

Quality Assurance Considerations for Supply Chain
Management in Large-Scale Capital Asset Acquisition
Projects

EFCOG

Safety Subgroup

QA Policies & Procedures Task Group

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EFCOG Safety Subgroup - Quality Assurance Considerations for Supply Chain Management in Large-Scale Capital Asset Acquisition Projects

This document was developed as a lesson's learned tool to provide personnel with information to help ensure subcontractors for large scale projects perform work to expected quality performance standards for nuclear grade or technically challenging tasks. Specifically, the focus is to provide guidance for large scale projects (e.g., chosen as projects with total project cost 50 Million dollars and above) managed under DOE Order 413.3B (including any associated administrative changes or subsequent minor revisions), *Program and Project Management for the Acquisition of Capital Assets*, having significant technical and/or quality program flow down where the supplier performing the work may have limited nuclear grade design and/or build experience. Guidance can be applied to projects in which the design authority is maintained by the purchaser. This guidance document was developed considering lessons learned from recent projects conducted by Savannah River Remediation (SRR) and other Prime Contractors in the DOE complex. Benchmarking data and information from Energy Facility Contractors Group (EFCOG) member sites and Commercial Nuclear utilities, where similar supply chain challenges exist, were also evaluated and blended into this document, as appropriate. Project teams can consider this information in developing supply chain management strategies for their specific projects, large or small. This information is meant as a tool for quality assurance professionals to effectively plan and manage these acquisitions under a DOE Order 413.3B project life cycle.

DISCLAIMER: Information in this document is a compilation of strategies that users can consider as desired in planning project acquisitions to reduce project technical or schedule/cost risks. The strategies are meant to complement DOE Orders, Standards, Guides, etc. relative to project management and procurement and in no way, is to be considered as additional requirements. Terms such as "must" and "shall" are used in the discussion, but are simply used to stress relative importance of a topic/concept and not imply new requirements. Likewise, information in this document may not be applicable or beneficial to utilize in all situations.

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1. Purpose

The purpose of this document is to provide personnel with information to help ensure subcontractors for large scale projects (particularly Engineering, Procurement, and Construction projects) perform work to expected quality performance standards (e.g., nuclear facility or technically challenging tasks). Specifically, the focus is to provide guidance for large scale project procurements for projects managed under DOE Order 413.3B, *Program and Project Management for the Acquisition of Capital Assets* (including any associated administrative changes or subsequent revisions that do not significantly alter the order scope or requirements), having significant technical and/or quality program flow down where the supplier performing the work may have limited experience in the applicable flow down requirements. This guidance covers projects in which the design authority is maintained by the purchaser. This guidance document was developed considering lessons learned from recent projects conducted by Savannah River Remediation (SRR) and other Prime Contractors in the DOE complex. Benchmarking data and information from Energy Facility Contractors Group (EFCOG) member sites and Commercial Nuclear utilities, where similar supply chain challenges exist, were also evaluated and blended into this document, as appropriate. Project teams should consider this information in developing supply chain management strategies for their specific projects recognizing that all information may not be suitable to adopt for their particular project acquisitions. Further, while geared towards large scale project scopes under DOE Order 413.3B, the strategies included in this guidance can be considered and customized by the user for any procurement to help ensure successful supply chain performance.

2. Introduction

DOE and Commercial Nuclear Utility activities increasingly are utilizing the supply chain to perform design/build methods for major asset acquisition scopes of work. This utilization can be challenging and costly in that many suppliers are commercial vendors required to 1) perform to new, more rigorous quality standards including enhanced documentation requirements for nuclear grade projects, 2) have not utilized their nuclear quality processes in many years, if ever, or 3) have undergone significant organizational changes since they were last verified to have performed nuclear grade work. These situations can result in challenges in procurement execution, particularly for firm-fixed price contracts noted to be the typical contract vehicle preferred for many procurements within the Commercial Nuclear Industry and across the DOE complex. The Federal (DOE Complex) projects also includes federal competitive acquisition expectations which results in added complexity. Complicating the situation further, Commercial Vendors, in many instances, are being asked to complete first of a kind/unique work scope(s) and/or use of non-traditional technical approaches. For major acquisition scopes, the vendor may be required to manage extensive sub-tier supplier networks. These complexities result in risks to the purchaser and supplier which can lead to significant project cost or schedule increases from procurement change orders and/or equitable adjustments, particularly if Fixed Priced Contracts are used.

Many strategies are available and should be considered to address this complexity and mitigate the resultant risks for capital asset acquisition projects. For instance, early risk identification, regular risk evaluation and analysis, development of achievable and effective risk mitigation strategies, continuous monitoring of risk reduction progress and effectiveness, and mitigation course correction when appropriate and/or required is a programmatic approach which can be applied. Despite best efforts of even the most experienced of nuclear grade suppliers, less than adequate performance may still occur. However, the strategies discussed in this document in concert with DOE 413.3B and associated guides can help minimize the likelihood of failure and should help improve early detection and correction of negative trends and deficiencies that may arise, minimizing overall project risk.

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Initially, an SRR team, comprised of construction quality assurance, project management, engineering, and supply chain quality assurance representatives was assembled to develop this guide. Several sessions were held to establish the strategy and format as well as to identify activities that were effective and those that were ineffective to ensure a supplier is prepared to effectively execute technical and quality requirements before design/procurement/fabrication activities began. The team benchmarked external resources such as DOE Orders/Guides, EFCOG members and materials, and NRC Nuclear Supply Chain conference materials for applicable information to include in the guide. Additionally, the team identified areas of opportunity and associated key activities necessary for mitigation.

The activities identified were assigned to the corresponding critical decision step (i.e. CD-0 through CD-4). Attachment 1 contains the critical decision steps, Key Activities for Successful Execution of Projects (KASE activities) and associated key activities. Attachment 2 further breaks down the key activities into those critical attributes applicable to each activity and includes key procedural or other documents as resources to be considered (e.g., applicable DOE Order 413.3 Guides). The critical attributes are specific actions that should be considered for incorporation into a project specific management strategy. The key activities and critical attributes contained in Attachments 1 and 2 do not constitute an all-inclusive list. The guidance provided herein should be considered a starting point for future projects with the unique aspects and challenges of each project evaluated and addressed. Attachment 3 provides more specific information on items to consider including procurement scopes of work, purchase orders, etc. Attachment 4 contains a list of supporting elements to be used as potential indicators in evaluating or monitoring vendor effectiveness.

