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Advanced Nuclear Technology: Supplier Quality Management for New Nuclear Plant Construction Projects

2013 TECHNICAL REPORT

Advanced Nuclear Technology: Supplier Quality Management for New Nuclear Plant Construction Projects

This document does NOT meet the requirements of 10CFR50 Appendix B, 10CFR Part 21, ANSI N45.2-1977 and/or the intent of ISO-9001 (1994).

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Abstract

This report provides guidance for new nuclear power plant construction projects on supplier quality-related risks associated with the procurement of materials, equipment, and services intended for use in a safety-related plant application. This guidance takes an in-depth look into the procurement-related challenges that new construction projects face and at measures for overcoming these challenges. A methodology is provided for identifying, managing, evaluating, and mitigating quality-related risks to prevent or mitigate negative impacts on the project costs and schedule.

Keywords
Supplier quality
Quality assurance
Commercial-grade dedication
Nuclear construction

Executive Summary

Purpose

The intent of this report is to provide guidance to all parties involved in the construction of new nuclear power plants (Owners, Engineer/Procure/Construct firms [EPCs], Purchasers, Suppliers, and so on) regarding Supplier quality issues and to promote quality risk mitigation during procurement of materials, equipment, and services intended for use in safety applications.

The requirements of 10 CFR 50 Appendix B and ASME NQA-1 are applied to the design, procurement, and construction of new nuclear power plants in the United States to assure that the materials, equipment, and services used in construction and operation of these facilities comply with project regulatory, technical, and quality requirements and will properly perform their safety functions in service to ensure that the public will be adequately protected. However, the number of quality issues that occur during production, and the matter of how late in the procurement and construction process the issues are identified and corrected, have significant implications for new nuclear plant construction project costs and schedules.

Supplier Quality Issues

Potential Supplier quality-related issues may include:

- Supplier experience
- Change in Supplier production operations
- Cultural, language, and communication challenges
- Technical or quality requirements on standard products
- First-of-a-kind engineering
- Time since last production of an item
- Schedule pressures
- Limited experience with commercial grade dedication

Risk Management

Proper management of Supplier quality issues can prevent negative impacts to project cost and schedule. A well-prepared Purchaser will review the potential Supplier quality issues associated with the Purchaser's supply chain prior to procurement.

The management of risks associated with Supplier quality issues falls into three categories:

- Effective implementation by Purchasers and Suppliers of key elements of their Appendix B / NQA-1 nuclear QA programs
- Adoption of recommended good practices by Project Owners, Lead EPC firms, Purchasers, and Suppliers to prevent Supplier quality issues from occurring
- A recommended approach to managing the risks of Supplier quality issues—the use of a procurement event by procurement event basis

Benefits

Following this guidance can result in benefits for all involved parties including the Owner, Lead Project EPC, and Suppliers. These benefits include the following:

- Financial benefits resulting from reduced rework and the associated labor hours
- Performance benefits including meeting project schedule or budget goals
- Better understanding of technical and quality requirements that can strengthen business relationships

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Section 1: Introduction

This report and the associated training materials provide guidance on methods used to identify, evaluate, and mitigate Supplier quality-related risks that could negatively impact the construction schedule or project cost for new nuclear plant construction projects. The guidance focuses on risks associated with the procurement of materials, equipment, and services intended for use in safety-related plant applications.

The target audience of this guidance includes all entities procuring or providing such items under their 10 CFR 50 Appendix B (hereafter "Appendix B") or ASME NQA-1 (hereafter "NQA-1") programs at all levels of the project supply chain. This includes Project Owners, Engineer/Procure/Construct (EPC) firms, engineering firms, construction firms, and Suppliers.

This guidance assists Purchasers by providing good practices information, and by defining risks and providing risk mitigation tools that can be used to assure that materials, equipment, and services intended for use in nuclear safety-related applications are delivered on schedule and meet regulatory requirements on delivery.

An EPRI Technical Advisory Group (TAG) developed this guidance. The process used by the TAG to develop this guidance is described in Appendix A.

Section 2: Issue

Several new nuclear power plant construction projects are presently underway or being considered in the United States. Significant challenges exist in ensuring that the materials, equipment, and services provided to these projects will consistently meet project and regulatory requirements at delivery and that delivery dates will meet project schedule requirements.

The requirements of Appendix B and NQA-1 are applied to the design, procurement, and construction of new nuclear power plants in the United States to assure that the materials, equipment, and services used in construction and operation of these facilities comply with project regulatory, technical, and quality requirements and will properly perform their safety functions in service to ensure that the public will be adequately protected.

However, the number of quality issues that occur during production, and the matter of how late in the procurement and construction process the issues are identified and corrected, have significant implications for new nuclear plant construction project costs and schedules. For example, identification at final inspection and test of noncompliances with project technical or quality requirements in a major piece of equipment that has taken twelve months or more to produce can lead to significant project rework costs and schedule delays. The discovery of inadequate commercial grade dedication (CGD) during an inspection by the regulator at a supplier of base plates that have already been installed in the plant is another example. In such a case, field inspections or replacements due to corrective action can result in large consequences to the project cost and schedule.

Successful completion of new nuclear construction projects on schedule and on budget requires efficient and effective planning and execution of quality assurance (QA) and other Supplier oversight activities at many levels of the project supply chain. The selection of quality oversight activities and the timing of those activities need to consider the potential impact on cost and schedule due to possible nonconformances when selecting oversight actions to assure final compliance with all technical and quality requirements.

The magnitude of this challenge is increased by the fact that many nuclear Suppliers do not have extensive prior experience with large-scale production to current United States nuclear regulatory requirements, codes, and standards.

Section 3: Definitions

10 CFR 50 Appendix B / ASME NQA-1 Supplier – A Supplier providing safety-related materials, equipment, or services as basic components produced under their approved nuclear QA program.

Basic Component – *See definition in 10 CFR Part 21* [1].

Commercial Grade Item – When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, *commercial grade item* means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items for which the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (that is, one or more critical characteristics of the item cannot be verified)[1] [1].

Commercial Supplier – A Supplier providing commercial grade materials, equipment, or services produced under their commercial quality program or controls.

Project Owner – The company or entity that initiates and finances the construction project and holds the NRC license for construction and operation of the facility.

Project EPC – The Supplier that, under contract with the Project Owner, is responsible for engineering the project, ensuring that the necessary materials, equipment, and services are procured, and constructing the nuclear project.

Purchaser – "The organization responsible for establishment of procurement requirements and for issuance or administration, or both, of procurement documents" [2].

Purchasers issue purchase orders or contracts for materials, equipment, or services at any level of the project supply chain.

[1] This definition is applicable at the time of writing of this report to nuclear power plants licensed under 10 CFR Part 50. Current draft rulemaking to revise 10 CFR 21 includes proposed changes to this definition.

Safety Conscious Work Environment (SCWE) – Defined by the NRC as a work environment in which "employees feel free to raise safety concerns, both to their management and to the NRC, without fear of retaliation" [3].

Supplier – "Any individual or organization that furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtier levels" [2].

Section 4: Assumptions

It is assumed that the required audit, surveillance, inspection, and test activities are in place and used in a manner compliant with project requirements, and with Purchaser and Supplier commitments to NQA-1 and the requirements of Appendix B.

Consistent with U.S. NRC-stated positions in SECY 03-0117, implementation of an ISO 9000 QA program is not considered equivalent to NQA-1 or Appendix B. ISO 9000 QA programs are one example of a commercial quality program.

It is assumed that all Purchasers and primary Suppliers in the supply chain for safety-related materials, equipment, or services will fully comply with the requirements of 10 CFR Part 21 and that Purchasers will include the requirement to comply with 10 CFR 21 in purchasing documents whenever 10 CFR 50 Appendix B or ASME NQA-1 is imposed.

