



## Environmental Management Office of Standards and Quality Assurance

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### Quality Procedure

Subject Area: *Supplier Qualification*

QP-7.1, Revision 0

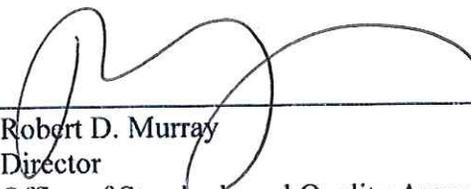
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1. PURPOSE

This procedure establishes the responsibilities and process for supplier qualification activities conducted by Environmental Management (EM) Headquarters (HQ) Office of Standards and Quality Assurance in accordance with EM-QA-001, *Environmental Management Quality Assurance Program*.

2. SCOPE

The scope of this procedure is to describe the supplier qualification and requalification process performed by the EM Headquarters Office of Standards and Quality Assurance if the Office is procuring an item or service; or at the request of EM Headquarters Offices, DOE Field Office facilities or projects, or other entities. Performance of this activity can be conducted in accordance with the requesting organization's implementing document if available. Supplier qualification activities addressed in this procedure include:

- Initial Supplier Qualification
- Ongoing Supplier Evaluation
- Supplier Requalification

3. APPLICABILITY

This procedure applies to EM Headquarters Office of Standards and Quality Assurance personnel and contractors participating in supplier qualification activities conducted on items or services procured; or on behalf of Offices at EM Headquarters, DOE Field Office facilities or projects, or other entities.

4. REQUIREMENTS & REFERENCES

The most current version of the following documents is applicable to this procedure:

Requirements:

- 4.1 ASME NQA-1-2008/2009, *Quality Assurance Requirements for Nuclear Facility Applications*
- 4.2 DOE Order O 414.1D, *Quality Assurance*
- 4.3 EM-QA-001, *EM Quality Assurance Program*

References:

- 4.4 QP-7.2, *Approved Suppliers List*
- 4.4 QP-10.1, *Audits*
- 4.5 QP-10.2, *Independent Assessments*
- 4.6 SSQ-3.1, *Corrective Action*

- 4.7 DOE-EM-SRP-2010, 2<sup>nd</sup> Edition, *Standard Review Plan (SRP) Protocol for EM Review/Field Self-Assessment of Site-Specific Quality Assurance Programs (QAPs)/Quality Implementation Plans (QIPs)*; March 2010

## 5. DEFINITIONS

- 5.1. Approved Suppliers List (ASL) – A listing of suppliers who have been evaluated by the EM Headquarters Office of Standards and Quality Assurance and found to have established a quality program capable of providing items and services under the conditions and requirements of DOE Order 414.1D, EM Quality Assurance Program (EM-QA-001), and NQA-1 2008/2009a.
- 5.2. Item – An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, software program, structure, subassembly, subsystem, system, or unit.
- 5.3. Requesting Entity - The Office or organizational unit within DOE EM including Headquarters, Field Offices and its facilities and projects requesting supplier qualification or requalification support.
- 5.4. Service – The performance of activities such as software design, software modeling, design, fabrication, inspection, nondestructive examination, consulting, calibration, testing, repair, or installation.
- 5.5. Supplier – Any individual or organization that furnishes items or services in accordance with procurement documents. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their sub-tier levels.
- 5.6. Supplier Qualification – The process of performing an evaluation of the supplier’s capability to provide items or services in accordance with the requirements of the procurement document prior to its issuance for inclusion of the supplier on the ASL.
- 5.7. Supplier Requalification – The process of performing an evaluation of the supplier’s continued capability items or services in accordance with the requirements of established contractual documents to establish that the supplier remains on the ASL.

## 6. RESPONSIBILITIES

- 6.1. Deputy Assistant Secretary (DAS) for Safety, Security and Quality Programs
- 6.1.1 Directs the Office of Standards and Quality Assurance to implement this procedure in accordance with the Oversight Policy.
- 6.2. Director, Office of Standards and Quality Assurance

- 6.2.1. Assigns Audit or Assessment Team Leads for supplier qualification or requalification activities.
- 6.2.2. Responsible for the preparation, revision, and approval of this procedure.
- 6.2.3. Responsible for obtaining adequate resources to ensure that supplier qualification and requalification activities are performed in accordance with this procedure.

Note: If the Office resources are provided to support the supplier qualification or requalification for the item or service procured; or for the Headquarters or Field Office, the procedure for the requesting entity may be used to implement this activity if available.

- 6.2.4. Approves and issues the audit or assessment plan and the notification memorandum generated through the Contracting Officer as part of the supplier qualification and requalification process.
- 6.2.5. Approves and issues the audit or assessment report and signs the transmittal memorandum generated through the Contracting Officer as part of the supplier qualification and requalification process.
- 6.2.6. Ensures that activities and controlled documents governed by this procedure are satisfactorily implemented at EM Headquarters Office of Standards and Quality Assurance.

