

From Ground Zero to Audit-Ready:

Implementing an NQA-1 Quality Management System

Manufacturers, fabricators, service providers, and commercial suppliers entering the nuclear supply chain need more than a written quality program; they need a system that can be demonstrated through records, shop-floor controls, and audit-ready objective evidence. This article presents a phased approach for establishing an auditable NQA-1 quality management system (QMS), focusing on the controls, implementation priorities, and readiness practices needed to move from conventional quality practices to nuclear-grade expectations.

NQA-1, 10 CFR Part 50 Appendix B, and Supplier Qualification

A supplier entering the nuclear market generally must implement the American Society of Mechanical Engineers (ASME) NQA-1 standard, work through a qualified third-party dedication entity, or support customer-led dedication of the items or services provided. The guidance in this article is written from the perspective of a manufacturer or service provider rather than a nuclear facility. It does not attempt to provide a complete method for third-party dedication or Commercial Grade Dedication (CGD). Instead, it frames CGD at a practical level and directs suppliers toward engineering-led procedures aligned with NQA-1 Part II, Subpart 2.14, customer requirements, and applicable regulatory guidance.

The ASME NQA-1 standard outlines 18 requirements essential for nuclear-grade manufacturing, ranging from organizational structure (Reqs. 1-2) to design, document

control, and records (Reqs. 3, 5-6, and 17); procurement and supplier qualification (Reqs. 4 and 7); material management (Reqs. 8-9); inspection and testing (Reqs. 10-12); and nonconformance management (Reqs. 15-16). The full set of requirements, which also includes handling, storage, and shipping (Req. 13), operating status (Req. 14), and audits (Req. 18), supports traceability, control, and auditability across the quality program.

In the nuclear industry, an NQA-1 quality management system is typically flowed down as a facility customer requirement and serves as one method for implementing the quality criteria in 10 CFR Part 50, Appendix B. Nuclear facility customers often invoke Appendix B and flow down NQA-1 expectations to suppliers to support effective implementation.

Although ASME offers an NQA-1 supplier certification program, it is not universally required. The nuclear industry has not yet adopted this certification program as a mainstream supplier-entry requirement, so its value may vary by customer, market segment, and supplier size.

Why Culture Comes First

Building an NQA-1 program (or ISO 19443 for that matter) from the ground up is a major organizational change because the standard depends on traceability, documented decisions, disciplined work controls, and timely correction of conditions adverse to quality.

For a manufacturing facility without an existing quality management system (QMS), the transition requires careful, systematic planning. Foundational management controls should be established first, followed by technical, procurement, inspection, testing, and verification controls.

Before implementation begins, a nuclear safety culture must be established and documented. This culture is not limited to conventional industrial safety concerns such as slips, trips, and falls, although those issues remain important. Nuclear safety culture includes the behaviors, decision-making, accountability, and questioning attitude needed to protect safety-related functions and preserve the integrity of safety-related items and services. The Quality Department supports other departments through verification and continuous improvement rather than acting in a policing capacity. In short, Quality should function as a service department, not a policing department.

In nuclear manufacturing, quality cannot be treated as a final inspection activity; it must be built into planning, purchasing, production, verification, and records. A phased implementation approach helps an organization move from informal practices to nuclear-grade controls in a controlled and auditable way. The following overview summarizes that progression:

Table 1 -- Phased Implementation Overview

Phase	Primary Focus	Key Activities	Primary NQA-1 Requirements Addressed
Phase 1	Establish governance, culture, and personnel qualification	Create the QAM and policy, define organizational independence, assign QA authority, and begin qualification planning.	Requirements 1 and 2

Phase 2	Build document, procurement, work, and traceability controls	Control procedures, drawings, records, design activities, procurement documents, supplier qualification, material identification, and special processes.	Requirements 3 through 9 and 17
Phase 3	Verify performance, correct problems, and demonstrate readiness	Implement inspection, testing, calibration, status control, handling/storage/shipping controls, nonconformance control, corrective action, and internal audits.	Requirements 10 through 16 and 18

3-Phase Implementation Strategy

Attempting to deploy all 18 requirements at once can overwhelm a workforce. The phased structure in this article organizes implementation into manageable steps so the organization can build capability, allow the culture to adjust, and give personnel time to learn and apply the requirements effectively.

