

www.em.doe.gov



Energy Facility Contractors Group

Office of Environmental Management And Energy Facility Contractors Group

Quality Assurance Improvement Project Plan

| Project Focus Area | Task # and Description | Deliverable |
|--|---|---|
| Project Area 1: Requirements Flow Down | Task #1.9 - Complete White Paper covering procurement QA process flow diagram | Draft White Paper and Amended Flow Diagram |
| Project Area 4: Graded Approach Implementation | Task #4.4 - In coordination with Project Focus Area #1, provide an EM expectation for application of the graded approach to procurement. | EM Graded Approach Procedure for Procurements |

| Approvals: | Yes/No/NA |
|--|-----------|
| Project Managers: S. Waisley, D. Tuttel | Y |
| Executive Committee: D. Chung, J. Yanek, N. Barker, D. Amerine | Y |
| EM QA Corporate Board: | Y |

Forward

In 2008, the Department of Energy (DOE) Environmental Management (EM) developed a Quality Assurance (QA) Improvement Project Plan (Project Plan) to improve QA performance across EM operations. The plan is supported by EM and Energy Facility Contractors Group (EFCOG) representatives through the EM QA Corporate Board. The initial plan addresses five high priority QA issues which resulted in establishing five Project Focus Area teams:

- 1. Requirements Flow Down
- 2. Adequate NQA-1 Suppliers
- *3. Commercial Grade Item and Services Dedication Implementation and Nuclear Services*
- 4. Graded Approach to Quality Assurance
- 5. Line Management Understanding of QA and Oversight

This document responds to Project Focus Areas #1 and #4, Requirements Flow Down and Graded Approach to Quality Assurance.

Project Focus Area Team #1 was tasked by the EM QA Corporate Board to develop a model that would provide consistency to the approach for flow down to subtier suppliers/subcontractors performing work under prime contractors to the EM Program. Project Focus Area Team #4 was tasked to develop a process for applying the Graded Approach for QA in Procurement to be used by both Federal and contractor QA programs.

This document provides EM with a defined process and model for consistent application of a graded approach for QA in Federal and contractor procurement programs for flowing down QA program requirements to subtier contractors and suppliers. Application of this model and process is consistent with the requirements of DOE Order 414.1C, 10 CFR 830, and American Society of Mechanical Engineers' (ASME) Quality Assurance Requirements for Nuclear Facility Applications (NQA-1) version 2004 with addenda through 2007.

Table of Contents

| 1.0 Purpose | | | |
|--------------|---|----|--|
| 2.0 B | ackground | 3 | |
| 3.0 R | equirements Flow Down and Graded Approach | 3 | |
| 3.1 | Requirements Flow down | | |
| 3.2 | Graded Approach | | |
| 4.0 I | mplementation | 3 | |
| 5.0 P | rocurement Process Attributes | 3 | |
| 5.1 | Identify Requirements Applicable to Item/Service | | |
| 5.2 | Determine Risk of Failure | | |
| 5.3 | Establish the Quality Level | | |
| 6.0 Q | Quality Levels | 3 | |
| 6.1 | Review and Approval | | |
| 6.2 | Supplier Evaluation | | |
| 6.3 | Supplier Monitoring | | |
| 6.4 | Acceptance of Items | | |
| Figure | 1 – Supplier Flow Down | 17 | |
| Table 1 | – EM Graded Approach Risk Level and Activity Matrix | 18 | |

Graded Approach for Procurement

1.0 Purpose

This document provides the method for applying a graded approach to procurement activities across Department of Energy (DOE) Environmental Management (EM). The document is to be used by EM Headquarters (HQ), EM Field/Project Offices, and EM Contractors to implement procurement processes associated with all work performed for the EM Program.

2.0 Background

In 2008, EM developed a Quality Assurance (QA) Improvement Project Plan (Project Plan) to improve QA performance across EM operations. The plan is supported by EM and Energy Facility Contractors Group (EFCOG) representatives through the EM QA Corporate Board. This document responds to Project Focus Areas #1 and #4, Requirements Flow Down and Graded Approach to Quality Assurance.

