11.





National Energy Technology Laboratory

OPERATING PLAN 414.1-1C

Title:		QUALITY ASSURANCE PROGRAM PLAN		
Owner:		Robert Reuther, ESS&H Division, Office of Institutional and Business Operations		
Approving Official:		Thomas Wilson, Jr., Director, Office of Institutional and Business Operations		
		{signature} /s/ Martin E. Davis for		
Approval Date:		4/21/10		
Last Reviewed		4/21/10		
Date:		4/21/10		
Cancellation:		Operating Plan 414.1-1B, Quality Assurance Program Plan		
		TABLE OF CONTENTS		
1.	PURPOSE			
2.				
3.	_	GUIDING PRINCIPLES AND CRITERIA		
4.				
		terion 1 – Program3		
		terion 2 – Personnel Training and Qualifications4		
		terion 3 – Quality Improvement5		
		Criterion 4 – Documents and Records		
5.	PERFORM	PERFORMANCE FUNCTION		
	a. Cri	terion 5 – Work Processes7		
		terion 6 – Design9		
		iterion 7 – Procurement10		
		terion 8 – Inspection and Acceptance Testing12		
6.		IENT FUNCTION		
		terion 9 – Management Assessment		
7	b. Criterion 10 – Independent Assessment			
7.		RESPONSIBILITIES		
		ef Operating Officer 17		
		ector, ESS&H Division		
8.		MENTS		
o. 9.	•	ICES		
). 10.		DEFINITIONS		
10.				

REVISION HISTORY20

ATTACHMENTS

There are no attachments to this operating plan.

FORMS

There are no forms in this operating plan.

1. **PURPOSE**

a. To document the quality assurance program plan (QAPP) for the National Energy Technology Laboratory (NETL) and to create the framework for the NETL quality management system.

2. **APPLICABILITY**

a. This plan is applicable to all organizational elements, employees, and operations of NETL.

3. GUIDING PRINCIPLES AND CRITERIA

- a. The NETL QA Program conforms with the requirements of DOE Order 414.1, Quality Assurance, and fosters processes within the organization that:
 - Achieve, maintain, and improve quality.
 - Minimize environment, safety, and health risks and impacts while maximizing reliability and performance.
 - Ensure planning, organization, direction, control, and support to achieve the objectives of the program.
 - Review, evaluate, and improve overall performance, including that of site support contractors, using an assessment process based upon approved quality policies.
- b. The NETL QA Program consists of 10 criteria categorized into three separate functional areas as recommended by DOE Guide 414.1-2, Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A and DOE Order 414.1, Quality Assurance. The functional areas are management, performance, and assessment, which are further explained in Sections 4, 5, and 6 of this plan, respectively.

4. MANAGEMENT FUNCTION

a. <u>Criterion 1 – Program</u>

NETL's mission is to deliver research and development services and products. Therefore, the goal of this quality assurance program is the delivery of data that meets the programmatic needs and goals of the laboratory. This requires planning, performing, and assessing the adequacy of work, including work assigned to site support contractors. NETL Order 414.1, Quality Assurance, provides the policy and requirements for the NETL Quality Assurance Program.

- (1) NETL management retains the responsibility and accountability for the scope and implementation of the program. However, all NETL and site support contractor employees are responsible for achieving quality in their activities. Management cultivates the achievement and improvement of quality at all office levels and helps ensure that this QAPP is understood and implemented.
- (2) The scope, depth, and rigor of application of requirements to a specific activity is determined by the use of a graded approach, which ensures that the selection of the controls and verifications applied to items and work activities are consistent with their importance to the mission, the environment, the safety, the cost, the schedule, and the success of the program. The graded approach is used to evaluate hazards or risks and to determine the appropriate controls that are needed to address those hazards or risks. This process is accomplished by deliberate planning and is based on activity-specific factors, which include:
 - The relative importance of the specific activity to safety or to the production of critical data.
 - The magnitude of any hazards or risks involved.
 - The life-cycle stage of an activity.
 - Impact/consequences on the programmatic mission of NETL.
 - The particular characteristics of the activity.
 - Adequacy of existing safety documentation.
 - Complexity of products or services involved.
 - History of problems for the activity.

