensure use of existing procedures and programs to maintain configuration management, to ensure that access controls are identified and defined, to set forth organizational relationships, to document equipment status and operability requirements, to ensure that personnel safety measures are in place, and to provide work controls so as to provide an accurate knowledge of the status of those portions of the plant facility under its jurisdiction. If not previously in place, additional procedures governing these controls should be written.

304 Preparation for Operation

In parallel with the turnover of components, systems, and areas, preparation should be made for plant facility operation. These efforts include, but are not limited to, plant facility procedure preparation, staffing, training, and qualification requirements.

304.1 Plant Facility Procedures
PlantFacility procedures should be prepared, reviewed, and approved. Procedure content should incorporate industry operating experience feedback, implementation of a lessons-learned program, and corrective action recommendations.

### 304.2 Staffing, Training, and Qualification

Staffing, training, and qualification requirements should be determined and adequate time allocated to train and qualify personnel for plantfacility positions. The following measures should be considered:

(a) Identify organizational roles, responsibilities, and qualification requirements.
(b) Determine organization composition and develop job descriptions, taking into account previous operating experience, including information contained in regulatory guides, industry standards, and regulatory commitments.
(c) Establish formal training programs for licensed and non-licensed personnel. Training programs should include provisions for initial and continuing training, as well as qualification and requalification training.

### 305 Start-Up Test Program

The start-up test program should encompass those functions necessary to load fuel, attain initial criticality, power ascension, and full power operation. The program should be conducted with adherence to licenses, standards, and plantfacility procedures. The start-up test program should delineate:

(a) organization responsibilities
(b) organizational interfaces
(c) regulatory and non-regulatory commitments
(d) testing/system interfaces
(e) test review and approval
(f) schedule and tracking systems
(g) test execution, review, and approval
(h) retest execution, review, and approval
(i) resolution of component and system open items and deficiencies
(j) start-up test report submission

The start-up test program should be conducted in accordance with regulatory commitments and guidance, industry standards, the plantfacility policies, directives, and procedures. Test coordination, communication, documentation, corrective actions, and system interfaces should be controlled to prevent an adverse effect on start-up testing activities. For example, the collective impact caused by preoperational test completion, system surveillance testing requirements, and plantfacility maintenance activities including post-maintenance testing should be coordinated to assure a managed interface.

### 400 RECORDS

Record copies of procedures, reports, personnel qualification records, training records, test documentation records, construction test records, administrative records, turnover package records, configuration management records, and licenses should be prepared. These records should be retained with other project records as required by code, standard, specification, or project procedures.
100 GENERAL

Counterfeit or fraudulent items can vary significantly from specified standards and requirements, even though the certification and records provided indicate that these requirements were met. As a result, suppliers may distribute items, knowingly or not knowingly, that do not meet the purchase requirements or provide documentation that misrepresents the actual conformance to published performance, technical specifications and/or applicable standards.

The inadvertent use of a Counterfeit, Fraudulent or Suspect Item (CFSI), within a nuclear facility, can pose potential threats to the safety of workers, the public and the environment. CFSI, if installed, may result in the inability of a system, structure, or component to perform its intended safety function in case of an event or incident. Therefore, it is important to raise awareness about the potential threat caused by CFSI.

An effective quality assurance program should include provisions to detect, prevent, and control counterfeit and fraudulent items. This standard covers a broad range of activities, and countermeasures that are appropriate for one user may not be appropriate for another. Therefore, users of this standard should implement CFSI countermeasures that are appropriate for their activities.

The intent of this subpart is to provide nonmandatory guidance to enhance the capability of an organization and its suppliers to prevent, detect and control counterfeit, fraudulent or suspect items when implementing the requirements of this standard.

This guidance is a concise list of measures that can be incorporated in the programmatic implementation of the Part I requirements identified in this subpart.

101 DEFINITIONS

**Counterfeit items:** A Counterfeit Item, as used in this subpart, is an item that is intentionally manufactured, or altered, to imitate an original item, without a legal right to do so.

**Fraudulent items:** A Fraudulent Item, as used in this subpart, is an item that is intentionally misrepresented, or altered, with the purpose to deceive the receiver of the Item. Fraudulent Items include those items provided with incorrect identification, inaccurate records and/or falsified certifications.

**Suspect items:** A Suspect Item, as used in this Subpart, is an item which is suspected of being Counterfeit or Fraudulent, and additional information or investigation is needed to determine whether the item is acceptable, non-conforming to requirements, or in fact Counterfeit or Fraudulent.

102 IDENTIFICATION OF POTENTIAL CFSI

Below is a list of common discrepancies that if identified should lead to additional investigation to determine the authenticity of an item

a) A nameplate, label or tag that appears to have been altered, copied or painted over; is unusual in location; has an uncommon method of attaching or marking; shows discrepant or incomplete data; or is missing

b) Indications of removal of previous marking in the marking area (e.g. grind marks, remains of adhesives or labels)

c) Surface irregularities, such as corrosion or wear, where they should not appear

d) Assembled items fit together poorly
e) An item is inconsistent with other items from the same supplier or reflects characteristics that vary from what the supplier has indicated in its catalogue
f) Items, sold as new, exhibiting evidence of prior use, beautification, re-manufacturing or refurbishment
g) Documentation that appears to be incomplete, altered or lacking expected traceability with the item(s) provided

An item being evaluated would not be considered as CFSI, but rather nonconforming, when one or more of the following conditions exist
a) Defects resulting from design errors or common production quality control failures
b) Damage during shipping, handling, or storage
c) Improper installation
d) Deterioration during service

Additional guidance is provided in Part III, subpart 3.1-7.1, section 705, Determining Authenticity, of this Standard.

