



Department of Energy  
Washington, D.C. 20545

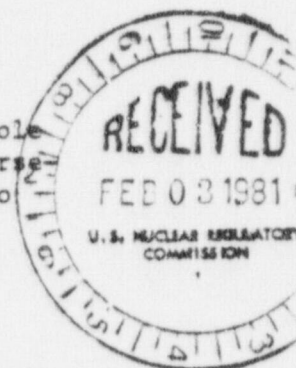
PROPOSED RULE *PR misc matter  
Reg Guide*



MEMORANDUM FOR Secretary of the Commission  
ATTN: Docketing and Service Branch  
U.S. Nuclear Regulatory Commission

We have reviewed the draft regulatory guide FP 029-4, "Standard Format and Content for the Safety Analysis Report for an Independent Spent Fuel Storage Installation (Dry Storage)," dated December 1980. In the area of quality assurance provisions, we find a potential dichotomy between the Department of Energy and the Nuclear Regulatory Commission which should be reconciled.

The draft regulatory guide attached endorses the ANSI N46.2-1978 standard, "Quality Assurance Program Requirements for Post Reactor Fuel Cycle Facilities," as being specifically applicable to an independent spent fuel storage installation (ISFSI). We note, also, that the draft regulatory guide recognizes the existence of other quality assurance standards, such as ANSI/ASME NQA-1-1979, "Quality Assurance Program Requirements for Nuclear Power Plants," which may be applicable in whole or in part to an ISFSI. At this time, we are concerned that the endorsement of ANSI N46.2-1978 standard in this regulatory guide is likely to result in a dichotomy of Department of Energy and contractor quality assurance programs and Nuclear Regulatory Commission standard review plans.



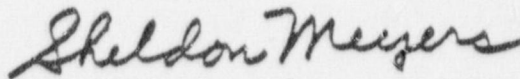
The position of this office, as stated in the attached NE Order 5840, is that ANSI/ASME NQA-1-1979 is the single preferred National consensus standard for the Department's civilian nuclear waste management and reactor programs and projects, including the ISFSI. This position is consistent with the recommendation of the Nuclear Standards Management Board (NSMB) of the American National Standards Institute that there be a single programmatic quality assurance standard--ANSI/ASME NQA-1-1979--for nuclear facilities to implement the NSMB recommendation. Actions have been taken or planned by the American Society of Mechanical Engineers to include additional fuel cycle representatives on the Nuclear Quality Assurance Committee, to change the title and scope of ANSI/ASME NQA-1-1979 from "nuclear power plants" to "nuclear facilities," and to amend the contents of that standard by incorporating appropriate parts of the ANSI N46.2-1978 standard.

The position of this office relative to the application of ANSI/ASME NQA-1-1979 to nuclear waste repositories has been discussed informally in several recent meetings with the Nuclear Regulatory Commission staff who are supportive of this position. In this regard, this office is encouraging and supporting the development of supplementary quality assurance requirements specifically for application in those areas where ANSI/ASME NQA-1-1979 may be either inappropriate or inadequate.

Acknowledged by card... *1/26/81*

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Therefore, it is requested, that for the reasons above, the Commission change its endorsement from ANSI N46.2-1978 to ANSI/ASME NQA-1-1979 for an ISFSI in the draft regulatory guide FP 029-4. Any questions regarding these comments should be addressed to John W. Rowen (353-3169) of my staff.



Sheldon Meyers  
Deputy Assistant Secretary  
for Nuclear Waste Management  
Office of Nuclear Energy

Attachment

cc: D. Reisenweaver, NRC

# U.S. Department of Energy

Washington, D.C.

ORDER

RE-5840

Assistant Secretary for Nuclear Energy

9/15/80

SUBJECT: QUALITY ASSURANCE POLICY FOR NUCLEAR ENERGY

1. PURPOSE. This order sets forth policy, assigns responsibility, and provides guidance for establishing, implementing, and maintaining quality assurance programs in programs and projects within the Office of the Assistant Secretary for Nuclear Energy (ASNE). It constitutes a broadening and strengthening of previous policy statements and related actions on quality assurance for nuclear energy programs and supersedes ETN Directive 5840.1.
2. SCOPE. This order is applicable to ASNE Headquarters elements, and to field and project offices and contractors, including integrated contractors, and other Government agencies, engaged in ASNE programs and projects. It applies to activities affecting quality, including, but not limited to, site characterization, designing, constructing, testing, operating, maintaining, decontaminating and decommissioning of facilities; technology development; production of materials, components, and systems; and acquisition of research, development, and demonstration data on nuclear energy.

