# **U.S.** Department of Energy

Washington, D.C.

**ORDER** 

DOE 5700.6B

9-23-86

SUBJECT: QUALITY ASSURANCE

- 1. PURPOSE. To provide Department of Energy (DOE) policy, set forth requirements, and assign responsibilities for establishing, implementing, and maintaining plans and actions to assure quality achievement in DOE programs.
- 2. CANCELLATION. DOE 5700.6A, QUALITY ASSURANCE, of 8-13-81.
- 3. SCOPE. The provisions of this Order apply to all Departmental Elements and contractors performing work for the Department as provided by law and/or contract and as implemented by the appropriate contracting officer. Except as indicated in paragraph 4 below, this Order applies to all DOE programs including: those directed toward siting, design, construction, testing, operation, maintenance, and decommissioning of facilities; development and production of materials, components and systems; and acquisition of research and technology data.

#### 4. EXEMPTIONS.

- a. The existing quality assurance programs for nuclear weapons administered by the Assistant Secretary for Defense Programs, and the Naval Reactors Program administered by the Deputy Assistant Secretary for Naval Reactors, fulfill the purpose stated above and, therefore, are exempt from the remainder of this Order.
- b. By statute, all programs administered by the Energy Information Administration are exempt from the requirements of this Order.
- c. A partial or complete variance from this Order may be granted when compliance with the Order may be inconsistent with external regulatory, legislative, or judicial requirements imposed on a DOE program. Such variances shall be recorded by means of a memorandum of understanding (MOU) to be signed by the Assistant Secretary for Environment, Safety, and Health (EH-1) and by the requesting Program Senior Official (PSO). The MOU will contain the basis for the granting of the variance, the identification of the specific portion of the Order to which the variance applies, and, when applicable, the alternative measures that will be implemented to accomplish the intent and purpose of the Order's requirements.

#### 5. REFERENCES.

a. DOE 5480.1B, ENVIRONMENT, SAFETY, AND HEALTH PROGRAM FOR DEPARTMENT OPERA-TIONS, of 9-23-86, which sets forth responsibilities and requirements for the program.

- b. 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.
- c. DOE 5700.1C, MAJOR SYSTEMS ACQUISITIONS, of 9-6-83, which establishes requirements and objectives and assigns responsibilities and authorities necessary to the acquisition of major systems.
- d. DOE 5700.4A, PROJECT MANAGEMENT SYSTEM, of 11-17-83, 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. Title 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," which sets forth the subject criteria.
- f. American National Standard Institute/American Society of Mechanical Engineers standard, ANSI/ASME NQA-1-1983, "Quality Assurance Program Requirements for Nuclear Facilities," which defines the requirements for such facilities.
- g. Office of Special Nuclear Projects, "Quality Assurance Program Requirements for Space and Terrestrial Nuclear Power Systems," of 10-82, which sets forth requirements for the program. This document is available from the Office of Special Nuclear Projects (NE-52).

#### A. DEFINITIONS.

 $\infty$ 

9

- a. <u>DOE Program</u> is an organized set of activities within a resource area having common objectives based on strategy set forth to meet assigned goals. It may include one or more projects and research and development activities in support of new, improved, or more efficient supply, or conservation systems or procedures.
- b. Implementation Plan is a concise description of the approach, resources, and time period planned for implementing this Order on a site wide basis, including a description of the execution of quality assurance responsibilities and authorities by the field organization and any proposed generic exemptions to the Order.
- c. Management Appraisal is a determination of managerial effectiveness in establishing and implementing quality assurance program plans which conform to Departmental policy requirements. It is based on an analysis of functional appraisals, internal audits, and other information, and on the application of appropriate criteria. It is a review and evaluation of management performance covering all quality assurance and management responsibilities to assure proper quality assurance program balance.