103 SITUATIONS INCREASING THE RISK OF CFSI

The following situations may increase the risk of CFSI
a) Requirements are poorly defined in the purchasing specification(s)
b) Items are ordered or fabrication is started with incomplete or unapproved design information, with an increased risk when items are expensive to manufacture
c) Urgent delivery is requested for items that are known to need a certain time to be properly manufactured
d) The financial, technical and quality capabilities of the potential supplier(s) have not been checked thoroughly
e) The price proposed by the potential supplier(s) is significantly below the market’s price and/or competitor’s price
f) Use of a new supplier, not properly qualified by the purchaser
g) The supplier has a history of changes in name, ownership and/or management

200 PREVENTION

With respect to effectively managing the potential risk associated with the inadvertent use of CFSI in a nuclear facility, the following are aspects for a quality assurance program that a nuclear organization may want to consider.

201 QUALITY ASSURANCE PROGRAM

Requirement 2 of Part I can be supplemented as follows
a) The quality assurance program should include measures and processes to prevent, detect and control CFSI; a tool such as the Self-Assessment Checklist described in EPRI 1021493, Counterfeit and Fraudulent Items, can be used to identify the appropriate measures
b) Internal assessments of the quality assurance program should include an evaluation of the measures to prevent CFSI and should consider CFSI incidents
c) Indoctrination and training of personnel performing or managing activities affecting quality should include awareness of CFSI, especially in the areas of engineering, production, procurement, inspection and audits
d) A strong nuclear safety culture should be promoted within the organization; as part of the organization’s nuclear safety culture, each individual should be
   1) aware of CFSI and their potential negative impact to safety
   2) supported and feel responsible to alert the organization of potential CFSI

202 PROCUREMENT DOCUMENT CONTROL

Requirement 4 of Part I can be supplemented as follows
a) Procurement documents should include contractual requirements that address CFSI for the supplier, including implementation of measures to prevent, detect and control CFSI
b) Procurement documents should require the supplier to notify CFSI to affected customers
c) Procurement documents should require the supplier to take measures to assure that their sub-tier suppliers notify them of CFSI
d) Available databases (i.e. government and/or industry) and operating experience should be used to verify that the potential supplier has no history of providing counterfeit or fraudulent items
e) Information should be requested from the supplier as to how the potential to inadvertently provide CFSI as part of the order is minimized

203 CONTROL OF PURCHASED ITEMS AND SERVICES

Requirement 7 of Part I can be supplemented as follows
a) Items should be purchased directly from the manufacturer or an authorized manufacturer's distributor/representative
b) Confirmation should be obtained from the manufacturer or via other independent means that the potential supplier is currently authorized by the manufacturer for the scope or type of item to be provided
c) Direct evaluation of suppliers (by auditing or performing inspections on site) should be the preferred method for evaluation and qualification
d) Assessment of suppliers should include an evaluation of the measures taken to prevent, detect and control CFSI
e) Available information sources (i.e. government and/or industry) should be checked to determine if previous incidents suggest that the items being purchased are at risk of CFSI
f) Enhanced acceptance criteria should be specified for items known to be at risk of CFSI

300 DETECTION

The importance of recognizing the potential impact of CFSI on the operational safety of a nuclear facility is fundamental for a nuclear organization. Therefore, the detection of CFSI should be included as a key program process of a nuclear quality assurance program.

301 ORGANIZATION

Requirement 1 of Part I can be supplemented as follows: Identification of quality problems should include the detection of CFSI

302 QUALITY ASSURANCE PROGRAM

Requirement 2 of Part I can be supplemented as follows: Assessments of the adequacy and effectiveness of the quality assurance program should include the detection of CFSI

303 CONTROL OF PURCHASED ITEMS AND SERVICES

Requirement 7 of Part I can be supplemented as follows
a) Individuals performing receiving inspections should be made aware of attributes associated with the common characteristics of counterfeit and fraudulent items (see section 102 of this subpart)
b) Receiving inspection should include inspecting items for signs of potential counterfeit or fraudulent attributes
c) Receiving inspection instruction and/or checklist should include specific criteria to detect CFSI, which should be checked for accuracy and completeness by engineering and quality assurance personnel
d) When appropriate, additional receipt inspection should be performed for items being procured from a source other than the item manufacturer or the manufacturer's authorized distributor/representative
e) Receiving inspection should include the verification of authenticity of certifications and records with the originator on a sampling basis and, in all cases, when the supplied documentation is suspect

f) Engineering and quality assurance personnel shall be engaged when the authenticity of an item is in question

304 INSPECTION

Requirement 10 of Part I can be supplemented as follows

a) Individuals performing inspections should be made aware of attributes associated with the common characteristics of counterfeit and fraudulent items (see section 102 of this subpart)

b) Inspection should include inspecting items for signs of potential counterfeit or fraudulent attributes

c) Inspection instruction and/or checklist should include specific criteria to detect CFSI; which should be checked for accuracy and completeness by engineering and quality assurance personnel

d) Inspectors performing in-process inspection should be aware of unusual properties, indications, deformation and/or surface characteristics

e) Engineering and quality assurance personnel shall be engaged when the authenticity of an item is in question

305 AUDITS

Requirement 18 of Part I can be supplemented as follows

a) For internal audits as well as for supplier audits, audit instructions and/or checklists should include verification that measures to prevent, detect and control CFSI are adequate, effective and implemented

b) Audit personnel should be selected to include knowledge in materials, processes, documents, and properties that permit detection of CFSI during audits

400 CONTROL

For dealing effectively with items suspected to be counterfeit or fraudulent, the following controls can be considered.

