May 2[illegible]

NUCLEAR REGULATORY COMMISSION

[10 CFR Part 50]

QUALITY ASSURANCE REQUIREMENTS FOR NUCLEAR POWER PLANT ITEMS WHICH ARE IMPORTANT TO SAFETY

AGENCY: U.S. Nuclear Regulatory Commission

ACTION: Proposed Rule

SUMMARY: The Nuclear Regulatory Commission is proposing to amend its regulations to clarify the quality assurance program requirements for those structures, systems and components of nuclear power plants which are important to safety.

DATES: Comment period expires [60 days after notice in the FEDERAL REGISTER].

ADDRESSES: Interested persons are invited to submit written comments and suggestions on the proposal and/or the supporting value/impact analysis to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Single copies of the value/impact analysis may be obtained on request from S. D. Richardson, Office of Standards Development, U.S. Nuclear Regulatory Commission, telephone (301) 443-5913. Copies of comments received by the Commission may be examined in the Commission's Public Document Room at 1717 H. Street, NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT:

S. D. Richardson, Office of Standards Development
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555 or telephone (301) 443-5913

SUPPLEMENTARY INFORMATION: Appendix A, "General Design Criteria for Nuclear Power Plants," to 10 CFR Part 50 establishes requirements for structures, systems, and components important to safety; that is, structures, systems, and components that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public. Criterion 1 of these general design criteria, "Quality Standards and Records," requires that a quality assurance program be established and implemented in order to provide adequate assurance that those structures, systems, and components will satisfactorily perform their safety functions.

Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50 establishes quality assurance requirements for the design, construction, and operation of certain structures, systems, and components; namely, those that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. When these quality assurance criteria were published for comment on April 17, 1969 (34 FR 6599), the Statement of Considerations noted that they would supplement Criterion 1 of the General Design Criteria. To the knowledge of the NRC staff, this intended relationship between the quality assurance program specified in Criterion 1 of the General Design Criteria and the quality assurance requirements established in Appendix B to 10 CFR Part 50 has

not been fully implemented. Therefore, the extent of implementation by applicants and licensees of the quality assurance requirements of Appendix B for a number of nuclear power plant structures, systems, and components is unknown to the NRC staff and may have resulted in potentially inadequate quality assurance requirements for the design, construction, and operation of a number of structures, systems, and components important to safety. Typical examples of structures, systems, and components for which the Appendix B quality assurance program criteria may not have been fully implemented are in-core instrumentation, reactor coolant pump motors, reactor coolant pump power cables and radioactive waste system pumps, valves and storage tanks.

Although it was recognized in developing both Appendix A and Appendix B that some structures, systems, and components are more important to safety than others and, therefore, that it is not appropriate that all structures, systems, and components which perform a safety function have the same quality assurance measures applied, the practice during design and construction of nuclear power plants in many cases is to apply the same quality assurance requirements to all structures, systems, or components to which Appendix B applies. This was never the intent of either Appendix A or Appendix B. A graded approach to application of quality assurance requirements is specified in Criterion 1 of Appendix A which states, "Structures, systems, and components important to safety shall be designed, fabricated, erected, and tested to quality standards commensurate with the safety functions to be performed," (emphasis added) and in Criterion II of Appendix B which states, "The quality assurance program shall provide control over activities affecting the quality of the identified structures,

systems, and components [illegible] consistent with their importance to safety." (emphasis added) Despite the specification of a graded approach, the tendency has been to impose a "full blown" quality assurance program for some structures, systems, and components important to safety while requiring no special quality assurance controls for others. This has resulted in a more narrow definition of the structures, systems, and components that come under the quality assurance program requirements of Appendix B than was intended.

