

U.S. Department of Energy

Washington, D.C.

ORDER

DOE 5700.6C

8-21-91

SUBJECT: QUALITY ASSURANCE

1. PURPOSE. To establish quality assurance requirements for the Department of Energy (DOE).
2. CANCELLATION. DOE 5700.6B, QUALITY ASSURANCE, of 9-23-86.
3. SCOPE. The provisions of this Order apply to the work performed by all Departmental Elements and management and operating (M&O) contractors as provided by law and/or contract and as implemented by the Department's Contracting Officer. If conflicts between this and other Departmental Orders exist, the quality assurance requirements of DOE 5700.6C take precedent.
4. EXEMPTIONS. Specifically excluded from this Order is:
 - a. Work associated with nuclear weapons administered by the Assistant Secretary for Defense Programs. (Work associated with the design, construction, fabrication, operations, maintenance, decommissioning, and decontamination of facilities and equipment used to produce weapons are not excluded from this Order. Appropriate attention shall be given to the weapons component and production facility interfaces.)
 - b. Work administered by the Energy Information Administration.
 - c. Work conducted under the Naval Nuclear Propulsion Program (subparagraph 9f).
 - d. Work licensed by the U.S. Nuclear Regulatory Commission (NRC) or an NRC Agreement State and subject to the quality assurance requirements of that agency.
 - e. Research and development work results which undergo peer review for publication.
5. REFERENCES. The following references are provided for general information.
 - a. DOE 1324.2A, RECORDS DISPOSITION, of 9-13-88, which defines Federal records and the requirements for their maintenance and retention/disposition.

DISTRIBUTION:

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INITIATED BY:

Office of Nuclear Energy
Office of Environment,
Safety, and Health.



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- b. DOE 2030.4A, REPORTING FRAUD, WASTE , AND ABUSE TO THE OFFICE OF INSPECTOR GENERAL, of 3-19-91, which establishes policies and procedures for reporting fraud, waste, and abuse to the Department of Energy's Office of the Inspector General (IG).
- c. DOE 4330.4A, MAINTENANCE MANAGEMENT PROGRAM, of 10-17-90, which provides general policy and objectives for the establishment of programs for the management and performance of cost-effective maintenance and repair of DOE property, including facilities.
- d. DOE 4700.1, PROJECT MANAGEMENT SYSTEM, of 3-06-87, which provides the principles and requirements governing the development, approval, and execution of DOE's outlay program acquisitions as embodied within the project management system.
- e. DOE 5480.1B, ENVIRONMENT, SAFETY, AND HEALTH PROGRAM FOR DEPARTMENT OPERATIONS, of 9-23-86, which sets forth responsibilities and requirements for the program.
- f. DOE 5480.4, ENVIRONMENTAL PROTECTION, SAFETY, AND HEALTH PROTECTION STANDARDS, of 5-15-84, which specifies the application of mandatory environmental protection, safety, and health protection (ES&H) standards to DOE operations.
- g. DOE 5480.19, CONDUCT OF OPERATIONS, of 7-9-90, which establishes requirements for conduct of operations at DOE facilities to ensure acceptable operations, provide for continuing improvements in operations, and ensure the maintenance of acceptable margins of safety.
- h. Standards which provide additional interpretive guidance for the development and implementation of quality assurance programs, including the following:
 - (1) American Society of Mechanical Engineers (ASME)/NQA-1, Quality Assurance Program Requirements for Nuclear Facilities,
 - (2) ASME/NQA-2, Quality Assurance Requirements for Nuclear Facility Applications,
 - (3) ASME/NQA-3, Quality Assurance Program Requirements for the Collection of Scientific and Technical Information for Site Characterization of High-Level Nuclear Waste Repositories,
 - (4) International Atomic Energy Agency (IAEA) International Nuclear Safety Advisory Group's Safety Series No. 75-INSAG-3, Basic Safety Principles for Nuclear Power Plants, and
 - (5) International Standard for Standardization (ISO) 9000, Quality Management and Quality Assurance Standards-Guidelines for Selection and Use.

- i. Environmental Protection Agency (EPA) guidance documents that apply to environmental protection and/or remediation, including the following:
 - (1) QAMS 004, Guidelines and Specifications for Preparing QA Program Plans,
 - (2) QAMS 005, Interim Guidelines and Specifications for Preparing QA Project Plans,
 - (3) Chapter 1 of SW-846, Test Methods for Evaluating Solid Wastes,
 - (4) EPA 540, Data Quality Objectives for Remedial Response Activities, and
 - (5) IEPA 530, Technical Guidance Document: Construction QA for Land Disposal Facilities.
- j. American Society for Testing and Materials (ASTM) standards, including ASTM C1009, Establishing a QA Program for Analytical Chemistry Laboratories Within the Nuclear Industry.