401 ORGANIZATION

Requirement 1 of Part I can be supplemented as follows

a) The organization should establish procedures for reporting CFSI to the appropriate level of management, which may include the involvement of legal department or authorities

b) Audit, Inspection and Test Personnel should have means to report CFSI to the person(s) designated by management for dealing with CFSI

402 CONTROL OF NONCONFORMING ITEMS

Requirement 15 of Part I can be supplemented as follows

a) An item suspected to be counterfeit or fraudulent should be identified, segregated and processed as a nonconforming item; engineering and quality assurance personnel should be involved in the decision process

b) The disposition “use-as–is” should only be implemented when the suspect item has been found not to be fraudulent or counterfeit and has been verified to meet specified requirements

c) If an item is suspected to be counterfeit or fraudulent, the item should be kept as evidence and not returned to the supplier until a decision is reached

d) If an item is found to be counterfeit or fraudulent, notification should be made to the affected internal entities and external organizations including suppliers, original equipment manufacturers, customers, relevant authorities and/or relevant databases (i.e. government and/or industry)
**CORRECTIVE ACTION**

Requirement 16 of Part I can be supplemented as follows:

a) Other items purchased from the same supplier should be subject to adequate evaluation to determine if they should be treated as CFSI.

b) Like items provided by the supplier should be removed from service or operations should be restricted so as not to exceed technical safety limits.

c) Additional evaluations, inspections, or testing should be performed to assure compliance with specified requirements for similar items in the organization’s inventory supply system.

d) Restrictions should be applied on further procurements from the affected supplier unless adequate controls are in place to eliminate the potential for CFSI.

**RECORDS**

As part of an organization’s approach to addressing CFSI, documents associated with potential CFSI should be retained and processed as records in accordance with the organization’s quality assurance program.

**REFERENCES**

a) EPRI 3002002276, Revision 1 of 1019163, Plant Support Engineering: Counterfeit and Fraudulent Items; Mitigating the Increasing Risk, dated July 2014.


g) NRC Information Notice 89-70, Possible Indications of Misrepresented Vendor Products, dated October 1989.

SUBPART 4.2.8
Guidance on Quality Assurance for Low-Level Waste Shipping from Nuclear Facilities

100 GENERAL

This Subpart provides quality assurance guidance for use in developing and implementing a low-level waste (LLW) shipping program designed to comply with low-level waste classification and waste characteristics requirements prior to shipment from US nuclear facilities to final disposal sites. The purpose of this guidance is to assist in designing a quality assurance program that identifies the applicable federal, state and local regulations, correctly characterizes and packages the LLW for shipment, and validates that compliance with the receiving facility waste acceptance criteria is met prior to release of the shipment for disposition.

Unique terms used in this guidance are defined; potentially applicable regulatory requirements and reference documents are specified in Table 1; procedures that should be developed listing activities that should be performed and checked before shipment are noted; and a flow diagram for the LLW shipping process is included in Figure 1.

101 Definitions

The following definitions are provided to ensure uniform understanding of terms as used in this Subpart.

Certificate of Destruction (COD): The Certificate of Destruction is provided by the disposal facility and definitively marks the final phase of the Cradle-to-Grave responsibility chain assumed by hazardous waste generators. The Certificate of Destruction verifies the final destination of the waste and documentation sent to the generating facility.

Generator: An individual, facility, corporation, government agency, or other institution that creates waste for certification, treatment, or disposal.

Hazardous Materials Shipper and Carrier: Per 49 CFR 171.8, any person who does either or both of the following:

- Performs, or is responsible for performing, any pre-transportation function required under 49 CFR 171.8 for transportation of the hazardous material in commerce.

- Refers to as shipper in this Subpart.

Tenders or makes the hazardous material available to a carrier for transportation in commerce. Referred to as the carrier in this Subpart.

A carrier is not an offeror when performing a function in accordance with 49 CFR 171.8. (e.g., reviewing shipping papers, examining packages to verify that they are in conformance, or preparing shipping documentation for its own use) or when the carrier transfers a hazardous material to another carrier for continued transportation in commerce without performing a pre-transportation function.

Land Disposal Restricted (LDR) Waste: Waste that is both restricted and prohibited from land disposal in accordance with 40 CFR 268.

Radioactive Waste Management Basis (RWMB): Per DOE directives the radioactive waste management controls applied to facilities, operations, and activities to provide near- and long-term protection of public, workers, and the environment. The radioactive waste management basis consists of controls and analyses such as facility waste certification programs, facility waste acceptance requirements, low-level waste disposal facility closure plans, performance assessments, composite analyses, and other facility-specific processes, procedures, and analyses performed to comply with DOE directives at www.directives.doe.gov.

Site Treatment Plan (STP): In compliance with the Federal Facility Compliance Act (FFCA), a plan for developing treatment capacities and technologies to treat all of the facility’s mixed low-level waste,
regardless of the time generated, to the standards of the Resource Conservation and Recovery Act (RCRA).

_Treatment Storage and Disposal Facility (TSDF):_ A permitted disposal facility is any site where waste is intentionally placed and at which the waste will remain after closure. **Note:** If an area meets the definition of a facility that is engaged in waste treatment, storage, and/or disposal, the facility compliance is with the standards under 40 CFR Parts 264/265 for hazardous waste in a mixed low-level waste (MLLW) facility.