Section 5: Supplier Quality Issues

Issues with the quality of safety-related materials, equipment, and services provided to new nuclear power plant projects have the potential to significantly impact final project cost and schedule. While the multiple checks included in properly implemented Appendix B / NQA-1 QA programs provide a high level of assurance that these issues will be identified prior to the plants going into operation, it is critical that quality issues are identified and resolved at a point in the production or construction process where project impacts are prevented or minimized.

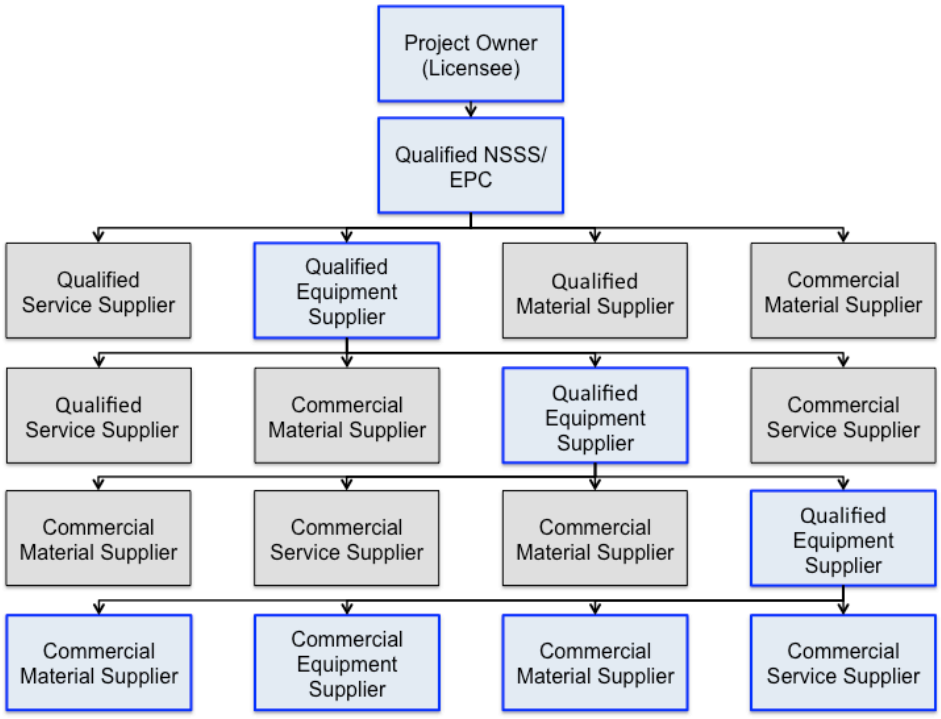

Figure 5-1
Project supply chain map

Figure 5-1 is a generalized project supply chain map for safety-related materials, equipment, and services. At each level of the supply chain, key information is provided to the subtier Suppliers establishing technical and quality requirements as well as contractual terms and conditions including price, payment, and delivery schedule requirements. At each level, Purchasers convert requirements from their

upper-tier customers into requirements for their Suppliers to obtain materials, equipment, and services needed to produce and provide their products. Also at each level, Purchasers make critical decisions about Supplier selection; whether to procure as safety-related from NQA-1 Suppliers or to procure as "commercial grade" and dedicate as allowed by 10 CFR 50 Appendix B and10 CFR 21; and selecting the level of Supplier oversight the provider will impose. Each of these decisions inherently involves risk vs. cost tradeoffs that must be properly evaluated, with oversight focused on areas where quality, cost, or schedule risks are most probable and have the greatest potential impact on cost or schedule.

The EPRI Supplier Quality Management TAG identified types of Supplier quality issues and related risk factors that should be considered as part of identifying, evaluating, and mitigating risks to project cost and schedule associated with Supplier quality issues. TAG members identified these issues through consideration of prior industry experience, "lessons learned," and recent direct experience. Information developed by a prior EPRI TAG during the development of EPRI report 1016693, *Guidance for Managing the Impact of Procured Item Quality Issues on Generating Asset Economic Performance,* was also used as a key input to identification of risk factors.

Sources of "lessons learned" information included review of issues during the earlier (1970s through early 1980s) nuclear plant construction era in the United States; recent experience at foreign nuclear power plant construction projects; recent experience on major modification efforts at operating United States nuclear power plants; and recent experience on large non-power-plant nuclear construction projects in the United States.

The TAG identified a number of potential causes of Supplier quality issues. These are discussed in Section 5.1 below.

5.1 Level of Supplier Experience with 10 CFR 50 Appendix B and ASME NQA-1 QA Program Implementation

Experience has shown that issues with implementation of QA programs and processes occur at a higher rate in the early period following adoption of an NQA-1 program by a Supplier. Audit findings can be significant enough to result in delays in delivery, the need to switch to alternate procurement methods, or the need to turn to an alternate Supplier.

Even Suppliers with significant prior history working under nuclear QA programs may have issues with proper implementation of the QA program requirements on project scopes of supply. Many nuclear Suppliers have not had to process large orders for safety-related equipment—such as the orders placed for new nuclear construction projects—for many, many years. Their current staff may have very limited experience producing their products to their nuclear QA program. Suppliers may expand production and hire new staff, or outsource a portion of the order to others in order to meet the delivery schedule, without adequate training. Procedures used for nuclear safety-related production may be out of date.

Purchasers should evaluate the actual experience of the Supplier staff carefully during Supplier selection, and when developing Supplier oversight plans.

5.2 Significant Change in Supplier Production Operations

Disruptions in the Supplier's operations can result in a reduction in the quality of products provided. Sources of disruption may include the Supplier being purchased by another firm, particularly if a consolidation of facilities and reduction of staff ensued; loss of experienced staff through retirements or turnover; a major redesign of the product; recent rapid increase in production, management, or QA staff levels; or a major change in production tooling. Re-sourcing of sub-Supplier provided materials, equipment, or services to new, unproven Suppliers, or adding new Suppliers to cover an increase in customer demand without proper care in qualification and oversight, can lead to quality and delivery issues.

A common example is the use of a new foreign casting Supplier versus the previous local casting Supplier. Often the decision is made purely upon price, without proper consideration of potential schedule implications. A foreign sub-Supplier can have quality/delivery issues that impact the overall project schedule performance. This is especially true if the Supplier does not inspect the sub-Supplier's products before taking delivery of them. When there are problems, significant delays can result from re-casting/re-manufacturing the part, as well as assembly, inspect, test, and delivery of the final component.

Another example occurred on a recent overseas nuclear construction project. A valve manufacturer purchased another valve Supplier, which was under contract to produce a number of large butterfly valves. Near the end of a production run, the facility that had been producing the valves was closed. The contract valves (which were mostly complete) were shipped to a different valve facility for completion of assembly. The new valve facility only had experience manufacturing small-bore valves (less than 2-1/2 inches). Workers in the small-bore valve facility had never seen large-diameter valves before, let alone butterfly valves, resulting in issues with final assembly and the delivery schedule.

5.3 Placement / Acceptance of Significantly Larger Orders for NQA-1 Materials, Equipment, or Services Than Have Been Produced Historically

Suppliers that have been performing well supplying small quantities of product can be stressed to the point that quality of work is affected when larger orders typical of new power plant construction projects are taken on.

Many nuclear Suppliers have primarily been producing spare and replacement parts for their equipment currently installed in the operating nuclear power plant fleet for a very long time. Their production staff may have very limited or no recent experience with production of entire new components to nuclear specifications and QA program requirements. In some cases, the first large orders to such firms are nearly as high a risk as ordering items from Suppliers who have just entered the nuclear business.