### 6.3. Audit Team Leads and Assessment Team Leads

- 6.3.1. Coordinates with requesting entity and procurement to ensure that procurement evaluation criteria are evaluated in accordance with the specifications of the requesting entity.
- 6.3.2. Selects the team members and technical specialists or subject matter experts, if needed, participating in the supplier qualification/requalification process upon consultation with the Director, Office of Standards and Quality Assurance and the requesting entity.
- 6.3.3. Develops the plan and associated notification memorandum.
- 6.3.4. Prepares checklists, Criteria Review and Approach Documents (CRADS), or lines of inquiry (example LOIs from the Standard Review Plan Protocol) based upon the applicable standards and requirements to which the supplier qualification/requalification process is being conducted, or based on evaluation criteria and instructions provided by the requesting entity. Often used criteria can be developed into standardized checklists for repeat usage.

- 6.3.5. Ensures that the team members are qualified and prepared for the supplier qualification/requalification process. Assigns areas of evaluation to specific team members.
- 6.3.6. Leads the performance of the supplier qualification/requalification process and conducts briefings with the management of the audited organization.
- 6.3.7. Documents and reports the results of the supplier qualification/requalification process with input from each team member on their assigned areas of evaluation.
- 6.3.8. Uploads the report and supporting documentation associated with this procedure into the Issues Management System, including issues to include findings, observations, recommendations, and noteworthy practices.

Note: The Office of Standards and Quality Assurance currently uses the EM Corrective Action Hub as its Issues Management System. It can be accessed at <http://correctiveactionhub.em.doe.gov/>

#### 6.4 Supplier Qualification and Requalification Audit and Assessment Members

- 6.4.1 Prepare for supplier evaluations (qualification and requalification activities) by reading applicable quality requirements and evaluation criteria specified in procurement documentation, reviewing checklists, and participating in pre-award/post-award evaluation conference calls.
- 6.4.2 Responsible for getting qualified and prepared for the supplier qualification and requalification audits and assessments by reading applicable procedures and plans, reviewing previous audit reports and corrective actions for the supplier, reviewing checklists, and participating in pre-audit and pre-assessment conference calls.
- 6.4.3 Evaluate the assigned area(s) of evaluation or QA program element(s).
- 6.4.4 Provide input to the Team Lead documenting the results of the assigned area(s) of evaluation or audited QA program element(s).

### 7. GENERAL INFORMATION

This procedure provides the review and acceptance of supplier QA programs, including monitoring work performed by suppliers in accordance with approved requirements. Document Control is achieved by following the procedural instructions contained within this procedure. Audits and assessments mentioned in the proceeding sections are conducted in accordance with the current version of the following established procedures:

- QP-10.1, *Audits*
- QP-10.2, *Independent Assessments*.

## 8. SUPPLIER QUALIFICATION/REQUALIFICATION PROCESS

### 8.1. Scheduling Supplier Qualification/Requalification Activities

- 8.1.1 An initial qualification of a prospective supplier (prior to award as part of the bid evaluation process) or a newly identified supplier (after the contract is awarded) is performed when requested by management of the requesting entity. The requesting entity provides the name of the supplier, address, contact, phone number, and scope of the item/service that is to be supplied. This process of qualification is described in Section 8.2, Initial Supplier Qualification, of this procedure.
- 8.1.2 As specified in QP-7.2, *Approved Suppliers List*, a supplier requalification audit is normally scheduled on a triennial basis or as needed to meet project needs (i.e., significant changes are made in a supplier's quality program or change in the supplier's scope of work). The EM Headquarters Office of Standards and Quality Assurance notifies the management of the supplier's requesting entity, including the Contracting Officer, of an upcoming audit within six months of the supplier requalification due dates.
- 8.1.3 As specified in QP-7.2, *Approved Supplier List*, a supplier assessment is scheduled on an as needed basis to meet project needs (i.e., performing assessments such as surveillances during critical project phases) or to address emerging or ongoing quality issues with the supplier. The EM Headquarters Office of Standards and Quality Assurance notifies the management of the supplier's requesting entity, including the Contracting Officer, of a planned supplier assessment.

