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

ORDER

DOE O 414.1

Approved: 11-24-98
Review Date: 11-24-00

SUBJECT: QUALITY ASSURANCE

1. OBJECTIVES. To establish an effective management system (i.e., quality assurance programs) using the performance requirements of this Order, coupled with technical standards where appropriate, that ensure the following:

   a. Senior management provides planning, organization, direction, control, and support to achieve DOE 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 reviews, evaluates, and improves its overall performance and that of their contractors using a rigorous assessment process based upon an approved Quality Assurance Program [see 48 CFR 970.1001(d)].

2. CANCELLATION. DOE Order 5700.6C, QUALITY ASSURANCE, dated 8-21-91, 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 shall remain in effect until the contract is modified to delete the requirements in the canceled directives.

3. APPLICABILITY.

   a. DOE Elements. Departmental elements shall 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 responsible for managing and operating DOE-owned or -leased facilities (including work, such as a design or manufacturing, which may take place outside the physical boundaries of a DOE facility). The line organization must determine the other contractors to whom the requirements will apply based on the graded approach. Contractor compliance with the CRD will be required to the extent set forth in a contract.

Distribution:
All Departmental Elements

Initiated By:
Office of Environment, Safety and Health

ADMIN RECORD

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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. Some portions of DOE work are regulated by quality assurance requirements of other organizations: 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. To ensure the work meets their expectations, DOE elements may impose additional quality requirements and/or specific standards as necessary (e.g., the Office of Defense Programs nuclear weapons production standard, QC-1, or the Office of Civilian Radioactive Waste requirement, RW-033P). A single quality assurance program (QAP) may be used to satisfy the regulated work, as well as any additional requirements imposed by DOE elements and the requirements of this Order.

4. REQUIREMENTS.

a. General.

(1) DOE elements shall develop their QAPs by applying the quality assurance criteria specified in Paragraph 4b, using a graded approach.

(2) In developing and implementing their QAPs, DOE elements shall consider the guidance on quality assurance provided in Paragraph 6.

(3) DOE elements not presently in compliance with this Order or DOE 5700.6C shall develop and implement a QAP within 90 days of the date of this Order.

(4) Any changes to approved QAPs that address enhancements to 5700.6C made by this document shall be handled as a QAP revision.

(5) The QAP shall describe how the criteria will be satisfied, taking into consideration the risk associated with the work.

(6) DOE elements shall identify, document, and use appropriate standards (consistent with the National Technology Transfer and Advancement Act, PL 104-113, and Office of Management and Budget Circular A-119), wherever applicable, to develop and implement QAPs.

(7) The QAP shall describe how the graded approach will be applied.

(8) The QAP shall 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).

b. Quality Assurance Criteria.

(1) Management.

(a) Criterion 1—Program.

1 A written QAP shall be developed, implemented, and maintained.

2 The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.

3 The QAP shall describe management processes, including planning, scheduling, and resource considerations.

(b) Criterion 2—Personnel Training and Qualification.

1 Personnel shall be trained and qualified to ensure they are capable of performing their assigned work.

2 Personnel shall be provided continuing training to ensure that job proficiency is maintained.

(c) Criterion 3—Quality Improvement.

1 Processes to detect and prevent quality problems shall be established and implemented.

2 Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected.

3 Correction shall include identifying the causes of problems and working to prevent recurrence.

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

(d) Criterion 4—Documents and Records.

1 Documents shall be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design.

2 Records shall be specified, prepared, reviewed, approved, and maintained.

(2) Performance.

(a) Criterion 5—Work Processes.

1 Work shall be performed to established technical standards and administrative controls using approved instructions, procedures, or other appropriate means.

2 Items shall be identified and controlled to ensure their proper use.

3 Items shall be maintained to prevent their damage, loss, or deterioration.

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

(b) Criterion 6—Design.

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

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

3 Design interfaces shall be identified and controlled.

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

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

(c) Criterion 7—Procurement.