5.4 Cultural, Language, and Other Communication Challenges

There are many types of communication challenges. They start with ensuring that the requirements of the Purchaser's specifications are clear and that the Purchaser and the Supplier have a common, detailed understanding of those requirements as well as an understanding of how to meet those requirements. Secondly, there needs to be efficient communication and resolution of issues that arise during production that involve the technical requirements, quality requirements, and associated QA activities.

Factors such as large time zone differences, language differences, and cultural differences impact communications and result in differing understandings on the part of the Purchaser and the Supplier as to what the requirements are for the items.

5.5 Specification of "Special Order" Technical or Quality Requirements on Standard Products or Services

Asking a Supplier to do something differently on a given order than what they do every day during production of their standard products is one of the most difficult tasks to get right the first time and is even more prone to error than first production of an entirely new product.

Structure of the technical specifications is a factor in ensuring that special requirements are identified and met by the Supplier. Sometimes, special or unique requirements have not been properly highlighted and discussed with the Supplier, contributing to the Supplier missing these requirements and producing their standard product. Special or unique requirements should not be "buried" in the technical specifications but should be highlighted in a prominent manner.

Special or unique requirements should be a key point discussed during kickoff of the contract prior to production, to make sure that the Supplier clearly understands what is required by the contract and everyone understands how they will meet the requirement. If they cannot meet the requirement, and this was not previously discovered prior to awarding the contract, a meeting should be held to discuss alternate options or a path forward.

5.6 First-of-a-Kind Engineering / Production of the Items Being Ordered

Production of new items by Suppliers puts extra demands on both management and the production staff and often results in high error rates during early production. Early in production, additional oversight may be needed for prevention, detection, and correction of errors.

5.7 Time Since Last Production of the Items Ordered

If the Supplier only produces an ordered item occasionally, identify the last time that the Supplier produced the items. If the time since last production is significant, the risk of error, especially for complex items, may require additional risk mitigation activities.

5.8 Schedule Pressures

Production schedule pressures and/or Purchaser delivery schedule pressures can result in shortcuts being taken that result in quality issues in delivered items. Where schedule pressures are high, additional oversight and over-checks should be considered.

5.9 Limited Experience with ITAAC Inspection, Test, and Documentation

New nuclear power plant construction projects in the United States are licensed using the combined construction and operating license process (COL) under 10 CFR 50.52. A key part of this process includes identification in the application (COLA) of inspections, tests, analyses, and acceptance criteria (ITAAC) that will be used to verify that the plant as constructed meets design requirements and the requirements of the COL. The licensee (Project Owner) is responsible for ensuring that all required ITAAC actions are properly completed and documented. The entire ITAAC process is subject to NRC inspection.

Certain scopes of safety-related materials, equipment, and services will include inspections, tests, or analyses that are part of the ITAAC process. Detailed identification of requirements to perform these inspections, tests, or analyses and the acceptance criteria that must be met, including requirements for the level and type of documentation to be provided by the Supplier, should be clearly identified and defined in procurement documents, discussed during project kickoff meetings, and included as part of the order entry process. Failure to perform and properly document ITAAC-required activities could result in significant delays during the transition from construction to operation.

5.10 Limited Experience / Capabilities in Commercial Grade Dedication

From a regulatory perspective, Appendix B / NQA-1 Suppliers have several options available for procurement of materials, equipment, and services used in the manufacture of their safety-related products:

i. They can procure from approved Appendix B / NQA-1 sub-suppliers;

ii. They can use their Appendix B / NQA-1 program to establish suitability, procure from commercial suppliers, and use commercial grade dedication as the acceptance process that provides reasonable assurance that the specific materials, equipment, or services being procured will perform their safety function(s); or

iii. They can procure from commercial suppliers and apply their Appendix B / NQA-1 program controls to establish suitability for use AND to perform acceptance activities sufficient to assure their product will perform its safety function(s) without use of commercial grade dedication.

Experience has shown that, where approach (ii) is used, many Suppliers have limited experience with performance of CGD activities to industry standards and regulatory expectations. These Suppliers require information from the upper-tier project Suppliers / Lead EPC regarding safety functions and perhaps critical characteristics and acceptance criteria to properly dedicate commercial grade items. Failure to properly perform, approve, and document CGD activities may not be discovered until after item delivery and installation, which results in rework or replacements, with small or large impacts on project costs and schedule depending on the nature of the items dedicated and where they are used in the facility.

5.11 Limited Experience with the Specified Design Codes

Suppliers are often experienced in working to their local or national design codes of their home country. In today's global economy Suppliers are often branching out trying to provide their offerings in new markets. However, in some cases Suppliers do not have deep experience in designing and producing items to codes and standards specified by customers in other countries. Purchasers should plan to apply additional oversight in such cases, regardless of how experienced the Supplier says they are in the specified design code. Issues have arisen late in the design and production cycle, such as the question of who will sign off on design reports when the foreign Suppliers don't have ASME Section III Registered Professional Engineers on staff who can stamp/certify their design.

5.12 Counterfeit, Fraudulent, or Suspect Items

Purchasers at all levels of the project supply chain should be aware of the existence of counterfeit or fraudulent items in the global marketplace. Procurement practices, Supplier selection, receipt inspection, testing, and other quality control practices should be employed to prevent the introduction of counterfeit or fraudulent items into nuclear safety-related products. The U.S. Departments of Commerce and Energy have collected a significant amount of information on fraudulent items, in addition to the information found in communications from the U.S. NRC. Sources of information on counterfeit, fraudulent, or suspect items are listed in Section 8.2.

Section 6: Supplier Quality Issues—Risk Management Guidance

Recommended actions to manage the risk of Supplier quality issues that may negatively impact project cost or schedule are provided in this section of the report. These recommendations fall into three categories:

- Effective implementation by Purchasers and Suppliers of key elements of their Appendix B / NQA-1 nuclear QA programs
- Recommended good practices that should be adopted by Project Owners, Lead EPC firms, Purchasers, and Suppliers to prevent or mitigate Supplier quality issues
- A recommended approach to managing the risks of Supplier quality issues through use of procurement scope and Supplier-specific risk analysis and risk mitigation

6.1 Effective Implementation of Nuclear Quality Assurance Programs by Suppliers

All Suppliers providing safety-related material, equipment, or services (Appendix B / NQA-1 Suppliers) are expected to ensure that their Appendix B / NQA-1 QA programs are fully implemented and applied to safety-related procurements in accordance with their approved QA Program documents.

Strong and consistent executive engagement in support of meeting this objective is essential. Executives at Suppliers providing safety-related material, equipment, or services for nuclear power plants in the United States are expected to take personal responsibility for the effectiveness of their nuclear QA programs. This includes regular executive oversight activities sufficient to determine the effectiveness of the program, and to intervene early when performance indicates the effectiveness of the program is not sufficient.

Robust implementation of QA programs in a manner that meets the expectations of Project Owners, regulatory agencies, and customers is expected for all procurement activities for safety-related materials, equipment, and services. Key elements of a robust implementation include the items discussed below.

6.1.1 Establishing and Maintaining a Nuclear Safety Culture in the Workplace

There are many elements that are key to establishing and maintaining a nuclear safety culture in a Supplier's workplace. The purpose of implementing a nuclear safety culture is to assure that the primary focus in the workplace is to produce and deliver safety-related materials, equipment, or services that meet all specified technical and quality requirements, including QA and documentation requirements. Employees should maintain a questioning attitude and raise any concern during any stage of production with situations that have the potential to negatively affect the final product. Concerns with schedule or cost, while important, must be secondary to quality. Management must establish and promote this approach to nuclear safety-related work throughout the full production cycle.