Often referred to as the disposal facility as the land, building, and structures, and equipment which are intended to be used for the disposal of radioactive wastes (10 CFR Part 61)

_Treatment and Storage Facility (TSF):_ A permitted facility that does not have disposal capability and will treat authorized waste streams and ship waste to the final disposal site.

_Transfer Facility: Per 40 CFR 260.10, a transfer facility is any transportation related facility that includes loading docks, parking areas, storage areas and other similar areas where shipments of hazardous waste are held temporarily during the normal course of transportation._

_Uniform Waste Manifest: The shipping document [e.g. Environmental Protection Agency (EPA) Form 8700-22, Nuclear Regulatory Commission (NRC) Form 540, 541, or 542] originated and signed by the generator used to transfer the waste to the disposal facility._

_Waste Acceptance Criteria (WAC): The facility-specific testing, documentation and other requirements that is needed to be met for the acceptance of waste by the receiving disposal facility._

_Waste Support Organization(s) and Personnel: The waste management organization and personnel that contribute to supporting the organizations that manage, handle, inspect, review and authorize processes at the waste generating facility. A key component is the activities of waste life-cycle management._

_Waste Certification Program: Per DOE directives radioactive waste management the waste certification program shall designate the officials who have the authority to certify and release waste for shipment; and specify what documentation is required for waste generation, characterization, shipment, and certification. The program shall provide requirements for auditability, retrievability, and storage of required documentation and specify the records retention period._

_Waste Characterization: The identification of waste composition and properties by review of acceptable knowledge (which includes process knowledge), or by nondestructive examination, nondestructive assay, survey, or sampling and analysis, to comply with applicable packaging, storage, treatment, handling, transportation, and disposal requirements._

_Waste Classification: Per 10 CFR 61.55 Classification of LLW according to its radiological hazard. The classes include Class A, B, and C, with Class A being the lowest hazard. Waste containing a hazardous component [per the Resource Conservation and Recovery Act, (RCRA)] is classified as a MLLW._

_Waste Stream Profile: Defined waste or group of wastes from a process or a facility with similar physical, chemical, or radiological properties that is authorized by a TSDF to be shipped to that facility._

_Waste Staging: Per Department of Energy (DOE) directives, storing waste for the purpose of accumulation to facilitate transportation transfer, treatment and/or disposal._

_Waste Storage: Per DOE directives, the holding of radioactive waste for a temporary period, at the end of which the waste is treated, disposed of, or relocated elsewhere._

_Waste Certification Official (WCO): Per the Nevada National Security Site (NNSS) WAC, the WCO is the generator facility representative and Point of Contact (POC) for waste destined for disposition. The WCO is responsible for maintaining the authorized waste certification program, qualifying personnel, reviewing generating facility waste documentation and program compliance for the facility, and signing documentation that attests to waste meeting the receiving facility WAC. The WCO and Alternate WCO(s) are the only positions
authorized to certify shipments and waste packages.

Waste Disposal Request (WDR): Documentation of request for waste pick up from the generating facility that identifies waste characteristics in preparations for treatment and final disposal.

102 Application of Requirements to LLW Shipping Activities

In Table 1 of this Subpart, notes potentially applicable requirements and reference documents for planning and conducting LLW shipping activities. References are provided throughout this Subpart. Figure 1 of this Subpart summarizes the waste lifecycle activities for LLW shipping identified in Sections 200 through 900.

200 PREREQUISITES

A quality assurance program should be established and maintained at the waste generator facility with requirements that have been identified for maintaining quality. Quality assurance activities should be planned to ensure that activity and documentation requirements are met specific for LLW characterization and shipping. The following conditions should be confirmed as having been met before the remainder of this document is applied:

201 Planning and Procedures

Procedures, waste planning documents, waste shipping documents should be confirmed to have the proper contents and signatures consistent with current regulatory requirements and applicable references found in Table 1. A checklist should be developed for the steps to be followed from waste generation to waste disposal. Such checklists should be maintained as a record in Section 1100.

When planning, generators should consider additional needs for Hazard Category 2 and 3 nuclear facilities and other systems that perform important defense-in-depth functions. Planning also should consider Accountable Nuclear Material (ANM) that is determined based on material type and quantity and should be considered when reporting and forecasting for waste determination. ANM may include material recovered during deactivation, decommissioning or decontamination operations. ANM includes Special NM (see Section 51 of the Atomic Energy Act of 1954), byproduct material or source material as defined by the Atomic Energy Act, or any other material used in the production, testing, utilization or assembly of nuclear weapons or components of nuclear weapons that the Secretary of Energy determines to be NM.

The planning process allows for development and implementation of procedures identifying the generation of LLW and assuring that facilities do not generate problematic waste or waste with no identified path for disposal.

Planning should include due diligence performed by the generator with the intended disposal facility such that any waste treatment requirements, waste composition requirements, and the off-site facility WAC are understood before the LLW is prepared for shipment to the receiving disposal facility. Planning for mixed waste packaging and transportation requires that the container be chemically compatible with the waste form.

202 Requirement Implementation and Quality Maintenance

Written procedures should be established by qualified personnel as discussed in paragraph 301. The waste support organization may be the direct procedure/program developer and/or provide program oversight. The procedures should be reviewed annually to confirm that the quality assurance program for LLW shipping complies with applicable requirements of Part I, this Subpart, applicable requirements listed in Table 1, and shipping requirements applicable to each facility or site as specified in the disposal facility WAC.