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

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

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

(d) Criterion 8—Inspection and Acceptance Testing.

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

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

(3) Assessment.

(a) Criterion 9—Management Assessment. Managers shall assess their management processes Problems that hinder the organization from achieving its objectives shall be identified and corrected.

(b) Criterion 10—Independent Assessment.

1 Independent assessments shall 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 shall have sufficient authority and freedom from the line to carry out its responsibilities.

3 Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed.

5. RESPONSIBILITIES. Senior management shall be responsible for QAP implementation, assessment, and improvement (see Manual of Functions Responsibilities Authorities, DOE M 411.1-1).

a. Deputy Secretary.

(1) Serves as the Departmental focal point for quality assurance issues and provides leadership for quality assurance implementation.

(2) Charters the Quality Assurance Working Group (QAWG) under the leadership of the Office of Field Management to assist with these responsibilities.

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 contractor new and revised 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) Use management and independent assessments in accordance with Paragraph 4b(3) to verify Headquarters element QAP adequacy and implementation, 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),

(b) requirements for flow down of provisions of the CRD to any subcontract or sub-award, and

(c) the provisions of the CRD with which the contractor or subcontractor is to comply.

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, promulgate, 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.

(3) 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.

(4) Review proposed statutes (where appropriate), regulations, standards, and requirements for their application to and potential impact on DOE 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, and programs designed for the protection of special nuclear material, classified information, and sensitive unclassified information, has the following responsibilities:

(1) Assess and report to the Secretary of Energy on all aspects of safety related to the implementation of this Order, including performance of the Secretarial Offices, Field Elements, and contractors.

(2) Review and comment upon proposed quality assurance policy, regulations, standards, and requirements to assess their potential effects on the safety of operations at DOE facilities.

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 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) Ensure the adequacy and implementation of contractor QAPs by performing independent assessments in accordance with Paragraph 4b(3)(b) and other suitable methods.

(4) Use management and independent assessments in accordance with Paragraph 4b(3) to verify Field Element QAP adequacy and implementation and to improve organizational performance.

f. Director, Office of Field Management, is responsible for leadership of a QAWG comprised of appointed senior managers or designees from DOE Headquarters Elements, Field Elements, and DOE contractors that will–

(1) identify and resolve cross-cutting quality assurance issues within the Department;

(2) develop Departmental quality assurance positions and provide appropriate recommendations, advice, and counsel to the Deputy Secretary; and

(3) periodically report on the effectiveness of quality assurance policy.

g. 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, Paragraph A1(d).

6. REFERENCES. Guidance for implementing this Order is provided by the following:

a. DOE G 414.1-2* (previously DOE G 830.120), IMPLEMENTATION GUIDE FOR USE WITH 10 CFR 830.120 AND O 414.1, QUALITY ASSURANCE;

***NOTE: AS OF PUBLICATION DATE OF THIS ORDER, THIS GUIDE IS STILL IN DRAFT.**

b. DOE G 414.1-1, IMPLEMENTATION GUIDE FOR USE WITH INDEPENDENT AND MANAGEMENT ASSESSMENT REQUIREMENTS OF 10 CFR 830.120 AND ORDER 5700.6C, dated August 1996; and,

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, dated 6-30-97.

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. Service. The performance of work, such as design, construction, fabrication, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

h. 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.

BY ORDER OF THE SECRETARY OF ENERGY:

RICK FARRELL
DIRECTOR OF MANAGEMENT
AND ADMINISTRATION

CONTRACTOR REQUIREMENTS DOCUMENT

QUALITY ASSURANCE

A. General Requirements.

1. A contractor shall accomplish the following:

   a. Assign and identify the senior management position responsible for Quality Assurance Program (QAP) development, implementation, assessment, and improvement.

   b. Develop a QAP for the work as specified in its contract by applying the quality assurance criteria specified in Paragraph B below. The QAP shall –

      (1) include a discussion of how the criteria will be satisfied;

      (2) use a graded approach to apply the criteria of Paragraph B of this document;

      (3) describe how the graded approach will be applied;

      (4) discuss how the QAP integrates and satisfies quality requirements or similar management systems requirements (such as environmental or safety) from sources other than Paragraph B (see 48 CFR 970.5204-2).

   c. Identify, document, and use appropriate standards (consistent with the National Technology Transfer and Advancement Act, PL 104-113, and Office of Management and Budget Circular A-119), wherever applicable, to develop and implement the QAP.

   d. Submit the QAP to DOE for approval, prior to starting work under the contract, or as specified by DOE.