A critical element of procurements is the proper selection of safety functions, functional/code requirements, and quality program flow down requirements to ensure adequacy of the acquisition to meet design requirements. These selections warrant high focus of the project team to accurately define this in the scope of work development. A significant contribution to deficiencies of capital projects with safety related requirements often has centered around defining the Systems, Structures, or Components (SSCs) relative to being safety related or mission critical. The Quality Levels (quality requirements) for each SSC must be established early on in concert with the development of the Documented Safety Analysis. Other documents such as DOE Standard 1189, Safety in Design, provides guidance in properly establishing these requirements early in the project life cycle. Specifications/Scopes of work must flow down adequate information relative to safety functions, safety boundaries, etc. to enable proper control of Safety Related boundaries. Not this may require transmittal of hazard analysis, safety analysis, etc. to support this effort. The scope of this document does not provide additional guidance in these determinations but the project team must recognize that failure to conservatively establish these needs early will result in significant project risks.

3. **Definitions (abbreviated from Federal Acquisition Regulation sources)**

Best Value - The expected outcome of a purchase is determined by the buyer to provide the greatest overall benefit to buyer.

Firm Fixed Price Contract - Provides for a price that is not subject to any adjustment based on the contractor's cost experience in performing the contract. This contract type places upon the contractor maximum risk and full responsibility for all costs and resulting profit or loss.

Large-Scale Project – Projects with Total Project Cost greater than \$50 Million. This value was chosen to reflect the strategies in this document are geared towards projects of this magnitude and also is complementary to 413.3B project thresholds (e.g., 413.3B Admin Change 3). Selected information (e.g., vendor oversight planning) may be usable for smaller projects/acquisitions as well.

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Low Price Technically Acceptable Contract – Awarded to the lowest priced offeror who submitted a technically acceptable proposal.

4. Discussion

The information in this document is applicable during the entire project life cycle and is directed toward Project Managers, Project Engineering Managers, Project Quality Assurance, and Project Procurement personnel utilizing an integrated project team approach. It is imperative that the integrated project team members understand their joint, proactive responsibility to define the project and procurement strategies to help ensure successful delivery of project activities by considering the concepts presented in this document. It is also imperative that project team members are suitably qualified and proficient to perform their roles in defining requirements and managing suppliers of large scope acquisitions. Projects teams with insufficient experience or knowledge further increases risks when managing vendors who also have limited experience in complex requirement procurements.

Key elements of the overall approach contained in Attachments 1 and 2 enable effective supply chain performance as part of a DOE Order 413.3B project that includes such items as:

- 1) Acquisition considerations must be planned early in and adjusted throughout the Critical Decision Process. Identification of project tasks to mitigate supply chain risks for major subcontracted scopes of work must be developed and adjusted throughout the project life cycle commensurate with the acquisition strategy, understanding of vendor capabilities/vulnerabilities at award, and performance during contract execution. Project risk and contingencies processes should address realized less than desired performance of major suppliers.
- 2) Often the resource requirements for external/internal oversight, assessments, and surveillances of suppliers are not adequately covered in project baselines (both in terms of cost and schedule) of contractors. It is essential that these strategies are clearly defined and included in project quality execution strategies and project cost and schedule baselines, graded based on risk and scope to protect against less than adequate supplier performance.
- 3) Procurement Quality strategies must be included formally in project execution and quality assurance/quality control executions strategies throughout the project life cycle. Include such consideration as:
 - a) Extent of NQA-1 / other quality standards flow down for major acquisitions
 - b) Type of procurement to utilize (e. g., Best Value)
 - c) Any special vendor pre-bid or bid evaluation approaches
 - i) Pre-award conferences and audits of top 3 bidders to support best value selection
 - ii) Approaches to review key sub-tier suppliers included in vendor bids
 - iii) Post award conference to discuss oversight approaches
 - iv) Quality control strategies necessary to manage supply chain effectiveness and risk
 - v) Oversight of work activities prior to it being inaccessible for inspection
 - d) Oversight approaches must be utilized when developing the scope of work.
- 4) Risk, opportunities, and mitigation strategies should be included in project Risk and Opportunity analysis and project fiscal contingency/management reserves.
- 5) Critical review and selection of quality program flow down early in acquisition planning. For example, approaches to have a commercial supplier work to the purchaser's quality program would be different than if utilizing an experienced, effective nuclear grade supplier working to their procedures. The engineering and quality professionals on the project must consider these options early in the project life cycle to tailor the acquisition and oversight planning strategies accordingly. The more a particular scope of work may be requesting commercial suppliers to fulfill nuclear industry standards, the higher

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the risk and increased mitigation planning and efforts that will be required to ensure success, even if the vendor performs under the purchaser's quality program.