To correct the lack of a clear statement in the regulations of the applicability of the quality assurance criteria of Appendix B to the structures, systems, and components important to safety covered in Appendix A, a clarifying amendment is proposed to Criterion 1 of Appendix A. This proposed amendment would specifically state that the criteria for the quality assurance program required by the Appendix A, "General Design Criteria for Nuclear Power Plants," Criterion I, are those criteria contained in Appendix B. Additionally, it is the staff's intent to develop more detailed guidance, in Regulatory Guides, as necessary for determining the extent of quality assurance requirements to be applied to specific structures, systems and components which are important to safety. Both the proposed amendment and any additional guidance developed will be used to evaluate the quality assurance programs of both applicants and holders of construction permits and operating licenses for nuclear power plants.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Section 553 of Title 5 of the United States Code, notice is hereby given that adoption of the following

amendment to 10 CFR Part 50 is contemplated. All interested persons are invited to submit written comments or suggestions for consideration on the proposed amendment and/or the supporting value/impact analysis to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, by [60 days after notice in the FEDERAL REGISTER]. Single copies of the value/impact analysis may be obtained on request from S. D. Richardson, Office of Standards Development, U.S. Nuclear Regulatory Commission, telephone (301) 443-5913. Copies of comments received on the amendment proposed and the value/impact statement may be examined in the Commission's Public Document Room at 1717 H. Street, N.W., Washington, D.C. between 8:15 a.m. and 5:00 p.m.

PART 50 - DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. Appendix A to 10 CFR Part 50 is revised to read as follows:

Criterion 1 Quality standards and records

* * * * *

A quality assurance program in accordance with the criteria of Appendix B to 10 CFR Part 50 shall be established and implemented in order to provide adequate assurance that these structures, systems and components will satisfactorily perform their safety functions.

* * * * *

Authority: Sec. 161, as amended, Pub. L 83-703, 68 Stat. 948 (42 U.S.C. 2201); sec. 201, as amended, Pub. L. 93-438, 88 Stat. 1242 (42 U.S.C. 5841).

Dated at_____this_____day of_____, 19__.

For the Nuclear Regulatory Commission.

_____

Preliminary Value Impact Assessment for Revision to 10 CFR Part 50, Appendix A, Concerning Applicability of the Quality Assurance Criteria of 10 CFR Part 50, Appendix B, to the Quality Assurance Program Required by Appendix A.

## I. The Proposed Action

### A. Description

The proposed action is to initiate rulemaking to revise Appendix A to 10 CFR Part 50 to state that the criteria for the quality assurance program required by Appendix A (Criterion 1) are those criteria listed in Appendix B to 10 CFR Part 50. Subsequent to initiation of the proposed action, separate action will be initiated as necessary to provide additional guidance through a Regulatory Guide or Guides on the extent of quality assurance requirements to be applied to specific nuclear power plant structures, system and components which are considered important to safety.

### B. Need for Proposed Action

NUREG-0321, "A Study of the Nuclear Regulatory Commission Quality Assurance Program," dated August 1977, which was prepared by Sandia Laboratories, states on page 26 that "Appendix B to 10 CFR 50 is not used in the regulation of several areas whose importance to safety has been acknowledged by the NRC by issuing specific regulations and prescribing inspection." A specific example of one of these areas noted by NUREG-0321 is the handling of spent fuel and radioactive waste, the requirements for which are contained in Criteria 61, 62 and 63 of Appendix A to 10 CFR Part 50. Additionally, one NSSS

supplier has recently identified a number of plant systems (heretofore not identified as important to safety by licensees) for which environmental qualification as required by Appendix A and confirmed by Appendix B was not performed; but which if subjected to an adverse environment could potentially lead to control system operation that may challenge these plants' protection systems beyond their design bases.

As noted in the statement of considerations when the Appendix B criteria were published for comment (see Attachment 1), the criteria of Appendix B supplement criterion 1 of Appendix A. However, this intended relationship has not been consistently applied. Accordingly, there has been inconsistent treatment with regard to which of the various nuclear power plant structures, systems, and components should come under the quality assurance program requirements of Appendix B. This has resulted in potentially inadequate quality assurance requirements for the design, fabrication and operation of some structures, systems, and components important to safety. Typical examples of structures, systems, and components for which the Appendix B quality assurance program criteria have not been consistently implemented are in-core instrumentation, reactor coolant pump motors, reactor coolant pump power cables, and radioactive waste system pumps, valves and storage tanks.