For Project Focus Area #1, Requirements Flow Down, the Project Plan in part states "It is the responsibility of line management to ensure that:

- Appropriate technical and quality-related requirements are specified for products (i.e., System Structures and Components {SSC's}). Additionally, the appropriate technical resources (e.g., Engineering, QA, and Operations) are involved in the procurement process to define and appropriately tailor QA requirements into procurement documents.
- The QA organization is included in the decision-making process when establishing the QA requirements or when assessing the supplier's QA program and procedures.
- Requirements are clear with Acceptance/Inspection criteria identified.
- Requirements are flowed down through to suppliers, and, suppliers understand the requirements.
- Procurement processes are flexible enough to specify the applicable QA requirements, and that contractor supplier evaluation processes are adequate, allowing the vendor to satisfy its NQA-1/10 CFR 830-based QA program requirements.
- Requirements are evidenced in the products delivered for use.
- There are adequate oversight functions to ensure completion of all of the above."

For the Graded Approach section, the Project Plan partially states, "The graded approach to quality assurance can be applied consistently in EM complex facilities by establishing a common understanding of why DOE policy allows grading and how grading may be accomplished. In general, grading of quality assurance is based on the relative importance of an item or activity to the success of the mission."

Historically, the EM HQ, EM Field/Project Offices, and EM contractors have implemented the graded approach inconsistently across the EM Program. Surveys of various contractor organizations throughout the EM complex completed during the summer of 2008 provided insight into the degree of inconsistency across the complex. The inconsistencies begin as the Department prepares its Requests for Proposal (RFPs) and carry through the various contractor organizations as they prepare service and commodity oriented procurements to meet the needs of operating facilities and construction projects. In addition, with no common expectation, assessments on how the graded approach is implemented may be influenced by the individual assessor's perspective, leading to further inconsistency.

This document provides EM with a defined process for flow down of requirements and application of a graded approach for QA in Federal and contractor procurement programs. By applying this document across EM, consistency in the flowdown of requirements and application of the graded approach can be established. Application of this document is consistent with the requirements of DOE Order 414.1C, 10 CFR 830, and NQA-1-2004 with addenda through 2007.

3.0 Requirements Flow Down and Graded Approach

The two tasks described above were subsequently to be interdependent in that it is difficult to adequately discuss one without the other. The following discussion considers them separately such that requirements flow down is addressing "what is required" and the graded approach addresses "how is it implemented." The "what" deals with the specific technical or program elements that are applied to a specific procurement activity, and the "how" deals with the managerial controls applied by the procuring organization that are established commensurate with the risk/consequence associated with the procurement activity.

3.1 Requirements Flow Down

A model (Figure 1) was developed to describe the flowdown of requirements for procurement of items and services across the EM Program. Driving consistency in procurement begins with four principal areas:

- EM serving in the capacity of owner and regulator;
- Prime contractors (Managing and Operating/Integrating Contractors, Engineering, Procurement and Construction Contractors, etc...);
- Subcontractors performing work directly for prime contractors or directly to EM; and
- Subtier suppliers/subcontractors performing work.

EM Serving in the Capacity of Owner and Regulator

EM performs its owner/regulator duties while developing (modifying) its contracts. The EM Corporate Quality Assurance Program promulgated by the Principal Assistant Secretary for EM during October 2008 invoked the national consensus quality standard NQA-1-2004 and addenda through 2007. As EM forms Integrated Project Teams (IPTs) to develop acquisition strategies for new procurements, the IPTs are expected to fully and completely address the QA requirements associated with that acquisition, considering:

- Contract language that meets the needs of the specific project/program; and
- Review of the various NQA-1 parts and subparts to ascertain their applicability to procurement's specific scope.¹

Prime Contractors

As communicated in the model, EM has specific expectations of its Prime Contractors. Prime Contractors are expected to ensure safe design, construction, and operation of EM facilities/projects:

- The "safe operations" expectation requires intimate understanding of a wide variety of topical areas engaging multiple technical and engineering disciplines. Their critical importance makes these responsibilities difficult to delegate through subcontracts to subordinate entities. The body of expertise necessary to ensure safe facility operations is expected to reside with the Contractor;
- Analyzing the risk significance of the various SSCs is not generally subcontracted to outside entities. Therefore, the expectation is that the Technical or Design authority will perform this function for the operating facility or project under design or being constructed;
- Identifying critical safety attributes of components or items is expected. Often these attributes are determined acceptable when measured against various national consensus codes and standards that address the particular commodity;² and
- Procurement documents are expected to:
 - Communicate to subcontractors the key engineering/performance attributes and how they will be measured at delivery.
 - Provide contractual expectations regarding quality requirements to subordinate subcontractors or material suppliers. Taking care to precisely describe those technical and quality requirements applicable to the item or service to be delivered under the procurement is expected.