- 6) Determine specific elements to include in procurement documentation (specification/Scope of Work and/or other items in the Request for Proposal package) to help minimize risk of less than adequate performance, such as requiring oral presentations of primary and key subcontractors as part of bid packages. Oral presentations should include:
 - a) History of experience in implementing required quality assurance tasks
 - b) Self-assessment/audit plans for ensuring implementation of quality requirements
 - c) History of experience managing sub-tier suppliers
 - d) Performance metrics for work to be performed for monitoring technical and quality effectiveness
 - e) Quality oversight plans for project activities
 - f) Depth of knowledge and leadership experience on the subcontract team needed to execute the scope within the rigorous project requirements.
- 7) Critical review including key elements in the specification/Scope of Work and/or Request for Proposal should set expectations for performance and maximize key information to be presented by prospective bidders to demonstrate their ability to successfully implement the scope of work.
- 8) Design reviews associated with authorization to proceed for CD phases should include specific reviews of supply chain management approaches and flow down strategies in major acquisitions to ensure effectiveness of the strategies selected. Utilization of personnel with previous experience in complex vendor project management in the design review team or in-process procurement reviews, as well as experienced quality personnel as much as practicable.
- 9) The design reviews at 30%, 60% and 90% (or other similar maturation or key milestone stages) should include evaluation of the quality assurance strategy, experience and independence. Typically, the engineering execution planning defines the design maturation for 30%, 60%, and 90% design phases.
- 10) Project teams should consider major procurement proposals to be released as best value, with technical and quality pre-award evaluations tailored to select vendors with the best combination of cost, technical capability, and quality. Other contract vehicles can be selected (e.g., low price technically acceptable), but best value is recommended to enable improved risk management by the project team.
- 11) Specifications should require vendor quality control plans to be submitted for review and approval prior to start of work. Based on these plans, the purchaser reserves the right to identify, hold, and witness inspection points in addition to those included in the specification or plan. This will allow additional oversight based on submitted QC approaches and vendor capabilities demonstrated during award validations (e.g., more hold/witness points may be needed based on risks identified in the award process).
- 12) If Commercial Grade Dedication (CGD) is included in flow down for Safety Related SSCs, the specification should require all CGD's to be submitted to the purchaser for approval prior to ensure adequacy of the dedication package versus safety functions or alternate approach (e.g., tapering review strategy, sampling strategy) for the DOE prime contractor to ensure adequacy of the dedication packages. Evaluations of CGD' should ensure that the latest DOE or Energy Facility Contactors Operating Group (EFCOG) guidance for CGD adequacy is utilized.
- 13) Pre-bid meetings with prospective suppliers should also include briefings on expectations relative to major items such as specification compliance (including other disciplines), vendor quality procedure compliance, nonconformance, corrective action process expectations, storage, records and supplier deviation processing. The purchaser should provide the potential vendor expectations for processing deliverables such as engineering deliverables, quality verification records, and technical rigor expectations and discipline relative to supplier deviation disposition processing as level of rigor is often

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a high vulnerability area (See Attachment 2 for Pre-bid Vendor Education and Pre-bid Procurement Specification Review Meeting attributes).

- 14) The project team should critically review vendor submittals (including major sub-tier supplier information submitted with the bid proposal and validated in Oral Presentations if performed) to determine if vendors can perform the work scope with rigorous specification compliance and documentation rigor. This expectation must be included in the specification and require vendors to submit capability/history/plans for meeting this expectation with their bid package including capability of their key suppliers. A briefing of prospective bidders on nuclear grade procedural compliance, documentation expectations, submittal quality expectations, and effective use of corrective action processes will help ensure this expectation is communicated to prospective bidders and enable effective bid packages to be developed.
- 15) On-site audits/evaluations of suppliers prior to award should be thoroughly planned and executed by a team of Engineering and Quality representatives at a minimum to review prospective bidder capability to execute the technical and quality requirements of the specification. This evaluation should include a critical review of key sub-tier suppliers, particularly in situations where the prime contractor will subcontract major portions of the scope of work. It may be appropriate to perform onsite reviews on all short list prospective bidders to aid in effective vendor down select. Pre-award reviews/audits may warrant review of major sub-tier suppliers. Pre-award audits should be closed prior to award with any subsequent actions/verifications or releases tracked within the project plan and vendor award notifications from the purchaser in contract documents with the vendor.
- 16) Oversight strategies must be re-evaluated and adjusted as necessary after contract award to ensure the plans are consistent with the supplier selected to perform the contract. A vendor that is performing work scope to high rigor quality requirements for the first time will need significantly more pre-work coaching and ongoing oversight than one the is experience and has record of solid performance. Note this could be a project savings or cost based on the specific vendors selected. Also, any planned vendor oversight must be clearly described in the scope of work and final vendor contract award documents to ensure vendor support of this planned scope is covered adequately in the cost estimate.
- 17) In addition to oversight, consider establishing a coaching/mentor approach with the vendor to help establish culture and expectations prior to and during work. This would not relinquish the vendor's accountability to perform the contract scope as established, but will help establish a beneficial teaming environment to prevent future issues or misunderstandings. Coaching is particularly beneficial in such areas as procedure/technical requirement planning, engineering rigor, and corrective action management programs.
- 18) The vendor's performance indicators for item and equipment non-compliances, problem reports and corrective actions issued, supplier deviations submitted, etc., should be reviewed by the purchaser on an agreed-upon schedule for systemic issues to ensure specification compliance. Monitoring of this information is necessary to proactively direct needed improvements, adjust oversight plans, etc. This review should be performed utilizing a project Management Review Team type approach that includes trending of issues by the vendor. Potential indicators for consideration are included in Attachment 4. Note this rigorous performance tracking approach would be utilized in limited large or complex, long duration contracts such as major facility construction activities.
- 19) Expectations to ensure required records for the work scope are completed accurately to meet purchasers needs and requirements must be stressed prior to work and monitored early to reduce risk. Issues must be found early and corrected to ensure record suitability or final acceptance of the acquisition. Record deficiencies found at the end of a major acquisition can result in significant project risk.

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5. Best Value Determination

Applying a structured best value source selection process should provide assurance that site requirements will be flowed down to a supplier and its sub-tier suppliers and appropriately implemented to meet technical and quality requirements. This process should reduce risk and uncertainty associated with critical purchases, reduce staff resources needed to support unqualified suppliers in performing work, and provide assurance that goods and services are delivered on schedule and within budget.

Areas of consideration should include (see Attachment 4 for additional criteria):

- a. Bidder's technical and organizational approach should include:
 1. What is the level of supplier experience regarding design and build of the item? (e.g., past experience in performing work)
 2. Will the supplier subcontract the work? (e.g., Does the supplier and subcontractor have experience performing this kind of work together including quality requirements and rigor? Consideration should also be given to request the vendor to submit a quality management strategy document as part of the bid proposal to describe how they will effectively flow down and ensure sub-tier supplier conformance to requirements)
- b. Bidder's personnel qualifications should include:
 1. Does the supplier have qualified quality assurance personnel to implement and oversee the quality program?
 2. Will there be qualified engineering/design support personnel readily available to support the shop when the item is fabricated?
 3. Does the supplier have qualified welders and machinists available for fabrication?
 4. Does the supplier have qualified quality control and nondestructive examination personnel available for inspection activities?
- c. Bidder's resource commitment should include:
 1. Has the supplier identified the key fabrication and engineering and design individuals (e.g., shop leader, engineering/design leader, quality assurance, non-destructive testing) and level of experience (e.g., depth and breadth of experience for this type of work)
 2. Does the supplier have the physical capacity to perform the work (e.g., shop floor space, ceiling height, cranes, truck loading area), or does the supplier have a reasonable plan to obtain the capacity when needed?
- d. Bidder's Past Performance should include:
 1. Are there other customers (e.g., site or other DOE sites) who have had either negative or positive experiences with the supplier?
 2. Are there any reasons to believe that there have been positive or negative changes to previous performance?

