

## QUALITY ASSURANCE PROGRAM

### 1.0 Objective

The objective of this performance assessment is to evaluate the effectiveness of the laboratory's quality assurance program as implemented in the facility. The Facility Representative or Environmental, Safety, and Health Support Specialist evaluates implementation of site-wide policies, procedures, and programs with particular emphasis on development and implementation of facility-specific policies and procedures. In conducting this assessment, the Facility Representative Environmental, Safety, and Health Support Specialist observes work activities, interviews personnel, performs walkdowns, and reviews specific documents.

### 2.0 Definitions

Concern - A determination of a programmatic breakdown or widespread problem supported by one or more findings or observations.

Finding - An individual item which does not meet requirements.

Functional Area - A discrete group of related safety and support programs.

Lines of Inquiry - Questions that guide the assessor in planning and conducting the performance assessment.

Observation - A condition or practice that does not provide or promote effective protection of the health and safety of the public or DOE's workers or the environment.

Performance Assessment - An evaluation of a program or functional area to verify laboratory line management effectiveness in ensuring the health and safety of the public and of DOE's workers and in ensuring protection of the environment.

Performance Attributes - Key elements, functions, or activities to be assessed in a particular functional area.

### 3.0 References

- 3.1 DOE O 440.1A, *Worker Protection Management for DOE Federal and Contractor Employees*
- 3.2 DOE 5700.6C, *Quality Assurance*
- 3.3 10 CFR Part 50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*

- 3.4 10 CFR Part 830.120, *Quality Assurance Requirements for DOE Nuclear Facilities*
- 3.5 DOE G 440.1-6, *Implementation Guide for use with Suspect/Counterfeit Items* requirements of DOE O 440.1, *Worker Protection Management 10 CFR 830.120* and DOE 5700.6C, *Quality Assurance*
- 3.6 NQA-1-1989, *Quality Assurance Program Requirements for Nuclear Facilities*
- 3.7 ANSI/ASME N45.2, *Quality Assurance Requirements for Nuclear Facilities*

#### **4.0 Performance Assessment Activities**

The assessor reviews pertinent program documentation including policies, procedures, and program plans before beginning the assessment. Appendix A provides a suggested list of documents that the assessor may review during preparations for the assessment.

During the assessment, the assessor evaluates selected performance attributes by developing and using lines of inquiry for each performance attribute. Appendix B provides a listing of suggested performance attributes and lines of inquiry. In applying each line of inquiry, the assessor may complete diverse activities such as reviewing documents, interviewing facility personnel and support staff, observing work activities, and performing walkdowns. The assessor may choose to use existing surveillance guides in completing specific portions of the assessment. Surveillance Guides for the Quality Assurance functional area include:

QAS 2.1	Nonconforming Conditions
QAS 2.2	Staging/Storage of Components
QAS 2.3	Procurement
QAS 2.4	Instrument Calibration
QAS 2.5	Design Control
QAS 2.6	Quality Assurance Records

The Quality Assurance Program area includes all aspects of quality verification with the exception of design control. This element is addressed in assessment guide ENA 7.1, *Engineering Program*.

The emphasis of this assessment is on the effectiveness of the laboratory's quality assurance program as implemented in a specific facility. In performing this assessment, the assessor must balance review of site-wide programs, facility-specific policies and procedures, and implementation. The following questions provide the general framework that should be used in planning, conducting and documenting the assessment:

- Has the facility correctly identified activities that should be performed under the Quality Assurance Program?
- Has the laboratory's site-wide quality assurance program been effectively applied at the facility?
- Does line management take the lead in implementing the quality program?
- Has facility management demonstrated a commitment to quality?

## **APPENDIX A POTENTIAL DOCUMENTS FOR REVIEW**

- Site-wide Quality Assurance Program Manual
- Site-wide policy on quality assurance
- Facility-specific documents defining scope of quality assurance program
- Facility-specific quality assurance policy and procedures
- Training materials on quality assurance for facility employees
- Sample non-conformance reports
- Management assessment reports
- Independent assessment reports

## **APPENDIX B**

### **PERFORMANCE ATTRIBUTES AND LINES OF INQUIRY**

**PERFORMANCE ATTRIBUTE: I.** Laboratory Management has implemented a written Quality Assurance Program that ensures quality of work, effective control of processes, and clear accountability for results.

