

Reference
U.S. Department of Energy
Washington, D.C.

ORDER

DOE O 414.1A

Approved: 9-29-99

Review Date: 9-29-01

Chg 1: 7-12-01

SUBJECT: QUALITY ASSURANCE

1. **OBJECTIVES.** To establish an effective management system [i.e., quality assurance programs (QAPs)] using the performance requirements of this Order, coupled with technical standards where appropriate, that ensures the following.
 - a. Senior management provides planning, organization, direction, control, and support to achieve Department of Energy (DOE), including the National Nuclear Security Administration (NNSA), objectives.
 - b. Line organizations achieve and maintain quality.
 - c. Line organizations minimize environmental, safety, and health risks and impacts while maximizing reliability and performance.
 - d. Line organizations have a basic management system in place supporting this Order that is consistent with the principles and functions of DOE P 450.4, SAFETY MANAGEMENT SYSTEM POLICY.
 - e. Each DOE element, including the NNSA, reviews, evaluates, and improves its overall performance and that of its contractors using a rigorous assessment process based on an approved Quality Assurance Program [see 48 Code of Federal Regulations (CFR) 970.1001(d) and DOE P 450.5].
2. **CANCELLATION.** DOE O 414.1, QUALITY ASSURANCE, dated 11-24-98 is canceled. Cancellation of a directive does not, by itself, modify or otherwise affect any contractual obligation to comply with such a directive. Canceled directives that are incorporated by reference in a contract must remain in effect until the contract is modified to delete the requirements in the canceled directives.
3. **APPLICABILITY.**
 - a. **DOE Elements, including the NNSA.** DOE elements must follow this Order when performing their work.
 - b. **Contractors.** The contractor requirements document (CRD), Attachment 1, sets forth intended requirements to be applied to all contractors (e.g., management and integration, management and operation) responsible for DOE-owned or -leased facilities and

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Distribution:
All Departmental Elements

Initiated By:
Office of Environment, Safety and Health



associated items and services. This includes work that may take place outside the physical boundaries of a DOE facility or work performed by suppliers and subcontractors (such as design, manufacturing, or analytical laboratory services). DOE elements must use a graded approach to determine the other contractors to whom the requirements will apply. Contractor compliance with the CRD will be required to the extent set forth in a contract.

- c. Exclusions. Executive Order 12344, statutorily prescribed by P.L. 98-525 (42 U.S.C. 7158, note), establishes the responsibilities and authority of the Director, Office of Naval Reactors, for all facilities and work that comprise the Program, which is a joint Navy-DOE organization. These executive and legislative actions establish the Director's responsibilities for the safety of reactors and associated naval nuclear propulsion plants, the control of radiation and radioactivity associated with naval nuclear propulsion plants, and the operating practices and procedures applicable to naval nuclear propulsion plants. The Director must establish the quality assurance requirements implemented within the Program. Accordingly, this Order does not apply to the Naval Reactors Program.
- d. Other Quality Requirements.
 - (1) Some portions of DOE work are subject to regulation by quality assurance requirements from the Nuclear Regulatory Commission (NRC), an NRC Agreement State, the Environmental Protection Agency, DOE (10 CFR 830.120), or other government agencies. This Order applies to those portions of the work that are not so regulated.
 - (2) DOE elements may impose additional quality requirements and/or specific standards as necessary for certain types of work (e.g., the Office of Defense Programs nuclear weapons production standard, QC-1, or the Office of Civilian Radioactive Waste Management requirement, RW-0333P) to ensure that the work meets their expectations and the requirements of this Order.
 - (3) DOE endorses the use of a single integrated quality assurance program (QAP) to satisfy the requirements for the regulated work, any additional quality requirements imposed by DOE elements, and the requirements of this Order.

4. REQUIREMENTS.

a. General.

- (1) DOE elements must implement the quality assurance criteria in a manner sufficient to achieve adequate protection of the workers, the public, and the environment, taking into account the work to be performed and the associated hazards.