### 8.2 Initial Supplier Qualification

- 8.2.1 The requesting entity (a Headquarters Office or a Field Office facility, program, or project) provides the evaluation criteria and instructions prior to initiating the evaluation process. Initial supplier evaluations can be conducted prior to award during the bid evaluation process or once a contract is awarded to a new supplier. Initial supplier evaluations are based on one or more of the following qualification methods:
- Source evaluation of the supplier's facility, personnel, and programs to determine their technical and quality capabilities.
  - Evaluation of the supplier's current quality records supported by documented qualitative and quantitative information.
  - Evaluation of the supplier's history of providing identical or similar items or services that performs satisfactorily in actual use. The supplier's history shall reflect current capability. This could include a review of previous experience with the supplier, evaluation of the experience of other organizations provided as references by the supplier, or review of work performed by the supplier for other organizations.
- 8.2.2 The supplier audit or assessment team uses the evaluation criteria provided by requesting entity as Lines of Inquiry (LOIs) or as the basis of a checklist for performing the evaluation. DOE-EM-SRP-2010, 2<sup>nd</sup> Edition, *Standard Review Plan (SRP)- Protocol for EM-HQ Review/Field Self-Assessment of Site Specific Quality Assurance Programs (QAPs)/Quality Implementation Plans (QIPs)*, can also be used in evaluating QAPs/QIPs and document evaluation results.

### 8.2.3 Source Evaluation

- 8.2.3.1 A source evaluation is performed upon coordination with the requesting entity on suppliers to initially determine their capability to meet specific quality and technical requirements for procurement of items or services. Initial source evaluations are performed prior to award or after the award. Source evaluations are conducted in accordance with procedure QP-10.1, *Audits*.
- 8.2.3.2 Issues and related corrective actions identified during the source evaluation are processed through the Contracting Officer and addressed prior to initiating work in accordance with procedure SSQ-3.1, *Corrective Action*.

### 8.2.4 Records Evaluation

- 8.2.4.1 The supplier's current quality records supported by documented qualitative and quantitative information are evaluated. The following types of records are considered during this review:
- Quality Assurance Plans/Quality Implementation Plans
  - Procedures
  - Personnel qualifications and training records
  - Records as applicable:
    - Software Design records
    - Special process records
    - Inspection and test records
    - Measuring and test equipment records
    - Independent and Management Assessment schedules, plans, and reports
- 8.2.4.2 An initial Records Evaluation is performed on suppliers to initially determine their capability to meet specific quality and technical requirements for procurement of items or services. A Records Evaluation is performed in accordance with procedure QP-10.2, *Independent Assessments*.
- 8.2.4.3 Issues and related corrective actions identified in the Records Evaluation are processed through the Contracting Officer and addressed prior to initiating work in accordance with SSQ-3.1, *Corrective Action*.

### 8.2.5 Supplier History

- 8.2.5.1 The capabilities of the supplier are reviewed to ensure they have been maintained at an acceptable level. The review includes, as applicable, supplier performance, personnel qualifications, methods of testing, material used, and inspection capabilities as appropriate for the type of item being provided.
- 8.2.5.2 A Supplier History is performed to initially determine their capability to meet specific quality and technical requirements for procurement of items or services. The reviews are performed per procedure QP-10.2, *Independent Assessments*.

8.2.5.3 Issues and related corrective actions identified in the Supplier History Evaluation are processed through the Contracting Officer and addressed prior to initiating work in accordance with SSQ-3.1, *Corrective Action*.

8.2.5.4 The type of item or service and the review of the supplier's capabilities and performance are documented in an assessment report along with the necessary objective evidence to support the review.

### 8.3 Ongoing Supplier Evaluation

8.3.1 After initial qualification is obtained by a supplier, the supplier is evaluated through audits and assessments as specified by the requesting entity in accordance with procedure QP-10.1, *Audits*, and procedure QP-10.2, *Independent Assessments*, respectively.

### 8.4 Supplier Requalification

A supplier requalification is performed as scheduled to determine if the supplier still meets the technical and quality capabilities to provide items or services.

8.4.1 The EM Headquarters Office of Standards and Quality Assurance Director informs the management of a requesting entity, including the Contracting Officer if applicable, on ASL supplier requalification dates as well as any emerging quality or technical concerns and any other available documentation of supplier performance. A notification memorandum from the Director, Office of Standards and Quality Assurance, is issued to the supplier at least thirty (30) days prior to conducting the requalification.

8.4.2 Requalification of an approved supplier occurs normally on a triennial (once every three years) basis through an audit or as specified by the requesting entity. Audits are conducted in accordance with procedure QP-10.1, *Audits*.

## 9. RECORDS

Records listed below are collected per QP-4.3, *Quality Assurance Records*, as individual records or included in a records package, as specified. Final disposition of QA records resulting from audits is based on the EM Records Disposition process.

Lifetime QA Record: None

Nonpermanent Records:

- Supplier Qualification and Requalification Reports and associated notification memoranda

Non-QA Records: None

## 10. FORMS

There are no forms associated with this procedure.

## 11. ATTACHMENTS

There are no attachments associated with this procedure.

**RECORD OF REVISION**

DOCUMENT: QP-7.1, Revision 0 Subject Area: *Supplier Qualification*

Revision Number	Description of Changes	Revision on Pages	Effective Date
0	Original	All	8/31/2015