b. <u>Criterion 2 – Personnel Training and Qualifications</u>

To effectively accomplish the NETL mission, all employees must be capable of performing their assigned tasks. The quality of a finished item, process, or product is directly related to the training and experience of those individuals completing the task. Qualification and training processes ensure personnel achieve and maintain the required capabilities. NETL Order 360.1, Federal Employee Education, Training, and Development, provides the policy and requirements for personnel training and qualifications for federal employees. Requirements for site support contractor employees are included in the site support contracts.

- (1) NETL management commits resources to provide the training and qualification processes for personnel in the organization and to ensure that personnel that are hired or transferred into positions meet the specified requirements.
- (2) Policies and procedures that describe personnel selection, training, and qualification requirements are established for each function that directly impacts the environment, the safety, the cost, the schedule, and the success of the program. These include the minimum applicable requirements for education, experience, skill level, and physical condition. Before personnel are allowed to work independently, management ensures those personnel have the necessary experience, knowledge, skills, and abilities. Personnel may be qualified based on:
 - Previous experience, education, and training.
 - A performance demonstration or test to verify previously acquired skills.
 - Completion of a training or qualification program.
 - On-the-job training.
- (3) Training goals, plans, and other training materials are consistently developed, reviewed by experienced personnel, approved by management, and used to deliver training.
- (4) Training plans are prepared for all personnel, including those responsible for managing, planning, and controlling work. Continual training maintains and promotes improved job performance.
- (5) Training plans consider changes in hazard conditions, technology, work methods, and job responsibilities. Training procedures also specify the type of training records to be maintained.

c. <u>Criterion 3 – Quality Improvement</u>

Feedback from customers, employees, and stakeholders is used to improve items, services, and the processes that produce them. Feedback is also used to address nonconformities and opportunities for improvement that are discovered through internal and external assessments.

- (1) Quality problems are identified by NETL employees, including site support contractor employees.
- (2) NETL prioritizes and focuses its resources on corrective and preventive actions and on those quality issues that have the greatest potential for posing adverse risks

- to the environment and human health, impacting the safety of personnel, and affecting the reliability of research and critical data.
- Quality improvement is a management principle that is carried out to improve a process that results in the production of critical data. All aspects of work activities and the management system are subject to continual improvement through an assessment and feedback process, which includes the use of an operating experience program. Identified improvement actions are shared with appropriate employees and organizational elements. Management tracks the actions to ensure that they are providing the anticipated improvements.
- (4) A quality issue can be identified by anyone. However, the documentation and evaluation to determine the significance of the issue is to be performed only by qualified individuals.
- (5) The method for determining the significance of an issue and the process for handling that issue, which includes a process to prevent reoccurrence, is documented in NETL procedures.
- (6) Management is involved in approving corrective or preventive actions for significant quality issues and auditing the actions to closure.
- (7) Improvement in quality is a disciplined management process based on the premise that all work is planned, performed, measured, and improved. NETL management ensures that the focus is on improving the quality of processes and research data by establishing priorities, promulgating policy, promoting cultural aspects, allocating resources, communicating operating experience, and resolving significant management issues and problems that hinder NETL from achieving its objectives.
- (8) Since employees are the best resource for contributing ideas for improving work processes, products, and services, they are involved in work process design and evaluation and in providing the feedback necessary for improvement.

d. Criterion 4 – Documents and Records

Documents and records are required to effectively manage, perform, and assess work. Documents and records will include applicable requirements to indicate that work has been properly specified and accomplished. NETL Order 243.1, Records Management Program, provides the policy and requirements for the NETL Records Management Program.

(1) Procedures identify documents and records that must be developed and controlled. Resources are committed to ensure that documents and records are maintained, traceable, and accessible at all times.