- (2) DOE elements must develop their QAPs by applying the quality assurance criteria specified in Paragraph 4b, using a graded approach.
- (3) DOE elements must consider the guidance on quality assurance provided in Paragraph 6 to develop and implement their QAPs.
- (4) DOE elements not presently in compliance with this Order must develop and implement a QAP within 90 days of the date of this Order. QAPs approved in accordance with DOE O 414.1 must be revised to address enhancements made by this Order.
- (5) The QAP must describe how the criteria will be satisfied.
- (6) DOE elements must identify, document, and use appropriate standards (consistent with the National Technology Transfer and Advancement Act, P.L. 104-113, and Office of Management and Budget Circular A-119), wherever applicable, to develop and implement QAPs.
- (7) The QAP must describe how the graded approach will be applied.
- (8) The QAP must discuss how it integrates and satisfies quality requirements or similar management system requirements (such as environmental or safety) from sources other than this Order (see DOE P 450.4).
- (9) DOE elements must respond to safety issues identified in Office of Oversight (EH-2) reports using a written corrective action plan (CAP). DOE elements must apply the SAFETY ISSUE CORRECTIVE ACTION PROCESS (see Attachment 2) for CAP development and implementation.

b. Quality Assurance Criteria.

- (!) Management.
 - (a) Criterion 1--Program.
 - 1 A written QAP must be developed, implemented, and maintained.
 - 2 The QAP must describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.
 - 3 The QAP must describe management processes, including planning, scheduling, and resource considerations.

(b) Criterion 2—Personnel Training and Qualification.

- 1 Personnel must be trained and qualified to ensure they are capable of performing their assigned work.
- 2 Personnel must be provided continuing training to ensure that job proficiency is maintained.

(c) Criterion 3—Quality Improvement.

- 1 Processes to detect and prevent quality problems must be established and implemented.
- 2 Items, services, and processes that do not meet established requirements must be identified, controlled, and corrected according to the importance of the problem and the work affected.
- 3 Correction must include identifying the causes of problems and working to prevent recurrence.
- 4 Item characteristics, process implementation, and other quality-related information must be reviewed and the data analyzed to identify items, services, and processes needing improvement.

(d) Criterion 4—Documents and Records.

- 1 Documents must be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design.
- 2 Records must be specified, prepared, reviewed, approved, and maintained.

(2) Performance.

(a) Criterion 5—Work Processes.

- 1 Work must be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means.
- 2 Items must be identified and controlled to ensure their proper use.
- 3 Items must be maintained to prevent their damage, loss, or deterioration.

4 Equipment used for process monitoring or data collection must be calibrated and maintained.

(b) Criterion 6—Design.

1 Items and processes must be designed using sound engineering/scientific principles and appropriate standards.

2 Design work, including changes, must incorporate applicable requirements and design bases.

3 Design interfaces must be identified and controlled.

4 The adequacy of design products must be verified or validated by individuals or groups other than those who performed the work.

5 Verification and validation work must be completed before approval and implementation of the design.

(c) Criterion 7—Procurement.

1 Procured items and services must meet established requirements and perform as specified.

2 Prospective suppliers must be evaluated and selected on the basis of specified criteria.

3 Processes to ensure that approved suppliers continue to provide acceptable items and services must be established and implemented.

(d) Criterion 8—Inspection and Acceptance Testing.

1 Inspection and testing of specified items, services, and processes must be conducted using established acceptance and performance criteria.

2 Equipment used for inspections and tests must be calibrated and maintained.

(3) Assessment.

(a) Criterion 9—Management Assessment.

1 Managers must assess their management processes.

2 Problems that hinder the organization from achieving its objectives must be identified and corrected.

(b) Criterion 10—Independent Assessment.

- 1 Independent assessments must be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.
- 2 The group performing independent assessments must have sufficient authority and freedom from the line to carry out its responsibilities.
- 3 Persons conducting independent assessments must be technically qualified and knowledgeable in the areas assessed.

5. RESPONSIBILITIES. Senior management must be responsible for QAP implementation, assessment, and improvement (see Paragraph 6.d.).a. Deputy Secretary.