6. DEFINITIONS.

- a. Assessment/Verification. The act of reviewing, inspecting, testing, checking, conducting surveillances, auditing, or otherwise determining and documenting whether items, processes, or services meet specified requirements. The terms assessment and verification, as used in DOE 5700.6C, are synonymous: their use is determined by who is performing the work. Assessments are performed by or for senior management. Verifications are performed by the line organization.
- b. Item. An all-inclusive term used in place of any of the following: appurtenance, facility, sample, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, documented concepts or data.
- c. Process. A series of actions that achieves an end or result.
- d. Program Secretarial Officer (PSO). The heads of DOE offices with responsibility for specific facilities. These include the Assistant Secretaries for Conservation and Renewable Energy; Nuclear Energy; Defense Programs; and Fossil Energy and the Directors of the Offices of Energy Research: Civilian Radioactive Waste Management; Environmental Restoration and Waste Management; and New Production Reactors.
- e. Quality. The degree to which an item or process meets or exceeds the user's requirements and expectations.
- f. Quality Assurance. Actions that provide confidence that quality is achieved.

- g. Quality Assurance Program. The overall program established by an organization to implement the requirements of this Order. The Program assigns responsibilities and authorities, defines policies and requirements, and provides for the performance and assessment of work.
 - h. Service. The performance of work, such as design, fabrication, inspection, nondestructive examination, repair, or installation.
 - i. Senior Management. The manager or managers responsible for mission accomplishment and overall operations. For the DOE, the DOE PSOs and Field Office Managers are responsible for mission accomplishment and overall operations. For DOE M&O contractors, the General Manager or similar top position is responsible for mission accomplishment and overall performance in accordance with the requirements of their contracts or other agreements.
 - j. Work. Process of performing a defined task or activity; for example, research and development, operations, maintenance and repair, administration, software development and use, inspection, safeguards and security, data collection, and analysis.
- 7. POLICY. It is DOE policy to establish quality assurance requirements to ensure that risks and environmental impacts are minimized and that safety, reliability, and performance are maximized through the application of effective management systems commensurate with the risks posed by the facility and its work. This Order implements the policy of the Department to ensure that quality assurance requirements are clearly specified for the broad spectrum of work performed by DOE and its contractors, including safeguards and security.
- 8. OBJECTIVES. DOE's objectives are to ensure the following:
 - a. That senior management provides planning, organization, direction, control, and support to achieve the organization's objectives;
 - b. That the line organization achieves quality; and
 - c. That overall performance is reviewed and evaluated using a rigorous assessment process.
- 9. REQUIREMENTS.
 - a. General.
 - (1) Senior management shall be responsible for Quality Assurance Program (QAP) implementation, assessment, and improvement. Departmental Elements and M&O contractors shall develop their QAPs by applying the quality assurance criteria specified in subparagraph 9b. The quality assurance program shall include a discussion of how the criteria will be satisfied taking into consideration the risk associated with the work. Appropriate standards shall be used, wherever applicable, to develop and implement QAPs.

- (2) Guidance for developing and implementing QAPs is provided in Attachment I. This guidance may not be appropriate in its entirety for application to every type of work. Additional Implementation Guides, such as for research and development work, will be developed, and after approval, be incorporated into the provisions of this Order.
- (3) Contractors shall obtain DOE approval of new QAPs prior to commencing work. Contractors working to existing quality assurance programs shall ensure that their QAPs meet the requirements of this Order and shall re-submit their QAPs, together with an implementation plan, to the Lead Program Secretarial Officers (PSOSs) for approval within 180 days after this Order becomes effective. Quality assurance programs shall be regarded as approved by DOE 180 days after submittal, including any modifications which have been made or directed by DOE during this period, or receipt of a letter, whichever occurs first.
- (4) DOE contractors may, at any time, make changes to their DOE-approved QAPs. Changes made over the previous year to DOE-approved QAPs shall be submitted annually to the Lead PSO for review. All changes shall be regarded as approved by DOE 90 days after submittal, including any modifications which have been made or directed by DOE during this period, or receipt of a letter, whichever occurs first. The submittals shall identify the changes, the pages affected, the reason for the changes, and the basis for concluding that the revised program continues to satisfy the requirements of this Order. Changes made to correct spelling, punctuation, or other editorial items do not require explanation.
- (5) Assessments of DOE and contractor work shall be conducted based on the DOE-approved quality assurance program.
- (6) Programs, guides, and policies which implement this Order shall meet the requirements of DOE 1324.2A. (The Records and Reports Branch, AD-241.1, is available for any needed assistance regarding records management.)

b. Quality Assurance Criteria.

