

QUALITY ASSURANCE

1.0 SCOPE

This Performance Assessment Guide for Quality Assurance will be used to carry out the oversight responsibility of the U.S. Department of Energy (DOE) Brookhaven Group. This guide was prepared to assist in conducting performance-based assessments of both DOE prime contractors and subcontractors to ensure that their quality assurance programs identify, disposition, and take corrective action on issues that affect satisfactory facility performance. The goals are to determine if a quality assurance program has been established at the laboratory level that maximizes the effectiveness of respective activities/processes and minimizes the risk of economic loss or worker/public injury/illness consistent with the risk of the activity or process.

Quality assurance assessments will be directed at all prime contractors and subcontractors working at DOE sites. DOE line management must ensure that contractors comply with DOE Orders and Federal and State regulations. Information developed from this assessment will determine the degree to which this is being done as well as the effectiveness of the laboratory's program.

It is important to recognize that a quality assurance program is a systematic way of doing business that has as its purpose the ATTAINMENT AND VERIFICATION that a desired outcome will be achieved for a given activity or process. That desired outcome generally involves meeting "customer" expectations (i.e., satisfying the customer) and carrying out that activity/process safely for both the worker and the public. The concept of using a graded approach based on risk (both safety and economic) is inherent in any quality assurance program. Therefore, in performing this assessment of quality assurance, a balanced approach in evaluating both the attainment and verification functions should be maintained. For further discussion of balancing the approach, see the Guidance to Assessor portion of this guide.

2.0 ATTRIBUTES AND LINES OF INQUIRY

This section provides lines of inquiry to help assess whether the laboratory has implemented a program that ensures that quality assurance requirements are incorporated into line activities. This section will be used to evaluate the laboratory's line organization. For additional guidance, see Section 4.0, "Guidance to Assessor."

2.1 Planned and periodic independent assessments are conducted to measure item quality and process effectiveness and to promote improvement. (This section is primarily for assessment of how DOE assesses its QAP for DOE.)

- Does the laboratory have an independent assessment group that conducts planned and periodic assessments?
- Do the independent assessments focus on improving items and processes by emphasizing the laboratory 's achievement of quality?
- Do personnel performing independent assessments have sufficient authority and freedom from the line organization to carry out their responsibilities?
- Do their responsibilities include monitoring work performance, identifying abnormal performance and precursors to potential problems, identifying opportunities for improvement, reporting results to a level of management having authority to effect corrective action, and verifying satisfactory resolution of problems?
- Are personnel who perform independent assessments technically knowledgeable and do they focus on improving the quality of the items and effectiveness of the processes?
- Are personnel performing independent assessments prevented from having direct responsibilities in the area they are assessing?
- Are independent assessments conducted using criteria that describe acceptable work performance and promote improvement?
- Is the scheduling of assessments based on the status, risk, and complexity of the item or process being assessed? Is additional focus given to areas of poor performance?
- Are the results of the assessments tracked and resolved by management in the area assessed? Are followup reviews of deficient areas performed as necessary?
- Does the laboratory 's responses to assessments include the following, as applicable: action to correct the deficiency; cause identification; actions to prevent recurrence; lessons learned; and actions taken for improvement?

2.2 A program for implementing a formal quality assurance program exists.

- Are written quality assurance policy statements, which commit the laboratory to implement a formal QAP, issued?
- Is the management organization for ensuring the implementation of an appropriate QAP defined?