- d. Program Senior Official is a senior outlay program manager, and includes the Assistant Secretaries for Conservation and Renewable Energy, Fossil Energy, Nuclear Energy, and Defense Programs, and the Directors of Energy Research and Civilian Radioactive Waste Management. For purposes of this Order, this definition also includes the Administrators of the Bonneville and Western Area Power Administrations.
- e. Quality Assurance involves all those planned and systematic actions necessary to provide adequate confidence that a facility, structure, system, or component will perform satisfactorily and safely in service. The goal of quality assurance is to assure that: research, development, demonstration, scientific investigations, and production activities are performed in a controlled manner; that components, systems, and processes are designed, developed, constructed, tested, operated, and maintained according to engineering standards, quality practices, and Technical Specifications/Operational Safety Requirements; and that resulting technology data are valid and retrievable. Quality assurance includes quality control, which comprises all those actions necessary to control and verify the features and characteristics of a material, process, product, or service to specified requirements.
- f. Audit/Appraisal is a planned and documented activity performed in accordance with procedures to determine, by examination and evaluation of objective evidence, the adequacy of and extent to which applicable elements of the quality assurance program have been developed, documented, and effectively implemented in accordance with specified requirements. Audits can be internal examinations of programs or activities under an organization's control and within its organizational structure or external examinations of programs or activities of another organization.
- Quality Assurance Overview is an organized set of activities performed as independent functions. Its purpose is to assure that all aspects of quality-related activities at the program, project and contractor level of management are adequately addressed. Such activities include:
  - Periodic and timely reviews of program/project documents, activities, actions and plans;
  - (2) Review of new major procurements and management and operating contracts;
  - (3) Review of extend/compete packages for management and operating contracts; and
  - (4) Review of DOE Orders with relevance to the incorporation of the DOE quality assurance policy, where necessary.
- h. Quality Assurance Plan is a document that contains or references the quality assurance elements established for an activity, group of activities, a scientific investigation or a project and describes how conformance with such requirements is to be assured for structures, systems, computer

software, components, and their operation commensurate with (1) the scope, complexity, duration, and importance to satisfactory performance, (2) the potential impact on environment, safety and health, and (3) requirements for reliability and continuity of operation.

### 7. POLICY.

- a. Plans and actions to assure quality achievement in Departmental programs shall be established, implemented, and maintained with primary emphasis on achieving a high degree of operational success and with due consideration to health and safety, environmental protection, performance, reliability, and other concerns.
- b. Quality assurance activities shall be required, developed, funded, and managed as integral activities in Departmental programs, be provided for in program budget and manpower guidance, and be responsive to program needs and objectives.
- c. Quality assurance requirements shall be defined and the activities established and implemented in consonance with DOE Orders.
- d. The responsibility to achieve quality in DOE programs is a line management function. Through quality assurance overview, EH-1 has the responsibility to assure quality achievement for the Secretary and for the Program Senior Officials.

## 8. OBJECTIVES.

S

9

 $\boldsymbol{\omega}$ 

- a. To assure that management attention and support are provided at all levels within DOE and contractor organizations, as necessary, for effective quality assurance program definition and execution.
- b. To establish an independent, institutional coordination and overview function to develop and coordinate quality assurance policies and overall guidelines.

## 9. REQUIREMENTS.

- a. Departmental programs will benefit from quality assurance activities which, when properly implemented, will enhance quality, productivity and cost effectiveness and will complement established management control systems. Effective quality assurance programs shall include, as a minimum, the following elements:
  - (1) Assignment of organizational responsibility and authority for activities affecting quality and activities that assure quality achievement;
  - (2) Definition of quality and quality assurance objectives and requirements;

I

- (3) Implementation of procedures and work instructions;
- (4) Independent verification of quality attainment and quality assurance program effectiveness; and
- (5) Early detection and correction of deficiencies.
- b. The quality assurance plan and actions required to implement the stated policy shall be defined for each program/project/activity, as appropriate.
- c. Requirements for quality assurance activities shall be established and resources provided based on analyses of DOE program needs and objectives at the earliest practicable time consistent with program schedules.
- d. Quality assurance activities shall be implemented by DOE organizations and contractors using written procedures and instructions appropriate to the activities to be performed. Maximum use should be made of existing quality assurance practices that effectively support program needs and objectives.
- e. DOE program quality objectives should be defined in terms of measurable characteristics. Independent measurements should provide a means for determining the extent to which the quality objectives are met and for identifying and correcting deficiencies.
- f. Quality assurance activities and the requirements for those activities shall be identified in program plans. In accordance with Federal and DOE standards policies, national consensus standards are to be applied where suitable ones are available. The judicious and selective application of elements of appropriate, recognized standards is encouraged. In the nuclear area, ANSI/ASME NQA-1 (see paragraph 5f) is the preferred standard for quality assurance.
- g. Confirmation of quality attainment and quality assurance program effectiveness may be accomplished by various means, such as program reviews, and surveillance of specific activities or results of technical significance.
- h. Internal quality assurance audits shall be performed as a primary activity by any organization that implements quality assurance criteria or requirements, such as DOE laboratories, energy technology centers, power administrations, and DOE contractors. DOE field organizations, project offices, and Headquarters program offices may also conduct internal quality assurance audits at their option in fulfillment of their responsibilities.
- i. Field organizations and project offices shall perform external quality assurance audits of DOE laboratories and contractors under their direction, supported by other DOE organizations and consultants, as necessary.
- j. Causes of significant deficiencies shall be identified and corrected to prevent recurrence.