This phased approach prepares a manufacturing facility for customer supplier qualification audits, internal supply chain audits, applicable certification assessments, and other readiness reviews that may be required before safety-related work is awarded.

Practical First Steps

- Assign an executive sponsor and define independent QA authority.
- Perform a gap assessment against the applicable NQA-1 requirements and customer quality clauses.
- Draft the Quality Assurance Manual (QAM), quality policy, and initial implementing procedures.

- Build a training and qualification matrix for personnel who affect product or service quality.
- Prioritize document control, procurement control, records control, material traceability, inspection, and corrective action.

Detailed Implementation Guidance

Phase 1: Establish Governance, Culture, and Personnel Qualification

- **Create the Independent Quality Assurance Structure**
 - Establish the framework required by NQA-1 Introduction, Requirement 1 (Organization) and Requirement 2 (QA Program and Personnel Qualifications/Training).
- **Define Organizational Independence:** Create organizational charts that show QA personnel reporting directly to upper management, rather than to production, project, or finance supervision.
- **Appoint a Dedicated QA Manager:** This individual must have the authority to halt production when a condition adverse to quality (CAQ) is identified and must report directly to top management to maintain independence from cost and schedule pressures.
- **Draft a Quality Assurance Manual (QAM) and Quality Policy Statement:** This high-level document serves as the organization's operational quality policy. It describes how the facility will comply with NQA-1 as one means of implementing 10 CFR Part 50, Appendix B. A cross-functional QAM team with representatives from multiple departments can help ensure that the manual and policy statement serve the entire organization. This approach encourages teamwork, strengthens

buy-in, and reinforces that nuclear quality is a company-wide responsibility rather than a QA-only function.

The quality policy statement should be concise, but it must clearly describe independence, compliance expectations, and management commitment. The following sample language may be adapted by a manufacturer to reflect its own organization, scope, and customer requirements:

Example Quality Policy Statement

Our nuclear quality policy is to protect safety-related functions by complying with applicable NQA-1 requirements, customer quality clauses, and approved procedures. Each employee is responsible for following established controls, documenting work accurately, and raising concerns when quality or safety could be affected.

At X Company, safety and quality are our highest priorities. The Quality Department and its personnel operate independently of production and cost pressures and report directly to top management. The Quality Manager has full authority to create, manage, and monitor the Quality Management System and to ensure that it remains effectively implemented. This includes the following focus areas:

- ***Independent Reporting:*** *The Quality Manager has authority to maintain the QMS, verify implementation, and stop work when necessary to protect public safety, employee safety, product integrity, or compliance.*
- ***Applicable Compliance:*** *We comply with applicable NQA-1 requirements, customer specifications, and approved procedures for the items and services within our scope.*
- ***Error Prevention:*** *We identify issues early, correct causes, and reduce opportunities for recurrence through controlled processes and documented corrective action.*
- ***Continuous Improvement:*** *We strengthen personnel competence, evaluate process performance, and improve procedures when evidence shows change is needed.*

- **Stop Work Authority:** *Every worker has the right and duty to stop unsafe or nonconforming work and to report the concern immediately to the appropriate supervisor, Safety Manager, and/or Quality Manager.*
- **Traceable Quality:** *We maintain accurate records that show what was performed, what materials were used, who performed or verified the work, and whether acceptance criteria were met.*

Example Quality Goal

Our goal is to earn trust through reliable performance, disciplined execution, and complete quality records. We provide nuclear-grade products and services that meet customer requirements and support safe, reliable operation.

- **Identify Critical Roles and Roles Requiring Authorization:** Pinpoint all positions that directly affect safety-related functions or impact work quality, including welders, non-destructive examination (NDE) technicians, inspectors, and auditors. Identify all positions whose work touches or affects product or service quality and maintain documented objective evidence of their competence.
- **Train and Certify Personnel (ref. NQA-1 Requirement 2)**

An NQA-1 system relies heavily on documented personnel competence. The workforce must move from informal on-the-job training to a structured qualification program. Before beginning this transition, the organization should create a procedure that defines the qualification process and required qualifications. This may also require a written practice for NDE technicians and certain testing roles, using guidance such as the American Society for Nondestructive Testing (ASNT) SNT-TC-1A. For welding roles, the organization should consult applicable design codes and American Welding Society (AWS) or American Society of Mechanical Engineers (ASME) references.