Subcontractors Performing Work Directly For EM or EM Prime Contractors

¹ As expressed in the Introductions to Parts I and II, Requirement 300 of NQA-1 requires "the organization invoking this Part shall be responsible for specifying which requirements, or portions thereof, apply, and appropriately relating them to specific items and services." Applying Parts III and IV of NQA-1 should also be a consideration.

² For example, in terms of concrete, critical attributes will likely be measured against the various consensus standards promulgated by the American Society of Testing Materials (ASTM) and in engineering specifications developed in accordance with design approaches described by the American Concrete Institute (ACI).

Suppliers/Subcontractors to EM or Prime Contractors have the responsibility to develop and implement quality programs ensuring that the EM or Prime Contractor identified technical and quality requirements are adequately addressed by their work processes, or if procured, through their procurement process. Expectations include, but are not limited to:

- Flow down of the appropriate requirements to their suppliers;
- Ensuring the adequacy of subtier subcontractor performance through surveillance, assessments, audits (capability and compliance) and receipt inspection;
- Material receipt, inspection, and testing;
- Storage and segregation of materials; and
- Ensuring adequate measurement and test equipment (M&TE).

Subtier Suppliers/Subcontractors Performing Work

Subtier Suppliers/Subcontractors to Subcontractors have the responsibility to develop and implement quality programs that ensure the identified technical and quality requirements that were flowed down are adequately addressed by their work processes, or if procured, through their procurement process. Expectations include:

- Flow down of the appropriate requirements to their suppliers;
- Ensuring the adequacy of subtier subcontractor performance through surveillance, assessments, audits (capability and compliance) and receipt inspection;
- Material receipt, inspection and testing;
- Storage and segregation of materials; and
- Ensuring adequate measurement and test equipment (M&TE).

3.2 Graded Approach

EM Field/Project Offices and EM Contractors are required to establish and implement a QA Program (QAP) and to maintain a QA Implementation Plan (QIP) that meet the requirements of the EM QAP, DOE O 414.1C (Order) and, for activities governed under 10 CFR 830 (Rule), 10 CFR 830.121. Criterion 7 of both the Order and the Rule requires:

- Procure items and services that meet established requirements and perform as specified;
- Evaluate and select prospective suppliers on the basis of specified criteria; and
- Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

The Order and the Rule further require the use of a national consensus standard in the development of the QA program. EM HQ, EM Field/Project Offices and EM Contractors are required by the EM Corporate QAP to use NQA-1 2004 and addenda through 2007. DOE Guide 414.1-2A, *Quality Assurance Management System Guide*, section 4.7 and NQA-1 Part 1, requirements 4 & 7 identify the following areas associated with procurement and procurement documentation:

- Content of Procurement Documents
- Procurement Document Review
- Procurement Document Changes
- Supplier Evaluation and Selections
- Bid Evaluation
- Control of Supplier Generated Documents

- Supplier Performance Monitoring
- Acceptance of Item or Service
- Control of Supplier Nonconformances
- Commercial Grade Items and Services

Along with the Order and Rule, NQA-1 allows implementing these requirements through a graded approach. Although there are many different interpretations or definitions of graded approach, one that has been selected as representative of these is quoted below from Subpart 4.2 of NQA-1, paragraph 300 which states:

The graded approach is the application process for administrative controls. It is a process by which the level of analysis, extent of documentation, and degree of rigor of process control are applied commensurate with their significance, importance to safety, life cycle state of a facility or work, or programmatic mission.

The graded approach does not allow for a requirement to be waived, but rather allows for varying levels of managerial controls to be applied to provide adequate assurance, commensurate with risk, that the requirement is being met. As such, for all procurement activities the expectation is that all areas are addressed. However, the methods used to implement the requirements can vary commensurate with the risk of the activity. The graded approach, when implemented, is applied to the following key process activities associated with procurement:

- Review and approval of the procurement activity;
- The methods used to evaluate the supplier's capability;
- The methods used to monitor supplier's performance ; and
- The methods used to accept the deliverable.