6. Conclusion

This document provides the steps to take and the information to be considered in selecting and contracting with commercial suppliers for large scale, nuclear grade or similar quality rigor projects. This guidance is intended to cover all phases of the project, including pre-conceptual planning, design and analysis activities, and construction implementation activities. This guidance is not all inclusive, and the unique aspects/challenges of each project should also be considered.

Attachment 1 – Key Activities

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Critical Decision	KASE/Project Phase Activity	Key Activity
	Upfront Planning Phase	Establish Integrated Project Team - Ensure QA is part of the team
	Pre-Conceptual Phase	Develop Project Risk and Opportunity Management Plan/Report (update as necessary throughout the critical decision process) - Develop mitigation strategy for vendors who have no, limited, or questionable experience with DOE/Nuclear site requirements - Develop mitigation strategy for vendors who have no, limited, or questionable experience with NQA-1 requirements / other quality standards (i.e., strategy on how to bring vendors to acceptable level) - Develop mitigation strategy for vendors who have no, limited, or questionable experience with extensive/intrusive oversight by customer QA and QC representatives.
CD-0 – Request Approval for Concept Relative to Mission Needs		
	Conceptual Design Phase	Prepare Preliminary Project Execution Plan Prepare a Team Execution Plan - Outline strategy for Quality Assurance - Outline strategy for staffing needs, particularly staffing to perform subcontractor oversight and development - Incorporate mitigation strategies from Risk and Opportunity management analysis for QA and vendor as appropriate - Establish decision process for vendor selection, including ranking criteria - Develop a Supplier Quality Program Checklist. Develop and document QA/QC oversight plan (update as necessary throughout the critical decision process) - Detail the degree of vendor oversight as well as oversight strategy (e.g., on site representation by coach/mentor, periodic program assessment/audit approach during work execution of prime and sub-tiers) - Estimate resource requirements for vendor and project team - Establish QC oversight responsibilities - Estimate staffing requirements based on risk and opportunity analysis to provide support to the vendor - Develop draft task analysis sample Develop commercial grade oversight approach if safety related (e.g., identify that all CGD's by suppliers will require review and approval prior to use). Develop and document life-cycle QA/QC oversight schedule (update as necessary throughout the critical decision process) including such activities as:

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Critical Decision	KASE/Project Phase Activity	Key Activity
	Conceptual Design Phase (cont.)	<ul style="list-style-type: none"> - Pre/Post award Vendor and sub-tier supplier assessment in accordance with applicable NQA-1 requirements/other quality standards - Post award Vendor implementing procedures - In progress surveillances – construction, design (accounting for functional classification) - Review of self-assessments for both the vendor and project - In progress Construction/fabrication/design/second and third level procedure compliance.
CD-1 – Request Approval for Project Authorization		
	Execution Phase - Preliminary Design	<p>Finalize Project Execution Plan –</p> <p>Update the Team Execution Plan</p> <ul style="list-style-type: none"> - Incorporate necessary changes to strategies supporting QA activities, i.e. audit schedule, vendor support, Quality requirements, vendor capability. <p>Review lessons learned from previous projects for applicability</p> <ul style="list-style-type: none"> - Develop and document mitigation strategies from applicable projects. <p>Develop Quality Assurance Plan (update as necessary throughout the critical decision process)</p> <ul style="list-style-type: none"> - Establish QA strategies for the project - Define roles and responsibilities as well as organizational structure expectations - Define approach to include oversight audits, surveillances, self-assessments, sub-tier vendor oversight - Charter Management Review Team/Corrective Action Review. <p>Corrective Action Review board membership and roles and responsibilities should be developed to:</p> <ul style="list-style-type: none"> • Provide active interaction between the vendor and Integrated Project Team • Provide environment for open discussion and resolution of issues • Provide for development of mutually agreed upon corrective actions as well as preventive actions. <ul style="list-style-type: none"> - Develop standard approach for records review and approval <ul style="list-style-type: none"> • Develop detailed plan for record review and submittal • Real time review and submittal. <p>Develop Procurement Specification</p> <ul style="list-style-type: none"> - Ensure applicable sections of NQA-1 / other quality standards are specified, including requirement for vendor to perform internal audits and self-assessments for compliance with QA requirements

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Critical Decision	KASE/Project Phase Activity	Key Activity
	Execution Phase - Preliminary Design (cont.)	<ul style="list-style-type: none"> - Ensure the flow down of requirements to sub-tier suppliers is specified in detail - Ensure oversight/audit expectations are specified in detail - Define document submittal requirements matrix - Identify key personnel (e.g. QA/QC managers) - Identify experience level related to large scale construction and nuclear experience - Develop standard approach for records review and approval. <ul style="list-style-type: none"> • Develop detailed plan for record review and submittal • Real time review and submittal.
CD-2 – Request Approval of Performance Baseline		
	Execution Phase - Final Design Execution Phase - Final Design (cont.)	<p>Update and issue the Team Execution Plan (reference Quality Assurance Plan for details)</p> <ul style="list-style-type: none"> - Incorporate necessary changes to strategies supporting QA activities, i.e. audit schedule, vendor support, Quality requirements, vendor capability. <p>Provide pre-bid vendor education for performing work at the site (coach/mentor):</p> <ul style="list-style-type: none"> - Safety and security requirements and expectations - Applicable NQA-1 requirements, other quality standards and expectations - QA/QC oversight expectations - Overview of supplier deviation disposition process - Engineering Document Requirements process - Experience for personnel on the project. <p>Perform formal pre-bid procurement specification review with prospective vendors (update as necessary throughout the critical decision process)</p> <ul style="list-style-type: none"> - Ensure thorough understanding of QA requirements so vendor will adequately staff (both quantity and experience) - Ensure vendor representation at pre-bid specification review includes QA, Engineering and Project Management disciplines - Assess vendor’s understanding of depth and breadth of project - Assess whether vendor management appears to be willing and able to support project with necessary staff and other available resources - Assess key personnel depth of understanding of requirements and expectations - Assess vendor’s capability to meet requirements and expectations - Ensure key personnel for project are identified - Staff for oversight based on subcontractor experience. <p>Perform on site vendor audits/Evaluation</p> <ul style="list-style-type: none"> - Planned by Quality Assurance and Engineering - Consider review of sub-tier suppliers