- **Document Personnel Qualifications:** Document the education, experience, and training for each worker in a quality-affecting role, and maintain those qualifications through annual reviews and periodic recertifications, as applicable.
- **Issue and Document Certifications:** Provide written certifications signed by management for specialized roles, such as Level II/III inspectors, NDE technicians, and Lead Auditors authorized to perform assigned duties. NQA-1 Requirement 2 includes specific qualification requirements for NDE technicians and Lead Auditors, so those requirements should be understood and incorporated into the program.

Phase 2: Build Document, Procurement, Work, and Traceability Controls

A company operating without a QMS often struggles with inconsistent documentation practices. Requirement 5 (Instructions, Procedures, and Drawings) and Requirement 6 (Document Control) provide the framework for establishing effective written controls.

- **Establish a Procedure for Procedures:** Create a standard format and approval process for all manufacturing instructions and engineering drawings so they are consistent, easy to follow, easy to train on, and straightforward to audit.
- **Create Process Procedures:** For each operational area that needs to be controlled under an NQA-1 quality management system, create a procedure or instruction detailing the purpose, scope, responsible parties, steps/instructions, outputs, documentation, and related records.
- **Build a Records Management System:** Set up secure storage areas, often requiring specific fire ratings if in cabinets or secured rooms, to protect lifetime

nuclear records from damage, loss, or deterioration. Temporary records also need to be controlled. If electronically controlling records and record storage, ensure there is a procedure for the process.

- **Enforce Version Control Through Periodic Internal Compliance Surveys:**

Use focused reviews, similar to mini audits, to verify that workers are using only the latest approved revision of each drawing, procedure, or instruction sheet.

- **Create Traceability and Work Controls**

- **Secure Material Traceability and Work Controls:** Mark material before cutting or processing so identification remains with each piece throughout production. Controls should also address material compatibility, including the use of appropriate tools for stainless materials when contamination could affect quality. Traceability documentation, including Certificates of Conformity (CoCs), Certified Material Test Reports (CMTRs), and procurement records, should be maintained with the work package or quality record set.
- **Control Material Origin, Status, and Special Processes:** Nuclear manufacturing requires objective evidence of material origin to prevent the use of suspect, counterfeit, or incorrect items. Requirement 8 (Identification and Control of Items) and Requirement 9 (Control of Special Processes) govern this stage.
- **Implement Unique Traceability Tags:** Use unique serial numbers, heat numbers, or stamps to track every piece of raw material from receipt through final production.

- **Control Handling, Storage, and Shipping:** Establish controls to protect items from damage, contamination, deterioration, mix-ups, loss of identification, and improper packaging during receipt, storage, movement, preservation, and shipment.
- **Standardize Design and Work Controls:** Replace informal engineering and manufacturing practices with documented verification, validation, configuration control, and controlled work instructions.
- **Establish Design Verification:** Ensure a qualified engineer—different from the original designer—reviews and checks all engineering calculations and drawings.
- **Control Software and Digital Systems:** Software used for design, inspection, calibration, records, production control, or acceptance activities may require validation, access control, configuration control, and documented change control.
- **Control Materials:** Use unique serial numbers, heat numbers, or tags to track every piece of raw material from receipt through final production.
- **Use Detailed Manufacturing Travelers:** Replace verbal commands with step-by-step travelers or routing sheets that workers must initial and date as they complete each task. These travelers can also document status per Requirement 8 and include inspection and testing sign-offs.
- **Qualify Special Processes:** Validate technical manufacturing methods, such as welding or heat treating, before production begins to ensure they meet applicable nuclear specifications and are documented accordingly. Also verify applicable design and testing code requirements, including situations where another

standard or code, such as ASME Section III, may invoke ASME NQA-1 requirements.

- **Manage Procurement and the Supply Chain:** Product quality depends on the materials, items, and services procured to support production. Requirement 4 (Procurement Document Control) and Requirement 7 (Control of Purchased Items and Services) protect supply chain integrity by requiring technical and quality requirements to be flowed down, verified, and documented.
- **Evaluate Suppliers and Build an Approved Suppliers List (ASL):** Before buying materials, audit your suppliers or evaluate their quality history to place them on an Approved Suppliers List (ASL).
- **Define Procurement Quality Requirements:** Write clear purchase orders that explicitly identify the technical and NQA-1 quality requirements suppliers must follow. Organizations that provide design services may also use a procurement specification to communicate custom requirements that accompany the purchase order.
- **Commercial Grade Dedication (CGD):** If you must purchase standard commercial parts to bring up to nuclear grade, establish a CGD process. This process should be driven by the responsible engineering organization, which performs the technical evaluation, determines critical characteristics, and defines acceptance criteria, including inspection and/or testing, in conjunction with quality representative(s). This article introduces CGD at a high level only; detailed implementation should be controlled through engineering-led procedures aligned

with NQA-1 Part II, Subpart 2.14, customer requirements, and applicable regulatory guidance.

