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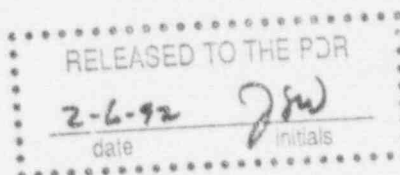
PROPOSED AMENDMENT TO 10 CFR PART 50
QUALITY ASSURANCE CRITERIA FOR NUCLEAR POWER PLANTS

Note by the Secretary

The Director of Regulation has requested that the attached report by the Director of Reactor Standards be circulated for consideration by the Commission at an early date.

W. B. McCool

Secretary



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ATOMIC ENERGY COMMISSION

PROPOSED AMENDMENT TO 10 CFR PART 50
QUALITY ASSURANCE CRITERIA FOR NUCLEAR POWER PLANTS

Report to the Director of Regulation

by the

Director, Division of Reactor Standards

THE PROBLEM

1. To consider the publication for public comment of a proposed amendment to 10 CFR Part 50, "Licensing of Production and Utilization Facilities," which would add an Appendix B, "Quality Assurance Criteria for Nuclear Power Plants." The purpose of the proposed amendment is to establish quality assurance requirements for the design, construction, and operation of those structures, systems, and components of nuclear power plants that prevent or mitigate the consequences of accidents which can cause undue risk to the health and safety of the public. These requirements would apply to all activities during the design, construction, and operating phases of nuclear power plants which affect the safety-related functions of those structures, systems, and components.

BACKGROUND AND SUMMARY

2. Subparagraph 50.34(a)(7) of Part 50 requires applicants for licenses to include in the preliminary safety analysis report a description and evaluation of the quality assurance program to be applied to the design, fabrication, construction, and testing of structures, systems, and components of the facility. Subparagraph 50.34(b)(6) of Part 50 requires that the final safety analysis report contain information concerning measures to be taken to assure safe operation of the facility, including such things as managerial and administrative controls, and plans for

operations and maintenance, surveillance, and periodic testing of structures, systems, and components. In addition, Criterion 1 of the proposed "General Design Criteria for Nuclear Power Plant Construction Permits," which provide guidance in establishing the principal design criteria for nuclear power plants (proposed Appendix A of Part 50), requires a program to assure that those systems and components of reactor facilities which are essential to the prevention of accidents which could affect the public health and safety, or to mitigation of their consequences, shall be designed, fabricated, and erected to quality standards that reflect the importance of the safety functions to be performed.

3. In order to assist applicants and licensees in the development and implementation of the necessary quality assurance programs, the regulatory staff has developed the quality assurance criteria in the proposed Appendix B in cooperation with the staff of the Division of Reactor Development and Technology. The development of these criteria has taken into account the experience accumulated to date in designing, constructing, and operating licensed nuclear power plants and Commission-owned reactors. In addition, the quality assurance requirements developed and used for work under the cognizance of the Department of Defense and the National Aeronautics and Space Administration were considered in developing the proposed AEC criteria in order to take advantage of the experience of these organizations.

4. The proposed criteria would apply to all structures, systems, and components of nuclear power plants that prevent or mitigate the consequences of accidents which can cause undue risk to public health and safety. They would apply to all activities affecting the safety-related functions of these structures, systems, and components throughout the design, construction, and operation phases. Specific activities covered in these phases include

designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, refueling, maintaining, repairing, and modifying. As used in the criteria, quality assurance comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, component, or system will perform satisfactorily in service.

STAFF JUDGMENTS

5. The Divisions of Reactor Licensing, Compliance, Operational Safety, Reactor Development and Technology, and the Office of the General Counsel concur in the recommendation of this paper. The ACRS has reviewed and concurs in publication of the proposed criteria. The draft public announcement was prepared by the Division of Public Information. The Office of Congressional Relations concurs in the draft letter to the Joint Committee on Atomic Energy.

RECOMMENDATION

6. The Director of Regulation recommends that the Atomic Energy Commission:

a. Approve publication of the proposed "Quality Assurance Criteria for Nuclear Power Plants" allowing 60 days for public comment. The purpose of the proposed criteria, which would be an amendment to 10 CFR Part 50 in the form contained in Appendix "A", is to provide quality assurance requirements for the design, construction, and operation of those structures, systems, and components of nuclear power plants that prevent or mitigate the consequences of accident which can cause undue risk to the health and safety of the public. These requirements would apply to all activities during the design, construction, and operating phases of nuclear power plants which affect the safety-related functions of those structures, systems, and components;

b. Note that the Advisory Committee on Reactor Safeguards concurs in publishing the proposed amendment to Part 50 for comment;

c. Note that the Joint Committee on Atomic Energy will be informed by letter such as Appendix "B"; and

d. Note that a public announcement such as Appendix "C" will be issued on filing of the notice with the Federal Register.