Although it was recognized in developing both Appendix A and Appendix B that some structures, systems, and components are more important to safety than others and, therefore, that it is not appropriate that all structures, systems, and components which perform a

safety function have the same quality assurance measures applied, the practice during design and construction of nuclear power plants in many cases is to apply the same quality assurance requirements to all structures, systems, or components to which Appendix B applies. This was never the intent of either Appendix A or Appendix B. A graded approach to application of quality assurance requirements is specified in Criterion 1 of Appendix A which states, "Structures, systems, and components important to safety shall be designed, fabricated, erected, and tested to quality standards commensurate with the safety functions to be performed," (emphasis added) and in Criterion II of Appendix B which states, "The quality assurance program shall provide control over activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety." (emphasis added)

A graded approach has been used for application of quality assurance requirements in the procurement of some equipment and material for nuclear power plants. For example, the quality assurance requirements imposed on suppliers of diesel generators are limited when the supplier has a demonstrated history of reliability based on the ability to assure satisfactory operation by means of pre-operational and periodic testing. However, this practice is not followed for most design and site-construction related activities. In many cases, it appears that the practice has been to apply the same controls to any structure, system, or component which was included in the quality assurance program (i.e., included in the "Q" list) and to consider that no quality assurance controls need be applied for the structures,

systems, or components outside the program. Despite the specification of a graded approach the tendency has been to impose a "full blown" quality assurance program for some structures, systems, and components important to safety while requiring no special quality assurance controls for others. This has resulted in a more narrow definition of the structures, systems, and components that come under the quality assurance program requirements of Appendix B than was intended.

Previous attempts to resolve the confusion by means of the issuance of a Regulatory Guide have resulted in numerous drafts of the guide which all failed to obtain staff approval. In response to a request for OELD opinion concerning the relationship between Appendix A and Appendix B, OELD (Jakel) stated in a memorandum dated July 25, 1978, that "Appendices A and B to Part 50 became effective May 21, 1971 and July 27, 1970, respectively. Obviously there has been no consistent administrative construction of the scope and relationship of these Appendices to each other." This relationship of Appendices A and B needs to be urgently clarified to ensure application of the appropriate quality assurance program requirements to each structure, system, and component important to safety for both operating and planned nuclear power plants.

C. Value/Impact of the Proposed Action

1. NRC

a. Value - The proposed action will provide guidance to the staff and clarify the staff's authority to ensure that the appropriate quality assurance program requirements are implemented for structures, systems and components important

to safety as required by Appendix A both during the operating license or construction permit review process and during operation of the plant.

b. Impact - The proposed action will represent on a case-by-case basis an increase in the review of the extent of the quality assurance requirements applied to specific nuclear power plant structures, systems, and components.

2. Other Government Agencies - Not applicable unless the government agency is an applicant, such as TVA.

3. Industry

a. Value - The proposed action will establish a clear requirement for the industry that a quality assurance program, consistent with the criteria of Appendix B, be established and implemented for the identified structures, systems and components important to safety in fulfillment of Criterion 1 of Appendix A.

b. Impact - The extent of the review of applicability of quality assurance requirements to those structures, systems, and components discussed in Appendix A will be increased with the potential for increased quality assurance requirements being applied. It is not proposed that quality assurance requirements for activities already completed be upgraded in accordance with the proposed action.

4. Public

a. Value - Clarification of the quality assurance requirements to be applied to the structures, systems, and components

of Appendix A should result in more attention paid to the quality of the structures, systems, and components of Appendix A, thus resulting in increased plant safety and reliability.

b. Impact - Due to potential for additional quality assurance requirements being applied, some of the costs associated with application of these quality assurance requirements could be paid by the public.

5. Workers (Relative to ALARA) Not applicable.

D. Decision on of the Proposed Action

Requirements should be provided which clarify the quality assurance program requirements of Appendix A to 10 CFR Part 50.

II. Technical Approach

Not applicable to this value/impact assessment since the proposed action does not address technical alternatives.

III. Procedural Approach

A. Procedural Alternatives

Potential procedures that could be used to clarify requirements concerning quality assurance requirements of those structures, systems, and components discussed in Appendix A to 10 CFR Part 50 are the following:

- Regulation
- Regulatory Guide
- Branch Position
- NUREG

Previous staff efforts to promulgate a Regulatory Guide that would clarify the relationship of Appendices A and B resulted in numerous drafts of the proposed Regulatory Guide all of which failed to obtain staff approval. In a memorandum dated July 19, 1979, the Office of Nuclear Reactor Regulation (W. P. Haass) pointed out that an inherent weakness of the proposed Regulatory Guide approach was that the guide proposed to resolve the confusion surrounding the relationship of Appendices A and B by itself without a corresponding change in regulations. As a result, the Interoffice Quality Assurance Task Force has requested the proposed change to Appendix A.

