



# Supplier Quality Management Training

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# Purpose of the Guideline

- Identify key regulatory requirements and Owner / Engineering, Procurement, Construction firm (EPC) expectations for participants in the nuclear supply chain
- Identify Good Practices for proper implementation of regulatory requirements and meeting Owner / EPC expectations
- Identify resources available that provide more information on specific areas
- Identify risk factors that have historically led to issues with the quality of supplied materials, equipment, or services
- Provide guidance on mitigation of supply chain risks that can adversely impact construction cost and schedule
- Targeted at Purchasers and Suppliers who have Appendix B / ASME NQA-1 Quality Assurance Programs

# Training Objectives

- Summarize the foundational requirements of supplying materials, equipment, and services to new nuclear construction projects
  - 10 CFR Part 50 Appendix B Quality Assurance Program Requirements
  - 10 CFR Part 21
  - ASME NQA-1 QA Program Requirements
  - Nuclear Safety Culture and Safety Conscious Work Environment
  - NOT a course in the details of meeting requirements of these foundational requirements

# Training Objectives

- Familiarize attendees with risk factors that are related to the occurrence of issues with the quality of items supplied to the nuclear power industry
- Discuss the role of Purchasers and Suppliers in identification and mitigation of project risks associated with emergence of quality issues
- Identify Good Practices that can reduce the impact of Supplier Quality Issues
- Discuss the use of Procurement Event Risk Screening and Risk Mitigation Plans



# Supplier Quality Management Training

## Nuclear Supply Basics

# Regulatory Requirements – 10 CFR Part 21

- Defines what is safety related in a nuclear facility – “Basic Component”
- Requires evaluation of any defects in supplied Basic Components and notification to the NRC of defects which could create a substantial safety hazard
  - Responsibility of any entity providing “Basic Components” to a nuclear project
- Defines the role and terminology associated with Commercial Grade Dedication

# 10 CFR Part 21

## Basic Component

(1)(i) When applied to nuclear power plants licensed under 10 CFR part 50 or part 52 of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:

(A) The ***integrity of the reactor coolant pressure boundary***;

(B) The ***capability to shut down the reactor and maintain it in a safe shutdown condition***; or

(C) The ***capability to prevent or mitigate the consequences of accidents*** which could result in potential offsite exposures comparable to those referred to in § 50.34(a)(1), § 50.67(b)(2), or § 100.11 of this chapter, as applicable.

(ii) Basic components are items designed and manufactured under a quality assurance program complying with appendix B to part 50 of this chapter, or commercial grade items which have successfully completed the dedication process.

Basic Component = Safety Related

# 10 CFR Part 21

## Dedication

(1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60, dedication is ***an acceptance process*** undertaken to provide ***reasonable assurance*** that a commercial grade item to be used as a basic component will ***perform its intended safety function*** and, in this respect, is deemed ***equivalent to an item designed and manufactured under a 10 CFR Part 50, appendix B, quality assurance program***. This assurance is achieved by identifying the ***critical characteristics*** of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. ***In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, appendix B.*** The process is considered complete when the item is designated for use as a basic component.



# 10 CFR Part 21

## Dedication

The dedicating entity is responsible for --

- (1) Identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and
- (2) Maintaining auditable records for the dedication process.

# 10 CFR Part 21

## Defect

- (1) A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation, ***the deviation could create a substantial safety hazard***;
- (2) The installation, use, or operation of a basic component containing a defect as defined in this section;
- (3) A deviation in a portion of a facility subject to the early site permit, standard design certification, standard design approval, construction permit, combined license or manufacturing licensing requirements of part 50 or part 52 of this chapter, provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance;
- (4) A ***condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit***, as defined in the technical specifications of a license for operation issued under part 50 or part 52 of this chapter; or
- (5) An error, omission or other circumstance in a design certification, or standard design approval that, on the basis of an evaluation, could create a substantial safety hazard.

**Deviation** means a ***departure from the technical requirements included in a procurement document***, or specified in early site permit information, a standard design certification or standard design approval.

