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ABSTRACT

Over that past year, the International Atomic Energy Agency, the U.S. Department of Energy and leadership of the ASME Committee on Nuclear Quality Assurance (NQA) have collaborated to develop new guidance for the global nuclear industry. Two parallel projects were established at the IAEA and NQA to develop guidance for the comparison and integration of the IAEA nuclear safety management system requirements, GS-R-3 with ASME nuclear quality assurance requirements, NQA-1. The guidance will provide regulators and industry with authoritative information necessary to evaluate an organization's safety management or quality management system developed under one of the requirements (e.g., GS-R-3) for compliance with the other (e.g., NQA-1). This information will be invaluable to users of these requirements, both of which are used globally. The IAEA and ASME will publish their guides independently, yet containing the same comparison details.

The proposed presentation will describe the projects, results of the comparison, and recommended actions for users of these two requirements documents.

INTRODUCTION

Background


The IAEA and ASME also provide implementing guidance for their requirements. IAEA Safety Standards Series No. GS-G-3.1 [3], GS-G-3.5 [4] and other IAEA safety guides specific to technical areas provide guidance or recommendations on how to fulfil the requirements specified in IAEA GS-R-3 [1]. NQA-1 [2] includes guidance in Parts III and IV of the standard.

As Member States adopt and apply IAEA GS-R-3 [1] requirements, regulatory bodies, operators or organizations providing nuclear items or products and services may be required to comply with the safety requirements in these IAEA standards while maintaining the certification or compliance of their items, products and services under ASME NQA-1 [2] and other relevant codes and standards. Although U.S. regulatory bodies are not revising their
rules to adopt GS-R-3 [1], the global nature of our contemporary nuclear industry drives a need to understand how work with both sets of requirements.

Consequently, organizations may adopt IAEA GS-R-3 [1] and ASME NQA-1 [2] as the basis of their management system or quality assurance program (QAP). IAEA GS-R-3 [1] requires these requirements to be integrated within one management system. Therefore, the necessity for guidance to assist organizations to satisfy these requirements became apparent to representatives of the IAEA and the U.S. Department of Energy.

Two parallel projects were proposed and approved by the IAEA and the ASME Committee on Nuclear Quality Assurance (NQA) to prepare the new guidance for publication by both organizations. The IAEA formed a Consultancy Group (CG) to evaluate the two sets of requirements and draft the “Safety Report”. NQA formed a Project Team consisting of many of the IAEA CG members and use CG output to draft a companion guide for publication in NQA-1 [2] Part IV. Both teams included a mix of members from various countries and organizations (government, regulators, corporations, standards bodies and IAEA staff). Each document contains the same detailed comparison tables to ensure the users have equivalent guidance whether they are reading the IAEA or NQA-1 [2] guide. The IAEA Safety Report and NQA Guide are completing the final stages of the publication processes. It is anticipated that the new documents will be published in 2010.

The guides help organizations by providing information on the similarities and differences between IAEA GS-R-3 [1] and ASME NQA-1 [2]. The objective of the new guides is to compare IAEA GS-R-3 [1] and ASME NQA-1 [2], to identify the similarities and differences between them and to provide information and guidance including recommendations to assist an organization to meet the requirements of both standards.

The documents compare the requirements in the following publications:

- IAEA Safety Standards Series No. GS-R-3, The Management System for Facilities and Activities [1]; and

- ASME NQA-1, Quality Assurance Requirements for Nuclear Facility Applications, Part I [2].

The guides are intended for:

- Regulatory bodies and customers who require, through regulation or contract, the management systems for nuclear facilities and activities to comply with the requirements of IAEA GS-R-3 [1] and ASME NQA-1 [2];

- Operators of nuclear facilities and activities who are either legally obliged, or choose as best practice, to implement the requirements of IAEA GS-R-3 [1] and ASME NQA-1 [2]; and

- Suppliers of products or services that are required to be produced in accordance with the requirements of IAEA GS-R-3 [1] and ASME NQA-1 [2].

Objectives of IAEA GS-R-3 [1] and ASME NQA-1 [2]

IAEA GS-R-3 [1] defines requirements for an organization to establish, implement, assess and continually improve a management system that integrates safety, health, environmental, security, quality and economic elements to ensure safety is not compromised. It fosters a strong safety culture and improved safety performance in all the activities of the organization.


Scope and Approach to the Development of NQA-1 [2] and GS-R-3 [1]

IAEA GS-R-3 [1] and ASME NQA-1 [2] apply to the lifecycle of nuclear facilities and activities, including siting, design, construction, commissioning, operation, and decommissioning. IAEA GS-R-3 [1] and ASME NQA-1 [2] foster the application of requirements in a manner that is consistent with the relative importance of the item or activity.