#### **LINES OF INQUIRY:**

1. Has senior management issued a written policy statement committing the organization to implement a formal Quality Assurance Program?
2. Has a quality assurance program document including implementing procedures been prepared and issued to establish organizational structure, functional responsibilities, levels of authority, and interfaces?
3. Does the Quality Assurance Program clearly establish that line management is responsible for achieving quality?
4. Does the quality assurance program document clearly define the activities to which it applies?
5. Are responsibilities and authority to stop work clearly assigned?
6. Does the Quality Assurance Program Manager report to a management level such that he/she has sufficient authority, access to work areas, and organizational freedom and independence to identify problems, recommend solutions, and verify implementation of solutions?
7. Has the Quality Assurance Program been approved by the Department of Energy?
8. Are changes to the Quality Assurance Program submitted at least annually to the Cognizant Secretarial Official?
9. Is the Quality Assurance Program available at the facility?
10. Has the Facility Manager formally endorsed the site-wide Quality Assurance Program?
11. Have the specific activities at the facility covered by the Quality Assurance Program been defined?
12. Have facility-specific procedures for implementing the Quality Assurance Program been developed, approved, and issued?

## **APPENDIX B PERFORMANCE ATTRIBUTES AND LINES OF INQUIRY**

**PERFORMANCE ATTRIBUTE:** II. Personnel shall be trained and qualified to ensure that they can perform their assigned work.

### **LINES OF INQUIRY:**

1. Have qualification requirements been established for specific job categories?
2. Does training ensure that workers understand processes, use of procedures, use of tools, quality requirements, and the basis for these requirements?
3. Have training plans been prepared for personnel to promote professional development and provide for maintenance of knowledge, skills, and abilities through periodic retraining?
4. Are training plans implemented? (Do personnel attend planned courses and do they attend classes or training for the full period of time?)
5. Is training based on curricula that have been developed to meet specific needs of job incumbents?
6. Is training presented by instructors with appropriate qualifications in instructional technology and where necessary, subject matter expertise?
7. Is training subject to ongoing review to determine the overall effectiveness of the program?
8. Is training upgraded in response to identified needs?
9. Are personnel who perform quality verification activities trained and qualified?
10. Do personnel receive training on the quality assurance program?

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**PERFORMANCE ATTRIBUTE:** III. The Quality Assurance Program includes processes to detect and correct quality problems and ensure continuous quality improvement.

#### **LINES OF INQUIRY:**

1. Have procedures been established for identifying and correcting quality problems?
2. Are items, processes or conditions that do not meet established requirements promptly identified, documented, analyzed, controlled, and corrected?
3. Are significant conditions that are adverse to quality reported to appropriate levels of management?
4. Does management act promptly in response to conditions that are identified as adverse to quality?
5. Have processes been established and implemented to prevent deficient conditions and improve quality through peer reviews, design reviews, reliability analyses, etc.?
6. Is performance data including quality related information routinely analyzed to identify adverse trends and opportunities to improve items or processes?
7. Are personnel identifying nonconforming items, conditions, or processes?
8. Do personnel have the freedom and authority to stop work pending corrective actions implementation?
9. Are root and contributing causes identified for nonconforming conditions and are corrective actions initiated to preclude recurrence?
10. Are nonconforming items, conditions, or processes properly controlled to prevent their inadvertent installation, use, or testing?
11. Do controls for identified non-conformances include provisions for notifying affected organizations and determining reportability?
12. Are nonconforming items, conditions, or processes reviewed and dispositioned by personnel with sufficient technical qualifications?

13. Is justification for disposition of each non-conformance documented?
14. Are re-worked, repaired and replacement items inspected and tested in accordance with original requirements or approved alternatives?

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### **PERFORMANCE ATTRIBUTES AND LINES OF INQUIRY**

**PERFORMANCE ATTRIBUTE:** IV. Appropriate processes have been established and implemented to control preparation, review, approval, distribution, and maintenance of documents and records.