B. Selection of Procedural Alternative

The purpose of the proposed action is to provide clarification of the requirements of Appendix A and therefore a revision to Appendix A has been selected as the proper procedural approach.

IV. Statutory Consideration

A. NRC Authority

This rulemaking would fall under the authority and safety requirements of the Atomic Energy Act. In particular, Criterion I of Appendix A to 10 CFR Part 50 requires that a quality assurance program be established and implemented in order to assure that the structures, systems, and components discussed in Appendix A will satisfactorily perform their safety function.

B. Need for NEPA Assessment

The proposed action is not a major action, as defined by 10 CFR Part 51.5(a)(10), and does not require an environmental impact statement.

.. Relationship to Other Existing or Proposed Regulations or Policies

No conflicts or overlaps with requirements promulgated by other agencies are foreseen. As discussed in Section I.B., the proposed action is intended to resolve a conflict in interpretation of the relationship between Appendices A and B to 10 CFR Part 50.

VI. Summary and Conclusions

A revision to Appendix A of 10 CFR Part 50 should be prepared to state that the criteria for the quality assurance program required by Appendix A are those criteria listed in Appendix B to 10 CFR Part 50.

[illegible] day of the calendar month during which the market administrator received the handler's utilization report on milk involved in such obligation, unless within such 2-year period the market administrator notifies the handler in writing that such money is due and payable. Service of such notice shall be complete upon mailing to the handler's last known address, and it shall contain, but need not be limited to, the following information:

(1) The amount of the obligation;

(2) The month(s) during which the milk, with respect to which the obligation exists, was received or handled; and

(3) If the obligation is payable to one or more producers or to an association of producers, the name of such producer(s) or association of producers, or if the obligation is payable to the market administrator, the account for which it is to be paid.

(b) If a handler fails or refuses, with respect to any obligation under this part, to make available to the market administrator or his representative all books and records required by this order to be made available, the market administrator may, within the 2-year period provided for in paragraph (a) of this section, notify the handler in writing of such failure or refusal. If the market administrator so notifies a handler, the said 2-year period with respect to such obligation shall not begin to run until the first day of the calendar month following the month during which all such [illegible]s and records pertaining to such [illegible]gation are made available to the market administrator or his representatives.

(c) Notwithstanding the provisions of paragraphs (a) and (b) of this section, a handler's obligation under this part to pay money shall not be terminated with respect to any transaction involving fraud or willful concealment of a fact, material to the obligation, on the part of the handler against whom the obligation is sought to be imposed.

(d) Any obligation on the part of the market administrator to pay a handler any money which such handler claims to be due him under the terms of this part shall terminate 2 years after the end of the calendar month during which the milk involved in the claim was received if an underpayment is claimed, or 2 years after the end of the calendar month during which the payment (including deduction or set-off by the market administrator) was made by the handler if a refund on such payment is claimed, unless such handler within the applicable period of time, files pursuant to section 8c(15)(A) of the act, a petition claiming such money.

EFFECTIVE TIME, SUSPENSION OR TERMINATION

§ 1079.90 Effective time.

The provisions of this part, or any amendments to this part, shall become effective at such time as the Secretary may declare, and shall continue in force until suspended or terminated pursuant to § 1079.91.

§ 1079.91 Suspension or termination.

The Secretary may suspend or terminate any or all of the provisions of this part, whenever he finds that it obstructs or does not tend to effectuate the declared policy of the act. This part shall, in any event, terminate whenever the provisions of the act authorizing it cease to be in effect.

§ 1079.92 Continuing power and duty of the market administrator.