IAEA GS-R-3 [1] adopts an integrated management system approach to be applied to all work of the organization. IAEA GS-R-3 [1] requires the integration of safety, health, environmental, security, quality and economic elements of the management system to ensure that safety is properly taken into account in all activities. It specifies requirements designed to achieve and enhance safety, while enhancing the satisfaction of interested parties. A management system based on IAEA GS-R-3 [1] includes safety culture, human performance, a process approach to the achievement of objectives and continual improvement of the management system and its processes.

The ASME NQA-1 [2] 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 Programme necessary to achieve, safe, reliable, and efficient utilization of nuclear energy, and management and processing of radioactive material.

ASME NQA-1 [2] was originally developed to implement quality assurance requirements for nuclear power plant design and construction in the U.S.A. ASME NQA-1 [2] now applies expanded quality assurance requirements to a range of nuclear facilities to address new technologies and safety issues. ASME NQA-1 [2] does not require an integrated management system approach as required by IAEA GS-R-3 [1].

Application

IAEA GS-R-3 [1] can be used by Member States to set management system requirements for nuclear facilities and activities to provide assurance of adequate safety.
ASME NQA-1 [2] can be imposed by a regulatory body through regulation or national codes and standards. ASME NQA-1 [2] can be used by a nuclear facility to meet quality requirements set by a regulatory body. Both IAEA GS-R-3 [1] and ASME NQA-1 [2] can be invoked by contract, adopted voluntarily, or used as the basis for assessing a management system or a quality assurance programme. These standards require responsibility for the management system and work carried out under the management system to be retained by the organization. Figure 1 is an example of how these standards can be applied.

Figure 1: An Example of the Application of IAEA GS-R-3 [1] and ASME NQA-1 [2]
HOW TO USE THE GUIDES TO ACHIEVE COMPLIANCE WITH GS-R-3 [1] OR NQA-1 [2]

Two Perspectives and Two Tables

The requirements of both standards are listed in two tables and have been compared utilizing the 18-criteria format of NQA-1 [2], Part I and the Process Approach of IAEA GSR-3. Guidance for evaluating existing practices or supplementing each program is summarized below each requirement section. In most cases the IAEA requirements are stated at a higher process level and the user must determine the need to develop detailed practices for implementation of the NQA-1 [2] requirements. In these cases, it is necessary to compare the implementing practices with the requirements of NQA-1 [2] to determine compliance. Two examples of the perspectives that must be considered and addressed by the guidance are: 1) A purchaser considering a supplier for nuclear facility that meets one of the programs but also need to meet the requirements governed by the purchaser’s program; 2) A supplier wanting to provide items/services to a purchaser who requires compliance with the program that is not the supplier’s current program. It should be noted that neither table provides any direction for Introductory/Informational material from the two documents.

How to Use the Tables

The first table presents a column of the requirements of NQA-1 [2], Part I, on a line-by-line basis, for all 18 requirements, and each sub-paragraph of each requirement. Immediately adjacent to the column for the NQA-1 [2] requirement is a second column that contains the corresponding GS-R-3 [1] requirement that specifically addresses the NQA-1 [2] requirement. In cases where GS-R-3 [1] does not specifically meet the NQA-1 [2] requirement, recommendations are provided that describe how best to meet the NQA-1 [2] requirement, within the GS-R-3 [1] program. It should be noted here that the recommendation is for the GS-R-3 [1] user to meet the NQA-1 [2] requirement, as opposed to trying to meet some requirement that may not be considered acceptable.

Likewise, the second table lists all 5 elements of the GS-R-3 [1] requirements, plus the specific sub-tier elements of each. In this second table, where a particular NQA-1 [2] requirement meets the specific GS-R-3 [1] requirement, it is so stated. Where there is no corresponding NQA-1 [2] element that meets the GS-R-3 [1] requirement, a recommendation is provided as to how the GS-R-3 [1] requirement should be met.

Examples of Table I and Table II are provided below for illustrative purposes.
Table I. The Extent to which GS-R-3 [1] Addresses NQA-1 [2] Requirements (For copyright reasons, the text of NQA-1 [2] is not included in this table. Key words are included as appropriate to help the reader identify the nature of the requirements. Users should refer to NQA-1 [2] for the full text of the requirements.)

