

**INSPECTION TECHNICAL PROCEDURE**

**I-101**

**QUALITY ASSURANCE ASSESSMENT**

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Revision 5

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# **INSPECTION TECHNICAL PROCEDURE I-101, REV. 5**

## **QUALITY ASSURANCE ASSESSMENT**

### **1.0 PURPOSE**

This inspection procedure provides WTP Safety Regulation Division (OSR) guidance to assess the Contractor's Quality Assurance (QA) organization's fulfillment and implementation of their procedures, processes, requirements, and responsibilities as identified in the Contractor's QA Manual (QAM).

### **2.0 OBJECTIVES**

This inspection verifies the Contractor's QA organization has implemented the processes, procedures, requirements, and responsibilities as identified in the Contractor's QAM. The reference to the QA Manager throughout this procedure is understood to include his/her delegee when applicable.

### **3.0 BACKGROUND**

Reviews of other OSR inspection procedures revealed several sections of this procedure were redundant to activities accomplished in other inspections. This procedure was revised to focus the inspection on the responsibilities of the QA Manager and QA department as those responsibilities relate to the Contractor's QAM, and are not covered in other OSR inspection procedures.

### **4.0 INSPECTION REQUIREMENTS**

#### **4.1 Management Program and Processes**

The inspectors should perform the following activities:

##### 4.1.1 Verify the QA Manager has the following:

- Functional authority, independence, and responsibility to assure the effective implementation of and compliance to the QA Program
- Responsibility to document interpretations of those activities to which the QA Program applies and the extent to which this policy applies to those activities
- No unrelated duties that would preclude full attention to assigned responsibilities. (QAM Policy Q-01.1, Section 3.3.1)

- 4.1.2 Verify the QA Manager reports to the BNI QA Manager for program definition and functionally to the Project Director for QA matters, and is responsible to ensure that an appropriate QA Program, the scope of which includes all the systems and activities that affect safety and quality, was established and implemented. (QAM Policy Q-01.1, Section 3.3.2)
- 4.1.3 Verify the QA Manager provides guidance and oversight for the project based on applicable requirements of 10 CFR 830, Subpart A, DOE Order 414.1A, DOE/RW-0333P, Revision 11, and NQA-1 (1989). (QAM Policy Q-01.1, Section 3.3.3.A)
- 4.1.4 Verify the QA Manager provides guidance on quality and safety to functional organizations and area project teams, and provides necessary resources to area project teams. (QAM Policy Q-01.1, 3.3.3.B and 3.3.3.R)
- 4.1.5 Verify the QA Manager directs, or could direct, that work be stopped on nonconforming materials or activities if:
- Other corrective action processes are ineffective in protecting the health and safety of the public and/or plant personnel
  - Continued work will require significant rework or repair to back fit corrective action
  - An organization, department, group, section, or individual, by a repetitive failure to comply with technical direction or administrative controls, contributes to a condition that is a significant QA Program deficiency. (QAM Policy Q-01.1, Section 3.3.3.E, and QAM Policy 16.2, Section 6.3)
- 4.1.6 Verify the QA Manager determines when appropriate actions have been taken to lift the stop work order to allow work to proceed. (QAM Policy Q-01.1, Section 3.3.3.F)
- 4.1.7 Verify the QA Manager provides a working interface and line of communication with other departments, appropriate industry representatives, and regulatory groups for QA matters. (QAM Policy Q-01.1, Section 3.3.3.I)
- 4.1.8 Verify the QA Manager establishes indoctrination and training programs for QA and Quality Control (QC) personnel. (QAM Policy Q-01.1, Section 3.3.3.J)
- 4.1.9 Verify the QA Manager provides input for QA indoctrination of personnel outside of the QA organization. (QAM Policy Q-01.1, Section 3.3.3.K)
- 4.1.10 Verify the QA Manager develops and maintains the QAM and the Quality Assurance Provisions Document (QAPD). (QAM Policy Q-01.1, Sections 3.3.3.P and 3.3.3.Q)
- 4.1.11 Verify the QA Manager determines if proposed revisions to the QAM affect the program description previously accepted by DOE. (QAM Q-02.1, Section 1.6.1)