(a) If, upon the suspension or termination of any or all of the provisions of this part, there are any obligations arising under this part, the final accrual or ascertainment of which requires further acts by any handler, by the market administrator, or by any other person, the power and duty to perform such further acts shall continue notwithstanding such suspension or termination: *Provided*, That any such acts required to be performed by the market administrator shall if the Secretary so directs, be performed by such other person, persons, or agency as the Secretary may designate.

(b) The market administrator, or such other person as the Secretary may designate shall (1) continue in such capacity until discharged by the Secretary; (2) from time to time account for all receipts and disbursements and deliver all funds or property on hand together with the books and records of the market administrator or such person, to such person as the Secretary shall direct; and (3) if so directed by the Secretary execute such assignments or other instruments necessary or appropriate to vest in such person full title to all funds, property, and claims vested in the market administrator or such person pursuant thereto.

§ 1079.93 Liquidation after suspension or termination.

Upon the suspension or termination of any or all provisions of this part the market administrator or such person as the Secretary may designate, shall if so directed by the Secretary, liquidate the business of the market administrator's office and dispose of all funds and property then in his possession or under his control, together with claims for any funds which are unpaid or owing at the time of such suspension or termination. Any funds collected pursuant to the provisions of this part over and above the amounts necessary to meet outstanding obligations and the expenses necessarily incurred by the market administrator or such person in liquidating such funds, shall be distributed to the contributing handlers and producers in an equitable manner.

MISCELLANEOUS PROVISIONS

§ 1079.100 Separability of provisions.

If any provision of this part, or its application to any person or circumstances, is held invalid, the application of such provision, and of the remaining [illegible] the United States to act as the agent of representative [illegible] the provisions of this part.

Signed at Washington, D.C., on April 14, 1959.

JOHN C. BLUM,
*Deputy Administrator,*
*Regulatory Programs.*

[F.R. Doc. 59-4581; Filed, Apr. 16, 1959; 8:51 a.m.]

# 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.

[illegible] such as [illegible] 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).

• • • • •

(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.

[illegible] item which provides a means to control the quality of the material, structure, component, or system to predetermined requirements.

I. ORGANIZATION

The applicant[1] 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 drawings of a type appropriate to the circumstances and under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable working environment, adequate calibration 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 personnal to execute the program.

[1] While the term "applicant" is used in these criteria, the requirements are, of course, applicable after such a person 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.

[1] 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.

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 analyses; compatibility of materials and of design interfaces; accessibility for in-service 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 measurement stand-

XIII. HANDLING, STORAGE, AND PRESERVATION

Measures shall be established for 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

indicated.

(Sec. 161, 68 Stat. 948; 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; 8:53 a.m.]

# FEDERAL MARITIME COMMISSION

[ 46 CFR Part 527 ]

[Docket No. 69-15]

## SHIPPERS' REQUESTS AND COMPLAINTS

### Proposed Reporting Requirements

Section 527.4 of General Order 14 (46 CFR Part 527) presently requires each conference and each other body with rate-fixing authority under an approved agreement to file with the Commission by January 31, April 30, July 31 and October 31 of each year a report covering all shippers' requests and complaints received during the preceding 3-month period or pending at the beginning of such period, such report to include certain detailed information further identified in paragraphs (a) to (f) of § 527.4 inclusive.

After a period of more than 3 years of receipts of these reports from parties to rate-making agreements, it has become well established that the continuation of the requirement of quarterly reports of shippers' requests and complaints insofar as two party rate-fixing agreements are concerned may be unnecessarily burdensome. The number of shippers' requests and complaints actually processed pursuant to these two party agreements over a 3-year period has been so minimal as to have little significant effect on the regulatory purposes to be served. To keep the Commission informed in those instances which do arise, it is proposed that the reporting requirement be changed from quarterly to annual.

Therefore, pursuant to section 4 of the Administrative Procedure Act (5 U.S.C. 553) and sections 15, 21, and 43 of the Shipping Act, 1916 (46 U.S.C. 814, 820, and 841(a)), notice is hereby given that the Commission proposes to amend Part 527 of 46 CFR, to change the reporting requirements of General Order 14 from quarterly to annual, for all two party rate-fixing agreements. It is proposed that Part 527 be amended by adding at the end of § 527.4 thereof the following sentences:

§ 527.4 *Reports.*

* * * Any group with rate-fixing authority under an approved agreement [illegible] annual reports shall be filed by January 31 of each year covering all shippers' requests and complaints received during the preceding calendar year or pending at the beginning of such calendar year.