      (1) QAPs approved in accordance with DOE 5700.6C, QUALITY ASSURANCE, are not required to be resubmitted for approval (see Paragraph A(2) for QAP changes that address enhancements to DOE 5700.6C made by this document).

      (2) The QAP shall be regarded as approved by DOE 90 days after submittal, unless approved or rejected by DOE at an earlier date, and shall include any modification made or directed by DOE.

e. Implement the QAP as approved and modified by DOE.

2. A contractor may, at any time, make changes to an approved QAP.

   a. Changes made over the previous year shall be submitted annually to DOE for review and approval.

   b. 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.

   c. Changes made to correct spelling, punctuation, or other editorial items do not require explanation.

3. Other Quality Requirements.

   a. Some portions of DOE work are regulated by quality assurance requirements for the Nuclear Regulatory Commission (NRC), an NRC Agreement State, the Environmental Protection Agency, DOE (10 CFR 830.120), or other government agencies. DOE O 414.1 applies to those portions of the work that are not so regulated.

   b. To ensure the work meets requirements, DOE elements may also impose additional quality requirements and/or specific standards, as necessary (e.g., the Office of Defense Programs nuclear weapons production standard, QC-1, or the Office of Civilian Radioactive Waste Management requirement, RW-033P).

   c. A single QAP may be used to satisfy the regulated work, any additional requirements imposed by DOE elements, and the work subject to requirements of this Order.

4. In developing and implementing QAPs, contractors shall consider the guidance on quality assurance provided below:

   a. DOE G 414.1-2* (previously DOE G 830.120), IMPLEMENTATION GUIDE FOR USE WITH 10 CFR 830.120 AND O 414.1, QUALITY ASSURANCE;

***NOTE: <u>AS OF PUBLICATION DATE OF THIS ORDER, THIS GUIDE IS STILL IN DRAFT</u>.**

b. DOE G 414.1-1, IMPLEMENTATION GUIDE FOR USE WITH INDEPENDENT AND MANAGEMENT ASSESSMENT REQUIREMENTS OF 10 CFR 830.120 AND ORDER 5700.6C, dated August 1996; and,

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, dated 6-30-97.

B. Quality Assurance Criteria.

1. Management.

a. Criterion 1—Program.

(1) A written Quality Assurance Program shall be developed, implemented, and maintained.

(2) The QAP shall describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.

(3) The QAP shall describe the management processes, including planning, scheduling, and resource considerations.

b. Criterion 2—Personnel Training and Qualification.

(1) Personnel shall be trained and qualified to ensure they are capable of performing their assigned work.

(2) Personnel shall be provided continuing training to ensure that job proficiency is maintained.

c. Criterion 3—Quality Improvement.

(1) Processes to detect and prevent quality problems shall be established and implemented.

(2) Items, services, and processes that do not meet established requirements shall be identified, controlled, and corrected according to the importance of the problem and the work affected. Correction shall include identifying the causes of problems and working to prevent recurrence.

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

d. Criterion 4—Documents and Records.

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

(2) Records shall be specified, prepared, reviewed, approved, and maintained.

2. Performance.

a. Criterion 5—Work Processes.

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

(2) Items shall be identified and controlled to ensure their proper use.

(3) Items shall be maintained to prevent their damage, loss, or deterioration.

(4) Equipment used for process monitoring or data collection shall be calibrated and maintained.

b. Criterion 6—Design.