#### **LINES OF INQUIRY:**

1. Is preparation, review, approval, issuance, use, and revision of essential work documents such as procedures, design criteria, work packages, and design packages controlled by a clearly defined process?
2. Is the scope of the document control system clearly defined?
3. Are revisions to controlled documents reviewed and approved by the organizations that reviewed and approved the original documents?
4. Are controlled documents distributed to and used by personnel performing and monitoring work?
5. Are superseded or cancelled documents appropriately controlled so that they are removed from document control centers or clearly marked "superseded" or "cancelled"?
6. Has a process been established to identify required records that must be maintained?
7. Have provisions been made for retention, protection, preservation, traceability, accountability, and retrievability of records?
8. Are records stored in facilities that provide adequate protection from fires, water, vermin, and other potential sources of damage or deterioration?
9. Is the facility using the General Records Schedule and guidelines provided by the National Archives and Records Administration in defining records that must be maintained?
10. Are records identifiable and readily retrievable?

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### **PERFORMANCE ATTRIBUTES AND LINES OF INQUIRY**

**PERFORMANCE ATTRIBUTE:** V. Effective administrative controls are established and implemented to govern work processes.

**LINES OF INQUIRY:**

1. Are work activities performed in accordance with approved instruction, procedures, orders, or directives to ensure that quality is attained and results from work activities can be reasonably predicted?
2. Is all equipment used for process monitoring or data collection calibrated and maintained?
3. Is work planned, reviewed, authorized, and performed under controlled conditions?
4. Are instructions, procedures, work packages, or other governing documents prepared by technically competent personnel?
5. Are instructions, procedures, work packages, and directives subject to required reviews by affected organizations, verified by an independent reviewer and validated by walkthroughs?
6. Do processes for performing maintenance, or installing new equipment ensure that equipment is controlled, traceable, and not defective?
7. Are equipment, components, and materials adequately labeled to ensure traceability?
8. Are processes established and implemented to control consumables and materials with limited shelf life, prevent use of incorrect or defective materials, and control samples?
9. Have controlled processes been established for handling, storing, shipping, cleaning, and preserving materials and equipment from the time they are received to the time they are installed or used?
10. Are special controls or requirements specified as necessary to preserve integrity of equipment, materials, and components?
11. Are instruments, sensors, and alarms used for controlling work or protecting employees maintained and calibrated?

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### **PERFORMANCE ATTRIBUTES AND LINES OF INQUIRY**

**PERFORMANCE ATTRIBUTE:** VI. An effective process has been established to ensure that equipment, components, materials, and services procured to support operations attain the requisite levels of quality.

#### **LINES OF INQUIRY:**

1. Are procured equipment, components, and materials verified to meet established quality requirements before installation or use?
2. Are acceptance criteria included in procurement documents?
3. Do procurement documents invoke applicable codes, standards, tests, inspections, or nondestructive examinations?
4. Have all prospective suppliers been evaluated to ensure that they can meet the established quality requirements?
5. Are surveillances or other evaluations performed periodically to ensure that suppliers continue to produce and provide components, equipment, materials, or services with the requisite quality?
6. Are purchased components, equipment, or materials accepted using approved methods such as review of manufacturing process control data, quality surveillance during manufacture, receipt inspection, performance testing, certificates of compliance, or nondestructive examinations?
7. Are all requirements in procurement documents verified to be met before components, equipment, or materials are installed in systems or used in operations?
8. Have special quality verification requirements been established for procurement of "off-the-shelf" components, equipment or material to maximize the probability that those items will perform as intended?

## **PERFORMANCE ATTRIBUTES AND LINES OF INQUIRY**

**PERFORMANCE ATTRIBUTES:** VII. Inspection and acceptance testing using established performance and acceptance criteria is performed to ensure that required quality is attained.