- (2) A secure document control system maintains and provides access to documents.
- (3) Records come in a variety of forms (e.g., electronic, written or printed, photographs) and are compiled into a records management system that ensures appropriate records are maintained.
- (4) The system includes provisions for records retention, protection, preservation, change, traceability, accountability, and retrievability.
- (5) While in storage, records are protected from damage, loss, and deterioration.
- (6) The Records Management Program has schedules for records retention and disposition.

5. **PERFORMANCE FUNCTION**

a. <u>Criterion 5 – Work Processes</u>

Each work process consists of a series of actions that are planned and carried out by qualified workers using specified procedures and equipment under administrative, technical, and environmental controls approved by management to achieve an end result. Work processes are documented per NETL Order 251.1, Directives Program. Standard operating procedures are developed per NETL Order 421.1, Safety Analysis and Review System. Operations are controlled by the requirements found in NETL Order 420.3, Conduct of Operations. Other directives are maintained to implement these requirements.

- (1) NETL management ensures that processes are in place to clearly identify and convey to workers, prior to beginning the work, the following information:
 - Hazards associated with the R&D activities, support operations, and facilities.
 - Technical standards applicable to the activity.
 - Safety, administrative, technical, and environmental controls to be employed during the work.
 - Data requirements for the work.
 - Acceptance criteria applicable to the data and associated processes.
- (2) Management ensures that NETL employees have the qualifications, equipment, procedures, and resources needed to accomplish the work.

- (3) Administrative work processes are documented per NETL Order 251.1, Directives Program. The scope and detail of documentation is commensurate with the complexity and importance of the work, the skills required to perform the work, and the hazards and risks or consequences of quality problems in the product, process, or service.
- (4) Control of processes, skills, hazards, and equipment is clearly specified, understood, and fully documented per NETL Order 421.1, Safety Analysis and Review System, and NETL Order 420.3, Conduct of Operations.
- (5) Workers responsible for the quality of the work strive to do the work in accordance with established procedures and work instructions.
- (6) A process for the identification and control of items is maintained to:
 - Prevent the use of incorrect or defective items.
 - Identify, control, and dispose of suspect or counterfeit items.
 - Provide for the control and maintenance of items.
- (7) The identification and control process applies from manufacture or receipt through delivery, installation, use, and decommissioning and disposal. The process provides for the identification and configuration control of installed or replacement items in accordance with specified requirements.
- (8) Physical identification of items is employed. Suitable identification information includes the unique part, lot, heat, model, version, or serial number on the item, or in records traceable to the item, or both.
- (9) Work processes protect items in accordance with specified technical standards and administrative controls to prevent their damage, loss, or deterioration.
- (10) Work processes specify protective methods for sensitive or perishable items, such as special handling, shipping, and storage controls for precision instrumentation and limited shelf-life items and for items requiring special protective environmental controls, such as for temperature or humidity.
- (11) Work processes ensure that equipment used for process monitoring and data collection is of the proper type, range, precision, and accuracy. Such equipment is calibrated and maintained in accordance with Criterion 8 below.

b. <u>Criterion 6 – Design</u>

NETL maintains formal design processes, which are implemented through the 414.1 series of directives, that provides control of design inputs, outputs, verifications, configurations, and changes, as well as technical and administrative interfaces appropriate to the importance of the design. Design work is based on sound engineering judgment and scientific principles, as well as on approved industry codes, standards, and guidelines.

- (1) The design of items, such as structures, systems, and components that involve a significant level of risk, are subject to more definitive design, control, and verification requirements.
- (2) Designs provide appropriate inspection, testing, and maintenance to ensure continuing reliability and safety of the items. The design considers the use and life expectancy of the items to allow appropriate disassembly and disposal requirements.
- (3) Design records include documentation of design input, output, changes, and verifications, as well as all supporting documents and records.
- (4) Design input is based upon end-user requirements. NETL's expectation is that the design will be technically correct and complete. Design input includes information such as design bases, health and safety considerations, expected life cycle, and performance parameters, as well as requirements for codes, standards, and reliability.
- (5) The design process translates design input into design output documents that are technically correct and compliant with the end-user's requirements. Aspects critical to the performance, safety, or reliability of the designed items are identified during the design phase. Design output documents are prepared to support other processes, such as procurement, fabrication, assembly, construction, testing, inspection, maintenance, and decommissioning.
- (6) Technical and administrative interfaces are identified and methods are established for the control and distribution of design requirements.
- (7) Computer software used to originate or analyze design solutions during the design process is validated for the intended use. Alternatively, the status of the code validation is identified and documented prior to use.
- (8) Design verification is performed to ensure that design output documents meet design input requirements, that changes have been approved and documented, and that supporting records have been controlled.