300 PRESHIPPING CHECKS

301 Personnel Qualifications and Training

The responsible organization should designate those activities that require qualification of personnel and the minimum requirements for such personnel. The responsible organization should establish written procedures for the qualification of personnel, and for the assurance that only those personnel who meet the requirements are permitted to perform specific activities.

All employees who perform a function of the DOT hazardous materials regulations (e.g.,
classification, filling or closing, and packaging, applying hazardous communications, loading) should be DOT trained and tested. (49 CFR 172.704, Training Requirements; 49 CFR 172.816, Driver Training)

Specific qualification guidance for personnel performing waste management, waste packaging, repackaging (lab-packing) and shipping are provided in paragraphs 301.1 through 301.5 of this Subpart.

301.1 Waste Characterization Personnel. Waste characterization may involve multiple regulations, each with specific characterization criteria. Full characterization may involve multiple disciplines. With regard to DOT characterization, all persons who perform a function of waste characterization should be trained and tested to the function(s) performed and be certified by their employer. Refer to 49 CFR PARTS 174, 175, 176, or 177 for additional training requirements. Additional requirements may involve NRC, DOE, EPA and State Specific requirements.

301.2 Waste Technical Operations Personnel. A training and qualification program should be implemented for radioactive waste management program personnel. The program should meet OSHA 40-hour Hazardous Waste Worker Training requirements and include a yearly update and DOT Hazardous Materials Training. The program should also include any contractually obligated training and qualification requirements.

301.3 Waste Authorized Shipper Personnel. Training and qualification as identified in Section 301.2 should be met and in addition should also include OSHA 8-hour Supervisor Training (Senior Operations only), training as specified by 49 CFR 172, Subpart H and The Hazardous Materials Shipper and Carrier.

Waste shipper responsibility should include carrier qualification and selection, shipment preparation for domestic and international transport, and procurement of commercial transport services - including all related functions such as rate analysis, carrier interface, bill payment, claims, and systems.

301.4 Health and Safety Personnel. Personnel supporting specific waste shipments should be trained to their program discipline (e.g., Industrial Safety, Radiological Safety, etc.)

Radiological safety support personnel should be trained in a Radiation Protection Program (RPP) that is mandated and includes worker safety, regulatory compliance, and oversight for the implementation. DOE nuclear facilities are required to meet requirements in 10 CFR 835 and 10 CFR Part 20 Subpart B, “Radiation Protection Programs.”

301.5 Auditing Personnel. Personnel performing quality assurance audits should include team members who have a background in waste regulations and waste management activities. Auditors should be knowledgeable in LLW/MLLW shipment activities. Auditors should audit both the waste characterization and uniform waste manifesting processes, including DOT hazardous materials compliance.

302 Characterization

All generator waste management activities should be planned and if waste is newly generated, waste minimization efforts should be considered, including elimination of secondary waste streams. The waste characterization process and waste stream profile development should be specified prior to generation, when possible. Re-characterization or additional characterization may be necessary for research and experimental needs. The facility waste generator is responsible for the waste characterization, using calibrated equipment where applicable, and the waste support organization may assist in preparation of documentation and oversight compliance. The waste profiling process (which includes DOT classification) leads to the shipping container prescription based on waste content characteristics and regulatory containment needs.

Based on regulatory review, the waste classification may involve additional management activities such as additional analysis, reporting requirements, increased containment or packaging requirements.

Characterization should be considered during the planning process prior to waste generation. Additional supporting characterization data and documentation then further justifies the characterization if the historical characterization
data is not sufficient to characterize the waste generated. Initializing characterization is documented in the waste stream profile.

302.1 DOE/EPA Waste Characterization/Classification. Radioactive waste classification may include either LLW or MLLW. Waste management activities performed should segregate and handle waste in accordance with applicable regulatory requirements and maintain personnel exposure to radiological hazards as low as reasonably achievable (ALARA) for preparation of shipment, per 10 CFR 835.

If the waste contains a hazardous constituent as defined under RCRA, the MLLW is driven by RCRA regulations in addition to DOE radioactive waste requirements. The hazardous waste management includes EPA waste code(s) assignment, and any additional land disposal restriction documentation identified by state regulations. If generated at a DOE facility, visual package certification and documentation may apply depending on DOE or non-DOE disposition. Documentation is included on the waste stream profile.

If applicable, DOE requires reporting for the RWMB and physical on-site radioactive waste management that includes waste staging or storage management prior to disposal at a TSDF.

302.2 DOT/NRC Characterization. The waste characterization process provides a description of how the waste should be classified for shipping and disposal (in accordance with 10 CFR Part 61.55) as either Class A, B, or C waste. The waste should meet the minimum waste characteristics in 10 CFR Part 61.56 and be labeled in accordance with 10 CFR Part 61.57. Dependent on the type and activity levels of radioactive materials to be shipped by the carrier, the shipper should select an appropriate transportation packaging for the waste (e.g., a Type A, A (F), or B). Dependent on a number of factors including, but not limited to, the radiation level, type and level of radioactive contamination (as defined in 10 CFR Part 71.4), and the type and activity levels of radioactive materials to be shipped, the shipment classification will differ and be identified by labeling and placarding.

All LLW should be transferred between licensee, disposal facility, waste collector, and waste processor according to 10 CFR 20, Appendix G, Section III, Control and Tracking, including using NRC Forms 540, 541, and 542 (Uniform Low-Level Waste Manifest).