- 4.1.12 Verify the QA Manager approves all revisions to the QAM. (QAM Q-02.1, Section 1.6.1)
- 4.1.13 Verify the QA Manager creates an atmosphere in the workplace where reporting and resolution of conditions adverse to quality is encouraged at all levels. (QAM Q-01.1, Section 3.3.4)
- 4.1.14 Verify the QA Manager retains full responsibility for the QA Program, even when activities have been delegated to others. (QAM Q-01.1, Section 3.3.5)
- 4.1.15 Verify the QA Manager gives full support to the Safety and QA Programs, thereby assuring that all work performed under his cognizance conforms to and supports the requirements of QAM Policy Q-01.1. (QAM Q-01.1, Section 3.3.6)

## **4.2 Personnel Training and Qualification**

The responsibilities of the QA Manager and QA department in the area of training and qualification are included in Inspection Procedure I-106, "Personnel Training and Qualification Assessment; therefore, this area will not be addressed in this inspection.

## **4.3 Quality Improvement**

The inspectors should perform the following activities:

- 4.3.1 Verify the QA Manager has the authority to cross-organizational lines to identify quality problems, to initiate, recommend, or provide solutions, and to verify implementation. (QAM Policy Q-01.1, Section 3.3.2)
- 4.3.2 Verify the QA Manager reviews and concurs with conditional use evaluations on nonconformance reports. (QAM Policy Q-15.1, Section 6.1.1.A)
- 4.3.3 Verify the QA Manager performs verification of implemented corrective actions. (QAM Policy Q-15.1, Section 6.1.1.B; QAM Policy Q-16.1, Section 6.1.1.C; and QAM Policy Q-18.1, Section 6.1.1.D)
- 4.3.4 Verify the QA Manager ensures that quality nonconformance control status tags are applied and removed as appropriate. (QAM Policy Q-15.1, Section 6.1.1.C)
- 4.3.5 Verify the QA Manager reviews and concurs on procedures for reporting and controlling conditions adverse to quality. (QAM Policy Q-16.1, Section 6.1.1.A)
- 4.3.6 Verify the QA Manager concurs with causal analysis and corrective action plans as required. (QAM Policy Q-16.1, Section 6.1.1.B)
- 4.3.7 Verify the QA Manager notifies the Project Director, or appropriate management, of any significant conditions adverse to quality. (QAM Policy Q-01.1, Section 3.3.3.M)

- 4.3.8 Verify the QA Manager trends conditions adverse to quality. (QAM Policy Q-01.1, Section 3.3.3.N and QAM Policy 16.1, Section 6.1)
- 4.3.9 Verify the QA Manager provides the Price-Andersen Amendment Act (PAAA) identification, documentation, and support function for the project. (QAM Policy Q-01.1, Section 3.3.3.O)
- 4.3.10 Verify the QA Manager evaluates conditions adverse to quality to determine reportability and Price-Andersen Amendment Act (PAAA) compliance. (QAM Policy Q-16.1, Section 6.1.1.E)

#### **4.4 Documents and Records**

The inspectors should perform the following activities:

- 4.4.1 Verify the QA Manager concurs on document control procedures developed by the Project Manager. (QAM Policy Q-06.1, Section 2)
- 4.4.2 Verify the QA Manager reviews documents that directly implement the QAM requirements, including changes. (QAM Policy Q-06.1, Section 3.7.1.D.2)

#### **4.5 Work Processes**

The inspectors should perform the following activities:

- 4.5.1 Verify the QA Manager reviews administrative and technical procedures, which implement requirements of the QAM. (QAM Policy Q-05.1, Section 6.2.1.A)
- 4.5.2 Verify the QA Manager reviews procedures, which incorporate independent inspection. (QAM Policy Q-05.1, Section 6.2.1.B)
- 4.5.3 Verify the QA Manager reviews and concurs with the procedures that implement the requirements of QAM Policy Q-02.4, *Special Reviews*, and participated in readiness reviews as required. (QAM Policy Q-02.4, Section 5.3.1)
- 4.5.4 Verify the QA Manager reviews special process procedures and work control documents that specify use of special processes to ensure the quality assurance requirements of QAM Policy Q-09.1, *Control of Special Processes*, are being appropriately incorporated. (QAM Policy Q-09.1, Section 6.2.1)
- 4.5.5 Verify the QA Manager reviews measuring and test equipment calibration implementing documents. (QAM Policy Q-12.1, Section 6.3.1)
- 4.5.6 Verify the QA Manager reviews implementing documents related to QAM Policy Q-12.2, *Installed Process Instrumentation*. (QAM Policy Q-12.2, Section 6.3.1)