- (9) Design verification is a formal, documented process for ensuring that the resulting items will comply with the requirements. Design verification methods include, but are not limited to, technical reviews, peer reviews, and alternate calculations. When appropriate, the verification process considers previous verifications of similar designs or verifications of similar features of other designs.
- (10) Design verification is performed by technically knowledgeable persons separate from those who performed the design. Interim verifications may occur at pre-determined stages of design development. The extent and number of design verifications is based on a graded approach and should depend on the designed product's complexity and importance to safety and project success.
- (11) NETL relies on verified design output to support other work, such as procurement, manufacturing, construction, or research. When the verification cannot be achieved in time for these activities, unverified portions of the design are identified and controlled. Design verifications are completed before relying on the system, structure, or component to perform its function and before installation becomes irreversible.
- (12) As-built and shop drawings are maintained after production or construction to show the actual configuration.
- (13) Design changes, including field changes and non-conforming items dispositioned for use-as-is or repair, are controlled by measures commensurate with those applied to the original design. Temporary modifications receive the same level of control as the designs of permanent modifications.
- (14) Responsibilities are assigned for design output documents, including the as-built, marked-up, and updated-during-construction- and -operation-phases documents, as well as for document control and records management.
- (15) The completed design is controlled, and design records include all controlled records generated during the design process.

c. Criterion 7 – Procurement

The NETL procurement process ensures those items and/or services provided by vendors meet the requirements and expectations of the end-user. The procurement process is planned and controlled to ensure that the end-user's requirements are accurately, completely, and clearly communicated to the supplier; supplier, designer, and end-user requirements are met during the production phase; and the proper product is delivered on time and maintained until use. The selection of NETL procurement requirements is commensurate with the importance of the purchased items or services.

- (1) Procurement documents include any specifications, standards, and other records referenced in the design documents. Critical parameters and requirements, such as submittal, product-related documentation, problem reporting, administrative documentation, personnel or materials qualifications, tests, inspections, acceptance criteria, and reviews, are clearly specified.
- (2) Potential suppliers are identified early in the design and procurement process to determine their capabilities. Prospective suppliers are evaluated to verify their capability to meet performance and schedule requirements. An effective evaluation method is an assessment of personnel and processes conducted at the supplier's facilities (a quality assurance program evaluation). This method may be used in combination with:
 - A review of the supplier's history in providing identical or similar items or services.
 - A review of shared supplier quality information.
 - An evaluation of certifications or registrations awarded by nationally accredited third parties.
 - An evaluation of documented qualitative and quantitative information provided by the supplier.
- (3) The qualified supplier's performance is evaluated periodically. Suppliers are monitored to ensure that acceptable items or services are produced and schedule requirements are met. Monitoring may include:
 - Surveillance of work activities.
 - Inspection of facilities and processes.
 - Review of plans and progress reports.
 - Processing of change information.
 - Review and disposition of non-conformances.
 - Selection, qualification, and performance monitoring of sub-tier suppliers.
- (4) The procurement process helps to identify the need for inspections and tests. Requirements for inspections and tests are obtained from design documents. Inspections ensure conformance with purchase requirements, including the verification that specified documentation has been provided by the supplier.