# 10 CFR Part 21

## Notification (partial requirements)

- (a) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to --
  - (1) **Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards** as soon as practicable, and, in all cases **within 60 days of discovery**, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected, and
  - (2) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer or designated person as discussed in § 21.21(d)(5).
  - (3) Ensure that a **director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation** described in paragraphs (a)(1) or (a)(2) of this section if the manufacture, construction, or operation of a facility or activity, a basic component supplied for such facility or activity, or the design certification or design approval under part 52 of this chapter—
    - (i) **Fails to comply** with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission or standard design approval under part 52 of this chapter, relating to a substantial safety hazard, or
    - (ii) **Contains a defect.**

# 10 CFR Part 21

## Notification (partial requirements)

*(b) If the deviation or failure to comply is discovered by a supplier of basic components, or services associated with basic components, and the supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to § 21.21(a).*

**As a Purchaser of Basic Components, you MUST include a requirement for the Supplier to meet 10 CFR Part 21 in all purchase orders or contracts that specify compliance with a QA program meeting the requirements of 10CFR50, Appendix B**

# 10 CFR Part 50 Appendix B – Quality Assurance Program Requirements

- Provides Quality Assurance requirements that must be met by all licensees
- Licensees can (and generally do) elect to flow down these requirements
- Suppliers can decide to comply with them
- Eighteen criteria covering all aspects of the quality assurance program
- Three criteria most closely associated with procurement of safety related materials, equipment, and services are:
  - Criterion III - Design Control
  - Criterion IV - Procurement Document Control
  - Criterion VII - Control of Purchased Material, Equipment, and Services

# 10 CFR 50 Appendix B – Criterion III

## Design Control (Partial Requirements)

- Measures shall be established to assure that ***applicable regulatory requirements and the design basis***, as defined in § 50.2 and as specified in the license application, for those structures, systems, and components to which this appendix applies ***are correctly translated into specifications, drawings, procedures, and instructions***.
- Measures shall also be established for the ***selection and review for suitability of application*** of materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems and components.
- The design control measures shall provide for ***verifying or checking the adequacy of design***, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program.

# 10 CFR 50 Appendix B – Criterion IV

## Procurement Document Control (Partial Req'ts)

- Measures shall be established to assure that ***applicable regulatory requirements, design bases, and other requirements*** which are necessary to assure adequate quality ***are suitably included or referenced in the documents for procurement of material, equipment, and services***, whether purchased by the applicant or by its contractors or subcontractors.

# 10 CFR 50 Appendix B – Criterion VII

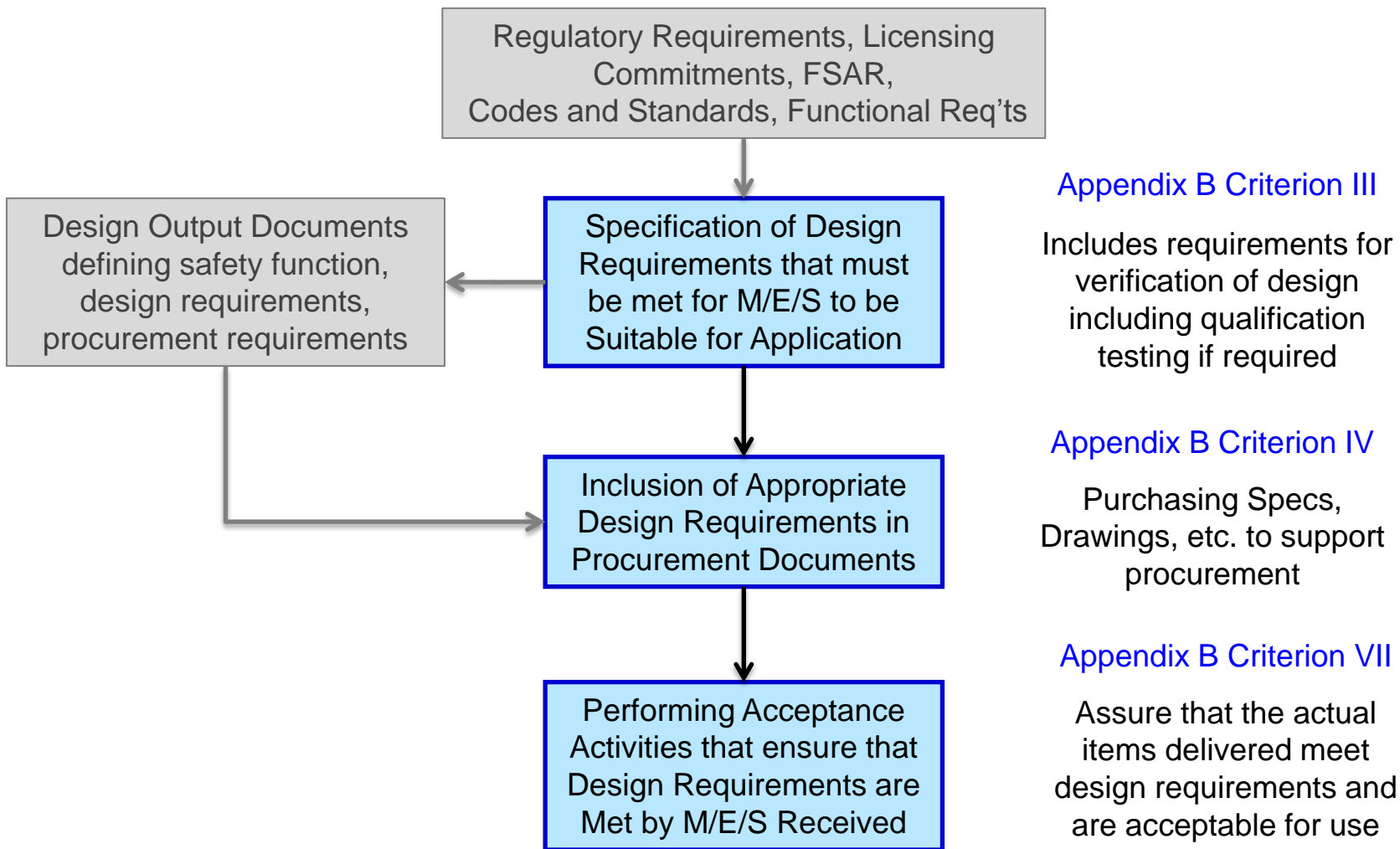
## Control of Purchased Material, Equipment and Services (Partial Req'ts)