- (1) Serves as the Departmental focal point for quality assurance issues and quality problem resolution, and provides leadership for quality assurance implementation. Charters the Quality Assurance Working Group (QAWG) under the leadership of a chairperson who assists with these responsibilities. The QAWG Chairperson is responsible for leading a QAWG comprised of appointed senior managers or designees from DOE Headquarters elements, field elements, and DOE contractors that will-
 - (a) identify and resolve cross-cutting quality assurance issues within the Department;
 - (b) develop Departmental quality assurance positions and provide appropriate recommendations, advice, and counsel to the Deputy Secretary; and
 - (c) periodically report on the effectiveness of quality assurance policy implementation.
- (2) Resolves disputes concerning corrective actions for safety issues contained in Office of Oversight reports.

b. Secretarial Officers (SOs).

- (1) Ensure that Headquarters, field elements, and contractors implement this Order in an integrated manner and coordinate the resolution of quality issues among these organizations.

- (2) Develop, approve, and implement a QAP governing the work of their organizations in accordance with the requirements of Paragraph 4, as applicable. Identify the senior management position specifically assigned this responsibility.
 - (3) Provide direction and resources for implementing the requirements for work within their purview.
 - (4) Review and concur with field element QAPs. Review and approve new and revised contractor QAPs within their purview or delegate this authority to the relevant field element manager. QAPs must be reviewed and approved—or rejected—within 90 days of receipt.
 - (5) Perform management and independent assessments to evaluate the adequacy and implementation of their Headquarters element QAP and to improve organizational performance.
 - (6) Designate individual(s) to be responsible for bringing the following to the attention of the appropriate Contracting Officer:
 - (a) each procurement requiring application of the CRD (Attachment 1) (and 10 CFR 830.120, where applicable),
 - (b) requirements for flow down of provisions of the CRD to any subcontract or sub-award, and
 - (c) provisions of the CRD with which the contractor or subcontractor is to comply.
 - (7) Prepare a CAP to address safety issues (i.e., quality problems) identified by the Office of Oversight reports.
- c. Assistant Secretary for Environment, Safety and Health (EH-1), acting as DOE's independent element responsible for safety aspects relative to public and worker health and safety and environmental protection, has the following responsibilities in addition to those prescribed in Paragraph 5b.
- (1) Develop and maintain quality assurance policy, requirements, guides, and standards for DOE work.
 - (2) Provide advice and assistance (including QAP reviews) to DOE elements and contractors concerning implementation of this Order.

Vertical line denotes change.

- (3) Provide a central point of contact for coordination within DOE and act as liaison with other agencies and groups in the development of quality assurance policy, standards, guidance, and requirements.
 - (4) Review proposed statutes (where appropriate), regulations, standards, DOE directives, and requirements for their application to and potential impact on DOE quality programs.
- d. Deputy Assistant Secretary for Oversight (EH-2), acting as the Department's independent element responsible for the oversight of environment, safety, and health, has the following responsibilities.
- (1) Assess and report to the Secretary of Energy on all aspects of safety related to implementation of this Order, including performance of the Secretarial Offices, field elements, and contractors.
 - (2) Review and comment on proposed quality assurance policy, regulations, standards, and requirements to assess their potential effects on the safety of operations at DOE facilities.
 - (3) Review and comment on proposed actions to correct safety issues identified in oversight reports.
- e. Field Element Managers.
- (1) Develop, approve, and implement a QAP governing the work of the field element in accordance with the requirements of Paragraph 4, as applicable. Identify the senior management position specifically assigned this responsibility. Submit the QAP to the Lead Program Secretarial Officer for review and concurrence.
 - (2) Review and, where delegated authority to do so, approve new and revised QAPs for contractors within their purview. QAPs must be reviewed and approved—or rejected—within 90 days of receipt from the contractor.
 - (3) Perform independent assessments of contractor organizations to evaluate the adequacy and implementation of their QAPs. Other suitable methods may be used in combination with independent assessments.
 - (4) Perform management and independent assessments to evaluate the adequacy and implementation of their Field Element QAP and to improve organizational performance. Perform independent assessments of corrective actions taken for safety issues identified by the Office of Oversight to verify effective implementation.