The inspection verifies that items were not damaged during shipment. Inspection may include the following methods:

- Inspection of materials or equipment at the supplier's plant.
- Receipt inspection of the shipped items.
- Review of objective evidence, such as certifications and reports.
- Verification or testing of items prior to or following shipment.
- (5) Critical or important acceptance parameters and other requirements, such as inspection/test equipment or qualified inspection/test personnel, are specified in the design documentation.
- (6) The selection of suppliers and the purchase of commercial-grade materials are evaluated to prevent the procurement of suspect or counterfeit items and to detect them before they are released for use. Information in DOE Guide 414.1-3, Section 4.1, as well as other applicable guidance, is used to minimize the possibility of procuring suspect or counterfeit items.
- (7) NETL maintains guidelines that assist in the procurement of quality items. DOE Guide 414.1-3, Section 4.3, is used for guidance to avoid the procurement and use of suspect or counterfeit items.
- (8) Supplier-generated documents are accepted through the procurement system and controlled and processed by NETL. These documents may include certificates of conformance, drawings, analyses, test reports, maintenance data, non-conformances, corrective actions, approved changes, waivers, and deviations.
- d. <u>Criterion 8 Inspection and Acceptance Testing</u>

NETL conducts inspections and tests to verify that physical and functional aspects of items, services, and processes meet all requirements and are fit for use. Inspections and tests are identified early in the design process and specified in the design output documents. Directives contained within the 414.1 series of directives provide specific details and processes for inspection and acceptance testing.

- (1) NETL personnel check items prior to their use to ensure that the items are correct and suitable for their intended application. These same personnel check the process output to verify that it meets or exceeds specified requirements.
- (2) Inspection and test planning is performed, and appropriate sections of approved codes or standards are used for acceptance requirements, inspections, and test

methods. Inspection and test planning contains provisions for at least the following:

- Identification of characteristics to be examined.
- Required qualifications of individuals who perform the examination.
- A description of examination methods, including equipment and calibration requirements.
- Acceptance and rejection criteria.
- Suitable environmental conditions.
- Required safety measures.
- Mandatory hold points, when applicable.
- (3) Inspections and tests are performed by technically qualified personnel who have the authority to access appropriate information and facilities to verify acceptance. These qualified personnel are independent of the activities being inspected or tested and have the freedom to report the results of the inspections and tests.
- (4) Final acceptance is verified and documented by authorized NETL personnel who are appropriately trained and have the authority to approve final acceptance.
- (5) The inspection or test process identifies the status of items, services, and processes requiring examination to ensure that only those with acceptable inspection and test results are used. The process provides for review and re-inspection or retest of changed inspection or test parameters.
- (6) Final inspections are usually distinct from inspections conducted during the work process. Final inspection confirms that the item, service, or process is ready for acceptance testing and/or operation. As such, it includes completeness, cleanliness, identifications and markings, calibration, alignment and adjustment, adequate records, or other characteristics indicating conformance to requirements.
- (7) Measuring and test equipment (M&TE) used for inspections, tests, and monitoring or data collection are calibrated and maintained using a documented process. M&TE is also checked prior to its use to ensure that it is of the proper type, range, accuracy, and precision, that it is uniquely identified, and that its calibration data are traceable.
- (8) Procedures within the 414.1 series are maintained for testing, retesting, adjusting, and re-calibrating the M&TE. M&TE is calibrated to standards traceable to the

National Institute of Standards and Technology (NIST) or to other nationally-recognized standards, when available and appropriate. If no nationally-recognized calibration method exists, the basis for calibration is approved by NETL line management and documented.

6. **ASSESSMENT FUNCTION**

a. Criterion 9 – Management Assessment

NETL management periodically assesses the performance of its functions to determine compliance with requirements, expectations, and mission objectives, so that improvements can be made. These assessments can take the form of project reviews, ES&H inspections, informal reviews and observations, budget reviews and planning, or other management functions that serve as assessment tools.