All radioactive shipments include shipping paperwork as defined in 10 CFR Part 20 and 49 CFR 172 Subpart C (waste profile, waste disposal request, uniform waste manifest, and chain of custody and driver’s documentation). The generating facility will receive a TSDF return uniform waste manifest and Certificate of Destruction.

302.3 Mixed Low-Level Waste Streams. Along with the guidance provided in Section 302.1, MLLW requires additional documentation and management according to hazardous waste regulations.

For a DOE facility, the radioactive components of the waste stream include reporting per DOE directives. The hazardous components contained in MLLW streams may include additional reporting to the state government environmental agency as specified in the Site Treatment Plan.

400 PROCUREMENT OF ITEMS AND SERVICES

Procurement activities for items and services that affect the quality of waste shipment should be adequately controlled. These controls ensure appropriate source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, source inspection, audit, and examination of items or services upon delivery or completion. These controls should be applied to items, such as waste containers and packaging, and services, such as laboratory analyses used for waste characterization as discussed in Section 302. Supplier evaluation and selection for analytical laboratory services may include third party accreditation under ISO 17025 or other appropriate quality standard.

500 CONTAINERS/ PACKAGING

Proper consideration of shipping containers can prevent repackaging for shipment compliance or shipment configuration. Maintenance, including storage of hazardous materials packaging, should
be such that degradation or impairment, including corrosion, will not adversely affect the integrity of the packaging/package or disqualify the package certification or qualification.

Radioactive waste management of containers at a DOE facility is required to meet DOE waste staging or storage management and 49 CFR Hazardous Materials Requirements. Appropriate container selection should be identified at the planning stage prior to waste generation.

Prior to scheduling shipments of material, container use should be evaluated (inner packaging, NRC and DOT authorized, contents, etc.). Validation inspection by the shipper and carrier should be completed when loading material onto a transport vehicle in accordance with 49 CFR 392.9.

For mixed waste packaging and transportation, the container is required be chemically compatible with the waste form.

600 EQUIPMENT AND CALIBRATION

Calibrated measuring and test equipment may be needed to certify that a transportation package used to transport LLW meets the requirements for its approval and is ready for shipment. LLW shipment may be delayed if quality control of measuring and test equipment is not performed or is inadequate.

601 Control of Measuring and Test Equipment.

Tools, gauges, instruments, and other measuring and test equipment used for activities affecting quality (e.g., waste characterization and classification, compliance with waste packaging requirements) should be adequately controlled. Equipment measurement and testing is part of the shipment preparation and inspection. Failure to provide evidence of calibrated measuring and test equipment may lead to a stop in shipments for off-site disposal. Equipment may include, but is not limited to, thermometers, balances, scales, air entrainment meters, volumetric buckets, field measuring devices, pressure gages, laboratory equipment used for waste characterization, and torque wrenches.

700 DISPOSITION

Waste disposal decisions should be considered at the planning stage prior to generation, providing input for container selection and meeting the receiving facility WAC and other acceptance requirements. The facility waste support personnel can assist in the documentation of waste contents, location and planning.

701 DOE Disposal

Off-site DOE LLW/MLLW disposition requires the certification steps of waste be performed through the waste certification program be completed simultaneously throughout the active waste management lifecycle. Generating facilities need an approved waste certification program prior to receiving authorization to ship for disposal. Facility acceptance criteria can be found in the off-site DOE facility WAC.

Select DOE facilities have approved on-site disposal capabilities and are subject to DOE radioactive waste management requirements.

702 Non-DOE Disposal

LLW/MLLW destined for commercial facility disposition are required to meet the receiving facility WAC and other acceptance requirements of the receiving facility and any additional state regulatory requirements for each disposal facility.

NRC regulated LLW may be disposed at an NRC or Agreement State (10 CFR Part 61 or Agreement State equivalent) licensed facility. If a licensee desires an alternate disposal path, the 10 CFR Part 20.2002 process should be used.

If the waste is DOE regulated LLW/MLLW destined for commercial facility disposition, the facility should develop a DOE Exemption and obtain DOE approval for each waste stream. Refer to DOE directives for requirements.

703 Shipping and Transport Paperwork

The disposal documentation package, at a minimum, includes the waste stream profile with characterization information, the off-site receiving facility waste profile, and the uniform waste manifest. With a completed waste disposal
package, the shipment can be transported to a treatment and storage facility (TSF) and/or a TSDF. DOT requires all shipping papers be maintained for two-years and uniform waste manifests for three-years.

If the waste stream is MLLW, an LDR certification form is required to be with the disposal documentation package.

800 SHIPPING VEHICLE INSPECTION

Trained personnel should perform waste packaging and transportation. The authorized waste shipper should verify specific details for the packaging, shipment configuration and off-site disposal requirements. If quality control of vehicle inspection is inadequate, shipment may be delayed and call for the shipment to be rescheduled. Inspection of adequate packaging closure should be part of the vehicle loading inspection.

801 Vehicles

A vehicle inspection should be completed in accordance with 49 CFR 397.101 prior to loading material onto a transport vehicle. Loading of containers should be done in accordance with 49 CFR 172.404. Refer to specific requirements for shipment transport (e.g., Air Shipment per 19 CFR 122.117 for samples only; Rail Shipment/Water Shipment and International Shipment mainly used by Off-site Source Recovery Programs; Shipment of Radioactive Material per 49 CFR 173.435 and 49 CFR 177, as applicable; Classified Matter per DOE directives).