### **LINES OF INQUIRY:**

1. Are required inspections and acceptance criteria determined before equipment is procured or work begins?
2. Does the organization conducting inspections ensure that personnel who perform work do not subsequently inspect their own work for acceptance?
3. Are inspections sufficiently planned so that critical characteristics, key process steps, inspection techniques, sample sizes, hold points, and qualification requirements for inspectors are established before inspections are conducted?
4. Are inspection results documented, evaluated, and trended to detect declining performance?
5. If acceptance criteria are not met, are corrective actions implemented and followup inspections performed to verify acceptance criteria are met?
6. Is testing, including bench tests, proof tests, pre-operational tests, post-maintenance tests, post-modification tests, and operational surveillance testing, performed to ensure that systems, components and equipment perform as intended?
7. Does the organization completing the testing ensure that personnel who perform work do not subsequently test their own work for acceptance?
8. Are test requirements and acceptance criteria specified by or approved by the organization responsible for design of the installation?
9. Are tests performed in accordance with written procedures that include prerequisites for performing the test, instructions for each step, requirements for completeness and accuracy of data, test equipment to be used, acceptance criteria, hold points, and test configuration?
10. Are results from tests documented, analyzed, and trended?
11. If acceptance criteria are not met, are corrective actions implemented and followup inspections performed to verify that acceptance criteria are met?
12. Are possible counterfeit parts expected, identified and sequestered securely?

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### **PERFORMANCE ATTRIBUTES AND LINES OF INQUIRY**

**PERFORMANCE ATTRIBUTES:** VIII. Instruments and equipment for measuring and testing response of systems and for calibration of process instrumentation are calibrated and maintained.

#### **LINES OF INQUIRY:**

1. Are measuring and test equipment used to calibrate or verify performance of other equipment or instruments that effect quality subject to a program of calibration, maintenance, and verification?
2. Is measuring and test equipment calibrated at intervals based on manufacturer recommendations and experience?
3. Is measuring and test equipment labeled, tagged and controlled to indicate its calibration status and to ensure that it is traceable to all calibration tests in which it has been used?
4. Is measuring and test equipment calibrated against standards that are traceable to national standards?
5. Is measuring and test equipment that is found out-of-calibration or out-of-tolerance tagged or segregated and not used until successfully re-calibrated?
6. Are all tests or calibrations that were performed with measuring and test equipment that was found to be out-of-calibration re-evaluated to determine their acceptability?
7. Are all calibrations performed in accordance with written procedures?

## **APPENDIX B PERFORMANCE ATTRIBUTES AND LINES OF INQUIRY**

**PERFORMANCE ATTRIBUTES:** IX. Management conducts periodic assessments or reviews to evaluate the effectiveness of the quality assurance program.

**LINES OF INQUIRY:**

1. Are periodic management assessments conducted to determine how well the quality assurance program is working and to identify problems or issues that hinder the organization from achieving its objectives?
2. Does senior management participate in and retain responsibility for conducting the assessments?
3. Are all levels of management involved in the assessment?
4. Are results from management assessments documented?
5. Does senior management take prompt action in response to recommendations resulting from management assessments?
6. Is the effectiveness of actions taken in response to recommendations from management assessments evaluated and reported to senior management?

## **APPENDIX B PERFORMANCE ATTRIBUTES AND LINES OF INQUIRY**

**PERFORMANCE ATTRIBUTES:** X. Periodic independent assessments are performed by technically qualified and knowledgeable personnel to verify quality and promote improvement.

### **LINES OF INQUIRY:**

1. Are assessments conducted by an independent organization with sufficient authority and freedom from the line organization to carry out its responsibilities?
2. Are periodic assessments performed for all functions essential to attaining required quality?
3. Are assessments conducted using criteria that establish acceptable work performance and promote improvement?
4. Do assessments include monitoring work performance?
5. Are results from assessments documented and reported to a level of management with the authority to implement corrective actions?
6. Are followup reviews performed to ensure satisfactory resolution of problems?
7. Do personnel performing assessments have the required skills in conducting assessments and sufficient subject matter expertise?
8. Does management ensure that personnel conducting independent assessments do not have direct responsibilities in the area they are assessing?
9. Is scheduling of assessments and allocation of resources based on status, risk, and complexity of the functions or processes assessed?
10. Is additional attention devoted to assessing areas of historical or recognized weakness?
11. Are results from assessments tracked and is management held accountable for ensuring timely closure of assessment findings?
12. Do responses to assessment findings include corrective actions, cause determinations, and lessons learned?

13. Do corrective actions include actions to correct deficiencies, prevent recurrence and promote improvement?
14. Are assessments conducted in accordance with established procedures?