6.1.1.1 Safety-Conscious Work Environment

A key part of establishing and maintaining a nuclear safety culture is establishing a safety-conscious work environment (SCWE). All Appendix B / NQA-1 approved Purchasers and Suppliers should establish and maintain a SCWE and a nuclear safety culture where all employees are empowered and expected to identify safety or quality issues and where Supplier management ensures that the identified issues are properly evaluated and resolved.

Additional resources on requirements and methods for maintaining a SCWE are listed in Section 8.3.

6.1.2 Effective Implementation of Corrective Action Programs

All Appendix B / NQA-1 Approved Purchasers and Suppliers shall make effective use of a corrective action program (CAP) to identify, evaluate, and resolve non-conformances identified in their products and processes as required by 10 CFR 50 Appendix B Criteria 15 and 16. This shall include capture of issues in non-conformance reports, timely evaluations, establishment of corrective actions, consideration of extent of condition, and completion of corrective actions.

Senior management support for rigorous and thorough implementation of the CAP is essential for it to succeed. Properly implemented, the CAP identifies and effectively resolves problems early, reducing the total number and the cost and schedule impacts of issues that arise. What is key to success is for management to clearly and consistently state expectations that issues will be properly captured, that the true causes and extent of conditions will be identified, and that the corrective actions taken will be effective at addressing the issues.

In the Purchaser/Supplier relationships that exist in the nuclear plant supply chain, non-conformances that may occur during production should be communicated early up the supply chain from the Supplier to the Purchaser when they are discovered. Purchasers should include requirements to this effect

in their contracts, and Suppliers should include guidance in their QA programs defining when a non-conformance rises to the level that early notification to the Purchaser is required. This guidance should be based on the potential for the non-conformance, if not properly resolved in a timely manner, to impact delivery dates or cost, or to prevent full compliance at shipment with all Purchaser requirements.

Supplier programs for identifying and resolving non-conformances should also be linked to procedures that govern compliance with 10 CFR 21 requirements. Non-conformances should be screened to determine the period of time the condition existed, and whether or not safety-related materials, equipment, or services were provided to Purchasers that may contain a defect (as defined in 10 CFR 21) [1]. If so, the Supplier may be required to notify Purchasers of the defect and assist in the determination of whether or not the defect constitutes a substantial safety hazard.

Additional resources on requirements for CAPs and methods to establish and maintain an effective program are listed in Section 8.4. Suppliers should familiarize themselves with the NRC's expectations for CAPs by reviewing the information in these references that provide links to the NRC's inspection modules for the corrective action program.

6.1.3 Use of Performance-Based Supplier Audit and Commercial Grade Survey Methods

Purchasers are required to perform audits of nuclear Suppliers as part of qualifying their QA programs and approving them to provide safety-related materials, equipment, and services. Purchasers may also need to perform commercial grade surveys of commercial Suppliers to support CGD of materials, equipment, or services as an alternate means of procurement.

Experience has shown that the quality of the audits and surveys performed is a key factor in avoidance or early identification and resolution of Supplier quality issues. Use of performance-based methods in performing these activities, rather than reliance on programmatic reviews alone, is a method of improving the quality and effectiveness of audits and surveys performed by Purchasers.

6.1.3.1 Performance-Based Audits of Appendix B / NQA-1 Approved Suppliers

All Appendix B / NQA-1 Approved Purchasers throughout the project supply chain are expected to utilize performance-based approaches to planning and executing audits of their Appendix B / NQA-1 Approved Suppliers. Performance-based audits are focused on the actual application of controls by the Suppliers during performance of their work and on ensuring that those controls, as applied in the field, provide reasonable assurance that the items delivered by the Supplier met specified requirements and will perform their safety functions in service.

Use of audits based only on simple programmatic checklists which verify that the Supplier's QA program documents and implementing procedure address all required program elements are not sufficient. Audit lines of inquiry should be developed and implemented that focus on the effectiveness of the application of these controls to the production, inspection, and testing controls as applied on the shop floor.

Additional resources on use of performance-based supplier audit techniques are listed in Section 8.5 of this report.

6.1.3.2 Performance-Based Commercial Grade Surveys of Commercial Suppliers

Similarly, all Appendix B / NQA-1 Approved Purchasers throughout the project supply chain are expected to utilize performance-based approaches to planning and executing commercial grade surveys of commercial Suppliers when surveys are used as part of a CGD plan. Performance-based commercial grade surveys focus on the actual documented controls applied by a commercial grade Supplier during performance of their work. The specific controls to be surveyed are those that are being credited in the CGD plan with providing reasonable assurance that the item will meet its design requirements and will properly perform its safety function in service. The survey must 1) determine that the controls applied, if properly implemented, would be adequate to provide the necessary level of assurance; 2) verify that the controls are documented properly in procedures, instructions, or other written documents that can be referenced in the Purchaser's order or contract; and 3) ensure through a combination of observation of implementation on the shop floor, review of Supplier production records, and interviews with Supplier production staff that the controls are in fact being used to control production.

6.1.4 Properly Addressing Appendix B / NQA-1 Approved Supplier Commercial Grade Dedication Programs During Audits

Purchasers should take special care to audit Appendix B / NQA-1 Approved Supplier's CGD programs if the Supplier will be either 1) dedicating commercial grade items or services for use in production of safety-related items for the project or 2) responsible for auditing CGD programs of other Suppliers in their role as Purchaser.

Inadequate CGD by Suppliers several levels down in project supply chains has resulted in stoppage of work and in extensive rework and project delays. Audits should include a detailed review of the Supplier's CGD program unless they are restricted from performing CGD and therefore also restricted from auditing other Supplier's CGD programs.

In general, initial qualification audits of Suppliers should include both a programmatic and procedural review of their CGD program controls and performance-based elements to review their program execution. This should include review of CGD technical evaluations, selection of critical characteristics based on properly identified safety functions, selection and proper use of acceptance methods, and selection of acceptance criteria that are properly tied to design documents.

Use of CGD Acceptance Method 2, Commercial Grade Survey, should be reviewed especially closely to ensure that the surveys are based upon engineering input and identify and review the specific documented controls in place at the commercial Supplier that control the critical characteristics of the items being dedicated. Purchase orders and receipt inspection documents associated with the CGD Method 2 procurement should be reviewed to verify that the surveyed controls are properly imposed on the Supplier and the Supplier certifies that they in fact used those controls to produce the material, equipment, or service being dedicated. Often, Suppliers have used checklists with varying levels of detail as surveys, without including the elements described above, resulting in a non-compliant application of Method 2. Commercial grade surveys are not the same type of review as audits. It is important that Purchasers do not follow audit formats and processes when performing commercial grade surveys.

Section 8.5 lists additional resources on proper application of CGD. Particular attention should also be paid to NRC Inspection Procedures 38703 and 43003 (sources listed in Section 8.6), the NRC's inspection procedure for commercial grade dedication programs.

Dedication of commercial calibration services being used as part of the Supplier's production process is also an item needing specific attention. The NRC has identified in communications to licensees and in public presentations their position on dedication of commercial calibration services, specifically those services provided by companies with certification programs based on being signatories to the International Laboratory Accreditation Cooperation (ILAC). A calibration supplier cannot be accepted solely based upon accreditation. However, the accreditation can be used as part of the dedication process used to approve the supplier's calibration services. (See Section 8.7 for a list of additional resources.)

6.1.5 Involvement of Engineering / Technical Staff in Supplier Audits and Commercial Grade Surveys

Appropriate involvement of engineering / technical staff in the development of appropriate lines of inquiry and participation in the audit / survey is an essential element of a performance-based approach. Experience has shown that incorporating appropriate technical input and having appropriate technical support during audits and surveys, along with actual participation, is a strong contributor to early identification and resolution of Supplier quality issues.

