

Basic Quality Management Beginner's Guide to Qualifying Distributors in the Nuclear Industry

Author's note: This beginner's guide is written as a plain-language educational overview for personnel who need to understand distributor qualification without first being experts in nuclear procurement quality assurance. It summarizes common industry practices and public source material while using original explanations, examples, and practical framing.

Qualifying distributors in the nuclear industry is a mandatory safety-focused process that helps ensure parts used in nuclear applications are genuine, safe, traceable, and supported by appropriate documentation. In practical terms, distributor qualification asks a basic question: can this organization consistently provide the correct item, with the correct paperwork, under the correct controls, for the intended nuclear application? Unlike ordinary commercial suppliers, nuclear suppliers—including distributors—must be able to demonstrate that the items they provide meet applicable technical, quality, and regulatory requirements.

Nuclear buyers cannot risk counterfeit parts, unverified materials, or incomplete documentation entering the supply chain. This guide explains how organizations evaluate and approve distributors to help keep nuclear facilities operating safely and reliably.

Why Nuclear Distributors Need Strict Rules

Nuclear facilities use thousands of parts, including valves, pipes, fasteners, instruments, and electrical components. If a small part fails in a regular factory, the equipment may simply stop. If a part fails in a nuclear reactor or safety-related system, it could contribute to a radiation release, a major power outage, or conditions that place workers, the public, or the environment at risk.

Because of this risk, parts are split into two groups:

- **Safety-related:** Parts that support safety functions, including protection of the reactor core and prevention or mitigation of radiological release.
- **Non-safety-related:** Parts used for normal plant operations that are not credited with performing a nuclear safety function.

There is also a third risk-significant group that is often customer driven, such as reliability significant or non-safety-related with special treatment classifications, but that topic is outside the scope of this article.

Distributors may sell both types of parts. To provide safety-related parts, a distributor must go through a documented review process called **qualification**. The primary standards and regulatory frameworks used for this process are discussed below.

The Rulebooks for Nuclear Quality

To qualify a distributor, buyers rely on requirements that may come from regulations, consensus standards, customer specifications, procurement documents, or contractual commitments. It is important to distinguish the source of each requirement because a legal requirement, an invoked industry standard, and a customer-imposed purchasing requirement may carry different obligations. The most common frameworks include the U.S. Nuclear Regulatory Commission (NRC), the American Society of Mechanical Engineers (ASME), and the International Organization for Standardization (ISO) (American Society of Mechanical Engineers, 2024; International Organization for Standardization, 2018; U.S. Government Publishing Office, 2025):

- **10 CFR Part 50, Appendix B:** A U.S. regulation that establishes quality assurance criteria for nuclear power plants and fuel reprocessing plants. These criteria apply to the quality assurance program used for activities affecting safety-related structures, systems, and components when invoked by the applicable licensing and procurement framework (U.S. Government Publishing Office, 2025).
- **ASME NQA-1:** A consensus nuclear quality assurance standard that provides requirements and guidance for establishing and implementing quality assurance programs for nuclear facility applications. For buyers, its value is practical as well as procedural: it gives auditors and procurement personnel a common structure for reviewing procurement, document control, inspection, testing, records, audit, and corrective action expectations. Customers often invoke NQA-1 contractually. See Requirement 7, paragraph 200, for guidance on qualifying a nuclear supplier (American Society of Mechanical Engineers, 2024).
- **ISO 19443:** An international quality management system standard based on ISO 9001:2015 for organizations in the nuclear energy supply chain that provide products or services important to nuclear safety. In supplier qualification discussions, ISO 19443 is often useful because it connects familiar quality-management language with nuclear-specific expectations such as safety culture, graded application, counterfeit item prevention, competence, and traceability (International Organization for Standardization, 2018).

U.S. Rules Versus International Rules

Different countries have different frameworks for evaluating nuclear distributors. A distributor qualified to sell parts in the United States may need different certifications or customer approvals to sell parts in Europe or Asia. The United States regulatory model engages:

- **Legal Focus:** The U.S. uses the **10 CFR Part 50 Appendix B** legal framework.
- **Utility Audits:** The NRC does not directly qualify distributors. Instead, the utilities (nuclear plant owners) or manufacturers do it.
- **NQA-1 Standard:** Utilities and manufacturers look for the **ASME NQA-1** standard during audits.

Other Qualification Methods through Joint Audits

Qualified Distributor qualification can also be supported through shared audit programs. These programs help reduce duplicate audits while still allowing member companies to evaluate supplier quality programs against nuclear industry requirements.

NUPIC: The Nuclear Procurement Issues Corporation supports joint supplier audits for nuclear utilities and international nuclear plant operators. A NUPIC audit may help multiple utilities rely on a common audit process instead of each utility auditing the same supplier separately; however, each organization remains responsible for evaluating the results under its own quality assurance program (Nuclear Procurement Issues Corporation, n.d.; U.S. Nuclear Regulatory Commission, 2025).

