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

Cancelled by DOE 5700.6B

7- 9-23-86

ORDER

DOE 5700.6A

7-21-81

SUBJECT: QUALITY ASSURANCE

- 1. <u>PURPOSE</u>. To provide Department of Energy (DOE) policy, set forth principles, and assign responsibilities for establishing, implementing, and maintaining programs of plans and actions to assure quality achievement in DOE programs.
- 2. CANCELLATION. DOE 5700.6, QUALITY ASSURANCE, of 1-16-81.
- 3. <u>SCOPE</u>. The provisions of this Order apply to all DOE programs and DOE elements involved in 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 Assistant Secretary for Defense Programs and for the naval reactors program administered by Deputy Assistant Secretary for Naval Reactors fulfill the purpose and, therefore, are exempt from the remainder of this Order.
- b. Except for temporary situations involving on-going programs, any proposed exemption of a program from the requirements of this Order shall be submitted by the cognizant program Secretarial Officers to the Under Secretary for approval. For on-going programs, the cognizant program Secretarial Officer has authority to authorize a one-time temporary [less than 6 months] program exemption from the requirements of this Order.

5. **DEFINITIONS**.

- a. <u>DOE Program</u>. 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. <u>Quality Assurance</u>. All those planned and systematic actions necessary to provide adequate confidence that a facility, structure, system or component will perform satisfactorily in service. The goal of quality assurance is to assure that research, development, demonstration, and production activities are performed in a controlled manner; that components, systems, and processes are designed, developed, constructed,

tested, operated, and maintained according to sound engineering standards, quality practices and technical specifications; 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.

- c. <u>Implementation Plan</u>. A concise description of the approach, resources, and time period planned for implementing each 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 exemptions to parts of DOE Orders.
- d. <u>Management Appraisal</u>. A determination of managerial effectiveness in establishing and implementing quality assurance program plans which conform to DOE policy requirements. It is based on an analysis of functional appraisals, internal audits, and other information and on the application of appropriate criteria. This is a review and evaluation of management performance covering all quality assurance and management responsibilities to assure proper quality assurance program balance.
- e. <u>Program Secretarial Officers</u> are outlay program managers to include the Assistant Secretaries for Conservation and Renewable Energy, Fossil Energy, Nuclear Energy, Environmental Protection, Safety, and Emergency Preparedness, Defense Programs, and the Director of Energy Research.
- v. POLICY.
 - a. Programs of plans and actions to assure quality achievement in DOE 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 within DOE programs, provided for in program budget and manpower guidance, and responsive to program needs and objectives.
 - c. In the area of environment, safety, and health, quality requirements shall be defined and the activities established and implemented in consonance with DOE Orders covering that area.

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7. OBJECTIVES.

- a. To ensure that management attention and support are provided at all levels within DOE and contractors 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 DOE quality assurance policies and overall guidance.