- Are the responsibilities of every member of the laboratory 's staff related to the QAP defined?
- Does the QAP promote effective and efficient achievement of the laboratory 's performance objectives?
- Is the QAP binding on all personnel within the laboratory ?
- Are criteria established to define levels of quality assurance required relative to the risk of the item or process?
- Does the QAP describe or provide reference to both the on-assessor and off-assessor organizational structures, functional responsibilities, levels of authority, and interfaces that function within the scope of the QAP?
- Are criteria established for developing individual QAPs or for combining similar work under a single QAP?
- Has a common vocabulary that is consistent and representative of the work being performed been adopted? Is key terminology defined and does personnel indoctrination include appropriate definitions?
- Are management controls established, responsibilities assigned and lines of communication established for the laboratory's work? Is work performed outside the laboratory properly identified and controlled?
- Does the laboratory require that initial work plans include estimates based on sound data and assumptions relating to personnel, material/service costs, availabilities, and productivity?
- Are pre-job reviews conducted for major work to verify the following: prerequisites are satisfied; detailed technical and quality assurance procedures have been reviewed and are adequate and appropriate; personnel have been trained and are qualified; and the proper equipment, material, and resources are available?
- Is the responsibility and authority for stopping unsafe or unsatisfactory work well defined? Are the criteria for restarting work specified? At a minimum, the requirements of DOE 5700.6C step A.1.k. should be required.

2.3 A program for ensuring adequate personnel training and qualification has been implemented.

- Are personnel trained and qualified to ensure they are capable of performing their assigned work?
- Are qualification requirements established for each specific job category within the laboratory?
- Does the training of personnel include basic fundamentals of the work to be performed and its context, education in the principles, enhancement of skills and practices, understanding of the processes and tools, variability of the processes and tools, the amount of control personnel have over the variability of the process, correct performance of the work, and an understanding of why quality requirements exist for the work?
- Does training address the consequences of improper work and the importance of "doing the job right the first time"?
- Does the laboratory have continuing training plans that address professional development, maintenance of proficiency, and progressive improvement?
- Does the training of management personnel include professional, managerial, communication, and interpersonal skills?
- For work requiring special skills or abilities are personnel required to demonstrate proficiency before being hired? Does the qualification procedure require such proficiency of each candidate and does it retest or train periodically thereafter to maintain each candidate's skills to meet current practices?
- Is the laboratory 's training presented by qualified instructors and are curricula provided that address specific needs?
- Does the laboratory have a method for ensuring that the training program is effective and is upgraded when improvements and enhancements are identified?

2.4 Processes are in place to provide for quality improvement.

- Does the laboratory have processes established and implemented with the objective of preventing problems and improving quality? Examples of such processes include but are not limited to those found in DOE 5700.6C step A.3.a.

- Are methods established to identify trends that adversely impact quality and to implement opportunities to improve items and processes?
- Are processes established and implemented to promote continuous improvement? Are expected performance standards and associated performance measures identified and continually improved?
- Does the laboratory encourage all personnel to identify nonconforming items and processes and to suggest improvements? Is it possible for all personnel to stop work until effective corrective action is taken to remedy a nonconforming condition?
- Does a corrective action program exist to identify, document, analyze, resolve, prevent recurrence and follow up on nonconforming items or processes? Is the extent of cause analysis for nonconforming items and processes commensurate with the importance or significance of the problem?
- To foster identification of nonconforming items and processes, does management at all levels foster a "no-fault" attitude? Is a process used for resolving professional differences of views and opinions? Is management actively involved in the quality improvement process and are adequate resources applied to resolve difficult issues?
- Are nonconforming items and processes properly controlled to prevent inadvertent test, installation, or use? Is the disposition of nonconforming items or processes properly documented and reviewed by the organization that originally reviewed and approved the items or processes or by a qualified designated organization?
- Are reworked, repaired, and replaced items and processes inspected and tested in accordance with original requirements or specified alternatives?
- Do personnel responsible for analyzing and dispositioning nonconformances have an adequate technical understanding of the subject and do they have access to pertinent information relative to the nonconformance?

2.5 A process for controlling documents and records is in place.

- Are processes established and implemented to control preparation, review, approval, issuance, use, and revision of documents that prescribe activities affecting quality?
- Is the scope of the document control system defined? Examples of such documents include but are not limited to those found in DOE 5700.6C step A.4.a.(2).