- (1) Direct participation by managers is essential to the success of the assessment process, because they are in a position both to evaluate the functions within the NETL structure and to effect change.
- (2) Strengths and weaknesses affecting the achievement of NETL objectives are identified so that meaningful action can be taken to improve processes. Those areas that present the greatest consequences of failure or the greatest benefit from improvements receive particular emphasis. Management assessments focus on identifying and resolving both singular and systemic management issues and problems that may prevent customer requirements and expectations from being met. Results from internal or external independent assessments are used as input to the management assessment.
- (3) NETL management assesses its processes for planning, organizing interfaces (internal and external to the organization), integration of management systems (e.g., safety, quality), use of performance metrics, training and qualifications, and supervisory oversight and support.
- (4) Direct observation of work is used as an assessment method to make the line manager aware of interactions at a work location. Other methods include worker and customer interviews, as well as safety and performance documentation reviews.
- (5) Performance measurement is based on objective standards, clearly defined goals, and results-oriented metrics, as well as meaningful review and feedback processes.
- (6) NETL management assessment results are documented and used as input to the organization's improvement process. Periodic review of performance metrics at appropriate management levels are used to validate organizational performance.

b. <u>Criterion 10 – Independent Assessment</u>

NETL management maintains a process to obtain an independent assessment of NETL's offices, programs, projects, contractors, and suppliers. The purpose of this type of assessment is to evaluate the performance of work processes with regard to requirements and expectations of customers, as well as efforts required to achieve NETL's mission and goals. The results of independent assessments provide an objective form of feedback to NETL management that is useful in confirming acceptable performance and is used for identifying improvement opportunities.

- (1) The independent assessment process uses a performance-based approach to focus on results. Performance-based assessments are conducted on activities that:
 - Relate directly to final objectives.
 - Emphasize safety and reliability.
 - Measure data quality.
- (2) NETL conducts independent assessments of its work and the work of its site support contractors to ensure that requirements are being met. Site support contractors also conduct independent assessments of their work and the work of their subcontractors to ensure requirements are being met.
- (3) Independent assessments advise NETL management on the quality of the processes, data, and deliverables produced by the offices within the NETL organization. Consequently, the independent organization conducting assessments reports to NETL management. This is to ensure organizational independence from the work and to provide access to levels of management authority capable of directing subordinate levels to take actions in response to the assessment results.
- (4) Personnel performing independent assessments have the necessary technical knowledge to accurately observe and evaluate activities being assessed. They have no direct responsibility for the assessed work or organization. The line manager directly responsible for the work is considered to be the customer for the assessment product.
- (5) The type and frequency of independent assessments is based on the status, complexity, risk, and importance of the activities or processes being assessed.
- (6) The criteria used for assessments describe acceptable work performance and promote improvement of the process or activity.

- (7) Assessments address management processes that affect work performance, such as planning, program support, and training.
- (8) Assessments may use methods such as monitoring operations, inspections, peer and technical reviews, previous assessment results, surveillance, end-user interviews, or combinations thereof.
- (9) The assessment focuses on improving data quality and process effectiveness by emphasizing improvement methods.
- (10) Independent assessment personnel base the evaluation on the approved system and do not reinterpret or redefine the requirements.
- (11) Independent assessor responsibilities include:
 - Evaluating work performance and process effectiveness.
 - Evaluating compliance to the management system requirements.
 - Identifying abnormal performance.
 - Identifying strengths and weaknesses affecting the quality of data or process outputs.
 - Identifying opportunities for improvements.
 - Documenting and reporting results.
 - Verifying effective resolution of reported problems.
- (12) The independent assessment process verifies the adequacy of corrective actions, including actions identified to prevent recurrence or to otherwise improve performance. Independent assessments that confirm acceptable performance in specific areas of NETL may reduce the frequency and depth of future assessments. Areas of poor or questionable performance receive increased attention in future assessments.
- (13) Documented assessment results are presented to NETL and provided to the appropriate levels of management for review. Strengths and weaknesses affecting the quality of data or process outputs are identified so that NETL management can take action to improve quality.
- (14) NETL management evaluates the assessment results to identify improvement actions and determine whether similar quality problems may exist elsewhere.

(15) NETL management tracks improvement actions until a resolution has been implemented and verified as completed.