***Measures shall be established to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents.*** These measures shall include provisions, as appropriate, for source evaluation and selection, ***objective evidence of quality furnished by the contractor or subcontractor***, inspection at the contractor or subcontractor source, and examination of products upon delivery. ***Documentary evidence that material and equipment conform to the procurement requirements shall be available at the nuclear powerplant or fuel reprocessing plant site prior to installation or use*** of such material and equipment.

- The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.



# Design to Acceptance



# Purchaser Options for Obtaining Safety Related Material, Equipment, and Services

- Procure from an Appendix B / NQA-1 Supplier
  - 10 CFR 21 applies and is imposed on purchasing documents by Purchaser
  - Design responsibility is shared between multiple parties (Nuclear Steam Supply System [NSSS], Architect/Engineering [A/E] firm, Purchaser, Supplier) dependent on the level of assembly. Clear definition of these design responsibilities is key.
  - Purchaser performs Acceptance to their Appendix B/ NQA-1 QA program requirements
    - Tests and inspections
    - Supplier Audits
    - Source Verification
  - Both the Purchaser and the Supplier “own” 10 CFR 21 evaluation and reporting requirements

# Purchaser Options for Obtaining Safety Related Material, Equipment, and Services

- Procure from a Commercial Supplier and use Commercial Grade Dedication as the Acceptance Process
  - 10 CFR 21 does NOT apply to the procurement
  - Purchaser “owns” Design and Suitability determination
  - Purchaser selects Critical Characteristics to be verified from the established design requirements (or via Failure Mode and Effects Analysis [FMEA] or other documented method)
  - Purchaser applies one or more of the four CGD acceptance methods (subject to regulatory limits)
    - Special Tests and Inspections
    - Commercial Grade Survey of Supplier Commercial Quality Controls
    - Source Verification
    - Acceptable Item and Supplier History
  - As the Dedicating Entity, Purchaser “owns” 10 CFR 21 evaluation and reporting requirements after acceptance

# Purchaser Options for Obtaining Safety Related Material, Equipment, and Services

- Procure from a Commercial Supplier and use Purchaser's Appendix B / NQA-1 QA Program to Accept
  - 10 CFR 21 does NOT apply to the procurement
  - Purchaser “owns” Design and Suitability determination
  - Supplier produces Materials, Equipment or Services required to their commercial quality program
  - Purchaser may require Supplier to work under Purchaser QA Program Controls for portions of the work
  - Purchaser assures items meet applicable design requirements through application of controls included in their Appendix B/ NQA-1 QA program requirements
    - Tests and Inspections
    - Supplier Audits
    - Source Verification
  - Purchaser “owns” 10 CFR 21 evaluation and reporting requirements