Audit and commercial grade survey checklists, along with planning tools such as Performance-Based Audit and critical characteristics-based survey worksheets provided by organizations such as the Nuclear Procurement Issues Committee (NUPIC) and the Nuclear Industry Assessment Committee (NIAC), are of use in preparing for audits and surveys of Suppliers, but care should be taken to ensure that appropriate technical input specific to the Supplier and the procurement scope is obtained and incorporated into the audit or survey plan. If proper care is not taken, there is a risk that the opportunity to conduct a true performance-based audit / survey will devolve into a "fill out the audit / survey form" programmatic review.

6.1.6 Effective Internal Audit Program

Effective internal audits of safety-related activities performed by each Appendix B / NQA-1 Supplier are a key element of early identification and correction of issues. The goal of the internal audit program should be to identify and correct any issues affecting the quality of items being produced early enough to avoid delivery date slippage, discovery of issues by Purchaser-initiated audits, or discovery of issues by regulatory inspection activities. The scope, frequency, and level of detail in the internal audit program should be set at levels that meet regulatory requirements and that are commensurate with the risk of impact to the project cost and project schedule should quality issues be discovered after production is complete or following delivery to the Purchaser.

6.2 Good Practices

The practices described below have been shown to be of significant benefit in reducing the number and impact of Supplier quality issues that occur during production or that are discovered following delivery, therefore reducing risks to project costs and schedules.

6.2.1 Owner / Lead EPC Good Practices

6.2.1.1 Owner / Lead EPC Level Overall Project Risk Procurement Impact Assessment

An assessment should be done by the Owner / Lead EPC to identify the level of impact that Supplier quality issues may have on the project budget and schedule for each major project procurement scope. The purpose of this assessment is to identify, at the top level, which portions of the project procurement scope represent the greatest risk to the overall project schedule and budget, and define the nature of those risks.

This assessment should focus on key aspects of the project that would not be generally known throughout the supply chain unless the Lead EPC informs Suppliers of the risks.

6.2.1.2 Awareness and Monitoring of NRC Inspection Activity at Project Suppliers

NRC inspections at project Suppliers can identify Supplier quality issues, the significance and extent of which can grow if not properly responded to and corrected promptly. It is a good practice for the Project Owner / Lead EPC to closely monitor such activity, and, when necessary, participate as an observer to be aware of emergent issues.

6.2.1.3 Overall Management of Project Supply Chain Commercial Grade Dedication Risks

CGD of items used in safety-related materials, equipment, and services must be performed in accordance with project regulatory, technical, and quality requirements. CGD activities at any level of the supply chain are subject to direct inspection by the regulator.

The current state of the industry is that Supplier knowledge and capabilities in properly performing CGD in a manner that meets project requirements and regulatory expectations varies widely. In many cases, Suppliers are new to the concept of CGD, as the use of the methodology to support new construction environments presents different challenges than application of CGD to support spare and replacement items for operating nuclear plants.

Detailed controls for the management and performance of CGD should be provided by the lead project EPC and passed down to all NQA-1 sub-Suppliers through purchase orders and contracts. These controls should include detailed oversight through audits and, if judged necessary, review and approval of CGD work products until such time as an adequate level of confidence is established in the Supplier's ability to properly perform CGD evaluations and acceptance processes as well as to provide appropriate audit and oversight of CGD programs being implemented at their sub-Suppliers.

A key consideration in evaluating Supplier CGD programs is to determine whether they have adequate design information and design capability to evaluate the safety functions of the material, equipment, and services that they provide, including evaluation of sub-assemblies and parts that they may procure. If they do not, then the technical evaluation and selection of critical characteristics, acceptance methods, and acceptance criteria may need to be performed by higher-level Suppliers or the project EPC firm, with the Supplier restricted to implementing acceptance processes only.

For complex safety-related equipment, development of a complete map of the chain of Suppliers that will be used to produce the item, including identification of whether each Supplier or sub-Supplier is providing material, equipment, or services under an Appendix B / NQA-1 program or as a commercial Supplier, is a useful tool to help identify areas of concern. This is critical information required to perform proper oversight of project risks related to CGD.

The supply chain map is built as Suppliers and sub-Suppliers place purchase orders during production. The Lead EPC contracts / purchase orders and pass-down requirements should require submittal of this information up the supply chain to the EPC.

6.2.1.4 Limiting the Number of Suppliers of Safety-Related Items

The level of effort, costs, and risks associated with the quality of procured safety-related items increases as the number of Suppliers used increases. Limiting the number of Suppliers allows more cost-effective oversight of the Supplier's performance. The overall number of Suppliers required for various scopes of supply will vary based on the need to obtain the necessary assurance of supply, delivery schedule requirements, and other factors, but the sourcing strategy should place proper weight on limiting the number of Suppliers to reduce the strain placed on technical and QA resources and budgets.

Using fewer safety-related Suppliers, with more rigorous oversight, is a better risk minimization approach than stretching oversight resources across many more Suppliers.

6.2.2 Purchaser / Supplier Good Practices

6.2.2.1 Use of an Effective Order Entry Process

All NQA-1 Suppliers should use an effective order entry process that raises and resolves any issues regarding the purchase order or contract, specifications, drawings, other documents or data specifying the scope of the order, and the technical and quality requirements applicable to the order prior to the start of production.

The level of rigor used for the order entry process should be commensurate with 1) the complexity of the order; 2) the potential financial risks associated with possible rework due to a lack of clear understanding between the Purchaser and the Supplier; and 3) the potential delays in the project schedule that could result from such a lack of understanding.

The order entry process should be designed to identify and resolve any issues where there is a lack of clarity or absence of sufficient information in the order and the associated documents prior to the start of production.

Purchaser involvement and oversight of the order entry process is always important, but it is especially important when the Supplier uses an electronic order entry process that interfaces directly with the factory floor. Developing an acceptable approach for Purchaser oversight to verify that the as-entered data is correct and meets Purchaser requirements should be a key early focus prior to the start of production. This effort can be complicated by the fact that Supplier cost and other proprietary information may be included in the order entry and production control systems.

Additional guidance on effective order entry processes can be found in Appendix B of this report along with a sample order entry checklist attachment.

6.2.2.2 Efficient and Effective Purchaser / Supplier Communication

Purchaser / Supplier Kickoff Meeting

Where appropriate based on the size, complexity, and potential cost and schedule impacts, a formal kickoff meeting between the Purchaser and Supplier may be essential. This is especially true when such risk factors as "first of a kind" engineering or production processes are being used or when including special order requirements that require a Supplier to do things differently than they normally do for an item they produce on a regular basis. The existence of large, complex procurement specifications may also make a kickoff meeting necessary to make sure both parties are properly identifying and addressing key parts of the work.

Well-Defined Purchaser / Supplier Communication Channels During Production

It is important to support rapid notification, evaluation, and resolution of issues that may arise during production. Creating clear, well-defined communication channels helps to eliminate the possibility of overlooking Supplier quality issues. Good communication channels will help reduce the number of issues that occur and quickly resolve question that arise during safety- and quality-related work.

Suppliers often work hard to correct a problem before making a decision to notify the Purchaser that there is a problem. This communication should occur in parallel with early efforts to correct the problem. The Purchaser may be able to assist in the problem resolution if they are made aware of the problem. Early identification and early communication are essential to a good Purchaser-Supplier relationship, and can reduce the impact of problem resolution on cost and delivery time. Early and effective use of the Supplier Deviation Disposition process is one example of a process that can support rapid identification of issues during production.

6.3 Procurement Event-Specific Supplier Quality Issues Risk Management

Sections 6.1 and 6.2 discussed how an effective nuclear QA program and implementation of good practices can help minimize risks of quality issues with supplied safety-related material, equipment, and services.

This section presents an approach for Purchasers at any level of the supply chain to perform a structured Supplier quality issues risk assessment and develop appropriate risk mitigation strategies on a procurement-by-procurement basis.