NIAC (Nuclear Industry Assessment Corporation). It supports shared supplier evaluations among member companies. NIAC helps procurement quality assurance professionals share assessment results, reduce redundant supplier audits, and apply a more consistent assessment approach. In plain language, these programs help buyers avoid repeating the same supplier review when credible assessment information is already available from an accepted industry process.

Europe and International Markets (The ISO Model)

- **ISO 19443:** European countries like France rely heavily on **ISO 19443**. This standard blends standard business quality (ISO 9001) with nuclear safety practices.
- **Third-Party Badges:** Instead of utility groups doing the audits, independent companies perform the assessments and issue the ISO certificates. A distributor gets certified once and can share it with any European plant buyer.

- **Safety Culture:** The European model places strong emphasis on a distributor's nuclear safety culture. Personnel involved in receipt, storage, handling, documentation, and shipment should understand how their work can affect nuclear safety, making documented training essential.

Emerging Global Markets

- **Export Restrictions:** The U.S. has strict export control laws handled by the Department of Energy and the NRC. A U.S.-qualified distributor must obtain appropriate authorization before shipping controlled parts or technical information to foreign plants.
- **Market Expectations:** In places such as the United Kingdom, United Arab Emirates, and the Czech Republic, having an **ISO 19443** certificate is increasingly important when competing for nuclear supply contracts.

The Steps to Qualify a Distributor

Buyers use a defined process to evaluate a new distributor before placing safety-related purchase orders. The process usually begins with a supplier questionnaire, followed by document review, technical evaluation, and, when warranted, an on-site survey or audit.

Distributor Qualification Checklist

A buyer's qualification review should be scaled to the safety significance of the item or service being procured. The checklist below is an original, simplified training aid that summarizes common evidence a buyer may review before adding a distributor to an Approved Supplier List.

Review Area	Typical Evidence	Purpose
Quality program scope	Quality manual, procedures, certifications, and customer-specific flowdowns	Confirms whether the distributor's program supports nuclear or safety-related procurement requirements.
Traceability	Certificates of conformance, material test reports, purchase records, and receiving records	Verifies that items can be traced to the original manufacturer or applicable source documentation.
Procurement controls	Approved supplier list, purchase order review process, and sub-tier supplier controls	Ensures requirements are correctly passed to sub-suppliers and verified at receipt.

Storage and handling	Warehouse controls, segregation practices, preservation requirements, and shelf-life controls	Protects parts from damage, degradation, misidentification, or unintended substitution.
Training and competence	Training matrix, qualification records, job-specific training, and refresher training	Shows that personnel understand applicable nuclear quality and safety expectations.
Nonconformance and corrective action	Nonconformance reports, corrective action records, trend data, and customer notification process	Confirms that problems are identified, contained, corrected, and communicated when required.
Counterfeit, fraudulent, or suspect items	Inspection controls, supplier screening, reporting process, and employee awareness training	Reduces the risk of unacceptable or misrepresented items entering the nuclear supply chain.

1. The Pre-Check Questionnaire

First, the buyer sends a questionnaire, often called a Request for Information. The distributor must answer questions about its business and quality controls:

- How long have they been in business?
- How many employees do they have?
- Do they have a formal quality manual or quality management system?
- Can they track where they bought every single part?
- Do they hold any quality management system certifications (verify scope)?

2. The On-Site Survey or Audit

If the questionnaire results are acceptable, the buyer sends trained auditors to the distributor's facility. This review may be called a survey or an audit. The auditors typically focus on four main areas when qualifying distributors:

- **Traceability:** The distributor must provide an unbroken documentation trail for each item back to the original manufacturer or applicable source documentation. For material items, this may include certificates of conformance, material test reports, heat numbers, lot numbers, and receiving records. It is preferred that items are provided in original manufacturer's packaging with traceable markings.

- **Storage and Handling:** Parts must be protected from damage, corrosion, contamination, commingling, and loss of identification. Auditors review warehouse organization, preservation controls, shelf-life practices, segregation, packaging, and environmental controls.
- **Training:** Employees must have documented training to handle nuclear-grade parts.
- **Error Control:** The distributor must have processes to identify, segregate, document, evaluate, and resolve nonconforming or suspect items before shipment. This includes nonconformance tracking, corrective action, customer notification when required, suspect/counterfeit item controls, and applicable 10 CFR Part 21 awareness or reporting provisions.

This survey or audit should be managed by a qualified Lead Auditor under the applicable quality program requirements and should include an audit or survey plan, checklist, and final report.