# Purchaser Options for Obtaining Safety Related Material, Equipment, and Services

- Each of these approaches to procurement of Safety Related M/E/S are allowed by current regulation
- Each has been and is being used to support operating nuclear power plants
- Construction project contracts/flowdowns/audit practices may require Purchasers to use only the first two approaches (NQA-1 Supplier or CGD)
- There are at present different levels of understanding among NRC staff regarding procuring items intended for use in safety related applications without use of CGD



# Supplier Quality Management Training

## Owner and Project EPC Expectations

# Owner and EPC Expectations

- All Purchasers and Suppliers in the Project Supply Chain for Safety Related Equipment will:
  - Rigorously implement all parts of their ASME NQA-1 Quality Assurance program
  - Provide strong management support and oversight of their Corrective Action Program
  - Provide and maintain a Safety Conscious Work Environment where all employees are empowered to raise concerns regarding nuclear safety issues, and have an expectation that these concerns will be heard and acted upon by management

# Owner and EPC Expectations

- All Purchasers and Suppliers in the Project Supply Chain for Safety Related Equipment will:
  - Promote development of a Nuclear Safety Culture where ensuring the quality of safety related materials, equipment, and services supplied is always of concern
  - Meet all technical, quality, cost and schedule commitments in contracts and purchase orders
  - Provide prompt notification to customers when meeting any commitment is at risk





# Supplier Quality Management Training

## Supplier Quality Issues

# Purchasers and Suppliers - Definitions

## Purchaser

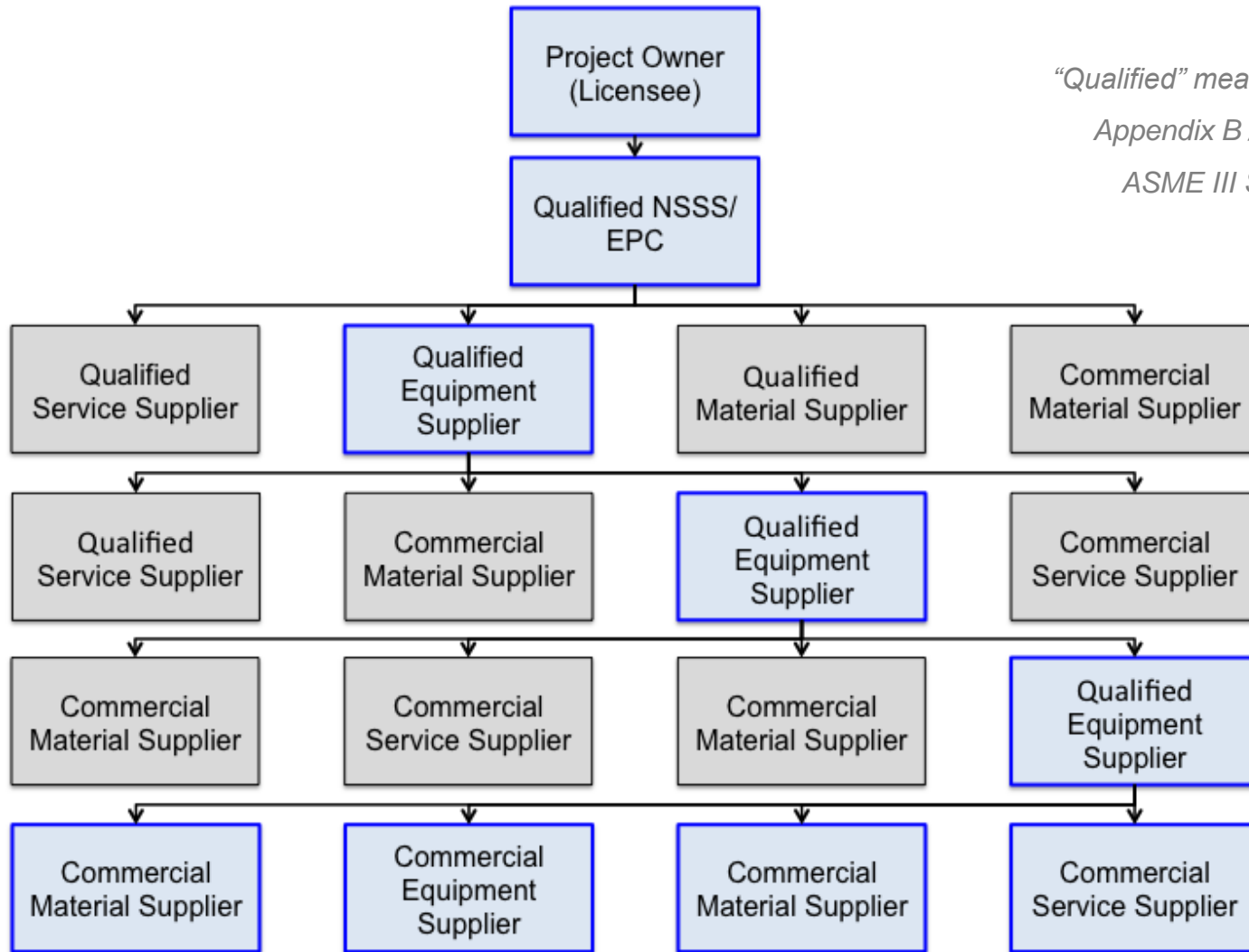
The organization responsible for establishment of procurement requirements and for issuance or administration, or both, of procurement documents. Purchasers issue purchase orders or contracts for materials, equipment, or services at any level of the project supply chain.