7. **RESPONSIBILITIES**

- a. <u>Chief Operating Officer</u>
 - (1) Serves as the quality manager for NETL and ensures that directives are developed to implement the requirements of this plan.
 - (2) Maintains this operating plan.
 - (3) Acts as liaison with DOE quality assurance points of contact.
- b. <u>Director, ESS&H Division</u>
 - (1) Acts as or appoints the NETL directives manager, who oversees the development and maintenance of, and recordkeeping associated with, NETL's directives.
- c. <u>Director, Office of Research and Development (ORD)</u>
 - (1) Acts as or appoints the manager for ORD's safety analysis and review system (SARS) as applied to research and development (R&D) projects, who oversees the development and maintenance of, and recordkeeping associated with, all R&D SARS studies, as well as all ORD-specific directives.

8. **REQUIREMENTS**

- a. DOE Order 414.1, <u>Quality Assurance</u>.
- b. NETL Order 414.1, Quality Assurance.
- c. Fossil Energy Headquarters Quality Assurance Program Plan.

9. **REFERENCES**

- a. DOE Guide 414.1-1, Management and Independent Assessments Guide.
- b. DOE Guide 414.1-2, Quality Assurance Management System Guide.
- c. NETL Order 224.2, Auditing of Programs and Operations.
- d. NETL Order 243.1, Records Management Program.

- e. NETL Order 251.1, <u>Directives Program</u>.
- f. NETL Order 360.1, Federal Employee Education, Training, and Development.
- g. NETL Order 420.3, Conduct of Operations.
- h. NETL Order 421.1, <u>Safety Analysis and Review System</u>.

10. **DEFINITIONS**

- a. <u>Audit or Assessment</u> A planned and documented activity that is performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents. An audit or assessment should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.
- b. <u>Corrective Action</u> A measure taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.
- c. <u>Certification</u> The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, or items, in accordance with specified requirements.
- d. <u>Critical Material</u> Material that, if damaged, could cause significant programmatic delay, jeopardize the operation or safety of a facility or experiment, allow significant release of chemicals, or create other undesirable conditions.
- e. <u>Graded Approach</u> The formality with which requirements are implemented based on the hazard and the potential consequences if that hazard is not mitigated.
- f. <u>Inspection</u> The verification function of examining, measuring, and/or testing to obtain data to determine whether an item or process conforms to specified requirements.
- g. <u>Nonconformance</u> A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity indeterminant or unacceptable.
- h. <u>Peer Review</u> A documented process whereby the quality and validity of technical work is evaluated by technical peers who do not participate directly in the work being evaluated.
- i. <u>Preventive Action</u> An action that helps ensure, through appropriate design, inspection, procurement, and other process controls and assessment activities, that a quality problem does not occur.

Operating Plan 414.1-1C, Quality Assurance Program Plan

- j. <u>Quality</u> The degree to which an item, research activity, or process safely meets or exceeds the end-user's requirements and expectations.
- k. <u>Quality Assurance</u> Those actions that, when carried out, provide confidence that quality is achieved.
- 1. <u>Suspect or Counterfeit Items</u> An item is suspect or counterfeit when visual inspection or testing indicates that it does not conform to established industry-accepted specifications or national consensus standards, or whose documentation, appearance, performance, materials, or other characteristics may have been misrepresented by the supplier or manufacturer.

11. **REVISION HISTORY**

VERSION	DATE	SUMMARY OF CHANGES
Original	11/1/06	To document the quality assurance program plan (QAPP) for the National Energy Technology Laboratory (NETL) and create the framework for the NETL quality management system.
A	9/11/07	Changes made include changing the subject matter expert from Dan McCollum to Robert Reuther, updating the text to ensure it reflects actual practice, clarifying several paragraphs of the plan, updating responsibilities, and other minor changes for clarification.
В	3/25/09	Minor grammatical corrections were made.
С	4/21/10	Changes made include minor grammatical corrections and some minor re-write of sections for clarification.