900 AUDITS

Audits are performed to verify waste shipping compliance to quality assurance program requirements, to verify that performance criteria are met, and to determine the effectiveness of the waste management program. The waste lifecycle is subject to assessment for validating the waste management program performance. Audits may be scheduled in accordance with multiple requirements of each regulatory entity in Table 1.

901 Internal Audits

Internal audits are conducted to verify compliance with applicable waste regulations and guidance. Development of annual audit schedules of the waste management program should be based on comprehensive assessments of the organization’s strategic, financial, operational, and regulatory risks that have been identified.

902 External Audits

External audits of waste shipment product suppliers, vendors, and waste receiving facilities should be conducted periodically to verify compliance with applicable requirements.

903 Audits by External Entities

Audits by external entities are performed by receiving facilities and regulatory entities. These audits may be scheduled in advance or unscheduled.

For DOE-regulated waste, the Radioactive Waste Acceptance Program (RWAP) of NNSS performs audits in accordance with DOE/NV-325-16-00, Nevada National Security Site Waste Acceptance Criteria dated November 2016 (or the most current revision). This, which is the governing document for waste determination, acceptance, planning and shipping requirements for disposal. All site communications go through the WCO and the facility’s approved waste certification program.

1000 POST-SHIPPING CHECKS

Following the completion of waste shipping activities, checks should be performed on the final disposal to verify that the final condition conforms with the return uniform waste manifest and validating receiving facility disposal.

1100 RECORDS

Record copies should be prepared and collected of procedures, reports, personnel qualification, test equipment calibration, test deviations or exceptions, packaging inspection and examination, and material/waste characterization. These records should be retained with other project records as required by code, standard, specification, or project procedures.

Electronic systems (e.g., Uniform Waste Manifests, Characterization Forms, etc.) may be the official record or include a reference to the official paper record. However, procedures should clearly identify program use.
As required by federal, DOE, and National Archives and Records Administration (NARA) requirements, Records Retention Schedules identify the final disposition for records. Records Retention Schedules should include mandatory instructions for the disposition of records that involve retention and transfer of permanent records, or destruction of records eligible for destruction if they are no longer needed.

Retention of records should be defined in the local Records Inventory and Disposition Schedule (RIDS).
This table lists requirements that may be applicable to maintaining a Waste Characterization and Shipment Quality Assurance program. This list is not all inclusive and other requirements may also apply. The requirements listed in this table were current at the time this Subpart was prepared. Consideration should be given for regulatory updates or changes that may have subsequently occurred.

<table>
<thead>
<tr>
<th>NRC Requirements and References</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>The NRC establishes waste classification requirements for packaging, preparation for shipment, and transportation of licensed material. The packaging and transport of licensed material are subject, but not limited to 10 CFR parts 20, 21, 30, 40, 61, 70, 71, and 73. The referenced requirements were resources at the time of this subpart being prepared, verify current regulatory requirements and references during use of this Subpart.</td>
<td></td>
</tr>
</tbody>
</table>

10 CFR Part 20, “Standards for Protection against Radiation”, Appendix G

Specifies “Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests” See Section I (Manifest), Section II (Certification) and Section III, Control and Tracking.


See 10 CFR 61.55 through 10 CFR 61.58 (Waste Classification, Characteristics, Labeling)

10 CFR Part 71, “Packaging and Transportation of Radioactive Material”

Specifies requirements for packaging, preparation for shipment, and transportation of licensed radioactive material.

NRC Form 540, 541, and 542

Uniform Low-Level Radioactive Waste Manifest (Shipping Paper, Container and Waste Description, and Manifest Index and Regional Compact Tabulation). (ADAMS Accession No. ML13083A180, ML13083A182, ML13083A184).


Provides examples of the review process for transfers of radioactive material, under 10 CFR 20.2002 and 10 CFR 40.13(a). (ADAMS Accession No. ML18296A068)

NUREG-BR/0204, Revision 3

Instructions for Completing the U.S. Nuclear Regulatory Commission’s Uniform Low-Level Radioactive Waste Manifest (ADAMS Accession No. ML20178A433).


Provides analysis on the use of activity scaling factors for several difficult to measure radionuclides found in low-level radioactive waste.


Provides guidance on how to measure and report four difficult to measure radionuclides know as the “Phantom 4”, including the use of activity scaling factors.
<table>
<thead>
<tr>
<th>Source</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRC Branch Technical Position on Concentration Averaging and Encapsulation (ML12254B065, ML12326A611)</td>
<td>Provides guidance on methods for averaging waste radionuclide concentrations over the volume of the waste being disposed.</td>
</tr>
<tr>
<td>Regulatory Guide 4.15, “Quality Assurance for Radiological Monitoring Programs. (ML071790506)”</td>
<td>Describes a method that the US Nuclear Regulatory Commission (NRC) considers acceptable for use in designing and implementing programs to ensure the quality of the results of measurements of radioactive materials in the effluents from, and environment outside of, facilities that process, use, or store radioactive materials during all phases of the facility’s life cycle.</td>
</tr>
<tr>
<td>Regulatory Guide 7.10, “Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material”</td>
<td>Describes an approach the NRC considers acceptable in meeting the applicable quality assurance requirements in 10 CFR Part 71 for the transport of licensed radioactive material in NRC-approved packaging.</td>
</tr>
</tbody>
</table>

**DOE Requirements and References**

DOE establishes operational requirements for managing the Department's materials transportation and packaging functions. Transportation of DOE materials over the nation's highways, railways, and waterways provides the Department maximum interface with the general public, stakeholders, and representatives of States, Tribes, and other local government organizations. The referenced requirements were resources at the time of this subpart being prepared, verify current regulatory requirements and references during use of this Subpart.