## 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

# Generalized Project Supply Chain

## Everyone is a Purchaser AND a Supplier (Almost!)



*“Qualified” means Approved  
Appendix B / NQA-1 /  
ASME III Supplier*

# Project Risks of Concern

- Quality Assurance programs in place on nuclear construction projects are effective at discovering and resolving issues with supplied safety related materials, equipment and services
- WHEN in the production/construction/installation process supplier quality issues are discovered, and how they are resolved, are key factors determining the magnitude of the impact they have on project cost and schedule
- The focus of the guideline is to identify risks from this project impact perspective, and determine when and where additional oversight should be applied to avoid unacceptable impacts to the project cost and schedule

# Risk Factors

- The EPRI TAG identified a number of risk factors that have been associated with emergent supplier quality issues in the past
- EPRI 1016693: Plant Support Engineering: Guidance for Managing the Impact of Procured Item Quality Issues on Generating Asset Economic Performance Final Report, July 2008, was a primary source for many of the risk factors provided here. (Restricted distribution, not available for public download)

# Risk Factors

Consideration of the following risk factors by Purchasers, and taking appropriate actions to mitigate them, can significantly reduce the probability of occurrence AND the potential impacts of Supplier Quality Issues on project cost and schedule.

# Risk Factors

- Level of supplier experience with Appendix B, Part 21, and NQA-1 QA Program implementation
  - Implementation issues with QA programs and processes occur at a higher rate in the early period following adoption of a NQA-1 program by a supplier
  - Audit findings can be significant enough to result in late deliveries, project delays
    - Need for rework
    - Change in procurement method (from NQA-1 to Commercial)
    - Seeking an alternate supplier

# Risk Factors

- Significant change in supplier production operations
  - Disruptions in the supplier's operations can result in a reduction in the quality of products provided
  - Types of disruptions include:
    - Supplier being purchased by another firm resulting in facility consolidation, staff reduction, etc.
    - Loss of experienced staff through retirements or turnover
    - Major redesign of the product
    - Major change in production tooling



# Risk Factors

- Placement/acceptance of significantly larger Orders for NQA-1 equipment or services
  - Long term nuclear suppliers may be overstressed when taking large orders typical of construction projects
  - Recent nuclear production focused mainly on spare parts, small scale component orders
  - Actual experience level of staff with producing full components to nuclear standards and QA program requirements may be limited
  - Risks associated with first large orders for whole components to experienced nuclear suppliers may be nearly as high as ordering from supplier that have just entered the nuclear business

# Risk Factors

- Cultural, Language, and Communication Challenges
  - There are many types of challenges that impact communications and results in differing understandings on the part of the Purchaser and the Supplier
    - Clarity of the Purchaser's specifications
    - Large time zone differences
    - Language differences
    - Cultural differences
  - Ensure 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 and how to meet those requirements

# Risk Factors

- First of a kind engineering / production
  - High error rates can occur during the production of new items by Suppliers and puts extra demands on both management and the production staff
  - Additional oversight early on in the production process may be needed for prevention, detection, and correction of errors
- “Special order” technical or quality requirements
  - Asking a Supplier to do something differently on an order than what they do every day during production of their standard items
    - May result in higher error rates than First of a Kind
  - Clearly identify all aspects that are special or unique and do not bury special requirements in the technical specification