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1</td>
<td>Organization</td>
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<tr>
<td>1-100</td>
<td>BASIC</td>
<td></td>
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<td></td>
<td>Key words:</td>
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1-200 STRUCTURE AND RESPONSIBILITY

<table>
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<tbody>
<tr>
<td>Key words:</td>
<td></td>
<td>Recommendations. GS-R-3 [1] users should address organizational freedom, independence of verification activities, and the following verification functions:</td>
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<tr>
<td></td>
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<td>(1) identifying quality problems</td>
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<td>(2) initiating, recommending, or providing solutions to quality problems through designated channels</td>
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<td>(3) verifying implementation of solutions</td>
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<td></td>
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<td>(4) assuring that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.</td>
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</table>

1-300 INTERFACE CONTROL

<table>
<thead>
<tr>
<th>2-100 BASIC</th>
<th></th>
<th>GS-R-3 [1] Requirements 5.4, 5.5 and 5.10.</th>
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</thead>
<tbody>
<tr>
<td>Key words:</td>
<td></td>
<td>Recommendations. GS-R-3 [1] users should establish the program at the earliest time consistent with the schedule for accomplishing the activities and provide for special controls, required by NQA-1 [2] (see recommendations under 2-200, 2-300, 2-400 and 2-500 for additional details).</td>
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2 QUALITY ASSURANCE PROGRAM

<table>
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<tbody>
<tr>
<td>201 Indoctrination</td>
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<td>Recommendations. GS-R-3 [1] users should ensure indoctrination to job responsibilities and authority includes general criteria, technical</td>
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<td>objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance requirements, required by NQA-1 [2]. GS-R-3 [1] users should conduct indoctrination and training commensurate with scope, complexity, importance of the activities, and the education, experience, and proficiency of the person consistent with the grading requirements in GS-R-3 [1] 2.6 and 2.7.</td>
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<tr>
<td>2-300</td>
<td>QUALIFICATION REQUIREMENTS</td>
<td>No corresponding requirement.</td>
</tr>
<tr>
<td></td>
<td>Key words: Designate activities that require qualification, written procedures.</td>
<td>Recommendations. GS-R-3 [1] users should ensure the responsible organization designates those activities that require qualification. The minimum requirements for personnel to verify quality and auditing are specified in paras. 301 through 304 of this Requirement. Consult relevant parts of NQA-1 [2] for guidance on implementation of this requirement.</td>
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<tr>
<td></td>
<td>301 Nondestructive Examination (NDE)</td>
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<td></td>
<td>302 Inspection and Test</td>
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<td>303 Lead Auditor</td>
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<td></td>
<td>303.1 Communication Skills.</td>
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<td></td>
<td>303.2 Training.</td>
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<td>303.3 Audit Participation.</td>
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<td>303.4 Examination.</td>
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<td>303.5 Maintenance of Proficiency.</td>
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<td>303.6 Requalification.</td>
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<td>304 Auditors</td>
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<td></td>
<td>305 Technical Specialists</td>
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<tr>
<td>2-400</td>
<td>RECORDS OF QUALIFICATION</td>
<td>No corresponding requirement.</td>
</tr>
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<td></td>
<td>Recommendations. GS-R-3 [1] users should ensure records of the implementation for indoctrination and training include one or more of (a) through (c) of this requirement. The GS-R-3 [1] Users should establish and maintain records for Auditor and Lead Auditor qualification and requalification;</td>
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<td></td>
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<td>and inspection and test personnel qualification and requalification.</td>
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## Example Table II. The Extent to which NQA-1 [2]A-2009 Addresses GS-R-3 [1] Requirements