Phase 3: Verify Performance, Correct Problems, and Demonstrate Readiness

The final phase verifies product quality, confirms process effectiveness, and establishes mechanisms to correct problems and prevent recurrence as part of continual improvement.

Inspection, Testing, Calibration, and Status Control

Requirement 10 (Inspection) and Requirement 12 (Control of Measuring and Test Equipment) require the facility to verify that processes yield compliant products.

- **Maintain Traceable Calibration:** Ensure all measurement and test equipment, such as calipers, gauges, and micrometers, is calibrated against national or international standards, including those maintained by the National Institute of Standards and Technology (NIST). When customer requirements apply, verify whether the calibration laboratory must be accredited to ISO/IEC 17025 and whether additional quality assurance requirements must be included in the program.
- **Establish Mandatory Hold Points:** Insert specific stops in the production traveler where work cannot continue until a quality group inspector or customer representative examines the item. Witness points may also be implemented in order to notify the customer of an upcoming critical work step, but they are not necessarily hold points.

- **Use Physical Status Indicators:** Use physical tags (such as Accept, Hold, or Reject) to clearly identify the inspection status of items on the shop floor.

Nonconformance, Corrective Action, and Internal Audits

An effective NQA-1 system requires disciplined self-evaluation and error correction. These activities are governed by Requirement 15 (Control of Nonconforming Items) and Requirement 16 (Corrective Action), and they are reinforced through internal audits under Requirement 18.

- **Isolate Nonconforming Items:** When a part is found to be defective, tag it immediately and move it to a locked hold area to prevent accidental use.
- **Launch a Corrective Action Program (CAP):** Document significant errors, perform structured root-cause analysis using tools such as 5 Whys or 8D, and revise processes to prevent recurrence.
- **Conduct Internal Audits:** Schedule regular internal audits of processes and procedures, led by qualified Lead Auditors, to verify that each department follows the QA Manual and implementing procedures. Lead Auditors have specific Requirement 2 qualifications, and auditors should also meet applicable qualification expectations. When possible, personnel should audit departments other than their own to support objectivity and broaden organizational understanding.

Execution, Readiness, and Marketing Strategy

Finally, audit readiness and market readiness should be considered together. Once manufacturers are ready to provide items and services to the nuclear industry, they should

be prepared to demonstrate qualification before a safety-related order is placed. Because the industry depends heavily on supplier qualification, organizations can improve market access by maintaining objective evidence, preparing for customer audits, and avoiding repeated or duplicative audits where shared-audit approaches are available.

Examples of objective evidence include signed travelers, inspection reports, test records, calibration certificates, material traceability records, supplier evaluations, purchase orders, documented flow-down reviews, training records, corrective action closures, and completed internal audit reports. Once approved, organizations may also present approval-status certificates or other qualification evidence in appropriate supplier profiles, capability statements, or customer-facing materials.

Audit Readiness: Customer Audits and Third-Party Audits

Audit readiness may be evaluated through internal audits, independent assessments, customer audits, or supplier organization audit processes. Manufacturers and service providers may also reduce repeated audits by participating in supplier organizations such as NIAC, where appropriate, because shared-audit approaches may reduce the need for multiple customer audits. Facility-type organizations may participate in organizations such as NUPIC, which represents companies that supply directly to nuclear facilities rather than manufacturers. NIAC and NUPIC are known to hold annual or semi-annual member meetings at the same locations and during the same timeframe, creating opportunities to network with suppliers and potential customers.