(1) Items and processes shall be designed using sound engineering/scientific principles and appropriate standards.

(2) Design work, including changes, shall incorporate applicable requirements and design bases.

(3) Design interfaces shall be identified and controlled.

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

(5) Verification and validation work shall be completed before approval and implementation of the design.

c. Criterion 7—Procurement.

(1) Procured items and services shall meet established requirements and perform as specified.

(2) Prospective suppliers shall be evaluated and selected on the basis of specified criteria.

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

d. Criterion 8—Inspection and Acceptance Testing.

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

(2) Equipment used for inspections and tests shall be calibrated and maintained.

3. Assessment.

a. Criterion 9—Management Assessment.

(1) Managers shall assess their management processes.

(2) Problems that hinder the organization from achieving its objectives shall be identified and corrected.

b. Criterion 10—Independent Assessment.

(1) Independent assessments shall 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 shall have sufficient authority and freedom from the line to carry out its responsibilities.

(3) Persons conducting independent assessments shall be technically qualified and knowledgeable in the areas assessed.

PREAMBLE to DOE Order O 414.1, QUALITY ASSURANCE

Quality Assurance Order, O 414.1 Enhancements:

The revised Quality Assurance (QA) Order includes certain enhancements arising from experience with implementing DOE 5700.6C and other changes that occurred in DOE since the Order was last revised in 1991. We evaluated the requirements in light of key policy initiatives and directives issued since that time, to include DOE P 450.4, 48 CFR 970.1001, 49 CFR 970.5204-2, and DOE G 450.4-1 (all of which address integrated safety management); 10 CFR 830.120 (Price-Anderson Amendments Act quality assurance rule); and DOE M 411.1 (Manual of Safety Management Functions Responsibilities, and Authorities).

Work to update and revise the guidance for this Order and the QA rule (10 CFR 830.120) is also nearing completion. DOE and contractor organizations should consult the guides referenced in the Order to develop and implement QA Programs (QAPs) consistent with the Department's expectations. The latest version of the draft QA Guide, DOE G 414.1-2, is available for review on our Quality and Safety Management Special Interest Group web site, at url: www.orau.gov/qsm. The current approved guide (G-830.120, Rev. 0) is available for use on DOE's directives web site at, url: www.explorer.doe.gov:1776/htmls/otherinfo.html. When approved and issued, DOE G 414.1-2 will supersede G 830.120.

From our evaluation and coordination with user groups, specific improvements have been made to the Order as follows:

- realigned the ten QAP criteria with those of the QA rule;
- strengthened the reference to and requirement to adopt appropriate technical standards in accordance with P.L. 104-113;
- added a responsibility to assign and identify the senior management position responsible for QAP development, approval, and implementation;
- added responsibilities for the Deputy Secretary, Office of Field Management, and the QA Working Group;
- addressed the linkage of quality system requirements of this Order with similar management system requirements from other internal and external sources;
- changed the requirement for the CSO approval of field element quality assurance programs to a review and concurrence: and
- used current organizational titles, roles, and responsibilities.

Recommended Actions for Implementing O 414.1

The Office of Nuclear Safety Policy and Standards (EH-31) recommends DOE and contractor organizations take the following actions to ensure maximum benefit from the management system approach defined in the new QA Order, DOE O 414.1:

- incorporate the contractor requirements document into all major contracts;
- review existing DOE and contractor QAPs to verify they are integrated with the Safety Management System established by DOE Policy, P 450.4;
- review existing DOE and contractor QAPs to verify appropriate national/international standards have been adopted and identified to implement the QAP;
- review DOE and contractor QAPs to verify processes for implementing the Quality Improvement criteria adequately address steps for response, tracking, correction/resolution, reporting, and closure of findings from all sources, including those from external sources (e.g., the DOE Office of Oversight, EH-2, and Federal/state regulators); and
- review DOE and contractor QAPs to verify the senior management position responsible for the QAP is identified.

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