- Are revisions to controlled documents reviewed and approved by the organization that originally reviewed and approved the documents? Are methods in place to designate an alternative organization based on technical competence and capability?
- Are time guidelines for distribution of new or revised controlled documents implemented?
- Are controlled documents distributed and used by personnel performing the work?
- Are methods in place to control superseded and canceled documents to ensure that only correct documents are used? Are record copies of superseded and canceled documents marked and kept for a specified retention period?
- Are processes established and implemented to ensure that sufficient records are specified, prepared, reviewed, approved, and maintained to accurately reflect completed work?
- Are records properly maintained, with provisions for retention, protection, preservation, traceability, accountability, and retrievability.
- For records that require special processing and control, such as computer codes or information on high-density media or optical disks, is the hardware and software required to maintain and access the records properly controlled to ensure the records are useable?
- Does the laboratory have a method to ensure that active records requiring special handling, storage, and processing are not sent to records holding facilities (reserved solely for inactive records)? For further information, refer to the General Records Schedule (GRS) for retention and disposition of records.
- Does the laboratory use the GRS and the DOE-unique schedules approved by the National Archives and Records Administration (NARA) for disposition of Government records?

2.6 A program for controlling work processes exists.

- Is work being performed to established technical standards and administrative controls?
- Are personnel performing the work responsible for the quality of their work?
- Are criteria describing acceptable work defined for the personnel performing the work?

- Does the laboratory have a process to ensure that the personnel performing the work are knowledgeable of the requirements for work they perform and the capability of the tools and processes they use?
- Are the laboratory's line managers ensuring that personnel reporting to them are provided the required training, resources, and administrative controls to accomplish their work?
- Are the laboratory's line managers reviewing work and related information to ensure that the desired quality is being achieved and to identify areas needing improvement?
- Is work planned, authorized, and accomplished under controlled conditions using technical standards, instructions, procedures, or other appropriate means of a detail commensurate with the complexity and risk of the work?
- Is a method in place to ensure work-related instructions, procedures, and other forms of direction are developed, verified, validated, and approved by technically competent personnel?
- Are processes established and implemented to identify, control, and maintain items?
- Is proper identification of items maintained to ensure appropriate traceability?
- Are processes established and implemented to control consumable items with limited shelf life, prevent the use of incorrect or defective items, and control samples?
- Are processes established and implemented to control the handling, storage, shipping, cleaning, and preservation of items to prevent damage, loss, or deterioration?
- Are processes established and implemented to ensure marking and labeling (which provide special controls or instructions to preserve an items integrity) is properly maintained throughout packaging, shipping, handling, and storage? Are requirements for off-assessor transportation established and implemented?
- Are special protective measures (such as containers, shock absorbers, accelerometers, temperature, and moisture level) specified and provided when required to maintain acceptable quality?
- Are processes established and implemented to control the calibration, maintenance, and use of measuring and test equipment used for monitoring and data collection?

- Is the monitoring and data collection equipment accuracy, range, and type suitable for its intended use? Are the types of monitoring and data collection equipment to be used specified? Does equipment have calibration certifications traceable to national standards, when possible?

2.7 A program for controlling design exists.

- Are processes established and implemented for design using sound engineering/scientific principles and appropriate standards, such as the General Design Criteria (DOE 6430.1A)?
- Does the laboratory have provisions for the control of design requirements, inputs, processes, outputs, changes, records, and organizational interfaces?
- Are design inputs, such as design bases, and design requirements properly translated into design outputs, such as specifications, drawings, procedures, and instructions.
- Does the laboratory have processes for controlling changes to final designs? Are the design changes subject to design control measures equivalent to those of the original design? Are design changes approved by the original design organization or a technically qualified designee?
- Does the laboratory have processes for controlling the design interfaces and coordinating the design efforts? Are the assignments of responsibilities among participating design organizations well defined and is the interface effective?
- Are design records maintained that include the following: important intermediate design steps, sources of input, final output, final design, and any revisions to the final design?
- Does the laboratory have a process for verifying the acceptability of design work? Are computer programs validated through previous use, testing, or simulation?
- Is design verification or validation performed by qualified individuals or groups other than those who performed the original design?
- Are verification methods established (e.g., design reviews, alternate calculations, and qualification testing)? Are methods established to limit verification of multiple uses of identical or previously proven designs?