Each procurement event has its own potential for impact on cost and schedule should Supplier quality issues occur. The nature of this impact varies based on a number of factors.

Purchasers should screen each procurement event for which Supplier quality issues could result in unacceptable project cost or schedule impacts to determine the extent to which known potential causes of Supplier quality issues are present.

6.3.1 Procurement Event Screening Process

A "procurement event" is a unique combination of a scope of safety-related materials, equipment, or services planned for award by a Purchaser to a potential Supplier. This Purchaser will incorporate the materials, equipment, or services being procured into products being produced for the Purchaser's customer.

The screening process should include the following:

- Identification of the potential causal factors that apply to the procurement event and that could result in Supplier quality issues with the material, equipment, or services being supplied
- Evaluation of the level of risk that Supplier quality issues may develop based on the existence of potential causal factors identified in Section 5 of this report or other causal factors known to the Purchaser
- Evaluation of the level of potential impact of Supplier quality issues on the cost or schedule for delivery to Purchaser's customer should such issues be discovered during the procurement, receipt inspection, production, final test and inspection, or post-delivery to the customer
- Use of a graded scoring system (for example, High/Medium/Low, or 1–5) to estimate 1) the level of potential impact on the cost or delivery schedule; and 2) the level of risk that Supplier quality issues could occur
- Selection and implementation of appropriate actions that should be taken by the Purchaser to either prevent Supplier quality issues or to detect and mitigate them in a manner that adequately reduces the risk of unacceptable impacts on the cost or delivery schedule

If there is no reasonably foreseeable way for quality issues with the delivered and installed items to significantly impact the cost or delivery schedule, then the procurement event can be excluded from further evaluation and special risk mitigation actions.

An example Procurement Event Risk Screening Form is provided in Appendix C.

6.3.2 Selection of Risk Prevention or Mitigation Actions

Each procurement event that is identified as containing unacceptable risks to cost or delivery schedules should be further evaluated to identify the specific risk prevention or mitigation actions that will be applied.

This evaluation should balance the cost and resources required to prevent or mitigate the risks of Supplier quality issues with the level of potential impact and the probability of occurrence. Actions to prevent occurrence are in many cases

more resource intensive than actions to detect and correct quality issues. If a detect-and-correct strategy can acceptably mitigate the risks, such an approach may more cost effective than an approach based on prevention.

In other cases, however, the impact of detecting an issue late in the production process or following shipment to the customer can be unacceptably high. One example would be discovering that base plates installed in safety-related concrete in the facility did not get proper CGD evaluations. Another example would be discovery that a major piece of equipment such as a pump or heat exchanger does not meet design requirements following a long production process, resulting in large project schedule impacts (delays for production of a new piece of equipment). In such cases, the extra costs associated with use of actions to prevent occurrence may be well justified.

When costs and resource requirements are equal, preventive actions should generally be preferred to mitigation actions.

6.3.3 Incorporation of Supplier Quality Issues Risk Assessment into the Sourcing and Supplier Selection Process

Where possible, it is recommended that potential Suppliers of important safety-related scopes of material, equipment, or services be assessed from a Supplier quality issues risk perspective as part of the Supplier evaluation and selection process.

Information on risk factors should be requested from Suppliers in their responses to bid documents issued by the Purchaser.

The level of Supplier quality risks present at each potential Supplier, and associated resources the Purchaser may need to apply to manage the risks, should be considered in the selection process and budgeted for by the Purchaser.

Visits by the Purchaser to Suppliers prior to a potential award are recommended to get a detailed understanding of important risk factors, and to plan Purchaser and Supplier actions to prevent or mitigate potential Supplier quality issues. Identifying these actions prior to award allows for building Supplier commitments into purchasing documents from the beginning, rather than negotiating them after the award, which is often much more difficult.

Section 7: Benefits of Effective Risk Management of Supply Chain Quality Issues

All new nuclear construction project participants can benefit from applying the guidance in this report to their procurement activities. Implementing actions to prevent quality issues from occurring, or to detect and mitigate quality issues before their cost or schedule impacts become large, is of benefit to every Purchaser, and accrues across the project to the benefit of the NSSS, EPC firms, and ultimately to the Project Owner.

7.1 Purchasers

All organizations that act as Purchasers within a nuclear construction project's supply chain have contractual commitments to their customers to provide materials, equipment, or services of specified quality to agreed delivery schedules and cost points. Effectively managing the risks of emergence of quality issues with their Suppliers can have a positive effect on their ability to satisfy their customers, and on their financial performance. Financial benefits resulting from effectively managing the risk of Supplier quality issues may include the following:

- Reduced rework and labor hours
- Reduced impact on shop floor operations due to rework and delays in shipments
- Reduced costs associated with expediting and overtime to recover schedule
- Avoided customer damages claims for missed deliveries
- Sustained profit margins that are at target levels

7.2 NSSS and EPC Firms

Requiring subtier contractors and Suppliers to actively manage the risks of Supplier quality issues in their supply chains can have an integrative positive effect over the entire scope under management by the Project NSSS and the Project Lead EPC(s). Effective oversight of subtier Purchaser actions to identify

and effectively manage risks and prevent or reduce the impacts of Supplier quality issues will improve overall cost performance and schedule adherence. It will also reduce the number of "crisis management" situations that occur, requiring project management intervention to lead recovery actions.

The improvements in cost and schedule performance and reduction in recovery efforts will improve overall performance of the NSSS and EPC firms against project goals, increasing the likelihood of a successful and profitable completion of the project.

7.3 Project Owners

The benefits obtained by effectively applying the good practices and risk management methods identified in this report ultimately accrue to the Project Owners. By setting and enforcing expectations that all parties working on the project will manage the risks and reduce the impacts of emergent Supplier quality issues, the Owners can ensure that the adverse project schedule impacts and cost overruns that can result from this cause are minimized.

This will increase the level of assurance that the project can be successfully completed at a total cost point that meets Owner expectations for delivery of an asset that meets financial return targets set in the project financial model.

Section 8: References

The purpose of this section is to provide a comprehensive list of references for quality management that may be useful to Suppliers and Purchasers. All documents listed below were used in the development of this guidance.

8.1 In-Text References

1. U.S. Code of Federal Regulations, Title 10, Chapter 1, Part 21, Reporting of Defects and Noncompliance, Office of the Federal Register, National Archives and Records Administration, U.S. Government Printing Office, Washington, D.C. http://www.nrc.gov/reading-rm/doc-collections/cfr/part021/
2. Quality Assurance Requirements for Nuclear Facility Applications (QA), ASME NQA-1-2008 (edition). American Society of Mechanical Engineers, New York, NY: 2008.
3. Guidance for Establishing and Maintaining a Safety Conscious Work Environment. http://www.nrc.gov/about-nrc/regulatory/allegations/scwe-mainpage.html

8.2 Counterfeit, Fraudulent, or Suspect Items

Plant Support Engineering: Counterfeit and Fraudulent Items. EPRI, Palo Alto, CA: October 2010. 1021493. http://www.epri.com/abstracts/Pages/ProductAbstract.aspx?ProductId=000000000001021493

Plant Support Engineering: Counterfeit, Fraudulent, and Substandard Items. EPRI, Palo Alto, CA: October 2009. 1019163. http://www.epri.com/abstracts/Pages/ProductAbstract.aspx?ProductId=000000000001019163

U.S. Nuclear Regulatory Commission. Generic Letter 89-02: Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products (Agencywide Reports Access and Management System (ADAMS) Accession No. ML031140060). Government Printing Office, Washington, D.C.: March 1989. http://www.nrc.gov/reading-rm/doc-collections/gen-comm/gen-letters/1989/gl89002.html