<table>
<thead>
<tr>
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<tbody>
<tr>
<td><strong>2.1 – 2.10 Management System</strong></td>
<td></td>
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<tr>
<td><strong>General Requirement</strong></td>
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</tbody>
</table>
| 2.1 | Key Words  
Recommendations.  
NQA-1 [2] users should ensure that health, safety, environmental, security and economic requirements will be implemented as part of continual improvement of the management system. |
| 2.2 | Key Words  
Safety | No corresponding specific requirement, but Part 1 “Introduction” addresses the safe utilization of nuclear energy and nuclear material processing.  
Recommendations.  
NQA-1 [2] users should address safety to the extent described by GS-R-3 [1] to ensure safety is paramount. |
| 2.3 | Key Words  
Management system, identify and integrate, statutory and regulatory requirements, interested parties, IAEA Safety Requirements, relevant codes and standards | No corresponding requirement.  
Recommendations.  
| **Key Words** | **Key Words** | NQA-1 [2] Requirement 2, section 100(c).  
Recommendations.  
NQA-1 [2] users should address all aspects of management system requirements. |
| 2.4 | Key Words  
Demonstrate the effective fulfilment | |
| **Safety Culture** | | |
| 2.5 | Key Words  
Graded, significance and complexity, hazards, potential impact, consequences | No corresponding requirement.  
Recommendations.  
| **Grading the Application of Management System Requirements** | | |
| 2.6 | Key words  
Recommendations.  
NQA-1 [2] users should deploy |
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<tbody>
<tr>
<td>2.7 Key Words</td>
<td>Grading of application</td>
<td>NQA-1 [2] Requirement 2, section 100 (a), Requirement 5, PART I “Introduction”. NQA-1 [2] Requirement 3, section 500 (d), Requirement 3, para. 801.4 (b), Requirement 4, para. 203, Requirement 6, section 300, Requirement 7, para. 501, and Requirement 7, para. 504 are requirements that are examples of a graded approach.</td>
</tr>
<tr>
<td>2.8 Key Words</td>
<td>Documentation, policy statements, description of management system and structure, description of functional responsibilities, accountabilities, levels of authority and interactions, description of processes and supporting information</td>
<td>NQA-1 [2] Requirements 1, 2, 6 and 17.</td>
</tr>
<tr>
<td>2.9 Key Words</td>
<td>Developed documentation of management system, readable, readily identifiable, available</td>
<td>NQA-1 [2] Requirement 2, section 100 (a) and PART I “Introduction”.</td>
</tr>
<tr>
<td>2.10 Key Words</td>
<td>Documentation reflect characteristics of organization, complexities of processes and interactions</td>
<td>NQA-1 [2] users should address the potential impact associated with the safety, health, environmental, security and economics in the application of the QA program. Also see PART III Subpart 2A-2 for additional guidance.</td>
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</tbody>
</table>

The organization should identify all processes and their interactions.

This section describes the extent to which IAEA GS-R-3 [1] addresses ASME NQA-1 [2] requirements. It identifies where the requirements are equivalent and provides guidance on how to modify an IAEA GS-R-3 [1] management system to integrate ASME NQA-1 [2] requirements, in Table I. APPENDIX A indicates the correspondence between the requirements in IAEA GS-R-3 [1] and ASME NQA-1 [2].

The following ASME NQA-1 [2] requirements are those for which there is “No corresponding requirement” in IAEA GS-R-3 [1] as identified in Table I. The numbering below corresponds to the NQA-1 [2] requirement and section.

2 QUALITY ASSURANCE PROGRAM

2-300 QUALIFICATION REQUIREMENTS

ASME NQA-1 [2] requires the organization to designate activities that require qualification. The minimum requirements for personnel to verify quality and to conduct audits are specified in paragraphs 301 through 305 of this section.

2-400 RECORDS OF QUALIFICATION

ASME NQA-1 [2] requires the organization to ensure the qualification of inspection, test, and lead auditor(s) and their certification is in writing according to the requirements specified in this section.

3 DESIGN CONTROL

ASME NQA-1 [2] requires the organization to implement requirements for design control. IAEA GS-R-3 [1] does not contain specific requirements for design control but GS-R-3 [1] requirements 5.1 to 5.10 address process management in general, which also apply to design control.

3-800 SOFTWARE DESIGN CONTROL

ASME NQA-1 [2] requires the organization to implement requirements for software design control.

4 PROCUREMENT DOCUMENT CONTROL

4-300 PROCUREMENT DOCUMENT REVIEW

ASME NQA-1 [2] requires the organization to implement requirements for the review of Procurement documents.

7 CONTROL OF PURCHASED ITEMS AND SERVICES

7-300 BID EVALUATION

ASME NQA-1 [2] requires the organization to implement requirements for bid evaluation including the determination of the Supplier’s capability.

7-400 CONTROL OF SUPPLIER-GENERATED DOCUMENTS

ASME NQA-1 [2] requires the organization to implement requirements for the submittal and evaluation of Supplier-generated documents and changes to ensure they are accomplished in accordance with the procurement document requirements.

7-700 COMMERCIAL GRADE ITEMS AND SERVICES
ASME NQA-1 [2] requires the organization to implement requirements for the utilization of commercial grade items or services.

7-800 RECORDS

ASME NQA-1 [2] requires the organization to implement requirements for records for the control of purchased items and services.

8 IDENTIFICATION AND CONTROL OF ITEMS

8-200 IDENTIFICATION METHODS

ASME NQA-1 [2] requires the organization to implement requirements for physical identification of items, how they are to be used to the maximum extent possible and relate to an applicable design or other pertinent specifying document.

8-300 SPECIFIC REQUIREMENTS

ASME NQA-1 [2] requires the organization to implement requirements for the control of item identification consistent with the planned duration and conditions of storage.