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Critical Decision	KASE/Project Phase Activity	Key Activity
		<ul style="list-style-type: none"> - Conduct on short list of vendors. <p>Formal Bid presentations by prospective vendors as part of contact award process</p> <ul style="list-style-type: none"> - Assess vendor’s understanding of depth and breadth – (do they have or will they have the capability to adequately staff and support?) - Assess vendor management’s support - Assess key personnel’s depth of understanding of requirements and expectations - Assess vendor’s demonstration of capabilities to meet requirements and expectations - Ensure key sub-contractors’ personnel are present - Assess vendors’ overview of their QA program, how it has been applied to similar projects, how it will be applied to this project - Revise Quality Assurance Plan based on input from prospective vendors’ presentation/assessment. <p>Quality Control Inspection/Oversight Plan (update as necessary throughout the critical decision process)</p> <ul style="list-style-type: none"> - Assess whether plan supports extensive oversight - Assess whether the plan has the necessary support from the vendor. <p>Perform formal Post award procurement specification review (coach/mentor)</p> <ul style="list-style-type: none"> - Ensure thorough understanding of QA requirements so vendor will adequately staff (both quantity and experience) - Ensure vendor representation at post award specification review includes QA, Engineering and Project Management disciplines - Ensure vendor representation at review includes same individuals as those at pre-bid review - Assess the need for Risk and Opportunity Report/schedule/cost/contingency plan adjustments based on result of post award formal review - Ensure thorough review of Engineering Document Requirements process - Ensure thorough review of Records/report requirements - Ensure thorough review of Quality Control Inspection Plan - Assess the need for revisions to the QA/QC Oversight Plan, Life-Cycle QA/QC Oversight Schedule, Quality Assurance Plan, Quality Control Inspection Plan based on vendor selection. <p>Develop technical and quality performance indicators for the project, see Attachment 4</p> <ul style="list-style-type: none"> - Review performance indicators with the project - Review applicable performance indicators with the vendor. <p>Partner with supplier to optimize benefit from audits and surveillances in meeting requirements and mitigating project risk.</p>

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Critical Decision	KASE/Project Phase Activity	Key Activity
CD-3 – Request Approval for Construction Start		
	Execution Phase - Construction	<p>Use Management Review Team/Corrective Action Review Board meetings to provide additional tier of project health oversight and build on partnering relationship with the vendor by reviewing and analyzing applicable documents and other information (coach/mentor and oversight)</p> <ul style="list-style-type: none"> - Audits and surveillances - Corrective action system issues - Lessons Learned - Corrective Action Reports - Quality of submittals - Second/third level procedure compliance - Weekly QA/QC meeting - Weekly engineering meetings - Review performance indicators - Nonconformance reports.
CD-4 – Request Approval for Operations Start	NA	NA

Attachment 2 – Critical Attributes

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Attachment 2 – Critical Attributes

Key Activity	Critical Attributes
Establish Project Team	<ul style="list-style-type: none"> - QA/QC representation with knowledge and experience of large scale projects: <ul style="list-style-type: none"> • Depth/breadth of QA oversight • Depth/breadth of QC oversight • Knowledge of vendor requirements necessary to support large projects.
Develop Project Risk and Opportunity Management Plan	<ul style="list-style-type: none"> - Typical Contributors to Risk Events - <ul style="list-style-type: none"> • Procurement Strategy • First-use Subcontractor/Vendor • Vendor Support • Unclear or over-specification of requirements - Resource/Conditions <ul style="list-style-type: none"> • Specialty Resources Required • Personnel Training & Qualifications • Resources not Available - If applicable, assess level of oversight needed based on firmness of Documented Safety Analysis and functional classification.
Prepare a Team Execution Plan	<ul style="list-style-type: none"> - Flow chart vendor selection process - Establish selection criteria and document - Develop a Supplier Quality Program Checklist, for example: <ul style="list-style-type: none"> • Do prospective vendor exhibit capabilities to perform work? • Does prospective vendor have infrastructure/personnel to perform work? • Does prospective vendor have experience in NQA-1 / other quality standards? • Does prospective vendor have experience in materials of construction/methods? • Is vendor knowledgeable of suspect counterfeit items and how to manage? • Does prospective vendor have experience in ASME B31.3 or other applicable codes in the procurement flow down • Does prospective vendor have experience with construction under NQA-1, other quality standards, DOE orders/oversight? • Does prospective vendor meet requirements for experience (QA/QC, Engineering, project management or other key position identified for the project) and is the experience relevant? • Does prospective vendor demonstrate ability to develop and submit quality documents for the project? • Does prospective vendor demonstrate the ability to develop and implement required QA plans?

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Key Activity	Critical Attributes
Develop Quality Assurance Plan	<ul style="list-style-type: none"> - Identification and flow down of Quality requirements to subcontractor(s) - Conduct of QA audits and surveillances - Management review team/corrective action review board - Review and documentation of lessons learned from previous projects - Development for key items: <ul style="list-style-type: none"> • Oversight strategy and plans (e.g., audits, surveillances, inspections, and hold points) • Quality Assurance requirements NQA-1 2008/2009 applicable parts(s) - Establish Charter, roles and responsibilities, membership, purpose, meeting schedule, and review criteria for the Management Review Team/Corrective Action Review Board.
Develop and document QA/QC oversight plan (high level)	<ul style="list-style-type: none"> - Add lessons learned to oversight/audit activities.
Review lessons learned from previous projects for applicability	<ul style="list-style-type: none"> - Incorporate into design - Incorporate into QA/QC oversight plans - Update lessons learned throughout project and review as appropriate.
Develop Procurement Specification	<ul style="list-style-type: none"> - Identification of key personnel: <ul style="list-style-type: none"> • QA/QC • Engineering • Project Management • Increase experience level for QA from 5 years to 10 years • QC experience level 5 years - Requirements for the Quality Control Organization - Quality Control Phasing requirements for a Quality Control Plan if applicable - Requirements for Quality Program flow down to vendor and sub-tier - Suppliers tailored based on vendor experience - Submittal requirements - Engineering Document Requirements submittal process - Engineering Document Requirements - Quality Verification Documents - Applicable Codes and Standards - Vendor quality control plans must be submitted for review and approval - Reserve the right to identify hold and witness points in addition to those in the specification - All CGDs (or alternate assurance strategy) must be submitted for approval if commercial grade dedication is included in flow down for SSCs - Vendor submittal of work history to demonstrate ability to meet procurement specifications - Vendor submittal of self-assessments/audit plans - Vendor submittal of documentation to demonstrate ability to manage sub-tier suppliers.