- 10. <u>RESPONSIBILITIES AND AUTHORITIES</u> for quality assurance policy coordination and overview, and for developing, implementing, and evaluating quality assurance activities in support of DOE programs are as follows:
  - a. Under Secretary (S-3) has overall responsibility and authority for DOE programs and may take necessary management actions to ensure safety, including directing the curtailment and suspension of operations when, in his or her opinion, such operations would result in an undue risk.
  - b. Program Senior Officials have the overall responsibility and authority for implementation of quality assurance policy. They shall:
    - (1) Develop and provide program and project direction to the field consistent with Order requirements related to quality assurance. Program and project direction must receive EH-1 concurrence if it is related to quality assurance and affects more than one field office.
    - (2) Subsequent to EH-1 review and concurrence, approve implementation plans for this Order.

Note: In the case of the Bonneville Power Administration and Western Area Power Administration where the Administrators of those organizations act as both Program Senior Officials and Heads of Field Organizations, they shall develop, approve, and implement quality assurance policy and guidance consistent with paragraphs 10b and 10d of this Order. Therefore, implementation plans developed by these organizations will reflect this situation and include quality assurance requirements appropriate for their operations, without necessarily obtaining EH-1 concurrence on the plans.

- (3) Define responsibilities and authorities for quality assurance activities for their programs.
- (4) Establish or approve the scope of quality assurance activities and criteria for those activities for individual programs.
- (5) Require that proper planning for resources and subsequent budget requests are provided in DOE program budget and manpower guidance for enabling effective quality assurance activities which are responsive to program needs and objectives.
- (6) Confirm that effective quality assurance activities are implemented by DOE and contractor organizations under their cognizance. In the execution of this responsibility, maximum use shall be made of the appraisals, reviews, and audits performed by EH including confirmation of the implementation of EH recommendations considered appropriate by the audited organization.
- (7) Take required corrective actions or cause corrective actions to be taken by other responsible organizations on identified quality and quality assurance-related issues and problems.

DIRECT OF TYPING A REST INTO FRAME

7

2

9

0 6

- (8) Through established program reporting channels, report on significant quality matters to EH-1 and other concerned DOE organizations.
- (9) Require that quality assurance programs under their cognizance meet applicable Federal codes, standards, and regulations.
- (10) For program activities not assigned to a field organization or project office for technical line management, perform the actions defined in subparagraph 10d below.
- (11) Participate, as appropriate, in selected field organization audits/
  appraisals of contractor facilities/operations. All participation
  shall be as full active members and scheduled for the year based on the
  annual submittal by the field organization of its proposed audit/
  appraisal schedule.
- (12) Take such action as may be appropriate to correct quality deficiencies that pose undue risk to the environment, safety, health, or property. Such actions may include directing the Head of a Field Organization to curtail or suspend operations.
- c. Assistant Secretary for Environment, Safety, and Health (EH-1) is responsible for establishment, coordination, and overview of DOE quality assurance policy. EH-1 shall:
  - (1) Develop DOE quality assurance policy; develop and issue quality assurance guidelines that are applicable to programs for their appropriate use; interpret this Order and make recommendations for change.
  - (2) Review and concur in field organization implementation plans for this Order, prior to approval. Prior to issuance, review and concur on documents issued by cognizant Program Senior Official(s) if they are related to quality assurance and affect more than one field organization.
  - (3) Perform independent quality assurance overviews, audits, and management appraisals of DOE programs and organizations, including verification of actions taken by the contractor(s) in conformance to established quality assurance programs and plans. The planning and conduct of overviews, audits, and appraisals will be coordinated with the appropriate field organizations and Headquarters program offices to minimize overlap/duplication of effort. The responsible field organization and Headquarters program office(s) may elect to participate in these audits/appraisals.
  - (4) Support and assist Program Senior Officials by preparation of training and familiarization information, performance of appraisals and audits of activities, and guidance in the selection of appropriate quality assurance standards, or on other quality assurance matters, as appropriate.
  - (5) Provide a focal point for liaison and coordination with DOE Departmental Elements and other agencies on DOE quality assurance policy.