4.5.7 Verify the QA Manager monitors quality assurance program implementation for handling, storage, and shipping activities. (QAM Policy Q-13.1, Section 6.1.1)

#### **4.6 Design**

The inspectors should perform the following activities:

4.6.1 Verify the QA Manager establishes the QA program for design control, and reviews engineering procedures that implement the stated requirements. (QAM Policy Q-03.1, Section 6.3.1)

4.6.2 Verify the QA Manager identifies [software] quality assurance requirements and policies. (QAM Policy Q-03.2, Section 6.2.1.A)

4.6.3 Verify the QA Manager develops and maintains [software] QA procedures and processes. (QAM Policy Q-03.2, Section 6.2.1.B)

4.6.4 Verify the QA Manager provides technical assistance/guidance to directors, managers, and staff in meeting [software] QA requirements. (QAM Policy Q-03.2, Section 6.2.1.C)

#### **4.7 Procurement**

4.7.1 Verify the QA Manager provides for the review and acceptance of contractor and vendor QA programs. (QAM Policy Q-01.1, Section 3.3.3.G)

4.7.2 Verify the QA Manager is responsible for evaluating and qualifying suppliers. The inspectors should verify the QA Manager establishes and maintains an Approved Suppliers Listing that documents those suppliers qualified per specific project procurement requirements. (QAM Policy Q-04.1, Section 6.5.1.A and QAM Policy Q-07.1, Section 6.5.1.D)

4.7.3 Verify the QA Manager establishes and maintains a site-wide schedule for all required external supplier audits. (QAM Policy Q-18.1, Section 6.1.1.E)

4.7.4 Verify the QA Manager reviews procurement documents to assure the following:

- Quality requirements are correctly stated, inspectable, and controllable
- There are adequate acceptance/rejection criteria
- Source surveillance or receipt inspection are specified
- Minimum documentation to be supplied are specified

- Procurement documents are processed in accordance with established requirements. (QAM Policy Q-07.1, Section 6.5.1.C)
- 4.7.5 Verify the QA Manager concurs in the selection of the source for field procurement requiring submittal of a quality program, to assure the source has been qualified in accordance with the requirements of QAM Policy Q-07.1, *Control of Purchased Items and Services*. (QAM Policy Q-07.1, Section 6.5.1.E)
- 4.7.6 Verify the QA Manager reviews supplier quality verification documentation for items that had not been inspected at the source. (QAM Policy Q-07.1, Section 6.5.1.F)
- 4.7.7 Verify the QA Manager identifies as nonconforming, discrepant material received at the site for which a supplier's completed nonconformance report had been received. (QAM Policy Q-07.1, Section 6.5.1.G)

#### **4.8 Inspection and Acceptance Testing**

The inspectors should perform the following activities:

- 4.8.1 Verify the QA Manager reviews special process procedures and work control documents that specify use of special processes to ensure the quality assurance requirements of this policy have been properly incorporated. (QAM Policy Q-09.1, Section 6.2.1)
- 4.8.2 Verify the QA Manager prepares and/or reviews quality-affecting documents that establish inspection requirements. (QAM Policy Q-10.1, Section 6.2.1.A)
- 4.8.3 Verify the QA Manager plans, performs, documents, and reports inspections and tests. (QAM Policy Q-10.1, Section 6.2.1.B)
- 4.8.4 Verify the QA Manager reviews test control procedures and work control documents that specified use of test controls to ensure that quality assurance requirements have been appropriately incorporated. (QAM Policy Q-11.1, Section 6.4.1)
- 4.8.5 Verify the QA Manager establishes and maintains a system for identifying the quality status of items, which includes, but is not limited to, acceptance, rejection, hold for inspection, and conditional use. (QAM Policy Q-08.1, Section 6.4.1, and QAM Policy Q-14.1, Section 6.1.1)

#### **4.9 Management Assessment**

The inspectors should perform the following activities:

- 4.9.1 Verify the QA Manager performs evaluations and self-assessments on a planned and periodic basis to verify the QA Program is being effectively implemented. (QAM Policy Q-01.1, Section 3.3.3.D)

- 4.9.2 Verify the QA Manager issues periodic reports to the Project Director and appropriate management on the status of quality activities. (QAM Policy Q-01.1, Section 3.3.3.L)
- 4.9.3 Verify the QA Manager reviews the status and adequacy of the QA Program, and provides reports to the Project Manager at least annually. (QAM Policy Q-18.3, Sections 3.1.1 and 3.1.4.A)

#### **4.10 Independent Assessment**

The inspectors should perform the following activities:

- 4.10.1 Verify the QA Manager defines the requirements for technical specialist, auditor, and lead auditor qualification and certification. (QAM Policy Q-02.3, Section 6.1.1.A)
- 4.10.2 Verify the QA Manager evaluates objective evidence to determine acceptability for auditor/lead auditor qualification against criteria in this policy. (QAM Policy Q-02.3, Section 6.1.1.B)
- 4.10.3 Verify the QA Manager provides for auditor/lead auditor training and a written examination of prospective lead auditors. (QAM Policy Q-02.3, Section 6.1.1.D and 6.1.1.E)
- 4.10.4 Verify the QA Manager ensures records of auditor/lead auditor qualification were established and maintained. (QAM Policy Q-02.3, Section 6.1.1.F)
- 4.10.5 Verify the QA Manager conducts audits using personnel qualified/certified per Policy Q-02.3, *Auditor/Lead Auditor Qualification and Certification*. (QAM Policy Q-18.1, Section 6.1.1.A)
- 4.10.6 Verify the QA Manager develops and distributes audit schedules. (QAM Policy Q-18.1, Section 6.1.1.C)
- 4.10.7 Verify the QA Manager conducts independent assessments, audits, and surveillances. (QAM Policy Q-01.1, Section 3.3.3.B)
- 4.10.8 Verify the QA Manager ensures the auditors are independent of the work being audited. (QAM Policy Q-18.1, Section 6.1.1.H)

### **5.0 INSPECTION GUIDANCE**

Inspection guidance is provided to assist in addressing the inspection requirements set forth in Section 4.0 of this procedure. For each area listed below, the inspectors will do the following:

- a. Review the Contractor's processes, procedures, requirements, and responsibilities that apply to the QA Organization.

- b. Review objective evidence that the procedures, processes, requirements, and responsibilities have been implemented, as applicable.
- c. Interview personnel responsible for performing quality assurance activities.

The guidance below includes suggested sample sizes of procedures to be reviewed and personnel to be interviewed. A different sample size may be chosen based on the status of the construction activities or on the initial observations in any area. The samples should be of sufficient size to provide confidence that (1) the Contractor has approved procedures; (2) the procedures are being implemented; and (3) the personnel are properly qualified for the work they are performing.

## **5.1 Management Program and Processes**

The inspectors should perform the following activities:

- 5.1.1 Review the Contractor's organization chart to confirm functional authority, independence, and responsibility to effectively implement the QA Program. The inspectors should review the QA Manager's position description to confirm he/she has responsibility to effectively implement the QA Program and no unrelated duties that would preclude full attention to assigned responsibilities. The inspectors should examine the QAM to verify the interpretation of activities to which the QAP applies and the extent to which the policy applies to those activities.
- 5.1.2 No further guidance provided.
- 5.1.3 Review objective evidence the QA Manager provides guidance and oversight for the projects based on applicable requirements of 10 CFR 830, Subpart A, DOE Order 414.1A, and NQA-1 (1989).
- 5.1.4 Interview the managers of functional areas and the area project teams to determine the level of support the QA Manager provides in the area of guidance on quality and safety and necessary resources. The inspectors should review documented evidence, if available, of the QA Manager providing necessary resources to area project managers.
- 5.1.5 Interview the QA Manager to determine if it has been necessary to direct work to be stopped on nonconforming materials or activities. The inspectors should review documented evidence of the work stoppage and restart activities to ensure they were conducted in accordance with QAM Policy 16.2, *Stop Work*.
- 5.1.6 Review documented evidence the QA Manager reviewed corrective actions and determined when appropriate actions had been taken to lift a stop work order allowing work to proceed.
- 5.1.7 Interview the QA Manager to determine the working interfaces and lines of communication with other departments, appropriate industry representatives, and regulatory groups. The inspectors should review objective evidence of the QA Manager's working interfaces and communication with regulatory groups.