This document describes the framework to be used by EM Field/Project Offices and EM Contractors. The framework minimizes the subjective nature of the graded approach by specifying "how" requirements are implemented, primarily at the Federal Project and Prime Contractor level, however, similar application by subcontractors and suppliers is appropriate. This document does not address attributes associated with the procurement process in such areas as:

- Sole Source Justifications
- Funding approval requirements
- Classification/Declassification
- Offer Solicitations

- Contract Award
- Payment for items/services
- Contract closeout
- Claims

4.0 Implementation

Each EM Field/Project Office and EM Contractor shall demonstrate how its procurement process incorporates the following:

- Identification and flowdown of requirements into procurement documents;
- Use of the standard EM procurement risk assessment process (see section 5.2) to quantify the risk³;
- Establishing Quality Levels (QLs) or equivalent identifier based on the quantified risk (to establish the rigor to be applied); and
- How each QA program requirement associated with procurement is implemented consistent with the QL of the procurement and compliant with this document.

The approach of each EM Field/Project Office and EM Contractor will be documented and submitted for approval as part of the site's QAP/QIP submittal⁴.

5.0 Procurement Process Attributes

In general, the following procurement process attributes vary according to QL:

- Review and approval of procurement activity
- Evaluation of supplier capability
- Supplier monitoring
- Acceptance of items and services

To assure consistency in how these attributes are implemented, EM Field/Project Offices and EM Contractors shall:

- Identify the requirements applicable to the item/service
- Determine risk/consequence of failure of the item/service
- Establish the QL
- Implement procurement controls as prescribed by the QL

Performing these activities diminishes the subjective nature of applying the graded approach.

5.1 Identify Requirements Applicable to Item/Service

Identification of requirements is a design input, and establishes the technical and quality program requirements to be applied to the item or service consistent with the

³ EM Office of Standards and Quality Assurance will provide the standard risk assessment process to be used by EM HQ, EM Field/Project Offices, and EM Contractors

⁴ Due to the wide variance in types of work activities performed, each Prime Contractor shall establish the appropriate number of Quality Levels for their work scope and clearly demonstrate (map) their levels to the expectations of this document.

intended use or application. The graded approach of "how" the requirements are to be applied is generally not used in flow down of requirements. Generally requirements either are or are not applicable to the item or service. The requirements associated with the item or service to be procured are defined by the customer organization and usually involve the technical authority or subject matter expert to ensure that appropriate national standards, codes, quality requirements, state requirements, laws, regulations, etc. are applied to the procured item.

> Identification of requirements applicable to the item or service not only involves technically oriented codes and standards, but also includes a well described expectation for implementation of QA standards with particular emphasis regarding the flow down of QA requirements to subcontractors and suppliers. Prime contractors are expected to describe which requirements of Part I and Part II of NQA-1 will be applied to the subordinate contractor's QA program. These are usually called out as QA specifications or QA requirements. In addition to any applicable NQA-1 requirements, other QA requirements that may be applicable such as Suspect/Counterfeit Items (SCI) controls, laboratory standards, or other stakeholder QA expectations that are not covered by NQA-1 are also addressed. Whether to submit QA program documents with bids and whether acceptance of the Supplier's QA Program is a condition of procurement shall be identified⁵.

Requirements for the supplier to flow down to a sub-tier supplier shall be identified in procurement documents. The requirements shall be commensurate with the scope of the sub-tier procurement. The supplier shall ensure the sub-tier supplier's QA Program is acceptable for the assigned task prior to procurement, and implement oversight functions as needed to ensure the supplied item or service is compliant.

In addition to identifying the requirements for the supplier's QA program, the QA specification shall be used to communicate the purchaser's expectations for implementation of the supplier's QA program, and to establish communication protocols for oversight functions. The QA specification shall be clear regarding the right of access by project and customer representatives to perform oversight functions such as audits and surveillances. Other considerations such as those listed below should be addressed as part of the graded approach dependent on risk/consequence of the activity and include:

- Identifying the conditions that need to be satisfied in order for fabrication or activity to commence;
- Protocols and communications requirements for witness and hold points. Witness and hold points, if required, shall be defined and communicated to the supplier for planning and inclusion in its fabrication control documents. Advance notification