# Risk Factors

- Time since last production
  - Identify the last time that the Supplier produced the items you are ordering
    - If the time since last production is significant, the risk of error may require additional risk mitigation
- Schedule Pressures
  - Production schedule pressures and/or Purchaser delivery schedule pressures can result in short cuts being taken that result in quality issues in delivered items
  - Where schedule pressures are high, additional oversight and over-checks should be considered

# Risk Factors

- Limited experience with Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC) inspection, test and documentation requirements
  - The 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
  - Clear Communications with Suppliers that have a role in completing ITAAC required tests and inspections is critical
  - Failure to perform and properly document ITAAC required activities could result in significant delays during the transition from construction to operation

# Risk Factors

- Limited experience/capabilities in Commercial Grade Dedication (CGD)
  - As discussed earlier, CGD is one method for Purchasers to obtain materials, equipment, or services for use in safety related applications
  - When CGD is the selected method, it is important that the dedicating entity's experience with CGD be evaluated
  - Many Suppliers have limited experience with performance of CGD activities to industry standards and regulatory expectations
  - Failure to properly perform CGD activities can result in large impacts on project costs and schedule
    - “Items of indeterminate quality”

# Risk Factors

- Limited Supplier Experience with the Applicable Nuclear Design Codes
  - This may be the case for two primary reasons:
    - The supplier has recently developed the capability to do design work to nuclear codes or standards
    - The supplier is certified to perform design to the nuclear codes and standards in place in many countries around the world, but does most of its design work to the codes and standards of their home country
  - Limited experience and limited qualified staff can lead to issues as simple as not having enough qualified staff available to sign off on Design Reports, delaying shipments.

# Risk Factors

- Counterfeit, Fraudulent, or Suspect Items
  - The potential for receipt and installation of CFSI into new nuclear construction projects must be recognized as a risk needing mitigation.
  - The US Departments of Commerce and Energy have collected a significant amount of information on fraudulent items
  - US NRC communications identify areas of risk to the nuclear power industry
  - Procurement practices, supplier selection, receipt inspection and testing practices should all be reviewed to identify and mitigate risks presented by CFSI



# Risk Factors

- The risk factors identified above are not all inclusive
- Purchasers should carefully review planned procurements to identify any and all supplier or scope specific risk factors that rise to a level requiring some mitigative actions



# Supplier Quality Management Training

## Supplier Quality Risk Management – Good Practices

# Management of Supplier Quality Issue Risks

- Effectively managing the risks associated with Supplier Quality Issues consist of two elements:
  - Implementing the basics of Supplier Quality well consistently (Good Practices)
  - Recognizing specific procurement scopes that entail larger than normal risks, and selecting and implementing appropriate actions to mitigate those risks (Risk Screening and Mitigation)

# Good Practices

- Effective implementation of QA programs by Suppliers
  - All Suppliers providing safety related material, equipment, or services 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
  - 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

# Good Practices

- Establishing and maintaining a 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”
  - Properly implemented, a SCWE provides for more rapid identification and resolution of quality issues, reducing potential impacts of Supplier Quality Issues on new nuclear construction projects

# Good Practices

- Effective implementation of Corrective Action Programs
  - All Appendix B/NQA-1 Approved Purchasers and Suppliers should make effective use of their 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
    - Non-conformance reports
    - Timely evaluations
    - Establishment of Corrective Actions
    - Consideration of extent of condition
    - Completion of Corrective Actions
  - Senior management support for implementation of the CAP is essential for it to succeed

# Good Practices

- 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
  - Use of audits/surveys based only on simple programmatic checklists that verify the Supplier's QA program documents and implementing procedure address all required program elements are not sufficient
  - Audits and surveys should focus on the effectiveness of the application of controls to the production, inspection, and testing as applied on the shop floor

# Good Practices

- Effective Management of Commercial Grade Dedication (CGD) Practices
  - As noted earlier, from a regulatory perspective, Suppliers have the option to either 1) perform acceptance to their NQA-1 program without use of commercial grade dedication or 2) use commercial grade dedication when procuring items intended for use in safety related equipment from commercial suppliers.
  - Purchasers may require use of CGD through their contract terms or auditing practices. If so, Purchasers should take special care that the Supplier has adequate expertise to perform CGD in a manner that meets regulatory requirements and industry expectations, as well as to properly audit sub tier suppliers performing CGD.
  - Inadequate CGD by Suppliers several levels down in project supply chains has resulted in stoppage of work and extensive rework and project delays