- (5) Prepare a CAP to address safety issues (i.e., quality problems) identified by the Office of Oversight.
 - f. Contracting Officers, based on the advice of the procurement request originator or other designated individual, must apply the provisions of the CRD to awards falling within the scope of this Order. Provisions must be incorporated in time for the contractors to comply with the requirements of Attachment 1.
6. REFERENCES. Guidance and responsibilities for implementing this Order are provided by the latest revision of the following:
 - a. DOE G 414.1-2 (previously DOE G 830.120), QUALITY ASSURANCE MANAGEMENT SYSTEM GUIDE FOR USE WITH 10 CFR 830.120 AND DOE O 414.1;
 - b. DOE G 414.1-1, IMPLEMENTATION GUIDE FOR USE WITH INDEPENDENT AND MANAGEMENT ASSESSMENT REQUIREMENTS OF 10 CFR 830.120 AND DOE 5700.6C, QUALITY ASSURANCE;
 - c. 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; and
 - d. DOE M 411.1-1, SAFETY MANAGEMENT FUNCTIONS, RESPONSIBILITIES, AND AUTHORITIES MANUAL.
7. DEFINITIONS.
 - a. Assessment. The act of reviewing, evaluating, inspecting, testing, checking, surveillance, auditing, or otherwise determining and documenting whether items, processes, systems, or services meet specified requirements and are performing effectively.
 - b. Graded Approach. The process by which the level of detail in analyses, documentation, and actions necessary to comply with requirements is commensurate with—
 - the relative importance to safety, safeguards, and security;
 - the magnitude of any hazard involved;
 - the life-cycle stage of a facility;
 - the programmatic mission of a facility;
 - the particular characteristics of a facility; and
 - any other relevant factors.

- c. **Item.** An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, or support systems.
 - d. **Quality.** The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.
 - e. **Quality Assurance.** All those actions that provide confidence that quality is achieved.
 - f. **Quality Assurance Program.** The overall program (management system) established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.
 - g. **Safety.** An all-inclusive term used synonymously with environment, safety, and health to encompass protection of the public, the workers, and the environment.
 - h. **Service.** The performance of work, such as design, construction, fabrication, decontamination, environmental remediation, waste management, laboratory sample analysis, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.
 - i. **Work.** The process of performing a defined task or activity; for example, research and development, operations, environmental remediation, maintenance and repair, administration, software development and use, inspection, safeguards and security, data collection, and analysis.
8. **CONTACT.** Questions concerning this Order should be addressed to Gustave E. Danielson, Office of Nuclear Safety Policy and Standards, 301-903-2954 or bud.danielson@eh.doe.gov.

BY ORDER OF THE SECRETARY OF ENERGY:



DAVID M. KLAUS
DIRECTOR OF MANAGEMENT
AND ADMINISTRATION

CONTRACTOR REQUIREMENTS DOCUMENT

DOE O 414.1A, QUALITY ASSURANCE

1. GENERAL REQUIREMENTS.

- a. A contractor must accomplish the following.
 - (1) Assign and identify the senior management position responsible for Quality Assurance Program (QAP) development, implementation, assessment, and improvement.
 - (2) Implement the quality assurance criteria in a manner sufficient to achieve adequate protection of the workers, the public, and the environment, taking into account the work to be performed and the associated hazards.
 - (3) Develop a QAP for the work as specified in its contract by applying the quality assurance criteria specified in Paragraph 2 below. The QAP must—
 - (a) discuss how the QA criteria will be satisfied;
 - (b) use a graded approach to apply the QA criteria;
 - (c) describe how the graded approach will be applied;
 - (d) integrate and satisfy quality requirements from sources other than Paragraph 2;
 - (e) integrate the QA criteria with the safety management system (SMS) description developed for 48 Code of Federal Regulations (CFR) 970.5204-2, or describe how the QA criteria will be applied to the SMS;
 - (f) describe how the QA criteria will be applied to subcontractors and suppliers.
 - (4) Identify, document, and use appropriate standards (consistent with the National Technology Transfer and Advancement Act, P.L. 104-113, and Office of Management and Budget Circular A-119), wherever applicable, to develop and implement the QAP.
 - (5) Determine the subcontractors and suppliers to whom the QA criteria will be applied.