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ATOMIC ENERGY COMMISSION

[10 CFR Part 50]

LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

Quality Assurance Criteria for Nuclear Powerplants

The Atomic Energy Commission has under consideration an amendment to its regulation, 10 CFR Part 50, "Licensing of Production and Utilization Facilities," which would add an Appendix B, "Quality Assurance Criteria for Nuclear Power Plants." Nuclear powerplants include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. The purpose of the proposed amendment is to provide quality assurance requirements for the design, construction, and operation of these structures, systems, and components. These requirements apply to all activities during the design, construction, and operating phases of nuclear powerplants which affect the safety-related functions of such structures, systems, and components.

The development of these criteria has taken into account cooperative Atomic Energy Commission-industry efforts on quality assurance requirements, the experience accumulated in designing, constructing, and operating licensed nuclear powerplants and Commission-owned reactors, and the quality assurance programs required for work under the cognizance of the Department of Defense and the National Aeronautics and Space Administration.

The quality assurance requirements established by these criteria are intended to assure that:

(a) Applicable regulatory requirements and the design bases, as defined in § 50.2 and as specified in the license application, for structures, systems, and components are correctly translated into specifications, drawings, procedures, and instructions.

(b) Systems and components fabricated and tested in manufacturers' facilities conform to these specifications, drawings, procedures, and instructions.

ATOMIC ENERGY COMMISSION

[10 CFR Part 50]

**LICENSING OF PRODUCTION AND
UTILIZATION FACILITIES****Quality Assurance Criteria for
Nuclear Powerplants**

The Atomic Energy Commission has under consideration an amendment to its regulation, 10 CFR Part 50, "Licensing of Production and Utilization Facilities," which would add an Appendix B, "Quality Assurance Criteria for Nuclear Power Plants." Nuclear powerplants include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. The purpose of the proposed amendment is to provide quality assurance requirements for the design, construction, and operation of these structures, systems, and components. These requirements apply to all activities during the design, construction, and operating phases of nuclear powerplants which affect the safety-related functions of such structures, systems, and components.

The development of these criteria has taken into account cooperative Atomic Energy Commission-industry efforts on quality assurance requirements, the experience accumulated in designing, constructing, and operating licensed nuclear powerplants and Commission-owned reactors, and the quality assurance programs required for work under the cognizance of the Department of Defense and the National Aeronautics and Space Administration.

The quality assurance requirements established by these criteria are intended to assure that:

(a) Applicable regulatory requirements and the design bases, as defined in § 50.2 and as specified in the license application, for structures, systems, and components are correctly translated into specifications, drawings, procedures, and instructions.

(b) Systems and components fabricated and tested in manufacturers' facilities conform to these specifications, drawings, procedures, and instructions.

(c) Structures, systems, and components constructed and tested at the nuclear powerplant site conform to these specifications, drawings, procedures, and instructions.

(d) Succeeding activities, such as operating, testing, refueling, repairing, maintaining, and modifying nuclear powerplants, are conducted in accordance with quality assurance practices consistent with those employed during design and construction. In addition to the requirement that operating activities be conducted in accordance with these quality assurance practices, there are other requirements which must be suitably developed and observed to assure safe operation; for example, technical specifications, schedules of maintenance and refueling, fuel management programs, and programs for operator training and qualification.

These quality assurance criteria would supplement Criterion 1 of the "General Design Criteria for Nuclear Power Plant Construction Permits."¹ They are intended to assist applicants (1) to comply with § 50.34(a)(7) which requires inclusion in the preliminary safety analysis report of a description and evaluation of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility, and (2) in the development of managerial and administrative controls to be used to assure safe operation, as required by § 50.34(b)(6)(ii). Specific references to the proposed Appendix B, "Quality Assurance Criteria for Nuclear Power Plants," would be added to § 50.34 (a) and (b).

These criteria will also be used for guidance in evaluating the adequacy of the quality assurance programs in use by holders of construction permits and operating licenses.

Pursuant to the Atomic Energy Act of 1954, as amended, and section 553 of title 5 of the United States Code, notice is hereby given that adoption of the following amendments to 10 CFR Part 50 is contemplated. All interested persons who wish to submit comments or suggestions in connection with the proposed amendments should send them to the Secretary, U.S. Atomic Energy Commission, Washington, D.C. 20545, Attention: Chief, Public Proceedings Branch, within 60 days after publication of this notice in the FEDERAL REGISTER. Copies of comments received may be examined in the Commission's Public Document Room at 1717 H Street NW., Washington, D.C.