8. PRINCIPLES.

- a. DOE programs will benefit from quality assurance activities which, when properly implemented, will enhance cost effectiveness and complement established management control systems. Effective quality assurance programs should include, as a minimum, the following elements:
 - (1) Assignment of organizational responsibility and authority for activities affecting quality and activities to assure quality achievement;
 - (2) Definition of quality and quality assurance objectives and requirements;
 - (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 required quality assurance activities to implement the stated policy shall be defined for each DOE program.
- c. Requirements for quality assurance activities shall be established and resources provided based on analyses of DOE program needs and objectives and at the earliest practicable time consistent with program schedules.
- d. Quality assurance activities shall be implemented by DOE organizations using written procedures and instructions appropriate to the activities to be performed. Maximum use should be made of existing quality assurance practices which are determined to be suitable to 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. Required quality assurance activities and the requirements for those activities should be identified through the judicious and selective application of requirements of appropriate, recognized standards. See attached Quality Assurance Guidelines.
- g. Independent verification of quality attainment and quality assurance program effectiveness may be accomplished by various means, such as by the performance of inspection, surveillance and audits of specific activities or results of technical significance. Internal quality assurance audits shall be required as a primary activity of DOE organizations. Field organizations and project offices shall perform external quality assurance audits of DOE laboratories and contractors under their direction, supported as necessary, by other DOE organizational units. Generic overview or specific program-independent audits of DOE programs may be directed by the Secretary's office; these will be conducted by DOE staff not having programmatic responsibility over the programs being audited. These audits will be coordinated by the DOE Office of Quality Assurance and Standards under the Assistant Secretary, Environmental Protection, Safety, and Emergency Preparedness.
- h. Causes of significant deficiencies shall be identified and corrected to prevent recurrence.
- 9. <u>RESPONSIBILITIES AND AUTHORITIES</u>. Responsibilities and authorities 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. The DOE Office of Quality Assurance and Standards under the Deputy Assistant Secretary for Environment, Safety, and Health, who reports to the Assistant Secretary for Environmental Protection, Safety and Emergency Preparedness, is responsible for establishment, coordination and overview of DOE quality assurance policy. Quality assurance policy is to be developed with the cooperation and concurrence of Program Secretarial Officers. The Director of Quality Assurance and Standards, shall:
 - Develop DOE quality assurance policy and guidelines for implementation of DOE quality assurance policies and activities; interpret this Order and make recommendations for changes, as appropriate, to the Deputy Assistant Secretary for Environment, Safety, and Health.
 - (2) Review field organization implementation plans for this Order, and provide critiques of the plans to the cognizant program Secretarial Officer prior to final approval.
 - (3) Perform independent quality assurance overview and management appraisals of DOE programs.

- (4) Using existing reporting systems wherever feasible, acquire and maintain a centralized base of information on the status and adequacy of DOE and contractor quality assurance programs, and communicate with concerned DOE management when action is needed to correct deficiencies.
- (5) Assist program Secretarial Officers, upon request, in preparation of training and indoctrination information, performance of management appraisals and audits of activities, guidance in the selection of appropriate quality assurance program standards and other quality assurance matters, as appropriate.
- (6) Provide a focal point for liaison and coordination with DOE organizational elements and other agencies on DOE quality assurance policy.
- (7) Have a clear channel for providing reports directly to the Under Secretary as required or a clear commitment by intervening management that such reports will be promptly transmitted through established reporting channels.
- (8) Maintain direct communication with quality assurance elements in field organizations and project offices.
- b. Overall responsibility and authority for implementation of quality assurance policy rests with the program Secretarial Officers. They shall:
 - (1) Develop guidance for implementation of quality assurance policy and coordinate that guidance with the Office of Quality Assurance and Standards for consistency, and with other DOE organizations and agencies as appropriate.
 - (2) Review and approve field organization implementation plans for this Order. Provide the Deputy Assistant Secretary for Environment, Safety and Health an opportunity to review and comment on each plan prior to granting final approval.
 - (3) Define responsibilities and authorities for quality assurance activities for their programs.
 - (4) Establish or approve the scope of quality assurance activities and requirements for those activities for individual programs.
 - (5) Assure that funds are provided in DOE program budget and manpower guidance, enabling effective quality assurance activities which are responsive to DOE program needs and objectives.

- (6) Verify that effective quality assurance activities are implemented by DOE and its contractor organizations under their cognizance by overview, surveillance, and audit, as appropriate.
- (7) Identify quality and quality assurance related issues and problems, and take required corrective actions or cause corrective actions to be taken by other responsible organizations.
- (8) Report on significant quality matters through established DOE program reporting channels to the Director of Quality Assurance and Standards, and other concerned DOE organizations.
- (9) Assure that quality assurance programs under their cognizance meet applicable Federal codes, standards, and regulations.
- (10) For DOE program activities not assigned to a field organization or project office for implementation, perform the actions defined in paragraph 9c below.
- c. Overall responsibility and authority for defining and ensuring effective implementation of required quality assurance activities to be established and implemented on DOE programs by contractors under their direction rest with the DOE field organization and project office managers. They shall:
 - (1) Define and obtain approval of the appropriate program Secretarial Officer of quality assurance requirements for those activities to be established and implemented by contractors on their assigned portion of DOE programs. Copies of those requirements will be provided to the Office of Quality Assurance and Standards. Develop implementation plans for this Order, to be transmitted to the cognizant program Secretarial Officer for approval.
 - (2) Assure that adequate funding for quality assurance activities is requested from program managers.
 - (3) Review and approve, when appropriate, contractor quality assurance policies, and implementing documents.
 - (4) Define responsibilities and authorities for quality assurance within their organizations and providing sufficient staff and other resources to assure effective implementation of internally executed activities.
 - (5) Maintain surveillance of contractor activities and ensure compliance with requirements.