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Key Activity	Critical Attributes
Provide pre-bid vendor education for performing work	<ul style="list-style-type: none"> • Develop standard slides • Identification of key personnel • NQA-1 basics – how to develop and implement program procedure requirements for NQA-1 • Procurement flow down • Quality overview • Pre-award audits • QA/QC oversight • QC Inspection Plan – development, reports, records • Nonconformance's/ Corrective actions <p>- Vendor submittal of performance indicators</p> <ul style="list-style-type: none"> • Design control • Training and qualifications • Development and importance of document control • Importance of verbatim compliance to procedures/work process • Need for corrective action program • Critical need for work planning systems • QA requirements • Importance of timeliness • Safety requirements • Expectation on high quality technical and quality submittals • 1-line initial and date required for error corrections • Change Process – Supplier deviation disposition.
Perform onsite vendor audits/evaluations	<ul style="list-style-type: none"> - Audit/evaluation plan should be developed by Quality Assurance and Engineering at a minimum - Plan should assess vendor's capability to execute the technical and quality requirements - Assess implementation of NQA-1 requirements/other quality standards, if applicable - Assess vendor's history of experience with NQA-1, other quality standards and Nuclear facilities tasks - Assess key personnel experience - Assess sub-tier suppliers as appropriate - Audit should be closed prior to award.
Perform formal pre-bid procurement specification review with prospective vendors	<ul style="list-style-type: none"> - Determine process for defining QA/QC staffing - Communicate expectations to ensure vendor has internal oversight capabilities - Staffing needs to support QC requirements - Staffing needs to support internal oversight requirements - Staffing needs to QA record/data submittal - Requirements for the Quality Control Organization - Quality Control Phasing if applicable - Requirements for a Quality Control Plan and Oversight - Requirements for flow down to sub-tier suppliers if applicable.

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Key Activity	Critical Attributes
<p>Formal Bid presentations by prospective vendors as part of contract award process</p>	<ul style="list-style-type: none"> - Establish standard format for what to address - Engineering Document Requirements submittal process - Quality requirements - submittals - Oversight requirements including possible witness and hold points - Procedure requirements - Staffing Plans/needs to support QC requirements - Staffing Plans/needs to support internal oversight requirements - Staffing Plans/needs to QA record/data submittal - Requirements for the Quality Control Organization - Quality Control Phasing if applicable - Requirements for a Quality Control Plan and Oversight - Requirements for flow down to sub-tier suppliers if applicable.
<p>Perform formal post award procurement specification review</p>	<ul style="list-style-type: none"> - Perform line by line review - Engineering Document Requirements submittal process - Quality requirements - Oversight requirements – including witness and hold points - Procedure requirements - Records requirements - Staffing Plans for vendor - Staffing Plans/needs to support internal oversight requirements - Staffing Plans/needs to QA record/data submittal - Requirements for the Quality Control Organization - Quality Control Phasing if applicable - Requirements for a Quality Control Plan and Oversight - Requirements for flow down to sub-tier suppliers if applicable.
<p>Management Review Team/Corrective Action Review Board meetings</p>	<ul style="list-style-type: none"> - Utilize the Management Review Team/Corrective Action Review Board meetings to review quality, timeliness of: <ul style="list-style-type: none"> • Audits and surveillances • Corrective action issues • Corrective Action Reports • Submittals • Second/third level procedure compliance • Weekly QA/QC meeting - Build on partnering relationship with the vendor - Review selected performance indicators.

Attachment 3 – Items to Consider

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Purchase Order/Requisition:

- Define Training requirements (QA Briefing)
- Define key personnel and reference to specification for minimum experience requirements
- Include details on expectations with respect to previous experience in nuclear construction under an NQA-1 program
- Define specific terminology that may be unique in its application with the procurements
- In addition, those individuals that were part of the work performed under an NQA-1 program are in fact part of the team. These individuals are above and beyond the key personnel.
- Provide Mobilization plan to ensure no loss of productivity in developing Quality Inspection Plan, Procedures, development of quality briefing and completion of quality briefing to achieve project schedule.

Specification:

- Define Training requirements
- Define key personnel qualifications.

Field Conditions:

- Define training requirements in hours for any items identified in the specification that are prerequisites for Notice to Proceed.

Attachment 4 – Supporting Elements

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Attachment 4 - Supporting Elements

Element	Supporting Elements	General Expectations
Product Quality	○ Inspection/Test Capability	<ul style="list-style-type: none"> ◆ Inspection/test/Non-destructive Test personnel are all qualified for the task performed. ◆ Inspection tooling is maintained within calibration. ◆ Functional gages are identified and verified. ◆ Inspections are conducted in a technically sound and efficient manner. ◆ Inspection hold/witness points are identified and performed by qualified personnel.
	○ Inspection/Test Planning	<ul style="list-style-type: none"> ◆ Inspection/test attributes are clearly defined. ◆ Planning is consistent with product complexity. ◆ Planning clearly delineates inspection/test methods. ◆ Inspection and NDT practices/techniques are verified for adequacy. ◆ Inspection/test procedures/instructions and documentation are clear and understood and followed by users.
	○ Internal Defect Rate	<ul style="list-style-type: none"> ◆ Product defect data should be maintained and normalized as needed. ◆ Defect reporting includes all product, process, inspection and test related issues (exclude documentation only issues). ◆ Defect rates should be maintained at or below defined threshold (e.g., 10 defects/1000 manufacturing hours). ◆ High defect rates or adverse trends are addressed aggressively.
	○ Rework/Scrap Rate	<ul style="list-style-type: none"> ◆ Monitored and managed to low levels relative to contract cost or manufacturing hours. ◆ Adverse rework and scrap trends are effectively addressed.
	○ Delivered Equipment Quality	<ul style="list-style-type: none"> ◆ Delivered equipment meets all contract requirements. ◆ Problems identified as affecting delivered product are quickly assessed and identified to the Customer. ◆ Problems are properly documented on nonconformance reports or other documentation and Customer acceptance is offered prior to factory acceptance. ◆ Customer satisfaction is continually monitored.
Management Responsibility	○ Quality Focus	<ul style="list-style-type: none"> ◆ A quality policy exists and is fully understood throughout the organization. ◆ Quality objectives are established consistent with the quality policy. ◆ Senior management ensures that there is an awareness of the quality policy and that objectives are maintained. ◆ The effectiveness of the Quality Management System (QMS) is implemented throughout the organization and is formally assessed periodically and reported to upper management.