- 5.1.8 Review objective evidence the QA Manager established indoctrination and training programs for QA and QC personnel. The inspectors should select a sample of three QA and three QC personnel to confirm they had completed their indoctrination and training programs.
- 5.1.9 Review objective evidence that the QA Manager provides input related to the QA training program for personnel outside of the QA organization. The inspectors should select a sample of six non-QA personnel and review their training records to confirm they had received indoctrination in QA when they began work on the project.
- 5.1.10 No additional guidance provided.
- 5.1.11 No additional guidance provided.
- 5.1.12 No additional guidance provided.
- 5.1.13 Interview several employees within non-QA organizations to determine whether they feel free to report and resolve conditions adverse to quality. The inspectors should review the new employee training and orientation materials to determine if new employees are encouraged to identify and correct problems.
- 5.1.14 No additional guidance provided.
- 5.1.15 No additional guidance provided.

## **5.2 Personnel Training and Qualification**

Inspection guidance for all QA manager and QA department training and qualification requirements are included in Inspection Procedure I-106, "Personnel Training and Qualification Assessment;" therefore, this area will not be addressed in this inspection.

## **5.3 Quality Improvement**

The inspectors should perform the following activities:

- 5.3.1 No additional guidance provided.
- 5.3.2 No additional guidance provided.
- 5.3.3 No additional guidance provided.
- 5.3.4 Review the Contractor's surveillance reports to confirm surveillance had been performed or scheduled on the application and removal of nonconformance status control tags..
- 5.3.5 No additional guidance provided..

- 5.3.6 No additional guidance provided.
- 5.3.7 No additional guidance provided.
- 5.3.8 No additional guidance provided.
- 5.3.9 Review the Contractor's organization chart to verify the Price-Andersen Amendment Act of 1988 (PAAA) Coordinator reports to the QA organization.
- 5.3.10 Select a sample of three conditions adverse to quality to confirm the QA Manager had evaluated them for PAAA reportability and compliance.

#### **5.4 Documents and Records**

The inspectors should perform the following activities:

- 5.4.1 Select and review a sample of three document control procedures developed by the Project Manager to confirm the QA Manager had concurred.
- 5.4.2 No additional guidance provided.

#### **5.5 Work Processes**

The inspectors should perform the following activities:

- 5.5.1 Select a sample of six administrative procedures and six technical procedures to verify objective evidence of the QA Manager's review.
- 5.5.2 Review independent inspection procedures to verify objective evidence of the QA Manager's review.
- 5.5.3 Review the procedures that implement the requirements of QAM Policy Q-02.4, *Special Reviews*, to verify objective evidence of the QA Manager's review. The inspectors should review objective evidence the QA Manager participated in readiness reviews as required.
- 5.5.4 Review special process procedures and work control documents to verify objective evidence of the QA Manager's review. The inspectors should review the special process procedures and work control documents to confirm the quality assurance requirements of QAM Policy Q-09.1, *Control of Special Processes*, had been appropriately incorporated.
- 5.5.5 Review the procedures that govern measuring and test equipment calibration to verify objective evidence of the QA Manager's review.
- 5.5.6 Review the implementing documents related to QAM Policy Q-12.2, *Installed Process Implementation*, to verify objective evidence of the QA Manager's review.

- 5.5.7 Confirm the QA Manager has monitored the implementation of the requirements for handling, storage, and shipping. The inspectors should review surveillance reports to confirm this area has been surveilled.

## **5.6 Design**

The inspectors should perform the following activities:

- 5.6.1 Review design and engineering procedures for objective evidence of the QA Manager's review. The inspectors should confirm there is a method that demonstrates all the stated requirements are adequately addressed in the design procedures.
- 5.6.2 No additional guidance provided.
- 5.6.3 No additional guidance provided.
- 5.6.4 No additional guidance provided.