- (6) Submit the QAP to the Department of Energy (DOE) for approval prior to starting work under the contract or as specified by DOE.
 - (a) QAPs approved in accordance with DOE O 414.1 must be revised to address enhancements made by this CRD. (see Paragraph 1b).
 - (b) The QAP will be regarded as approved by DOE 90 days after submittal, unless approved or rejected by DOE at an earlier date, and must include any modification made or directed by DOE.
 - (7) Implement the QAP as approved and modified by DOE.
- b. A contractor may, at any time, make changes to an approved QAP.
- (1) Changes made over the previous year must be submitted annually to DOE for review and approval.
 - (2) In the submittal, identify the changes, the reason for the changes, and the basis for concluding that the revised QAP continues to satisfy the requirements of this CRD.
 - (3) Changes made to correct spelling, punctuation, or other editorial items do not require explanation.
- c. Other Quality Requirements.
- (1) Some portions of DOE work are subject to regulation by quality assurance requirements from the Nuclear Regulatory Commission (NRC), an NRC Agreement State, the Environmental Protection Agency, DOE (10 CFR 830.120), or other government agencies. DOE O 414.1A applies to those portions of the work that are not so regulated.
 - (2) DOE elements may impose additional quality requirements and/or specific standards as necessary for certain types of work (e.g., the Office of Defense Programs nuclear weapons production standard, QC-1, or the Office of Civilian Radioactive Waste Management requirement, RW-0333P) to ensure that it meets their expectations, as well as those of DOE O 414.1A.
 - (3) DOE endorses the use of a single integrated QAP to satisfy requirements for the regulated work, any additional quality requirements imposed by DOE elements, and the requirements of this Order.
- d. Contractors must consider the guidance on quality assurance provided by the latest revision of the documents listed below in developing and implementing their QAPs:

- (1) DOE G 414.1-2 (previously DOE G 830.120), QUALITY ASSURANCE MANAGEMENT SYSTEM GUIDE FOR USE WITH 10 CFR 830.120 AND DOE O 414.1;
- (2) DOE G 414.1-1, IMPLEMENTATION GUIDE FOR USE WITH INDEPENDENT AND MANAGEMENT ASSESSMENT REQUIREMENTS OF 10 CFR 830.120 AND DOE 5700.6C, QUALITY ASSURANCE; and
- (3) 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.

2. QUALITY ASSURANCE CRITERIA.

a. Management.

- (1) Criterion 1—Program.
 - (a) A written QAP must be developed, implemented, and maintained.
 - (b) The QAP must describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.
 - (c) The QAP must describe the management processes, including planning, scheduling, and resource considerations.
- (2) Criterion 2—Personnel Training and Qualification.
 - (a) Personnel must be trained and qualified to ensure they are capable of performing their assigned work.
 - (b) Personnel must be provided continuing training to ensure that job proficiency is maintained.
- (3) Criterion 3—Quality Improvement.
 - (a) Processes to detect and prevent quality problems must be established and implemented.
 - (b) Items, services, and processes that do not meet established requirements must be identified, controlled, and corrected according to the importance of the problem and the work affected. Correction must include identifying the causes of problems and working to prevent recurrence.

- (c) Item characteristics, process implementation, and other quality-related information must be reviewed and the data analyzed to identify items, services, and processes needing improvement.

(4) Criterion 4—Documents and Records.

- (a) Documents must be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design.

- (b) Records must be specified, prepared, reviewed, approved, and maintained.

b. Performance.

(1) Criterion 5—Work Processes.

- (a) Work must be performed to established technical standards and administrative controls, using approved instructions, procedures, or other appropriate means.

- (b) Items must be identified and controlled to ensure their proper use.

- (c) Items must be maintained to prevent their damage, loss, or deterioration.

- (d) Equipment used for process monitoring or data collection must be calibrated and maintained.

(2) Criterion 6—Design.

- (a) Items and processes must be designed using sound engineering/scientific principles and appropriate standards.

- (b) Design work, including changes, must incorporate applicable requirements and design bases.