(1) Management.

- (a) Criterion I--Program. Organizations shall develop, implement, and maintain a written Quality Assurance Program. The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing adequacy of work. The QAP shall describe the management system, including planning, scheduling, and cost control considerations.

- (b) Criterion 2--Personnel Training and Qualification
Personnel shall be trained and qualified to ensure they are capable of performing their assigned work. Personnel shall be provided continuing training to ensure that job proficiency is maintained.
- (c) Criterion 3--Quality Improvement. The organization shall establish and implement processes to detect and prevent quality problems and to ensure quality improvement. Items and processes that do not meet established requirements shall be identified, controlled, and corrected. Correction shall include identifying the causes of problems and preventing recurrence. Item reliability, process implementation, and other quality-related information shall be reviewed and the data analyzed to identify items and processes needing improvement.
- (d) Criterion 4--Documents and Records. Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design. Records shall be specified, prepared, reviewed, approved, and maintained.

(2) Performance.

- (a) Criterion 5--Work Processes. Work shall be performed to established technical standards and administrative controls. Work shall be performed under controlled conditions using approved instructions, procedures, or other appropriate means. Items shall be identified and controlled to ensure their proper use. Items shall be maintained to prevent their damage, loss, or deterioration. Equipment used for process monitoring or data collection shall be calibrated and maintained.
- (b) Criterion 6--Design. Item and processes shall be designed using sound engineering/scientific principles and appropriate standards. Design work, including changes, shall incorporate applicable requirements and design bases. Design interfaces shall be identified and controlled. The adequacy of design products shall be verified or validated by individuals or groups other than those who performed the work. Verification and validation work shall be completed before approval and implementation of the design.
- (c) Criterion 7--Procurement. The organization shall ensure that procured items and services meet established requirements and perform as specified. Prospective suppliers shall be evaluated and selected on the basis of specified criteria. The organization shall ensure that approved suppliers can continue to provide acceptable items and services.

- (d) Criterion 8--Inspection and Acceptance Testing. Inspection and acceptance testing of specified items and processes shall be conducted using established acceptance and performance criteria. Equipment used for inspections and tests shall be calibrated and maintained.

(3) Assessment.

- (a) Criterion 9--Management Assessment. Management at all levels shall periodically assess the integrated quality assurance program and its performance. Problems that hinder the organization from achieving its objectives shall be identified and corrected.
- (b) Criterion 10--Independent Assessment. Planned and periodic independent assessments shall be conducted to measure item quality and process effectiveness and to promote improvement. The organization performing independent assessments shall have sufficient authority and freedom from the line organization to carry out its responsibilities. Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed.

10. RESPONSIBILITIES AND AUTHORITIES .

- a. Lead Program Secretarial Officers have the responsibility to ensure that the requirements of this Order are implemented. Additionally, they have the following responsibilities: "
 - (1) Ensure that DOE Field Offices and contractors to which this Order applies implement the requirements in Paragraph 9, as applicable;
 - (2) Provide program and project direction and resources for work within their purview;
 - (3) Review and approve quality assurance programs and changes thereto within their purview;
 - (4) Assess quality assurance program adequacy and implementation;
 - (5) For nuclear work, provide the Assistant Secretary for Nuclear Energy (NE-1) with recommendations for additions or revisions to nuclear quality assurance standards, guides, and codes; and for non-nuclear work, provide similar recommendations to the Assistant Secretary for Environment, Safety and Health (EH-1);
 - (6) Ensure that Field Office Managers comply with Paragraph 10e, below;
 - (7) Remain accountable for those responsibilities which they delegate;