U.S. Nuclear Regulatory Commission. Information Notice 2008-04: Counterfeit Parts Supplied to Nuclear Power Plants (Agencywide Reports Access and Management System (ADAMS) Accession No. ML093620098). Government Printing Office, Washington, D.C.: April 2008. http://pbadupws.nrc.gov/docs/ML0936/ML093620098.pdf

U.S. Nuclear Regulatory Commission. Staff Review of Counterfeit, Fraudulent, and Suspect Items (CFSI) (Agencywide Reports Access and Management System (ADAMS) Accession No. ML112130293). Government Printing Office, Washington, D.C.: November 2011. http://pbadupws.nrc.gov/docs/ML1121/ML112130293.pdf

8.3 Safety-Conscious Work Environment

Guidance for Establishing and Maintaining a Safety Conscious Work Environment. http://www.nrc.gov/about-nrc/regulatory/allegations/scwe-mainpage.html

Nuclear Power Plant Personnel-Employee Concerns Program – Process Tools in a Safety Conscious Work Environment. NEI, Washington, D.C.: December 2003. NEI 97-05 [Rev. 2]. http://www.nei.org/filefolder/NEI_97-05_-_Nuclear_Power_Plant_Personnel-Employee_Concerns_Program-_Process_Tools_In_A_Safety_Conscious_Work_Environment_Rev_2.pdf

8.4 Corrective Action Program

Corrective Action Processes for New Nuclear Power Plants During Construction. NEI, Washington, D.C.: February 2010. NEI 08-02 [Rev. 3]. http://pbadupws.nrc.gov/docs/ML1005/ML100540799.pdf

U.S. Nuclear Regulatory Commission. Effectiveness of Licensee Process to Identify, Resolve, and Prevent Problems: IP40500. Government Printing Office, Washington, D.C.: May 1999. http://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/ip40500.pdf

U.S. Nuclear Regulatory Commission. Routine Inspections of Nuclear Vendors: IP43002. Government Printing Office, Washington, D.C.: April 2011. http://pbadupws.nrc.gov/docs/ML1108/ML110871933.pdf

U.S. Nuclear Regulatory Commission. Reactive Inspections of Nuclear Vendors: IP43003. Government Printing Office, Washington, D.C.: April 2011. http://pbadupws.nrc.gov/docs/ML1108/ML110871939.pdf

8.5 EPRI Documents

Guidelines for Performance-Based Supplier Audits (NCIG-16). EPRI, Palo Alto, CA: June 1990. NP-6630.
http://www.epri.com/abstracts/Pages/ProductAbstract.aspx?ProductId=NP-6630

Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07). EPRI, Palo Alto, CA: June 1988. NP-5652.
http://www.epri.com/abstracts/Pages/ProductAbstract.aspx?ProductId=NP-5652

Plant Support Engineering: Guidance for Managing the Impact of Procured Item Quality Issues on Generating Asset Economic Performance. EPRI, Palo Alto, CA: 2008. 1016693. [NOTE: This report has limited distribution due to the rules under which it was produced and is not available for general download on the EPRI web site]

Supplemental Guidance for the Application of EPRI Report NP-5652 on the Utilization of Commercial Grade Items. EPRI, Palo Alto, CA: March 1994. TR-102260.
http://www.epri.com/abstracts/Pages/ProductAbstract.aspx?ProductId=TR-102260

8.6 Regulatory Documents

Combining Licenses, 10CFR50.52. Licenses, Certifications, and Approvals For Nuclear Power Plants, Government Printing Office, Washington, D.C.
http://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-0052.html

Guidance for Establishing and Maintaining a Safety Conscious Work Environment. http://www.nrc.gov/about-nrc/regulatory/allegations/scwe-mainpage.html

NUREG-1055, Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants: A Report to Congress, Washington D.C.: May 1984. http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1055/#pub-info

U.S. Code of Federal Regulations, Title 10, Chapter 1, Appendix B to Part 50, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Facilities, Office of the Federal Register, National Archives and Records Administration, U.S. Government Printing Office, Washington, D.C.
http://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-appb.html

U.S. Code of Federal Regulations, Title 10, Chapter 1, Part 21, Reporting of Defects and Noncompliance, Office of the Federal Register, National Archives and Records Administration, U.S. Government Printing Office, Washington, D.C. http://www.nrc.gov/reading-rm/doc-collections/cfr/part021/

U.S. Nuclear Regulatory Commission. Generic Letter 91-05: Licensee Commercial-Grade Procurement and Dedication Programs. Government Printing Office, Washington, D.C.: April 1991. http://www.nrc.gov/reading-rm/doc-collections/gen-comm/gen-letters/1991/gl91005.html

U.S. Nuclear Regulatory Commission Information Notice 2011-01, Commercial-Grade Dedication Issues Identified During NRC Inspections (Agencywide Reports Access and Management System (ADAMS) Accession No. ML103220180), Government Printing Office, Washington, D.C.: February 2011. http://pbadupws.nrc.gov/docs/ML1032/ML103220180.pdf

U.S. Nuclear Regulatory Commission. Inspection of Commercial-Grade Dedication Programs: IP43004. Government Printing Office, Washington, D.C.: April 2011. http://pbadupws.nrc.gov/docs/ML1108/ML110871957.pdf

U.S. Nuclear Regulatory Commission. Commercial Grade Dedication: IP38703. Government Printing Office, Washington, D.C.: April 1996. http://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/ip38703.pdf

8.7 Calibration Services

U.S. Nuclear Regulatory Commission. Letter to Arizona Public Service Company: Palo Verde Nuclear Generating Station (Palo Verde), Units 1, 2, and 3 – Quality Assurance Program Reduction in Commitment Request (TAC Nos. MC4402, MC4403, and MC4404) (Agencywide Reports Access and Management System (ADAMS) Accession No. ML043000471), Government Printing Office, Washington, D.C.: November 2004. http://pbadupws.nrc.gov/docs/ML0430/ML043000471.pdf

U.S. Nuclear Regulatory Commission. NUPIC General Membership Meeting on February 8-11 (Agencywide Reports Access and Management System (ADAMS) Accession No. ML100570045), Government Printing Office, Washington, D.C.: March 2010. http://pbadupws.nrc.gov/docs/ML1005/ML100570045.pdf

U.S. Nuclear Regulatory Commission. NUPIC/Vendor Meeting: Commercial-Grade Calibration Services NVLAP/A2LA (Agencywide Reports Access and Management System (ADAMS) Accession No. ML061140305), Government Printing Office, Washington, D.C.: June 2005. http://pbadupws.nrc.gov/docs/ML0611/ML061140305.pdf

8.8 Industry Codes, Standards, and References

ANSI/ISO/ASQ Q9001:2008, American National Standard, Quality Management Systems – Requirements, American National Standards Institute/International Organization for Standardization/American Society for Quality, 2008.

ANSI N45.2, Quality Assurance Program Requirements for Nuclear Power Plants. American National Standards Institute, Washington, D.C.

Quality Assurance Requirements for Nuclear Facility Applications (QA), ASME NQA-1-1994 (edition). American Society of Mechanical Engineers, New York, NY: 1994.

Quality Assurance Requirements for Nuclear Facility Applications (QA), ASME NQA-1-2008 (edition). American Society of Mechanical Engineers, New York, NY: 2008.

Quality Assurance Requirements for Nuclear Facility Applications (QA), ASME NQA-1a-2009 (addenda). American Society of Mechanical Engineers, New York, NY: 2009.

8.9 NRC Inspection Procedures and References

For a complete list of the U.S. NRC inspection procedures, please visit the NRC web site at http://www.nrc.gov/reading-rm/doc-collections/insp-manual/inspection-procedure/.

Previous inspection reports performed by the NRC can also be found on the NRC web site at http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp/insp-reports.html.