3. Joining the Approved Supplier List (ASL)

If the distributor passes the on-site audit, they are added to the buyer's **Approved Supplier List**. Only companies on this list can receive contracts to provide safety-related parts to that nuclear facility. If the distributor does not pass, any nonconformances identified during the audit must be resolved and accepted by the lead auditor before the audit can be closed with an approved status. Continued approval relies on periodic reassessments of the quality management system.

How to Handle Standard Commercial Distributors Without a Nuclear-Grade Quality Management System

Many distributors do not maintain a full nuclear quality assurance program because the cost and administrative burden can be high. If a nuclear facility needs a standard commercial item for a safety-related application, it may use a special acceptance path called **Commercial Grade Dedication (CGD)**. CGD is not the same as qualifying the distributor's entire quality management system. Instead, CGD focuses on a specific commercial item and establishes objective evidence that the item is acceptable for its intended safety function (U.S. Nuclear Regulatory Commission, 2022). Items and services are accepted for nuclear use through the CGD process – usually Methods 1 and 2 – to ensure compliance. To perform CGD, an item must meet both of the following requirements: 1. It must have a safety function; 2. It must meet one of the CGD definitions noted in the beginning of NQA-1 Part II Subpart 2.14. If it does not meet either one of those, CGD cannot take place.

During CGD, a qualified nuclear organization or qualified third-party CGD service provider evaluates the item, its intended safety function, and the critical characteristics that must be verified. The process typically begins with a technical evaluation, a dedication plan, and selection of acceptance methods. Depending on the item and acceptance criteria, CGD may include testing, inspection, source verification, survey of the commercial supplier, or review of manufacturer controls. These activities may also require verification that extends back to the original manufacturer when the distributor alone cannot provide sufficient evidence. A practical way to think about CGD is this: the dedicating organization is building a documented bridge between a commercial purchase and a nuclear safety-related use. CGD should not be treated as a paperwork shortcut. It is a planned, documented process requiring experienced personnel, clear acceptance criteria, and rigorous oversight to ensure that the final dedication package supports use in a safety-related nuclear application (U.S. Nuclear Regulatory Commission, 2022).

Keeping the Qualified Status

Qualification is not a one-time approval. To remain on the approved supplier list, distributors must be monitored through recurring reviews:

- **Annual Performance Reviews:** Buyers review whether the distributor delivered orders on time, provided acceptable documentation, and avoided quality issues.
- **Re-Audits:** Every few years, auditors return to the warehouse to ensure quality remains high.

SMRs and the Changing Role of Distributors

The rise of Small Modular Reactors (SMRs) is changing how nuclear plants are built and how distributors operate. Traditional gigawatt-scale plants are massive construction projects built largely on-site. By contrast, SMRs are designed for greater use of factory assembly and modular delivery, which shifts more quality control activity into manufacturing and supply-chain environments. This article treats that shift as a procurement-quality issue: if more work moves into factories and supplier networks, distributors may carry more responsibility for preserving documentation, configuration, and traceability before parts ever reach a construction site.

This shift alters the nuclear supply chain for distributors in several major ways:

- **From Field Construction to Factory Assembly:** SMR developers are becoming major buyers of qualified parts and services. Distributors may ship more parts to central manufacturing hubs rather than directly to large, site-based construction projects.

- **Mass Production and Volume:** SMRs rely on repeatable designs and standardized modules. Distributors must be ready to supply higher volumes of identical, highly controlled nuclear-grade components instead of only specialized, one-off parts.
- **Specialty Material Bottlenecks:** SMRs may rely on advanced materials and high-performance electronics. Distributors that specialize in high-specification alloys, nuclear-grade materials, or specialized electronics may face stricter documentation and traceability expectations because of limited global supply options.
- **Bridging the Standardization Gap:** Because SMR developers are looking for cost-effective, repeatable supply chains, distributors may increasingly help bridge the gap between commercial suppliers and nuclear quality requirements. In some cases, this means supporting CGD activities so a commercial item can be accepted for a specific safety-related application.

Conclusion

Qualifying nuclear distributors is an intensive but necessary process for protecting public health, worker safety, and the environment. The nuclear supply chain cannot rely on trust alone; it must rely on documented evidence, controlled processes, traceable materials, and rigorous oversight. As SMRs move nuclear construction toward factory-based production, qualified distributors will become even more important to supply-chain safety and reliability. Their role will no longer be limited to moving parts from one location to another; they will be expected to support traceability, documentation, Commercial Grade Dedication, material verification, and compliance with both U.S. and international quality expectations. For project, procurement, and quality personnel, the key lesson is simple: nuclear distributor qualification is not just a purchasing activity—it is a safety function. A distributor that can prove where an item came from, how it was controlled, and why it is acceptable for nuclear use helps protect workers, the public, the environment, and the long-term success of advanced nuclear projects. Stated another way, distributor qualification turns supply-chain confidence into verifiable evidence.

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