9 CONTROL OF SPECIAL PROCESSES

9-100 BASIC

ASME NQA-1 [2] requires the organization to implement requirements for special processes that control or verify quality such as welding, heat treating, and nondestructive examination.

9-200 PROCESS CONTROL

ASME NQA-1 [2] requires the organization to control special processes by instructions, procedures, drawings, checklists, travelers, or other appropriate means.

9-300 RESPONSIBILITY

ASME NQA-1 [2] requires the organization performing special processes to adhere to the approved procedures and processes.

9-400 RECORDS

ASME NQA-1 [2] requires the organization performing special processes to maintain records as appropriate for qualified personnel, processes, and equipment of each special process.

10 INSPECTION

10-300 INSPECTION HOLD POINTS

ASME NQA-1 [2] requires the organization to implement requirements for mandatory inspection hold points beyond which work shall not proceed.

10-400 INSPECTION PLANNING

ASME NQA-1 [2] requires the organization to identify characteristics to be inspected, methods of inspection, acceptance criteria and sampling during inspection planning.

10-500 IN-PROCESS INSPECTION
ASME NQA-1 [2] requires the organization to implement requirements for the inspection of items under construction or otherwise in process to verify quality.

10-600 FINAL INSPECTIONS

ASME NQA-1 [2] requires the organization to review the results and resolution of inspection of nonconformances, inspect completed items, re-inspect or retest any modified, repaired, or replaced item and approve acceptance of the item.

10-700 INSPECTIONS DURING OPERATIONS

ASME NQA-1 [2] requires the organization to plan and execute periodic inspections (e.g., in-service inspections) or surveillances of structures, systems, or components to assure the continued performance of their required functions.

10-800 RECORDS


11 TEST CONTROL

11-200 TEST REQUIREMENTS

ASME NQA-1 [2] requires the organization to establish test requirements and acceptance criteria.

11-300 TEST PROCEDURES (OTHER THAN FOR COMPUTER PROGRAMS)

ASME NQA-1 [2] requires the organization to ensure that test procedures include or reference the test configuration and test objectives.

11-400 COMPUTER PROGRAM TEST PROCEDURES

ASME NQA-1 requires the organization to ensure that computer program test procedures provide for demonstrating the adherence of the computer program to documented requirements.

11-500 TEST RESULT

ASME NQA-1 [2] requires the organization to document, maintain and evaluate test results using a responsible authority to ensure that test requirements have been satisfied.

11-600 TEST RECORDS

ASME NQA-1 [2] requires the organization to establish and maintain test records.

12 CONTROL OF MEASURING AND TEST EQUIPMENT

12-300 CALIBRATION AND CONTROL


12-400 RECORDS

ASME NQA-1 [2] requires the organization to establish and maintain calibration records, including calibration reports and certificates that include the information and data necessary for interpretation of the calibration results and verification of conformance to applicable requirements.

13 HANDLING, STORAGE, AND SHIPPING
13-200 SPECIAL REQUIREMENTS

ASME NQA-1 [2] requires the organization to specify, provide and verify the existence of special equipment and special protective environments, when required.

13-400 TOOLS AND EQUIPMENT

ASME NQA-1 [2] requires the organization to use, control, inspect and test special handling tools and equipment.

13-500 OPERATORS

ASME NQA-1 [2] requires the organization to use operators that are experienced or trained in the use of special handling and lifting equipment.

13-600 MARKING OR LABELING

ASME NQA-1 [2] requires the organization to use marking or labelling as necessary to maintain and preserve the item.

17 QUALITY ASSURANCE RECORDS

17-300 AUTHENTICATIONS OF RECORDS

ASME NQA-1 [2] requires the organization to consider documents as valid records only after they have been authenticated.

17-500 RECEIPT CONTROL OF RECORDS

ASME NQA-1 [2] requires the organization to designate a person or organization responsible for receiving records and provide a method for controlling the receipt of records.

17-600 STORAGE

ASME NQA-1 [2] requires the organization to store records at a predetermined location(s) in a manner that minimizes the risk of loss, damage, or destruction.

18 AUDITS

18-200 SCHEDULING

ASME NQA-1 [2] requires the organization to schedule audits.

18-400 PERFORMANCE

ASME NQA-1 [2] requires the organization to conduct audits against specified requirements, using the examination of objective evidence to determine effective implementation of requirements.

18-500 REPORTING

ASME NQA-1 [2] requires the organization to ensure that the Lead Auditor endorses the audit report and issues it to the audited organization. It also specifies the contents of the audit report.

18-800 RECORDS

References