⁵ It is not the intent to flow down "NQA-1" to a supplier, but rather that the applicable requirements of NQA-1 are flowed down and the supplier's QA program evaluated against those specific requirements.

requirements to the purchaser prior to performing the activity affected by these witness and hold points shall be defined. The purchaser shall ensure sufficient witness and hold points are included to provide confidence that the item is acceptable. Points may include initial or first article monitoring or inspection, in-process inspections, and final inspections;

- Inspection requirements may include preparation and submittal of supplier's QC procedures and inspection personnel qualifications to the purchaser for review and acceptance prior to performing inspection activities;
- Need for how the disposition of nonconforming items that involve repair or useas-is shall be made and documented. Nonconformances to design requirements shall be subject to design control measures commensurate with those applied to the original design;
- Define a process for submittal and approval of requests for variances to design, fabrication, schedule requirements, etc... (e.g., supplier deviation requests) as appropriate;
- Requirements for the compliance documentation package to be supplied with the item to evidence the item's quality (e.g., completed Travelers, Inspection and Test reports, etc...) shall be identified. The QA specification or the procurement documents shall include a listing of such necessary documents;
- When a shipping release is used, how the release will be granted shall be identified (e.g., include or make reference to the shipping release form and identify the purchaser's organization authorized to approve the release); and
- The purchaser's right to stop work at a supplier due to non-compliances with the QA program.

5.2 Determine Risk of Failure

This is the critical step in applying a graded approach to procurement. The rigor must be commensurate with the risk of failure. DOE O 414.1C provides a list of attributes to be evaluated when determining the risk of failure. Through this document EM provides a common questionnaire as a process for evaluating risk⁶. The risk evaluation looks at risk of failure from two perspectives: 1) Safety and 2) Mission Criticality.

Risks associated with failure for SSCs that are specifically credited within a facility's associated documented safety analysis or hazard evaluation are generally well captured. Risks associated with improper performance of a service or delay in delivery that could have an impact on safe operations or critical timelines and milestones are not as well captured and require evaluation to ensure the appropriate rigor is applied to the procurement activity. For example, a pump used for

⁶ EM provided common computer-based procurement risk assessment process.

environmental ground water cleanup may not have nuclear safety implications, yet its failure or late delivery could have significant implications for meeting customer time lines or could degrade stakeholder perception of the organization's ability to meet expectations. Or, its failure could result in unnecessary exposure of personnel to hazards due to the need to remove/repair/replace the pump. These issues warrant elevated QA rigor to ensure successful completion of the procurement. The questionnaire provides consistency in evaluating the risk so the correct QA rigor can be applied.

The EM provided computer-based procurement risk assessment process is simply a computer based questionnaire designed around the critical attributes addressed in DOE O 414.1C for evaluation when determining risk of failure. The questionnaire addresses the following attributes:

- Adverse Safety Impacts
- Mission Interruption
- Environmental Damage
- Negative government or public perception
- Adverse Cost
- Expected Lifecycle

- Design Complexity
- Degree of Standardization
- Ease of failure detection
- Level of Personnel Qualifications/Special Skills
- Problem History
- Mission Critical

Depending on how the questions above are answered, a level of overall risk is obtained and used in establishing increased or decreased rigor associated with the procured item or service.

5.3 Establish the Quality Level

Based on the applicable requirements and the subsequent risk determination, a QL is assigned for the procurement activity. The QL establishes how key attributes of the procurement process (managerial controls) are applied for:

- The level of review and approval of the procurement activity
- The method used to evaluate the supplier's capability
- The method used to monitor supplier's performance
- The method used to accept the deliverable

This document suggests four QLs as described in the following section. For most EM Field/Project Offices and EM Contractors, four quality levels provide sufficient latitude to establish varying levels of procurement rigor. Some EM Field/Project Offices and EM Contractors may find having fewer (or more) levels is appropriate for the scope of work being performed. Each EM Field/Project Office and EM Contractor needs to develop a process that prescribes what quality levels are used to bin the above activities meeting the expectations identified in Table 1. It is not intended each organization change their process to use the QL convention. Each implementing organization needs to identify the convention used within their process that represents the same intent of quality levels, such as:

- Procurement levels (PL-1, PL-2, PL-3, PL-0)

- Quality Control levels (QC-1, QC-2, QC-3)
- Alpha/numeric levels (A, B, C, D or 1, 2, 3, 4)
- Full Quality, Enhanced Quality, Commercial Quality
- Construction, Technical Services, Engineered Item, Commercial
- Other conventions that conveys the intent of this expectation

Regardless of the convention used, the implementing organization must demonstrate how their convention implements the intent of the expectations of section 6.0 and Table 1.