- Is testing to verify or validate acceptable performance of a design feature performed under conditions that simulate the most adverse design conditions? Are methods established for considering and determining the most adverse conditions under which an item must perform satisfactorily?
- Is design verification completed before relying on the design to perform its function and before installation becomes irreversible? When this coordination is not possible, is the unverified portion of the design identified and controlled?

2.8 Programs are in place to control the procurement of items and services.

- Is a process established and implemented to ensure that purchased items and services meet established requirements and perform as specified?
- Are the applicable technical and administrative requirements invoked for procurement of items and services? Are acceptance criteria specified in the procurement document?
- Are appropriate controls used for the selection, determination of suitability, evaluation, and receipt of all purchased items, including commercial-grade items?
- Is a method for evaluating prospective suppliers used to ensure that only qualified suppliers are selected on the basis of specified criteria?
- Are qualified suppliers and sub-tier suppliers monitored periodically to ensure acceptable items and services are supplied?
- Are specified methods used for accepting items and services? Examples of such methods are contained in DOE 5700.6C step B.3.f.
- Are controls used to ensure a procured item satisfies the specification, inspection, and test requirements and the disposition of nonconformances properly completed prior to being placed in service?
- Is a method used to compare actual performance of items with original performance criteria and are the results reviewed to determine procurement effectiveness?
- Is the quality of purchased items and services verified at intervals to a degree consistent with the item's or service's complexity, risk, quantity, and frequency of procurement?

- Is a process used to ensure the DOE Office of Inspector General is forwarded information on suppliers who knowingly supply items or services of substandard quality?

2.9 Processes exist for inspection and acceptance testing.

- Is inspection and acceptance testing of specified items and processes conducted using established acceptance and performance criteria?
- Are administrative controls and status indicators used to preclude inadvertent bypassing of required inspections and to prevent inadvertent operation of the item or process?
- Are processes in place for implementing inspections when required? Are personnel prevented from inspecting their own work for acceptance?
- Is the level of inspection and degree of independence of inspection personnel based on risk and complexity?
- Does the laboratory have provisions to ensure inspection planning is properly accomplished? Do the inspection plans identify item characteristics and processes to be inspected, inspection techniques, acceptance criteria, hold points, and the organization responsible for performing the inspection?
- If acceptance criteria are not met, are deficiencies resolved and does reinspection occur as required?
- Are processes established and implemented to ensure testing is performed to demonstrate that items and processes will perform as intended?
- Is testing structured so that proving designs is not confused with proving the adequacy of work?
- Are processes in place for implementing tests when required? Are personnel prevented from testing their own work for acceptance?
- Are item and process test requirements and acceptance criteria provided by or approved by the organization responsible for design?
- Are administrative controls and status indicators used to preclude inadvertent bypassing of required tests of the item or process?

- Does the laboratory develop and use test procedures?
- If acceptance criteria are not met, are deficiencies resolved and does retesting occur as required?

2.10 Controls exist for measuring and test equipment.

- Does the laboratory's QA program specify the necessary controls for the measuring and test equipment to be used?

2.11 Management at all levels periodically assesses the integrated QAP and its performance.

- Does the laboratory perform periodic and planned management assessments with a focus toward improving quality?
- Are the management assessments focused on how well the integrated quality assurance program is working and on identifying and correcting problems that delay the laboratory from achieving its objectives?
- Does the senior management of the laboratory retain overall responsibility for management assessments? Are all levels of management involved in the assessment process, as appropriate?
- Are management assessment results documented? Does senior management take prompt action and document decisions made in response to the management assessment process? Does the organization follow up with an evaluation of the effectiveness of the actions taken in response to the assessments?

