U.S. Department of Energy

Washington, D.C.

ORDER

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Concelled By 00E 5-700.64 7 8-13-81

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. SCOPE. The provisions of this Order apply to 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.
- 3. <u>EFFECTIVE DATE</u>. This Order is effective immediately for all new DOE programs. Applicability to ongoing DOE programs shall be determined on an individual basis by the responsible DOE Program Assistant Secretary or the Director of Energy Research for their respective programs.

4. 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 the National Energy Plan or Presidentially 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. Quality Assurance. 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.

5. 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, requirements for quality assurance activities shall be defined and the activities established and implemented in consonance with DOE Orders covering that area.

6. 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.
- c. To identify responsibilities and authorities of Assistant Secretaries and the Director of Energy Research for establishing specific quality and quality assurance requirements for DOE programs within their cognizance.

7. 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 should 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. Where recognized standards do not fully satisfy specific needs of a DOE program, supplemental requirements should be developed. If it is concluded that no existing standard is suitable as a base, an interim standard may be developed.
- 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 should be regarded as a primary activity of DOE organizations. Field offices and project offices should 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 Quality Assurance Coordinator.
- h. Causes of significant deficiencies should be identified and corrected to prevent recurrence.
- 8. <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 Quality Assurance Coordinator, who is designated by and reports to the Under Secretary, is responsible for establishment, coordination and overview of DOE quality assurance policy. The DOE Quality Assurance Coordinator shall:

- (1) Develop DOE quality assurance policy, for the Under Secretary's approval, and overall guidance for DOE quality assurance activities; interpret this Order and make recommendations to the Under Secretary for changes, as appropriate.
- (2) Concur in proposed waivers to provisions of this Order. Subsequent to the reviews, recommend to the Under Secretary disposition of proposed waivers to the provisions of this Order.
- (3) Perform independent quality assurance overview, management appraisal and audit of DOE programs when deemed necessary or at the request of the Under Secretary.
- (4) 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 DOE program managers, 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) Provide periodic reports to the Under Secretary on the status of DOE quality assurance activities through established reporting channels.
- (8) Establish and chair the DOE Quality Assurance Steering Committee.
- (9) Maintain direct communication with Quality Assurance elements in field and project offices.
- b. Overall responsibility and authority for implementation of quality assurance policy rests with the DOE Program Assistant Secretaries and the Director of Energy Research. They shall:
 - (1) Develop guidance for implementation of quality assurance policy and coordinate that guidance with the DOE Quality Assurance Coordinator for consistency, and with other DOE organizations and agencies as appropriate.
 - (2) Document the basis and obtain approval through the DOE Quality Assurance Coordinator of the Under Secretary, for waivers of provisions of this Order.

- (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 DOE Quality Assurance Coordinator, and other concerned organizations.
- (9) For DOE program activities not assigned to a field or project office for implementation, perform the actions defined in paragraph 8c 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 office and project office managers. They shall:
 - (1) Define appropriate quality assurance activities and requirements for those activities to be established and implemented by contractors on their assigned portion of DOE programs.
 - (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.

- (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.