6.0 Quality Levels

QLs are established based on risk such that higher risk activities result in higher rigor associated with the review and approval of the procurement, supplier evaluation, supplier monitoring, and acceptance activities. Risk is defined by a cumulative evaluation using the standard EM process against variables such as Nuclear Safety, Personnel Safety, Environmental Impacts, Mission Impacts, Cost, Regulatory Requirements, and Stakeholder perception. For a four level system, based on cumulative risk, the QLs are:

- QL-1 High risk
- QL-2 Medium risk
- QL-3 Low risk
- QL-4 Commercial quality or very low risk

<u>QL-1</u>: Important to safety or mission, high risk procurement where additional quality controls are needed to verify critical attributes **and** a <u>high</u> level of assurance is needed to ensure expectations associated with additional quality controls are being met.

<u>QL-2</u>: Important to safety or mission, medium to high risk procurement where quality controls are needed to verify critical attributes **and** a <u>moderate</u> level of assurance is needed to ensure expectations associated with additional quality controls are being met.

<u>QL-3</u>: Important to safety or mission, low to medium risk procurement where quality controls are needed to verify critical attributes.

<u>QL-4</u>: Minimal, if any, safety or mission impact - level of controls for those items, services, or processes where no additional quality controls beyond the providers published or stated attributes of the item, service, activity, or process are required. General acceptance processes to ensure item, quantity, and other characteristics are met.

6.1 Review and Approval

In all cases, procurement activities are approved by an organizational representative who has authority to expend funds and authority to acquire items or services. Who or how many personnel this takes will vary depending on the item/service being procured. It may be limited to a single individual for low risk items such as office supplies or other items purchased directly in support of administrative activities, or may require multiple approvals such as the requisitioner, a project controls specialist, and the cost account manager for items with higher risk or funding requirements.

In addition to those reviews, technical and support personnel reviews may be warranted to include Engineering, Safety, Industrial Hygiene, Quality, Environmental, and Radiological Controls or others depending on the requisitioned item or service.

Table 1 provides EM's minimum expectations for review and approval based on risk.

6.2 Supplier Evaluation

NQA-1 requires, prior to award, that the purchaser shall evaluate the supplier's capability to provide items or services in accordance with the requirements of the procurement documents. This must be done for all procurements. NQA-1 provides options for performing this evaluation. The specific methods addressed are:

- Supplier's history of providing an identical or similar product that performs satisfactorily in actual use. The Supplier's history shall reflect current capability;
- Supplier's current quality records supported by documented qualitative and quantitative information that can be objectively evaluated; and
- Supplier's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the Supplier's QA program.

The rigor behind the selected approach takes into account the risk determined QL. Which approach to take is generally determined based on current supplier knowledge, the item or service being procured, and the QL.

For low risk activities, such as office supplies, purchasing from a reputable vendor based solely on commercial industry presence can be sufficient to meet this requirement, as long as the decision to use the vendor for this service is documented (i.e., a material request form identifying the supplier). As the risk escalates additional evaluations may be warranted, but can be met by reviewing requested documents (to include the suppliers QA program and appropriate implementing procedures) that support the objective evaluation of the supplier's capabilities during the bid proposal.

For higher risk activities, an onsite evaluation of the implementation of the suppliers program using a detailed crosswalk to document implementation against the applicable NQA-1 sections that are flowed down becomes the most prominent method to ensure the supplier is capable of meeting the needs. Table 1 provides EM's minimum expectations for supplier evaluation based on risk.

6.3 Supplier Monitoring

Periodic monitoring of a suppliers performance is an area where implementation may vary. Although risk plays a role in determining the monitoring methods and frequency, scope of the activity also influences supplier evaluation. (For example, where the scope includes welding then enhanced supplier oversight and examination requirements for welder qualifications and performance should be considered early in the fabrication process especially for medium and high risk components.)