- (8) Develop and implement a quality assurance program governing the work of their organization in accordance with the requirements of Paragraph 9, as applicable;
 - (9) Designate an individual or individuals to be responsible for bringing the following to the attention of the Department's Contracting Officer: (a) each procurement requiring the application of this Order, (b) requirements for flowdown of provisions of this order to any subcontract or sub-award, and (c) identification of the parts of this Order with which the contractor or subcontractor is to comply. Unless another individual is designated, the responsibility is that of the procurement Request Originator (the individual responsible for initiating a requirement of DOE F 4200.33). Contracting Officers, based on the advice of the Procurement Request Originator or other designated individual, shall apply applicable provisions of this Order to awards falling within its scope.
 - (10) Ensure that appropriate attention is given to the weapons component and production facility interface, where applicable.
- b. Assistant Secretary for Nuclear Energy (NE-1), in addition to the responsibilities prescribed in subparagraph 10a, has overall responsibility for developing and coordinating Departmental policy for nuclear reactors and non-reactor nuclear facility safety. The Assistant Secretary for Nuclear Energy has the following additional responsibilities :
- (1) Develop, promulgate, and maintain quality assurance policy for DOE nuclear work;
 - (2) Provide advice and assistance to PSOs concerning implementation of this Order;
 - (3) In concert with EH-1, provide a central point for coordination within DOE and liaison with other agencies and groups in the development of quality assurance policy, standards, guidance, and requirements; and
 - (4) Review proposed statutes (where appropriate), regulations, standards, and requirements for their application to and potential impact on DOE programs.
- c. Director of the Office of Nuclear Safety (NS-1), acting as the Department's independent element responsible for nuclear safety oversight, has the following responsibilities:
- (1) Assess and report to the Secretary of Energy on all aspects of nuclear safety related to the implementation of this Order, including the performance of the Program Offices, Field Offices, and contractors; and

- (2) Review proposed quality assurance policy, regulations, standards, and requirements to assess their potential effects on the nuclear safety of DOE facilities.
- d. Assistant Secretary for Environment, Safety and Health (Eli-I), acting as DOE's independent element responsible for oversight of worker health and safety (including radiation protection), environmental protection, and safeguards and security, has the following responsibilities in addition to those prescribed in subparagraph 10a:
- (1) Develop, promulgate, and maintain quality assurance policy for DOE non-nuclear work;
 - (2) Develop, promulgate, and maintain quality assurance policy for environmental compliance and data collection activities that is consistent with the guidelines established by the Environmental Protection Agency's Quality Assurance Management Staff office;
 - (3) Provide advice and assistance to PSOs concerning implementation of this Order;
 - (4) In concert with NE-1, provide a central point of contact for coordination within DOE and liaison with other agencies and groups in the development of quality assurance policy, standards, guidance, and requirements;
 - (5) Review proposed statutes (where appropriate), regulations, standards, and requirements for their application to and potential impact on DOE programs; and
 - (6) Assess non-nuclear work to monitor implementation of this Order.
- e. DOE Field Office Managers have the following responsibilities:
- (1) As directed by the Lead PSO, ensure the adequacy and implementation of contractors' quality assurance programs by performing independent assessments in accordance with Paragraph 9b (3) (b). Coordinate work with, and utilize resources of, other cognizant DOE organizations, as appropriate; and
 - (2) Develop and implement a quality assurance program governing the work of the Field Office in accordance with the requirements of Paragraph 9, as applicable. Submit the program to the Lead PSO for approval.
- f. Administrators of the Power Marketing Administrations: Section 302 of the DOE Organization Act (PL 95-91) directs the Secretary to operate and maintain the Power Marketing Administrations by and through their Administrators. The Administrators have statutory and public utility responsibilities for the safety, security, and reliability of the systems operated by their organizations. The Administrators shall review and approve the quality assurance standards, policies, and activities appropriate for their facilities

and operations. Such determination shall include appropriate consideration of the criteria set forth in this Order.

- g. Director of the Naval Nuclear Propulsion Program: Executive Order 12344, statutorily prescribed by P.L. 98-525 (42 U.S.C. 7158. note) establishes the responsibilities; and authority of the Director, Naval Nuclear Propulsion Program (who is also the Deputy Assistant Secretary for Naval Reactors within the Department) for all facilities and work which comprise the Program, a joint Navy-DOE organization. These executive and legislative actions establish the responsibilities of the Director as including 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. Accordingly, the provisions of this Order do not apply to the Naval Nuclear Propulsion Program. The Director shall establish the quality assurance requirements implemented within the program.

11. INTERPRETATIONS. Requests for interpretation of the requirements of this Order shall be forwarded for action, together with proposed resolutions, to NE-1 for nuclear work and to EH-1 for non-nuclear work.

BY ORDER OF THE SECRETARY OF ENERGY:



JOHN J. NETTLES, JR.
Director of Administration
and Human Resource Management

Guidance for developing and implementing Quality Assurance Programs (QAPs) that satisfy the requirements of this Order is provided by G-830.120-REV. 0, IMPLEMENTATION GUIDE FOR USE WITH 10 CFR 830.120 QUALITY ASSURANCE, of 4-15-94.