- (c) Design interfaces must be identified and controlled.

- (d) The adequacy of design products must be verified or validated by individuals or groups other than those who performed the work.

- (e) Verification and validation work must be completed before approval and implementation of the design.

(3) Criterion 7—Procurement.

- (a) Procured items and services must meet established requirements and perform as specified.
 - (b) Prospective suppliers must be evaluated and selected on the basis of specified criteria.
 - (c) Processes to ensure that approved suppliers continue to provide acceptable items and services must be established and implemented.
- (4) Criterion 8—Inspection and Acceptance Testing.
- (a) Inspection and testing of specified items, services, and processes must be conducted using established acceptance and performance criteria.
 - (b) Equipment used for inspections and tests must be calibrated and maintained.
- c. Assessment.
- (1) Criterion 9—Management Assessment.
- (a) Managers must assess their management processes.
 - (b) Problems that hinder the organization from achieving its objectives must be identified and corrected.
- (2) Criterion 10—Independent Assessment.
- (a) Independent assessments must be planned and conducted to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.
 - (b) The group performing independent assessments must have sufficient authority and freedom from the line to carry out its responsibilities.
 - (c) Persons conducting independent assessments must be technically qualified and knowledgeable in the areas assessed.

ATTACHMENT 2

SAFETY ISSUE CORRECTIVE ACTION PROCESS **SUPPLEMENTAL QUALITY REQUIREMENTS** **FOR DOE ELEMENTS**

1. **OBJECTIVE.** To establish a uniform process and responsibilities that apply DOE quality assurance criteria to the resolution of safety issues identified by the Office of Oversight.
2. **GENERAL REQUIREMENTS.**
 - a. DOE elements must correct safety issues (i.e., quality problems) identified by the Office of Oversight according to the importance of the problem and the work affected.
 - b. DOE elements must develop and implement a corrective action plan (CAP) for safety issues identified by the Office of Oversight.
 - c. DOE Field Element Managers must ensure that contractors within their purview implement the approved CAP, as appropriate.
 - d. DOE elements must apply this process to safety issue identification, CAP development, and dispute resolution.
 - e. DOE elements must use the DOE Corrective Action Tracking System (CATS) for CAP tracking and status reporting. (See website <http://tis.eh.doe.gov/portal/ism/CATS.htm>.)
3. **SAFETY ISSUE IDENTIFICATION AND RESOLUTION PROCESS.**
 - a. **Safety Issue Identification.** The Office of Oversight must perform the following.
 - (1) Conduct an independent assessment of safety management at a specific DOE site or program in accordance with Office of Oversight protocols.
 - (2) Describe each identified safety issue clearly in the assessment report. Safety issues will express the specific nature of the condition in a clear, concise, and direct manner that will allow line management to translate it into corrective actions. As appropriate, safety issues are tied to a non-conformance with the relevant ES&H requirements or DOE directives (e.g., specific DOE Orders, regulatory requirements, DEAR provisions, or DOE P 450.4).
 - (3) Verify the factual accuracy of the reported assessment findings with representatives of the assessed organizations.

- (4) Submit the formal approved assessment report simultaneously to the Field Element Manager and applicable line Program Secretarial Officer (PSO).
 - (5) Complete the "Report" and "Issue information" data fields in the DOE CATS.
- b. **Corrective Action Plan Development.** The Cognizant Line Manager (CLM), in consultation with the applicable PSO, must prepare the CAP to address the safety issues raised in the formal oversight assessment report by performing the following.
- (1) The CLM prepares a single, comprehensive CAP to address the safety issues contained in a single assessment report.
 - (2) The CAP must include actions to correct the safety issues (e.g., clear variance from established requirements), determine the causes of the issue, and prevent recurrence of the issue.
 - (3) The CAP must describe the basis for the disposition of each identified safety issue. The CLM may determine that no action will be taken in response to a given issue. In this case, the CAP must describe the basis for this determination, demonstrating how safety will be maintained.
 - (4) The CAP must indicate the following for each safety issue requiring specific corrective actions:
 - responsible individual,
 - date of initiation,
 - expected date of completion,
 - how it will be tracked to closure, and
 - mechanism for independent verification of closure to ensure that the actions are appropriate to prevent recurrence.
- c. **Corrective Action Plan Approval.** The applicable PSO, or designee, must approve the CAP within 60 days of the issuance of the formal independent oversight assessment report.
- (1) The PSO may delegate this authority to the CLM or other designee. The PSO has the ultimate approval authority for CAPs.
 - (2) The CLM must complete the corrective action data fields for the approved CAP in the DOE CATS.
- d. **CAP Review.** The Office of Oversight must review the CAP by performing the following within 30 days of the CAP approval.