3.0 STANDARDS AND REQUIREMENTS

3.1 Specific DOE Orders and Standards.

- DOE O 200.1, "Information Management Program."
- DOE O 232.1A, "Occurrence Reporting and Processing of Operations Information."
- DOE O 440.1A, "Worker Protection Management for DOE Federal and Contractor Employees"
- DOE 2300.1B, "Audit Resolution and Followup."

- DOE 2321.1B, "Auditing of Programs and Operations."
- DOE 3790.1A, "Federal Employee Occupational Safety and Health Program."
- DOE 5480.19, "Conduct of Operations Requirements for DOE Facilities."
- DOE 5700.6C, "Quality Assurance."
- DOE 6430.1A, "General Design Criteria."

3.2 Title 10 CFR Requirements.

- 10 CFR 830.120, "Quality Assurance Requirements for DOE Nuclear Facilities."

3.3 Additional Standards.

- American Society of Mechanical Engineers (ASME) NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities."
- ASME NQA-2, "Quality Assurance Requirements for Nuclear Facility Applications."
- ASME NQA-3, "Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Assessor Characterization of High-Level Nuclear Waste Repositories."
- International Atomic Energy Agency (IAEA) International Nuclear Safety Advisory Group's Safety Series No. 75-INSAG-3, "Basic Safety Principles for Nuclear Power Plants."
- International Standard for Standardization (ISO) 9000, "Quality Management and Quality Assurance Standards-Guidelines for Selection and Use."
- American Society for Testing and Materials (ASTM) standards, including ASTM C1009, "Establishing a QA program for Analytical Chemistry Laboratories Within the Nuclear Industry."

4.0 GUIDANCE TO ASSESSOR

This assessment guide is intended to assist in conducting a performance assessment of quality assurance. It is not to be considered as all-inclusive, inflexible, or limiting reasonable assessment concentration when lines of inquiry responses dictate that an area must be more thoroughly probed.

In performing an assessment of quality assurance, it is very important to maintain balance between the **attainment and verification** functions that are essential parts of a quality assurance program.

Attainment is the act of achieving the desired outcome of the activity or process. Attainment is generally the responsibility of the "doers"—the workers, their supervision, and management. Verification is the act of determining, based generally on observable evidence, that the essential function is working properly. Quality must be attained before it can be verified.

Verification is typically the responsibility of the "checker or inspector/auditor," sometimes independent and sometimes within the craft function itself. For example, a worker who repairs and resets a critical safety relief valve on a pressure vessel is a "quality attainer." The peer inspector or craft foreman who verifies that the setpoint is properly set and the relief valve lifted at the correct pressure is a level of "quality verification." If an independent quality control inspector witnesses the setpoint test, then that is another level of "quality verification." Likewise, the instrument technician who calibrated the test gauges used for the setpoint test is a quality attainer as well as the engineer who specified the setpoint and relief capacity for the particular pressure application. If a second engineer did a design review of the setpoint selection/relief capacity, then that engineer was a level of "quality verification." Similar to the quality control inspector, the auditor who performs an audit of the measuring and test equipment calibration program or the design control program is a level of independent "quality verification."

In assessing quality assurance programs, be careful not to limit the assessment to only the quality assurance organization and its activities. It is important to evaluate the quality assurance organization to assess the verification functions, but this does little to assess the attainment of quality and the self-verification functions performed by first line supervisors and managers. Even when looking at the quality attainers, many assessments do not pay enough attention to the attainment function. For instance, many assessments of "quality assurance training" check to see that the maintenance workers have attended the 4-hour QA course and annual refresher training as evidence of training intended to meet the QA program requirements. While this training is necessary, it is more important to assess the ability of maintenance workers to "attain the quality," (i.e., to perform the tasks, themselves, satisfactorily). A meaningful QA training assessment would also evaluate the measures that ensure that only those workers who are properly trained and qualified to perform certain critical tasks are allowed to do those tasks. Then if a problem is found in that area, the natural followup question would be to determine if the quality verification function had detected this problem, and if so, what was being done about it. If it had not detected the problem, why not? Was the level of detail involved in quality verification inadequate? Were the quality verification personnel improperly trained?