<table>
<thead>
<tr>
<th>DOE Requirement</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOE Order 414.1D Chg 1. “Quality Assurance”</td>
<td>Defines roles and responsibilities for providing quality assurance for DOE products and services</td>
</tr>
<tr>
<td>DOE Order 460.1D, “Hazardous Materials Packaging and Transportation Safety”</td>
<td>Establishes safety requirements for the proper packaging and transportation of offsite shipments and onsite transfers of hazardous materials, including radioactive materials.</td>
</tr>
<tr>
<td>DOE Order 460.2A, “Departmental Materials Transportation and Packaging Management”</td>
<td>Materials transportation and packaging to ensure the safe, secure, efficient packaging and transportation of materials, both hazardous and nonhazardous.</td>
</tr>
<tr>
<td>DOE Order 471.6, “Information Security”</td>
<td>Establishes requirements and responsibilities for DOE Departmental Elements, including NNSA, to protect and control classified information as required by statutes, regulation, Executive Orders, government-wide policy directives and guidelines, and DOE policy and directives.</td>
</tr>
</tbody>
</table>

This standard focuses solely on low-level waste. Generally, candidate LSA material and SCO within the DOE complex are wastes generated from the clean-up and deactivation of WWII and Cold War era nuclear processing and weapons support operations. The level of effort required to characterize waste varies based on the type and origin of waste being generated.

EPA Requirements

EPA regulations identify specific substances known to be hazardous and provide objective criteria for regulated hazardous waste. The referenced requirements were resources at the time of this subpart being prepared, verify current regulatory requirements and references during use of this Subpart.

Title 40 CFR, “Protection of Environment”

The Resource Conservation and Recovery Act (RCRA) of 1976, is the public law that creates the framework for the proper management of hazardous and non-hazardous solid waste.

40 CFR 302, “Hazardous Substances”

This regulation designates under section 102(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (“the Act”) those substances in the statutes referred to in section 101(14) of the Act, identifies reportable quantities for these substances, and sets forth the notification requirements for releases of these substances.


Title 40- Protection of the Environment contains all of the regulations governing EPA’s programs. In any given state, EPA or the state’s hazardous waste regulatory agency enforces hazardous waste laws.

Environmental Protection Agency (EPA), Code of Federal Regulations, Title 40.

40 CFR 61 National Emission Standards for Hazardous Air Pollutants (asbestos)

40 CFR 761 Polychlorinated Biphenyls (PCBs)

DOT Requirements

The Department of Transportation (DOT) lists and classifies materials, which are designated by DOT as hazardous materials for purposes of transportation, and prescribes the requirements for shipping papers, packaging, marking, labeling, and transport vehicle placarding applicable to the shipment and transport of those hazardous materials. The referenced requirements were resources at the time of this subpart being prepared, verify current regulatory requirements and references during use of this Subpart.

DOT compliance activities usually are performed by the facility waste support organization with cooperation of the waste generator.


Establishes the minimum hazard communications for packages and shipments of radioactive materials/wastes subject to the DOT HMR.

Specifies the training and testing required for a person who performs a function of preparing or transporting a DOT regulated hazardous material/waste.
### Receiving Facility Licenses and Acceptance Summary

- **Waste receiving facilities must be licensed and provide WAC for generator shipments of waste for disposal.** Generating facilities refer to each receiving facility’s WAC. The referenced requirements were resources at the time of this subpart being prepared, verify current regulatory requirements and references during use of this Subpart.

- **DOE/NV--325-16-00, “Nevada National Security Site Waste Acceptance Criteria”**
  - Provides the requirements, terms, and conditions under which the NNSS will accept the following: DOE low-level radioactive waste, DOE mixed low-level waste, DOE classified waste/matter and US DOD classified waste/matter.

### State Specific Requirements

State authorization is a rulemaking process through which EPA delegates the primary responsibility of implementing the RCRA hazardous waste program to individual states. This process aids national consistency and minimum standards while providing flexibility to states in implementing rules. Generators are to know, understand and comply with state regulations for transporting through or for acceptance for disposal within that state.

Currently, 50 states and territories have been granted authority to implement the base, or initial, program. Many states are also authorized to implement additional parts of the RCRA program that EPA has since promulgated, such as corrective action and the LDR. State RCRA programs should be at least as stringent as...
the federal requirements, but states can adopt more stringent requirements as well. A STP may be required at the state’s discretion.

Similarly, NRC delegates regulatory authority to agreement states. Commercial waste disposal facilities located in NRC agreement states must meet agreement state regulations.

Refer to NRC agreement states, EPA Laws and Regulations and confirm state specific licenses and permits are followed.
Low-Level Waste Shipper Guidance

Waste Lifecycle

Key:
Blue = Waste Generator
Gray = Waste Support Organization (Field Coordinators, P&T, etc.)
White = Both
Bold Outline = Documentation Produced/Required
Dotted Outline = Multiple Validation Reviews

Acronym List
COD - Certificate of Destruction
LLW - Low Level Waste
NNSS - Nevada National Security Site
WCO - Waste Certification Official

Note: This waste reference is an overview of Sections 200-1000 and is not inclusive to all other possible waste types. Not all boxes may apply, each box should be considered if applicable per multiple regulation possibility. These are potential references as requirements are subject to update and change. Always reference local manual for implementation.