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- (6) Perform audits to verify adequacy and effectiveness of contractor quality assurance programs; coordinate audits with and utilize resources of other cognizant DOE organizations, as appropriate.
- (7) Identify quality-related issues and problems and cause corrective actions to be taken by responsible contractor organizations.

QUALITY ASSURANCE GUIDELINES

Basic Premises

- 1. Contractors, Department of Energy (DOE) Laboratories and Engineering Technology Centers engaged in DOE programs and projects are primarily responsible for the quality of design, construction, production, operation, data acquisition, reliability and safety of their activities. They are expected to establish, implement and maintain effective quality assurance programs as deemed necessary to meet program and project needs and objectives. The DOE's role, both at field organization and project offices, and at Headquarters, is to provide overall direction and resources and to provide an overview to assure that adequate quality assurance programs are established and maintained.
- 2. In accordance with Federal and DOE standards policy, national consensus quality assurance standards are to be applied where suitable ones are available. In the nuclear area, ANSI/ASME NQA-1 is the preferred standard for quality assurance. ANSI/ASME NQA-1 provides an acceptable basis for meeting the requirements of 10 CFR 50, can be more broadly applied than required in 10 CFR 50 to all aspects of a nuclear facility including the non-safety related aspects, and can be applied in a selective manner, depending on the complexity and significance of the particular program or project activity. Its principal deficiency is in its application to development and data acquisition activities. It should be noted that DOE and ASME are developing supplements to NQA-1 which will address this deficiency. For non-nuclear programs, the cognizant Program Secretarial Officer should select those national consensus quality assurance standards which best meet their program and project needs and objectives. These standards should be based on recommendations provided by the cognizant field organization or project office manager and should be reviewed by the Director of Quality Assurance and Standards. Where suitable national consensus standards do not exist, the cognizant Program Secretarial Officer should develop applicable quality assurance requirements with the assistance and guidance of the Office of Quality Assurance and Standards.
- 3. Quality assurance requirements should be applied on a selective basis, depending on the complexity, consequences of failure, and significance to program success, and included in contractual documents. For some activities, quality assurance requirements can be made quite simple; for example, in bench-type chemistry research, the principal requirements might include only assurance that reagents are correctly characterized, that measuring equipment is within calibration, and that data are taken in a form that can be understood by others and preserved for future use. Complex activities, which require development of large, expensive and potentially hazardous apparatus could require the complete spectrum of requirements,

such as those specified in ANSI/ASME NQA-1, possibly with supplementary requirements.

- 4. Where existing quality assurance standards, such as RDT F2-2 and ANSI/ ASME N45.2 are extensively used, and are considered adequate, they may continue to be applied, particularly where detailed implementing procedures are well established, personnel are trained in their use, and their conversion to another standard would not be cost effective. Similarly, standards which have been developed for specific applications, and which are being applied on interagency programs, such as NRA-1 and STS-1 for space and terrestrial systems, may continue to be applied.
- 5. In establishing quality assurance activities, primary emphasis shall be on achieving a high degree of operational success, recognizing that safety, environmental protection, reliability and performance are all integrally related.
- 6. Quality assurance activities should be required, developed, funded and managed as integral activities within the DOE programs and projects, provided for in programs and project budget and manpower guidance, and responsive to program and project needs and objectives.
- 7. The objective of reliability engineering is to contribute toward safe and predictable performance of major energy systems and facilities through the application of proven reliability engineering and design principles and in the evaluation of test, operation, and maintenance data. Reliability methods should be applied to assist in the technical decision making process, recognizing that the adequate data base and discipline that are needed to provide analytical assessments with suitable confidence may be lacking. Reliability engineering can be a useful adjunct to quality assurance activities.