7 6

m

3 9 55

0

LN

1. . . .

- (6) Maintain direct communication with field organizations and project offices; however, program direction must be provided by the cognizant Program Senior Official as indicated in paragraph 10b above.
- (7) Participate in selected field organization audits/appraisals of contractor facilities/operations. All participation shall be as full active members and scheduled for the year based on the annual submittal by the field organization of its proposed appraisal schedule.
- (8) Curtail or suspend operations at DOE facilities, under the conditions described below, when a clear and present danger exists to workers or members of the public. (Clear and present danger is a condition or hazard which could reasonably be expected to cause death or serious harm to plant workers or the public immediately or before such condition or hazard can be eliminated through normal procedures.)
  - (a) Whenever EH-1, in carrying out his or her responsibilities, determines that the environmental, safety, or health conditions at any DOE facility present a clear and present danger, EH-1 shall notify the Under Secretary that such a determination has been made. In addition, notification shall be provided to the Program Senior Official and the Head of the appropriate Field Element, Upon receiving such notification, the Head of the Field Element shall take immediate action to curtail or suspend the operation and to mitigate the danger.
  - (b) If appropriate action is not taken to curtail or suspend the operation and mitigate the identified danger, EH-1 shall advise the Secretary. In the event that the Secretary is unavailable, EH-1 is authorized to direct the PSO or field element to suspend or curtail an operation which EH-1 has determined is posing a clear and present danger until the danger has been mitigated.
  - (c) The authority reflected in subparagraph (8) may not be redelegated or assumed by acting officials and will terminate on 1-31-88, unless specifically renewed.

- d. <u>Heads of Field Organizations</u> have overall responsibility and authority for defining and assuring that required quality assurance activities are established and implemented. They shall:
  - (1) Obtain the approval of the appropriate Program Senior Official of quality assurance requirements for those activities to be established and implemented by contractors on their assigned portion of DOE programs.
  - (2) Develop and transmit an implementation plan for this Order to the cognizant Program Senior Official(s) for approval.
  - (3) Assure that adequate funding for quality assurance activities is requested from program managers.
  - (4) Review and approve, when appropriate, contractor quality assurance policies and implementing documents (e.g., Quality Assurance Plans).
  - (5) Define responsibilities and authorities for quality assurance within their organizations and provide sufficient staff and other resources to assure effective implementation of internally executed activities.
  - (6) Maintain surveillance of contractor activities and assure compliance with requirements.
  - (7) Perform audits/appraisals to verify adequacy and effectiveness of contractor quality assurance programs; coordinate audits/appraisals with, and utilize resources of, other cognizant DOE organizations, as appropriate.
  - (8) Identify quality-related issues and problems and cause corrective actions to be taken by the responsible organization.

رب د

S

S

α α

9

 $\infty$ 

 $\Box$ 

- (9) Provide the cognizant Program Senior Officials and EH-1 with a schedule showing the quality assurance audit/appraisals planned for the following fiscal year by August 1 of each year. An opportunity is to be given to these organizations to participate as active members of the appraisal team.
- (10) Provide copies of all quality assurance audit/appraisal reports to the cognizant Program Senior Officials and EH-1.
- (11) Take such action as may be appropriate to assure correction of quality deficiencies that pose undue risk to environment, safety, health, or property. Such actions may include curtailing or suspending operations.
- (12) Assure that, as appropriate, individual contracts specify that the contractor will comply with applicable quality assurance policies and requirements.



JOHN S. HERRINGTON Secretary