## **5.7 Procurement**

The inspectors should perform the following activities:

- 5.7.1 Review the Contractor's organization chart to confirm the personnel responsible for review and acceptance of subcontractor and vendor QA programs are within the QA organization.
- 5.7.2 Select three suppliers listed on the Approved Suppliers Listing and confirm the suppliers were evaluated and qualified by the Contractor's QA organization prior to being included on the listing. The inspectors should review objective evidence of the evaluations and qualifications. The inspectors should confirm the Approved Supplier's List is maintained with current and accurate information.
- 5.7.3 Confirm there is a site-wide schedule for all required external supplier audits. The inspectors should select three qualified suppliers and confirm the QA Manager performed supplier audits to evaluate supplier conformance with approved contractual requirements. The inspectors should review objective evidence of the supplier audits. The inspectors should confirm the QA Manager established and implemented a supplier re-qualification process. The inspectors should review objective evidence of re-qualifications of three suppliers.
- 5.7.4 No additional guidance provided.
- 5.7.5 Select three field procurements not requiring submittal of a quality program to confirm the Contractor's QA Manager concurred in the selection of the source for the field procurement. The inspectors should review objective evidence of the QA Manager's concurrence.

- 5.7.6 Select three supplier quality verification documents for items that had not been inspected at the source to confirm the QA Manager had conducted a review of the items. The inspectors should review objective evidence of QA Manager's review of these items.
- 5.7.7 Select three items determined by the QA Manager to be nonconforming at the site, for which a supplier's completed nonconformance report had not been received. The inspectors should review objective evidence of these nonconforming items.

## **5.8 Inspection and Acceptance Testing**

The inspectors should perform the following activities:

- 5.8.1 No additional guidance provided.
- 5.8.2 No additional guidance provided.
- 5.8.3 No additional guidance provided.
- 5.8.4 Review the Contractor's test control procedures and work control documents to verify objective evidence of the QA Manager's review.
- 5.8.5 Review the Contractor's procedures for identifying the quality status of items. The quality status controls must include, but not be limited to, acceptance, rejection, hold for inspection, and conditional use. The inspectors should review objective evidence that these quality status controls had been used on the project.

## **5.9 Management Assessment**

The inspectors should perform the following activities:

- 5.9.1 Interview the QA Manager to confirm the frequency of evaluations and self-assessments (i.e., at least annually) to verify the QA Program is being effectively implemented. The inspectors should review objective evidence of these evaluations and self-assessments.
- 5.9.2 No additional guidance provided.
- 5.9.3 No additional guidance provided.

## **5.10 Independent Assessment**

The inspectors should perform the following activities:

- 5.10.1 Review the requirements for technical specialist, auditor, and lead auditor qualification and certification.

- 5.10.2 Select three auditors and three lead auditors and review objective evidence of the QA Manager's evaluation for acceptability for auditors and lead auditors against the criteria of QAM Policy Q-02.3, *Auditor/Lead Auditor Qualification and Certification*.
- 5.10.3 Review objective evidence the QA Manager provides for auditor/lead auditor training and a written examination of prospective lead auditors.
- 5.10.4 Select a sample of three qualified auditors and three qualified lead auditors. The inspectors should review objective evidence of the establishment and maintenance of the qualifications.
- 5.10.5 No additional guidance provided.
- 5.10.6 No additional guidance provided.
- 5.10.7 No additional guidance provided.
- 5.10.8 Interview the QA Manager to determine the method(s) used to ensure auditors are independent of the work being audited. The inspectors should select three audits, and review objective evidence to confirm the auditors were independent.

## 6.0 REFERENCES

10 CFR 830, Subpart A, "Quality Assurance Requirements," *Code of Federal Regulations*, as amended.

DOE/RW-0333P, Revision 10, *Quality Assurance Requirements and Description (QARD)*.

*Implementation Guide for use with 10 CFR Part 830.120, Quality Assurance*, G-830.120-Rev. 0, U.S. Department of Energy, 1994.

24590-WTP-QAM-QA-01-001, Rev. 4, *Quality Assurance Manual*, effective date July 10, 2003.

## 7.0 LIST OF TERMS

DOE	U.S. Department of Energy
OSR	WTP Safety Regulation Division
QA	quality assurance
QAM	Quality Assurance Manual
QAPD	Quality Assurance Provisions Document
QAP	Quality Assurance Program
QARD	Quality Assurance Requirements and Description
QC	quality control