For ASNE Naval Reactors quality assurance programs, the Deputy Assistant Secretary for Naval Reactors is responsible for the provisions of Sections 5 and 6 below.

### 3. POLICY

- a. Effective quality assurance programs shall be established, implemented and maintained for ASNE programs and projects with primary emphasis on attaining program and project objectives, recognizing the dependence on consideration of environmental protection, safety, health, performance, reliability, and other important concerns.
- b. Quality assurance programs shall be specified, developed, funded, and managed as integral activities within ASNE programs and projects; provided for in program and project budget and manpower guidance; and responsive to program and project needs and objectives.

### 4. DEFINITION

Quality Assurance comprises all those planned and systematic actions necessary to provide adequate confidence that a facility, structure, system or component will perform satisfactorily in service.

Note that quality assurance means, for example, that activities affecting quality are performed in a controlled manner; that equipment is designed, developed, constructed, tested, operated, and maintained according to sound



engineering standards, quality practices and technical specifications; and that data are valid and protected. 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.

Note, also, that quality assurance is a multidisciplinary system of management controls which addresses safety, reliability, maintainability, operability, performance, and other technical disciplines. Quality assurance is not to be regarded as the sole domain of the Quality Assurance and Standards Division; rather, line organizations should look to that Division as a staff advisory resource in performing their quality assurance activities.

## 5. RESPONSIBILITIES AND AUTHORITIES

Overall responsibility for ASNE quality assurance is vested in the Assistant Secretary and is assigned to ASNE Headquarters, field, and contractor organizations as follows:

### a. Office of Safety, Quality Assurance, and Safeguards

The Director, Office of Safety, Quality Assurance, Standards and Safeguards is assigned lead responsibility for coordination and overview of ASNE quality assurance policy implementation. This assignment shall not diminish in any way the responsibility and authority of ASNE line managers for determining that quality assurance programs are effectively implemented. The Director, Division of Quality Assurance and Standards (QA&S), is designated the focal point for ASNE quality assurance policy coordination and overview. Additionally, the Director, QA&S, shall:

- (1) Provide leadership, guidance, and assistance to Headquarters and field offices, when requested, in developing and implementing improved quality assurance programs, requirements and methods.
- (2) Maintain an independent quality assurance overview of ASNE programs and projects for the Assistant Secretary.
- (3) Perform or assist in quality assurance audits of ASNE programs and projects when requested by the Assistant Secretary or line program management.
- (4) Interface with DOE organizational elements, other Government agencies, and private sector on ASNE quality assurance policies.
- (5) Develop quality assurance training courses to meet the specific needs of ASNE.
- (6) Review and comment on quality assurance aspects of top-level ASNE program and project documents, when requested by the Assistant Secretary or line program management.

(7) Identify generic quality-related issues and problems and recommend corrective actions to responsible ASNE line managements.

(8) Obtain resources for and provide technical direction to a Nuclear Quality Assurance Program Office (NQAPO) through the cognizant field organization for Nuclear Reactor Program tasks; coordinate requests for NQAPO assistance to other headquarters and field organizations with respect to scope of work, availability of personnel, and determination of priorities.

b. ASNE Deputy Assistant Secretaries, Office and Division Directors, and Program Managers shall:

- (1) Define responsibilities and authorities for quality assurance within their organization.
- (2) Provide adequate resources in overall program for quality assurance activities commensurate with ASNE program and project needs.
- (3) Include appropriate provisions for quality assurance in ASNE program and project documents.
- (4) Provide public/private sector programmatic quality assurance liaison.
- (5) Maintain overview and perform audits of quality assurance programs within their assigned areas of responsibilities; coordinate audits with and utilize resources of cognizant field organizations, as appropriate.
- (6) Establish quality assurance management control systems and milestone schedules jointly with field.
- (7) Identify quality-related issues and problems and request corrective actions to be taken by responsible line organizations, when appropriate.
- (8) Coordinate requests for NQAPO assistance with QA&S; provide funding to cover requested scope of work through cognizant field organization.

c. Field Office/Project Managers shall:

- (1) Define responsibilities and authorities for quality assurance within their organization.
- (2) Assure that adequate funding for quality assurance activities is requested to support ASNE programs and projects.
- (3) Review contractor quality assurance policies, programs, and implementing documents and require corrective action where judged that ASNE program and project objectives will not be met.