For information regarding vendor QA inspections, please visit the NRC web site at http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp.html and http://www.nrc.gov/reactors/new-reactors/oversight/quality-assurance/vendor-insp/insp-reports.html.

8.10 Industry Guidance

Additional information for industry guidance is available on the Nuclear Industry Assessment Committee (NIAC) web site at http://www.niacusa.org/index.php (information is only available to members).

The Nuclear Procurement Issues Committee (NUPIC) web site also provides industry guidance at http://www.nupic.com/NUPIC/Home/Home.aspx (information is only available to members).

Appendix A: Technical Advisory Group Formation and History

In August 2011, the Advanced Nuclear Technology Steering Committee approved a task to develop guidance on management of Supplier quality issues for new nuclear construction projects. In addition to developing a guidance document, this task was to include development of training addressing management of Supplier quality issues, targeted for use by Suppliers at varying levels of the nuclear construction project supply chain. The approved schedule called for completion of the guideline and training material development, and delivery of the first two training sessions, in the Spring of 2013.

An EPRI Technical Advisory Group (TAG) was formed and a contractor selected to support the work, with the first meeting held in the EPRI offices in Charlotte, North Carolina, on March 20–21, 2012.

At this first meeting, the scope to be addressed by the guidance was discussed, and the TAG decided to limit the scope to consideration of Supplier quality issues applicable to new nuclear plants being constructed to U.S. regulatory requirements, codes, and standards.

However, many of the risks identified in this guideline are expected to be directly applicable, or similar to, Supplier quality risks that would be experienced at any nuclear power plant construction project worldwide.

Appendix B: Order Entry / Contract Review Checklist

The following checklist is an example of the type of form that can be used to evaluate the cost, impact, resource needs, and schedule required to support a client's request for quotation (RFQ) or purchase order (PO) / contract. The intent is to properly plan and consider the impact on production and all parties involved before formal acceptance of the RFQ / PO / contract.

Meeting attendees should include:

1. QA Manager or designee
2. Production Manager or designee
3. Engineering Manager or designee
4. Scheduling/Planning Manager or designee
5. Procurement/Purchasing Manager or designee

When a department designee is utilized, he or she must be able to make decisions and commitments, including financial decisions, for the manager who is being represented.

The representative will be designated to take minutes and complete the attached checklist. Action items will be assigned as appropriate with deadlines. Follow-up and closure of action items will typically be by the Project Manager or Contract Manager or as established in company procedures or the QA manual.

ORDER ENTRY / CONTRACT REVIEW CHECKLIST

Client Name: _____

RFQ/PO/Contract Number: _____Rev: _____Date: _____

List Meeting Attendees:

_____

_____

_____

Person responsible for recording and distributing meeting minutes: _____

Considerations	Yes	No	N/A	Estimated Cost?	Comments and/or Action Items
1. Review as a team the complete document along with all specifications, drawings, and attachments.					
2. Do we have the quality program and technical expertise to perform the scope of work? Are we aware of the latest expectations from the owner, buyer, and/or regulators as it relates to this product?					
3. Does the scope of work warrant a Project Manager assignment?					
4. Will additional resources be required for Production, QA, QC, or Engineering?					
5. Is this a "first of its kind" design? Fabrication? Test? Equipment Qualification? Consider "adder" for unexpected surprises.					
6. Will additional supplier audits or surveys be required?					(List the suppliers)
7. Will additional product dedication and dedication plans be required?					(List the products)
8. Will additional facilities, equipment, or M&TE be required to fabricate and inspect?					(List the equipment and instruments)
9. Will additional procedures or work instructions need to be written? If so, who is responsible?					(List the new procedures)
10. Will additional training be required?					
11. Can the delivery date commitment be satisfied? What could impact the delivery and what contingency plans are needed?					
12. Do we have a designated company contact, and an area to locate visiting Witness Inspectors for Hold Points and/or Customer Representatives?					
13. Will we use software? Does it need to be in our SQA program?					(List the software program)
14. Do we have enough warehouse capacity if we have to store the product for a long period of time?					

15. Will CGD apply to this order? If yes, will we self-perform the dedication or go through a third party?					(List additional supplier support required or engineering/QC time for CGD)
16. Will a follow-up Order Entry / Contract Review Meeting be required upon receipt of missing information?					(List who should attend follow-up meeting)
17. Any exceptions, clarifications, and/or request for additional information will be documented and submitted to the client by whom?_____ By what date? _____					

Completed by: _____ Date: _____

Appendix C: Example Risk Screening Form

The following risk screening form is an example of the type of form that can be used to evaluate Supplier quality issues related to cost and schedule impacts.

Procurement Event Risk Screening Form

Project:

_____

Customer:

_____

Supplier:

_____

Procurement scope—material, equipment, and/or services being procured:

_____

_____

_____

_____

Summary of procurement event risk screening results:

_____

_____

_____

_____

_____

_____

Prepared by: _____ Reviewed by: _____

Approved by: _____

Procurement Event Risk Screening Form

Risk Description	(A) Level of Risk (1–5)	(B) Level of Potential Project Impact (1–5)	Overall Risk (A x B)	Prevention or Mitigation Actions and Basis
1. Quality issues resulting from level of Supplier experience with 10 CFR Appendix B and ASME NQA-1 QA program implementation				**Prevention Actions:** **Mitigation Actions:** **Basis:**
2. Quality issues as a result of recent significant change in supplier operations				**Prevention Actions:** **Mitigation Actions:** **Basis:**
3. Quality issues as a result of this order being significantly larger than NQA-1 orders for similar items / services processed recently by the supplier				**Prevention Actions:** **Mitigation Actions:** **Basis:**

Risk Description	(A) Level of Risk (1–5)	(B) Level of Potential Project Impact (1–5)	Overall Risk (A x B)	Prevention or Mitigation Actions and Basis
4. Quality issues as a result of cultural, language, or other communication challenges				**Prevention Actions:** **Mitigation Actions:** **Basis:**
5. Quality issues resulting from specifications of "special order" technical or quality requirements on standard products or services				**Prevention Actions:** **Mitigation Actions:** **Basis:**
6. Quality issues as a result of first-of-a-kind engineering / production of items being ordered				**Prevention Actions:** **Mitigation Actions:** **Basis:**
7. Quality issues resulting from the time since last production of the items				**Prevention Actions:** **Mitigation Actions:** **Basis:**

Risk Description	(A) Level of Risk (1–5)	(B) Level of Potential Project Impact (1–5)	Overall Risk (A x B)	Prevention or Mitigation Actions and Basis
8. Quality issues resulting from schedule pressures				**Prevention Actions:** **Mitigation Actions:** **Basis:**
9. Quality issues as a result of limited experience with ITAAC inspection, test, and documentation				**Prevention Actions:** **Mitigation Actions:** **Basis:**
10. Quality issues as a result of limited experience / capabilities in commercial grade dedication				**Prevention Actions:** **Mitigation Actions:** **Basis:**
11. Quality issues as a result of limited experience with the specified design codes				**Prevention Actions:** **Mitigation Actions:** **Basis:**

Risk Description	(A) Level of Risk (1–5)	(B) Level of Potential Project Impact (1–5)	Overall Risk (A x B)	Prevention or Mitigation Actions and Basis
12. Quality issues resulting from counterfeit, fraudulent, or suspect items				**Prevention Actions:** **Mitigation Actions:** **Basis:**
13. Other (specify)				**Prevention Actions:** **Mitigation Actions:** **Basis:**
14. Other (specify)				**Prevention Actions:** **Mitigation Actions:** **Basis:**

Appendix D: Training Slides

The associated training slides for this guidance are located in the attached PowerPoint file (3002000521_AppendixD.pptx).

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