The checklist below identifies items that should be effectively implemented before an audit:

Table 3 -- Audit-Readiness Checklist

√	Activity verified	Responsible party
	Approved Quality Assurance Manual and implementing procedures	
	Training and qualification matrix with supporting records	
	Calibration records and traceability evidence	
	Approved Suppliers List, supplier evaluations, and audit records	
	Purchase order quality clauses and completed flowdown reviews	
	Completed travelers, inspection records, test records, and status evidence	
	Nonconformance reports, corrective action records, and closure evidence	
	Internal audit schedule, audit reports, and follow-up actions	
	10 CFR Part 21 process evidence, including personnel training and reporting expectations when applicable. This process should include controls for handling and reporting suspect, counterfeit, and defective parts.	

- **Present Certifications and QMS Information Clearly:** List current certifications, quality program scope, inspection capabilities, special process qualifications, calibration approach, and NQA-1 readiness in website content, supplier profiles, capability statements, marketing materials, and customer discussions so potential customers can determine how and whether they can qualify the organization.

- **Be Transparent When Full NQA-1 Implementation Is Not Yet Complete:** If the organization is not yet fully implementing NQA-1, prepare commercial-grade dedication support documentation, clearly explain current capabilities, and identify what customer involvement or dedication support may be needed. Also, have suspect/counterfeit item controls and a 10 CFR Part 21 evaluation and reporting process in place, supported by objective evidence of personnel training and defined reporting expectations.
- **Use Supplier Organizations Strategically:** Consider supplier organizations such as NIAC, where appropriate, to support shared audit approaches, customer visibility, and networking within the nuclear supply chain.

Even when the quality management system is mature, customer-specific requirements remain critical. NQA-1 implementation must be aligned with customer purchase orders, quality clauses, technical specifications, source inspection requirements, reporting expectations, and applicable code requirements. Supplier readiness is strongest when written procedures, shop-floor practices, and completed records tell the same consistent story. If customer requirements override the organization's codes, standards, or internal procedures, that direction should be documented with objective evidence to avoid regulatory or customer audit nonconformances.

Quick Reference: Summary of the 18 NQA-1 Requirements

The following table summarizes the 18 core NQA-1 requirements that a quality management system must address. It is intended as a practical cross-reference to the phased implementation guidance presented earlier in the article.

Table 2 -- Summary of the 18 NQA-1 Requirements

Requirement Number	Requirement Name	Core Implementation Focus
1	Organization	Independent Quality Assurance reporting structure
2	Quality Assurance Program	Training, certification, and the QA Manual
3	Design Control	Verifying calculations and software
4	Procurement Document Control	Including quality requirements in purchase orders
5	Instructions, Procedures, Drawings	Creating clear, written steps for all work
6	Document Control	Ensuring workers use correct revisions
7	Control of Purchased Items/Services	Evaluating suppliers and auditing their shops
8	Identification and Control of Items	Traceability via heat numbers, tags, or stamps
9	Control of Special Processes	Qualifying welding, heat treating, and NDE
10	Inspection	Planning independent checks during production
11	Test Control	Demonstrating items will perform in service
12	Control of Measuring and Test Equipment	Calibrating tools back to national standards
13	Handling, Storage, and Shipping	Preventing damage, contamination, deterioration, or loss of identification
14	Inspection, Test, and Operating Status	Identifying accepted, held, rejected, or otherwise controlled items
15	Control of Nonconforming Items	Segregating nonconforming items so they are not used
16	Corrective Action	Identifying root causes so errors do not recur
17	Quality Assurance Records	Storing quality records safely for the required retention period
18	Audits	Checking your own system to ensure compliance

Conclusion

Ultimately, implementing an NQA-1 quality management system changes how a manufacturer plans, performs, verifies, and documents work. The strongest programs are built in phases, supported by safety culture, reinforced through traceability, and proven through objective evidence. Organizations that can demonstrate that discipline are better positioned to support nuclear projects, meet customer expectations, and pursue long-term opportunities in the nuclear supply chain.

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Author Information

Laura Suddath is an NQA-1 subject matter expert and quality assurance professional with experience supporting nuclear quality programs, supplier evaluation and audit, Commercial Grade Dedication guidance, technical documentation, and implementation of quality requirements for safety-related work. Her work focuses on translating complex nuclear regulatory and code requirements into practical, auditable controls for engineering, procurement, and fabrication activities. Laura is a Quality Engineer, Lead Auditor (AS9100 and NQA-1) and Certified Welding Inspector.

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For information or questions about this article, please contact Laura Suddath at laurasuddath@gmail.com.