For low risk activities, monitoring can be performed simply through receipt inspection of deliverables. As risk escalates, the monitoring strategy should address:

- Source inspections
- Witness points, hold points
- On-Site surveillances/assessments
- Submittal reviews

For higher risk activities, development of a subcontractor oversight plan is warranted to ensure intentional monitoring of the subcontractor's performance. The oversight plan would address the specific time frames and scope of any on-site surveillances/assessments to provide assurance of quality of the deliverable. Depending on the nature of the subcontracted activity, the plan could also address the use of an integrated team of subject matter experts (engineers, inspectors, project managers, etc) to provide a broader perspective of the suppliers performance..

See Table 1 for EM's minimum expectations for supplier monitoring based on risk.

6.4 Acceptance of Items

NQA-1 provides the following methods for use for acceptance of an item or service:

- Supplier Certificate of Conformance (COC)⁷
- Source Verification
- Receiving Inspection
- Post Installation Test
- Combination of the Above
- For Services Only, Any or All of the Following May Be Used:
 - o Technical verification of data produced
 - Surveillance and/or audit of the activity
 - Review of objective evidence for conformance to the procurement document requirements

The procurement process shall specify which of these are to be used. With the exception of the supplier COC, the methods used have latitude with regard to "who" performs the activity. For example, some receipt inspections will require inspection by someone that has non-destructive examination qualifications, while others may be performed by a material coordinator or warehouseman with training in

⁷ Reliance on Supplier COCs as a principal component of receipt inspection and acceptance processes should be considered a weak practice. See NQA-1, Requirement 7, paragraph 503 for minimum criteria for use of COCs.

suspect/counterfeit item control, and others can be performed by other support personnel. See Table 1 for EM's minimum expectations and considerations for acceptance of items and services based on risk.

Figure 1 FLOW DOWN OF QUALITY ASSURANCE SPECIFICATIONS AND PROCUREMENT OF ITEMS AND SERVICES - GRADED APPROACH APPLICATION



| Quality Assurance Criteria | High Risk | Medium Risk | Low Risk | Commercial or Very Low Risk |
|-------------------------------|--|---|--|---|
| Review and approval | Requisitioner Project Controls Cost Account Manager QA Engineering Safety (1) Environmental (1) IH (1) RadCon (1) | Requisitioner Project Controls Cost Account Manager QA Engineering Safety (1) Environmental (1) IH (1) RadCon (1) | Requisitioner Project Controls Cost Account Manager QA (1) Engineering (1) Safety (1) Environmental (1) IH (1) RadCon (1) | Requisitioner Project Controls (1) Cost Account Manager (1) Engineering (1) Safety (1) Environmental (1) IH (1) RadCon (1) |
| Supplier Evaluation | Evaluation of supplier's implementation of its QA program if not procured as commercial grade item. Must be a site visit. | Evaluation of supplier's implementation of its QA program if not procured as commercial grade item. Site visit expected unless basis for not doing is justified and documented (4) | Identified components of the supplier QA program, supporting procedures, and processes submitted for review and acceptance. Review and acceptance is documented. | Supplier selection and approval based on commercial standard. |
| Acceptance (3) | QA Receipt Inspection Source Inspection/verification for Fabrications required Submittals formally reviewed by designated SMEs Acceptance testing | QA Receipt Inspection Source Inspection/verification for Fabrications required Submittals formally reviewed by designated SMEs or designated representative Acceptance testing | QA Receipt Inspection (1) Source Inspection/verification for Fabrications considered. Submittals formally reviewed by designated representative. | Receipt Inspection (non-QA) Submittals reviewed by designated representative |
| Monitoring (3) | Development of Subcontractor Oversight Plans (2) Receipt Inspection Acceptance Testing Submittal Review | Basis for not developing a Subcontractor Oversight Plan needs to be documented (2) (4) Receipt Inspection Acceptance testing Submittal Review | Receipt Inspection Submittal Review Assessment/surveillance | Receipt Inspection (non-QA) Submittal Review |

(1) Scope Dependent

(2) Due to higher risk, intentional oversight activities are planned out – could range from periodic surveillance to in-process inspections/witness or hold points.

(3) Acceptance and Monitoring methods listed need to be evaluated for implementation commensurate with the scope and nature of the activity.

(4) IF a Site Visit is not performed, THEN a subcontractor oversight plan is required