- (4) Maintain surveillance of contractor quality assurance management controls.
  - (5) Perform audits to verify adequacy and effectiveness of contractor quality assurance programs; coordinate audits with and utilize resources of cognizant ASNE Headquarters organizations, as appropriate.
  - (6) Identify quality-related issues and problems and cause corrective actions to be taken by responsible contractor organizations.
  - (7) Coordinate requests NQAPO assistance with QA&S; provide funding to cover requested scope of work through cognizant field organization.
- d. Contractors engaged in ASNE programs and projects are primarily responsible for the quality of design, construction, production, operation, and data acquisition. Contractors shall:
- (1) Implement and maintain effective quality assurance programs which are responsive to this policy and to specified standards and requirements, or as otherwise deemed necessary to meet program and project needs and objectives.
  - (2) Obtain review of quality assurance policies, programs, and implementing documents by cognizant ASNE line managers on detailed quality assurance programs.
  - (3) Identify significant quality-related issues and problems and take corrective action to minimize recurrence.

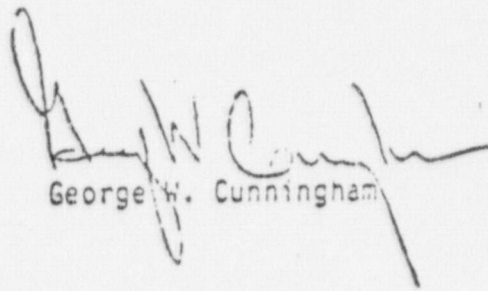
## 6. IMPLEMENTATION GUIDANCE

- a. Except as noted above, quality assurance programs for ASNE civilian programs and projects should be established, implemented, and maintained through the selective and judicious application of existing voluntary consensus standards.
- b. ANSI/ASME N45.2-1977, "Quality Assurance Program Requirements for Nuclear Facilities," has been endorsed by the U.S. Nuclear Regulatory Commission as an acceptable way of complying with the quality assurance criteria of 10 CFR Part 50, Appendix B, 10 CFR Part 60 and 10 CFR Part 70 for safety-related items. A new standard, ANSI/ASME NQA-1-1979, "Quality Assurance Program Requirements for Nuclear Power Plants," is more specific in its requirements, and is to be endorsed by the NRC for new licensed facilities. NQA-1 is preferred to N45.2 for application to licensed, licensable, and unlicensed ASNE facilities and to both safety- and nonsafety-related items that are important to the achievement of ASNE program and project objectives.
- c. Experience indicates that existing voluntary consensus quality assurance standards, such as NQA-1, may not be fully adequate to meet specific ASNE



program and project needs, particularly for research and development and site characterization activities, and should be supplemented by additional documented requirements as determined for the cognizant program or project manager.

- d. Other existing quality assurance program standards, such as RDT F2-2, which were developed for and have been extensively used by contractors for many ASNE programs and projects, should continue to be applied, particularly where procedures have been well established and personnel familiar with their use, and where conversion to another standard would not be cost effective.
- e. For ASNE programs and projects whose scope, complexity, importance, and duration do not warrant application of any of the standards mentioned above, other more suitable quality assurance standards or industry practices may be considered.
- f. Several examples of how quality assurance standards might be applied by reference in top-level ASNE program and project documents are provided in Attachment 1.



George W. Cunningham

GUIDANCE ON REFERENCING QUALITY ASSURANCE PROGRAM STANDARDS

Example 1. Quality Assurance Program Provisions for a Major Facility Contract Statement of Work Article based on NQA-1 Standard

"Establish and implement a Quality Assurance Program for the \_\_\_\_\_ Facility, in accordance with ANSI/ASME NQA-1 as supplemented by NE Standard F2-10, which will provide confidence that products, processes, services and data under the contract are satisfactory for the purpose intended, and that the Facility will perform satisfactorily in service."

Example 2. Quality Assurance Program Provisions for a Major Component Development Contract Statement of Work Article based on RDT F2-2 Standard

"Establish and implement a Quality Assurance Program for the design, development, fabrication and testing of the \_\_\_\_\_ component, in accordance with RDT F2-2, Sections 1 through 5 and 8 and Amendments 1 through 5 which will provide confidence that the component meets specified technical requirements and will perform satisfactorily in service."