# Good Practices

- 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

# Good Practices

- Effective internal audit program
  - 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
    - 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

# Good Practices

- Use of an Effective Order Entry Process
  - The level of rigor used at order entry should be consistent with:
    - The complexity of the order
    - Potential financial or schedule risks due to a lack of clear understanding between the Purchaser and the Supplier
    - Purchaser oversight of the order entry process is especially critical when the Supplier's order entry system interfaces directly with production controls on the floor.
    - Developing an approach to allowing Purchaser oversight without compromising proprietary information can be complicated
  - Errors not caught at order entry result in rework that may not be identified until after production is mainly completed

# Good Practices

- Efficient and Effective Purchaser / Supplier Communication
  - Purchaser/Supplier Kickoff Meeting
    - Attendance and scope of discussion as appropriate given the size, complexity, and potential impact of errors on cost and schedule
    - First of a Kind, custom order requirements, use of new production processes are factors to consider
  - Well Defined Purchaser / Supplier Communication Channels During Production
    - Enable rapid notification, evaluation, and resolution of issues that arise during production, reducing the number and impact of supplier quality issues
    - Early notification is a key, in certain cases the Purchaser may be able to evaluate and approve acceptable alternate approaches that result in more cost effective resolutions



# Supplier Quality Management Training

## Procurement Event Specific Risk Management

# Procurement Event Risk Management

- A “procurement event” is a unique combination of a scope of safety related materials, equipment, or services being considered for award to a specific potential supplier
- A Screening Evaluation is recommended for most procurement events to identify and estimate the level of potential supplier quality risks
- Development and implementation of a procurement event specific Supplier Quality Issues Risk Management Plan is recommended where the identified risks warrant

# Procurement Event Risk Screening

- A Screening Form can be used that includes:
  - Identification of the types of risk factors that are of concern
  - Identification of which risks are of concern for the procurement event scope and potential supplier
  - Ranking the estimated level of risk of occurrence of supplier quality issues due to each risk factor
  - Estimating the potential impact on cost and schedule of the supplier quality issues should they occur
  - Documenting the basis for a decision as to whether or not the risk and potential impacts justify development and implementation of a risk mitigation plan

# Procurement Event Risk Management Plan

- Potential actions that could be taken to prevent or mitigate risks should be described and considered
- Different prevention or mitigation actions may be appropriate based on the impact of the quality issues should they occur dependent on the scope and supplier
  - Use of pre-shipment final inspections may be sufficient for quality issues that would require minor actions to correct
  - Use of a broad range of mitigative actions early in production (pre-job briefing, hold points, independent verifications prior to work execution) may be appropriate if a complete rework would be required to correct the issue with a commensurate schedule impact



# Example Procurement Event Screening Form

<b>Risk Description</b>	<b>(A) Level of Risk  (1-5)</b>	<b>(B) Level of Potential Project Impact  (1-5)</b>	<b>Overall Risk  (A x B)</b>	<b>Prevention or Mitigation Actions and Basis</b>
1. Quality issues resulting from level of Supplier experience with 10 CFR Appendix B and ASME NQA-1 QA program implementation				<b>Prevention Actions:</b>  <b>Mitigation Actions:</b>  <b>Basis:</b>
2. Quality issues as a result of recent significant change in supplier operations				<b>Prevention Actions:</b>  <b>Mitigation Actions:</b>  <b>Basis:</b>
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				<b>Prevention Actions:</b>  <b>Mitigation Actions:</b>  <b>Basis:</b>
4. Quality issues as a result of cultural, language, or other communication challenges				<b>Prevention Actions:</b>  <b>Mitigation Actions:</b>  <b>Basis:</b>

# Incorporation of Risk Evaluation into the Sourcing and Supplier Selection Process

- In many cases, project suppliers may have already been selected without a structured Supplier Quality Issues Risk evaluation
  - Retrofitting risk prevention and mitigation actions after award can be a challenge due both to budget and contract issues
- Where possible, incorporation of a Supplier Quality Issues Risk evaluation into the sourcing and supplier selection process is recommended
  - Requesting risk factor related information in Request for Quotes/Requests for Proposals
  - Evaluation of risk factors and development of a preliminary plan and cost estimate for prevention and mitigation actions as part of the bid evaluation and supplier selection
  - May require visits to one or more potential suppliers

# Breakout Sessions