- (1) Determine if the CAP provides timely or adequate corrective actions for all or part of the identified safety issues.
 - (2) Provide comments and their basis to the CLM and PSO when it determines that the CAP does not provide timely or adequate corrective actions.
- e. CAP Comment Resolution. The CLM, in consultation with the PSO, must perform the following to address the Office of Oversight comments.
- (1) Determine if a CAP revision is needed.
 - (2) Revise the CAP appropriately.
 - (3) Inform the Office of Oversight of how their comments were dispositioned.
- f. Dispute Resolution. The Office of Oversight may elevate their concerns regarding disposition of its comments for dispute resolution in accordance with Paragraph 4.
- g. Deputy Secretary Briefing. The applicable PSO must provide an opportunity for the Deputy Secretary (Department's Chief Operating Officer) or designee to be briefed by the CLM, the Office of Oversight, and the Assistant Secretary for EH. The briefing may include identified safety issues, the CAP and planned corrective actions, and any associated resource issues.
- h. CAP Implementation. The CLM must implement the approved CAP and complete the associated corrective actions.
- (1) The CLM must track and report the implementation status of corrective actions. The status must be reported in the DOE CATS on a monthly basis (minimum) until the safety issue is closed.
 - (2) The Office of Oversight may review the timeliness and adequacy of ongoing implementation of identified corrective actions as part of routine or for-cause assessments. Unsatisfactory progress must be reported to the CLM and PSO.
- i. CAP Verification. The CLM must coordinate with the field organization, headquarters line organization, and PSO to conduct an independent assessment of all closed corrective actions. This verification must be performed by persons with sufficient independence from those who performed the work described in the CAP.
- j. Safety Issue Follow-up. The Office of Oversight may review completed corrective actions for adequacy in resolving the original safety issue. The Office of Oversight must identify a new safety issue for resolution when the CAP has not resolved the original safety issue.

4. CORRECTIVE ACTION PLAN DISPUTE RESOLUTION PROCESS.

- a. Disputes over the CAP or its implementation (such as timeliness or adequacy) must be resolved at the lowest possible organizational level. The organization that disagrees with the disposition of a given issue may elevate the dispute for timely resolution.
- b. The organization that disagrees with the disposition of a given issue must elevate the dispute in a step-wise manner through the management hierarchy.
- c. The dispute must be raised via a deliberate and timely dispute resolution process that provides each party with equal opportunity for input and a subsequent opportunity to appeal decisions up to the Secretary of Energy, if necessary.

U.S. Department of Energy
Washington, D.C.

PAGE CHANGE

DOE O 414.1A Chg 1

7-12-01

SUBJECT: QUALITY ASSURANCE

1. PURPOSE. To transmit revised pages to DOE O 414.1A, QUALITY ASSURANCE, dated 9-29-99.
2. EXPLANATION OF CHANGE. To change DOE O 414.1A, QUALITY ASSURANCE, to explicitly address its applicability to the National Nuclear Security Administration (NNSA). These changes facilitate the Department's organizational transition necessitated by establishment of the NNSA.
3. FILING INSTRUCTIONS.

<u>Remove</u>	<u>Dated</u>	<u>Insert</u>	<u>Dated</u>
Page 1	9-29-99	Page 1	7-12-01
Page 7	9-29-99	Page 7	7-12-01

After filing the attached pages, this transmittal may be discarded.

BY THE ORDER OF THE SECRETARY OF ENERGY:



FRANCIS S. BLAKE
Deputy Secretary