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Element	Supporting Elements	General Expectations
Management Responsibility (cont.)	<ul style="list-style-type: none"> ○ Senior Management Involvement 	<ul style="list-style-type: none"> ◆ Senior management is actively involved in supporting and improving the QMS. ◆ Management ensures processes needed to support the QMS are established, implemented, and attained. ◆ Senior management ensures that there is adequate internal communication of the quality objectives and effectiveness of the QMS. ◆ Senior management is involved in periodic reviews of the effectiveness of the QMS.
	<ul style="list-style-type: none"> ○ Customer Focus 	<ul style="list-style-type: none"> ◆ The organization understands the needs and expectations of the Customer and end-user. ◆ The organization monitors information related to customer satisfaction. ◆ Processes are established to ensure customer requirements are met. ◆ Customer feedback/complaints (e.g. complaint letters, etc.) are effectively and promptly addressed.
	<ul style="list-style-type: none"> ○ Continuous Improvement 	<ul style="list-style-type: none"> ◆ Quality policy includes a commitment to continuous improvement. ◆ Performance of key business and quality processes are monitored and improvement actions are continuously applied and tracked to closure. ◆ There is a culture of learning and improvement.
	<ul style="list-style-type: none"> ○ Infrastructure/ Resources 	<ul style="list-style-type: none"> ◆ Staffing is adequate to support timely and effective completion of contractual obligations. ◆ Personnel are properly trained to achieve contract objectives. ◆ Facility resources are properly allocated, utilized, and /or obtained to achieve contract objectives.
Sub vendor Management	<ul style="list-style-type: none"> ○ Sub vendor Selection 	<ul style="list-style-type: none"> ◆ Clear criteria for vendor selection are defined and used. ◆ New or unique suppliers are effectively and accurately assessed before PO placement. ◆ Clear criteria are used for becoming and remaining an “approved vendor.” ◆ Technical assessments of vendor capability are performed. ◆ Potential risks associated with sub vendor suppliers are identified early and mitigation plans established.
	<ul style="list-style-type: none"> ○ Sub vendor Purchase Orders 	<ul style="list-style-type: none"> ◆ Sub-tier POs contain all applicable pass down requirements (technical and administrative). ◆ POs are clear and easily understood by the sub vendor. ◆ There is a clear definition of deliverables.
	<ul style="list-style-type: none"> ○ Sub vendor Monitoring/Surveillance 	<ul style="list-style-type: none"> ◆ Some form of up-front quality surveillance planning is performed for each new contract. ◆ Oversight verification activities should: <ul style="list-style-type: none"> ○ Be risk-based, ○ Include process surveillance, ○ Include product inspections, and ○ Not emphasize Quality Systems audits over process and product surveillance. ◆ Cross functional personnel (e.g. engineering, purchasing) are used during oversight activities.

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Element	Supporting Elements	General Expectations
Sub vendor Management (cont.)		<ul style="list-style-type: none"> ◆ Records of supplier oversight are maintained.
	<ul style="list-style-type: none"> ○ Sub vendor Compliance/Quality 	<ul style="list-style-type: none"> ◆ A quantitative method of monitoring supplier performance is employed. ◆ Certifications are complete, accurate, and timely. ◆ Certification reviewers have the proper skills. ◆ There is an effective sub vendor corrective action program.
Corrective Action	<ul style="list-style-type: none"> ○ Nonconforming Material Control 	<ul style="list-style-type: none"> ◆ Defects/nonconformances are detected and documented. ◆ When corrected, nonconforming material is re-verified to demonstrate conformity. ◆ Nonconforming material is controlled to prevent unintended use. ◆ Effective risk release processes are used to include customer acceptance of defect resolution prior to release of hold points or factory acceptance. ◆ Defects/nonconformances are resolved in a timely manner
	<ul style="list-style-type: none"> ○ Corrective Action (C/A) System 	<ul style="list-style-type: none"> ◆ Once documented, defects/nonconformances are analyzed and dispositioned by appropriately skilled personnel. ◆ Actions are taken to eliminate the causes of nonconformances in order to prevent recurrence. ◆ Corrective Action Reports (CRs) are completed in a thorough and timely manner. ◆ The process is actively managed and periodically reviewed by management for effectiveness. ◆
	<ul style="list-style-type: none"> ○ Root Cause Analysis 	<ul style="list-style-type: none"> ◆ Causal analysis addresses all systemic reasons for nonconformities. ◆ Not all defects/nonconformities require root cause analysis. ◆ There is a methodology for deciding when to apply root cause analysis.
	<ul style="list-style-type: none"> ○ Corrective Action System Effectiveness 	<ul style="list-style-type: none"> ◆ Repeat defects/nonconformances are actively identified and eliminated. ◆ A measurable reduction in product defect rate indicates effectiveness. ◆ All Corrective Action Reports are evaluated to verify implementation of corrective action and for effectiveness of the actions taken.
Self-Assessment / Continuous Improvement	<ul style="list-style-type: none"> ○ Data Analysis 	<ul style="list-style-type: none"> ◆ Data analysis monitors at least these areas: <ul style="list-style-type: none"> ○ Continuous improvement of the organizations QMS processes ○ Customer satisfaction ○ Conformance to product requirements ○ Characteristics of processes, products and their trends ○ Supplier performance ◆ Data analysis is used as a source for determining improvement actions. ◆ Results of data analysis should be made available for top management review and endorsement.
	<ul style="list-style-type: none"> ○ Internal Audits 	<ul style="list-style-type: none"> ◆ Internal audits cover all areas of the quality system at a certain frequency.