1. In § 50.34, paragraphs (a)(7) and (b)(6)(ii) are amended to read as follows:

§ 50.34 Contents of applications: technical information.

(a) *Preliminary safety analysis report.* Each application for a construction permit shall include a preliminary safety analysis report. The minimum informa-

¹ The General Design Criteria were published for public comment as a proposed amendment to 10 CFR Part 50 in the FEDERAL REGISTER on July 11, 1967 (32 F.R. 10213).

tion² to be included shall consist of the following:

(7) A description and evaluation of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Appendix B, "Quality Assurance Criteria for Nuclear Power Plants," sets forth the requirements for quality assurance programs for nuclear power plants.

(b) *Final safety analysis report.* Each application for a license to operate a facility shall include a final safety analysis report. The final safety analysis report shall include information that describes the facility, presents the design bases, and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility as a whole, and shall include the following:

(6) The following information concerning facility operation:

(ii) Managerial and administrative controls to be used to assure safe operation. Appendix B, "Quality Assurance Criteria for Nuclear Power Plants," sets forth the requirements for such controls for nuclear powerplants.

2. A new Appendix B is added to read as follows:

APPENDIX B—QUALITY ASSURANCE CRITERIA FOR NUCLEAR POWERPLANTS

Introduction. Every applicant for a construction permit is required by the provisions of § 50.34 to include in its preliminary safety analysis report a description and evaluation of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Every applicant for an operating license is required to include, in its final safety analysis report, information pertaining to the managerial and administrative controls to be used to assure safe operation. Nuclear powerplants include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix establishes quality assurance requirements for the design, construction, and operation of those structures, systems, and components. These requirements apply to all activities affecting the safety-related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

As used in this appendix, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

The applicant may provide information required by this paragraph in the form of a discussion, with specific references, of similarities to and differences from facilities of similar design for which applications have previously been filed with the Commission.

Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

I. ORGANIZATION

The applicant³ shall be responsible for the development, implementation, and execution of the quality assurance program. The applicant may delegate to other organizations the establishment and execution of the quality assurance program, or any part thereof, but shall retain responsibility therefor. The authority and duties of persons and organizations performing quality assurance functions shall be clearly established and delineated in writing. Such persons and organizations shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. In general, assurance of quality requires management measures which provide that the individual or group assigned the responsibility for checking, auditing, inspecting, or otherwise verifying that an activity has been correctly performed is independent of the individual or group directly responsible for performing the specific activity. The applicant shall regularly review the status and adequacy of the quality assurance program. Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.

II. QUALITY ASSURANCE PROGRAM

The applicant shall establish at the earliest practical time a quality assurance program which complies with the requirements of this appendix. This program shall be documented by written policies, procedures, and instructions and shall be carried out throughout plant life. The applicant shall identify the structures, systems, and components to be covered by the quality assurance program and the major organizations participating in the program, together with their designated functions. The quality assurance program shall provide control, by means such as design review, verification, inspection, and documentation, over activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety. Activities affecting quality shall be accomplished under this program in accordance with instructions, procedures, or drawing of a type appropriate to the circumstances and under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable working environment, adequate cleanliness, and assurance that all prerequisites for the given operation have been satisfied. The program shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality; the need for verification of quality by inspection and test; and the need for indoctrination and training of personnel to execute the program.

³ While the term "applicant" is used in these criteria, the requirements are, of course, applicable to such a person as has received a license to construct and operate a nuclear powerplant. These criteria will also be used for guidance in evaluating the adequacy of quality assurance programs in use by holders of construction permits and operating licenses.

III. DESIGN CONTROL

Measures shall be established to assure that applicable regulatory requirements and the design basis, as defined in § 50.2 and as specified in the license application, for those structures, systems, and components to which this appendix applies are correctly translated into specifications, drawings, procedures, and instructions. These measures shall provide for the performance of design reviews by individuals or groups other than those who performed the original design, but who may be from the same organization. In addition to verification of the design, the applicant shall be responsible for assuring that the design is correctly described in the license application and that the contents of the safety analysis reports are accurate. Design reviews shall cover items such as the following: reactor physics, stress, thermal, hydraulic, and accident analysis; compatibility of materials and of design interfaces; accessibility for inservice inspection, maintenance, and repair; and delineation of acceptance criteria for inspections and tests. Reports of in-process and final design reviews shall be reviewed by management of the responsible design organizations. Design changes, including field changes, shall be approved by the organization that performed the original design unless the applicant specifically designates another responsible organization. Procedures shall be established among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

IV. PROCUREMENT DOCUMENT CONTROL

Measures shall be established to assure that applicable regulatory requirements, design bases, and other requirements which are necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the applicant or by its contractors or subcontractors. To the extent necessary, procurement documents shall require contractors or subcontractors to provide a quality assurance program consistent with the quality assurance requirements of this appendix.

V. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances. Instructions, procedures, and drawings shall include appropriate quantitative or qualitative means for determining that important operations have been satisfactorily accomplished.

VI. DOCUMENT CONTROL

Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe all activities affecting quality. These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval unless the applicant specifically designates another responsible organization.

VII. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

Measures shall be established to assure that all purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for

source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery. The effectiveness of the control of quality by contractors and subcontractors shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services. Test reports, inspection records, audit reports, certificates, and other evidence of quality shall be used in this assessment, and corrective action shall be taken where indicated.

VIII. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

Measures shall be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures shall assure that identification is maintained, either on the item or on records traceable to the item, throughout fabrication, erection, installation, repair, or modification. The measures shall be designed to prevent the use of incorrect or defective items, and items which have not received the required inspections and tests.

IX. CONTROL OF SPECIAL PROCESSES

Measures shall be established to assure that special processes including welding, heat treating, and nondestructive testing, are controlled in accordance with applicable codes, standards, specifications, criteria, and other special requirements, and are accomplished by qualified personnel using qualified procedures.

X. INSPECTION

A program for in-process and final inspection of activities affecting quality shall be established to assure conformance with documented instructions, procedures, and drawings. Examinations, measurements, or tests of material or products processed shall be performed for each work operation where necessary to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel shall be provided. Both inspection and process monitoring shall be provided when control is inadequate without both. Mandatory inspection hold points, which require witnessing or inspecting by the applicant's designated representative and beyond which work shall not proceed without the consent of its designated representative, shall be indicated in appropriate documents.

XI. TEST CONTROL

A test program shall be established to assure that all required testing, including proof testing, acceptance testing, and operational testing, is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents. The test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions. Test results shall be documented and evaluated to assure that test requirements have been satisfied.

XII. CALIBRATION OF MEASUREMENT AND TEST EQUIPMENT

Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are calibrated and properly adjusted at specified periods to maintain accuracy within necessary limits. Calibration shall be against certified measurements and-

ards which have known valid relationships to national standards.

XIII. HANDLING, STORAGE, SHIPPING, AND PRESERVATION

Measures shall be established to provide work and inspection instructions for handling, storage, shipping, and preservation of material and equipment to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmospheres, specific moisture content levels, and temperature levels, shall be provided and their existence verified.

XIV. INSPECTION, TEST, AND OPERATING STATUS

Measures shall be established to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items and the status of plant operating equipment. These measures shall provide for the identification of those items which conform to inspection and test requirements; nonconforming items shall be clearly marked for subsequent disposition. Procedures shall be provided for tagging equipment such as valves and switches when necessary to prevent inadvertent operation.

XV. NONCONFORMING MATERIAL, PARTS, OR COMPONENTS

Measures shall be established to control material, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures shall include procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items shall be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures. Ultimate disposition of nonconforming items shall be documented.

XVI. CORRECTIVE ACTION

Measures shall be established to assure that all conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and reported to appropriate levels of management. The measures shall also assure that the cause of the condition adverse to quality be determined and corrected to preclude repetition. The corrective action measures shall extend to the performance of all contractors and subcontractors as necessary. The identification of conditions adverse to quality, the cause of the condition, and the corrective action taken shall be documented.

XVII. QUALITY ASSURANCE RECORDS

Records shall be maintained sufficient to furnish documentary evidence of activities affecting quality for use in the management of the program. The records shall include, but not be limited to, construction and operating logs, and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.

XVIII. AUDITS

A comprehensive system of planned and periodic audits shall be carried out to assure compliance with all aspects of the quality assurance program and to determine the

effectiveness of the program. The audits shall be performed in accordance with written procedures or check lists by appropriately qualified personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Followup action, including re-audit of deficient areas, shall be taken where indicated.

(Sec. 161, 68 Stat. 943; 42 U.S.C. 2201).

Dated at Washington, D.C., this 14th day of April 1969.

For the Atomic Energy Commission.

W. B. McCool,
Secretary.

[F.R. Doc. 69-4591, Filed, Apr. 16, 1969;
8:42 a.m.]