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Element	Supporting Elements	General Expectations
Self-Assessment / Continuous Improvement (cont.)		<ul style="list-style-type: none"> ◆ Areas of concern (i.e. based on performance data) are emphasized. ◆ Internal audits are introspective and viewed as an opportunity to assess and improve performance. ◆ Internal audits include independent re-inspections and retest of product ◆ Internal audits include Customer participation ◆ Findings are documented, completely dispositioned, and factored into the overall self-assessment process.
	○ Preventive Action	<ul style="list-style-type: none"> ◆ An active program exists to identify potential causes of problems. ◆ A defined method exists to identify potential problems ◆ Data analysis is not to be the sole means of preventive action ◆ Error Proofing of processes is a goal.
	○ Management Review / Support	<ul style="list-style-type: none"> ◆ Senior management ensures sufficient resources are available to support continual improvement activities. ◆ Management is a key driver to establish and follow continual improvement activities to effective completion. ◆ Senior management demonstrates a commitment to continuous improvement.
Process Control	○ Process Procedure Adequacy	<ul style="list-style-type: none"> ◆ Process procedures are clear and comply with governing specifications. ◆ Process procedures are updated to incorporate latest requirements.
	○ Compliance	<ul style="list-style-type: none"> ◆ Verbatim compliance to all written processing procedures. ◆ Personnel unable to comply with written guidelines identify when they cannot – action is taken to rectify this situation.
	○ Repeatability	<ul style="list-style-type: none"> ◆ Process variables are known and controlled. ◆ Processes are performed consistently and results compared to established standards or limits.
	○ Training and Qualification	<ul style="list-style-type: none"> ◆ Personnel performing processes are fully trained and qualified to perform the process. ◆ The qualification process for personnel performing critical processes is defined. ◆ Training and qualifications are periodically assessed for continued effectiveness. ◆ Personnel are aware of the relevance and importance of their activities and how they contribute to meeting quality objectives.
	○ Process Performance	<ul style="list-style-type: none"> ◆ All critical manufacturing processes are monitored for effectiveness. ◆ Data collection systems should include process performance indicators ◆ 1st pass acceptance test rate is high and continuously improving (on a component by component basis). ◆ Process problems are quickly and effectively rectified.

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Element	Supporting Elements	General Expectations
Configuration Control	○ Product Configuration	<ul style="list-style-type: none"> ◆ Product configuration, including subcontracted products, is known and controlled at all times. ◆ Serialized components / products are uniquely identified. ◆ Inspection and manufacturing status of all hardware is readily apparent at all times.
	○ Document Control	<ul style="list-style-type: none"> ◆ Only authorized versions of documents should be available at the point of use. ◆ External documents that define product or process characteristics are controlled. ◆ The document control system prevents the use of more than one version of a particular document.
	○ Change Management	<ul style="list-style-type: none"> ◆ Design and development changes are recorded and maintained. ◆ Product changes occurring during manufacture are completely incorporated into all affected in-process hardware. ◆ Potential impact of known changes on constituent parts is understood ◆ Changes impacting shipped product are immediately identified to the Customer. ◆ All necessary approvals are obtained prior to processing the change and/ or before product release for shipment.
	○ Data Book Adequacy	<ul style="list-style-type: none"> ◆ When required, History books and/or Certification Data Sheets are accurate and complete. ◆ Reviews are performed by competent personnel. ◆ Customer feedback is periodically sought to assess performance.
	○ Record Control	<ul style="list-style-type: none"> ◆ Records required by contract are complete and legible ◆ Lifetime QA records are properly maintained and readily retrievable ◆ Procedures for control of records exist.
Engineering	○ Technical Capability	<ul style="list-style-type: none"> ◆ In-house engineering skills fully support existing product line(s) ◆ Subcontracted services, when used, are actively managed to support all contract requirements. ◆ The design basis of all product lines/designs is understood
	○ Design Documentation / Technical Submittals	<ul style="list-style-type: none"> ◆ Design documentation is complete and compliant with contract requirements ◆ Submittals undergo an appropriate level of over check/review prior to transmittal. ◆ Submittals have a minimal number of errors ◆ Customer comments are promptly and completely addressed
	○ Contract Review	<ul style="list-style-type: none"> ◆ The organization understands the requirements necessary to provide conforming product/service to achieve contract objectives ◆ Procedures exists documenting established contract review and quality planning activities. ◆ Contract objectives are clearly understood between Buyer and Seller
	○ Deficiency Reports	<ul style="list-style-type: none"> ◆ Deficiency Reports (e.g., Nonconformance Reports) are complete and submitted in a timely manner.

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<i>Element</i>	<i>Supporting Elements</i>	<i>General Expectations</i>
<i>Engineering (cont.)</i>		<ul style="list-style-type: none"> ◆ Technical justification is thorough and complete ◆ Repetitive issues reported on Deficiency Reports are identified and causes eliminated. ◆ All deficiency reports are dispositioned prior to product delivery
	○ <i>Knowledge Management</i>	<ul style="list-style-type: none"> ◆ An active knowledge management strategy exists ◆ Vulnerabilities are known and plans are established to address them
<i>Delivery Performance</i>	○ <i>Hardware Delivery</i>	◆ Hardware Contract Line items delivered to contract date (> 80% shipped on time)
	○ <i>Software Delivery</i>	◆ Software Contract Line items delivered to contract date (> 80% shipped on time)
	○ <i>Ability to Meet Needs</i>	<ul style="list-style-type: none"> ◆ All shipyard and User facility needs are supported. ◆ Emergent requests for equipment shipment and/or support are met in support of user facility schedules.
	○ <i>Project Planning / Project Management</i>	<ul style="list-style-type: none"> ◆ Contract plans to support on-time delivery are established. ◆ Changes to contract plans are communicated promptly to the Customer ◆ Shipping requests are made in accordance with contract administrative guidelines