Interested persons may participate in this rulemaking proceeding by filing with the Secretary Federal Maritime Commission, Washington, D.C. 20573, within ten (10) days of publication of this notice in the FEDERAL REGISTER, an original and fifteen (15) copies of their views or comments pertaining to the proposed rule. Any suggestions for changes in the proposed rule should be supported by statements relating the proposed change to the purposes of section 15 of the Shipping Act, 1916, and General Order 14, of the Commission's rules.

The Federal Maritime Commission, Office of Hearing Counsel, shall participate in the proceeding and shall file Reply to Comments within ten (10) days from the final date for filing comments by serving an original and 15 copies on the Federal Maritime Commission and one copy to each party who filed comments. Answers to Hearing Counsels' replies shall be submitted to the Federal Maritime Commission within 10 days of the final date for filing replies.

By the Commission.

[SEAL] THOMAS LISI,
*Secretary.*

[F.R. Doc. 69-4549; Filed, Apr. 16, 1969; 8:50 a.m.]

[ 46 CFR Part 528 ]

[Docket No. 69-16]

## SELF-POLICING REQUIREMENTS

### Proposed Exclusion of Two Party Rate-Fixing Agreements

Section 528.2 of General Order 7 (46 CFR Part 528) presently requires conference agreements and other rate-fixing agreements between common carriers by water in the foreign and domestic offshore commerce of the United States, to contain a provision describing the method or system used by the parties in policing the obligations under the agreement, including the procedure for handling complaints and the functions and authority of every person having responsibility for administering the system. This section also requires the filing of amendments to all agreements previously approved so as to comply with these requirements.

Under § 528.3, all conferences and carriers subject to the self-policing rules are required to file semiannual reports with the Commission in January and July showing the nature of each complaint received during the preceding 6-month period, the action taken, the nature of the violations found and the penalties or other sanctions imposed.

The self-policing requirements of General Order 7 have been in effect for more than [illegible] groups regardless of membership size under the agreement. The Commission's staff has observed that enforcement of compliance with the order has little, if any, benefit to the regulatory process insofar as two party rate agreements are concerned. In this limited type of agreement, the most effective method of policing of the obligations under it is the resignation or withdrawal of the dissatisfied party, thus resulting in termination of the agreement itself.

Therefore, pursuant to section 4 of the Administrative Procedure Act (5 U.S.C. 553) and sections 15, 21, and 43 of the Shipping Act, 1916 (46 U.S.C. 814, 820, and 841(a)), notice is hereby given that the Commission proposes to amend Part 528 of 46 CFR, to except all two party rate-fixing agreements from all of the requirements of General Order 7. It is proposed that a new § 528.4 be added to Part 528 reading as follows:

§ 528.4 *Two party rate-fixing agreements.*

Any group with rate-fixing authority under an approved agreement which has no more than two signatory parties to the agreement shall be excepted from all requirements of General Order 7.

Interested persons may participate in this rulemaking proceeding by filing with the Secretary, Federal Maritime Commission, Washington, D.C. 20573, within ten (10) days of publication of this notice in the FEDERAL REGISTER, an original and fifteen (15) copies of their views or comments pertaining to the proposed rule. Any suggestions for changes in the proposed rule should be supported by statements relating the proposed change to the purposes of section 15 of the Shipping Act, 1916, and General Order 7, of the Commission's rules.

The Federal Maritime Commission, Office of Hearing Counsel, shall participate in the proceeding and shall file reply to comments within ten (10) days from the final date for filing comments by serving an original and 15 copies on the Federal Maritime Commission and one copy to each party who filed comments. Answers to Hearing Counsels' replies shall be submitted to the Federal Maritime Commission within 10 days of the final date for filing replies.

By the Commission.

[SEAL] THOMAS LISI,
*Secretary.*

[F.R. Doc. 69-4550; Filed, Apr. 16, 1969; 8:50 a.m.]

[ 46 CFR Part 537 ]

[Docket No. 69-18]

## CONFERENCE AGREEMENT PROVISIONS RELATING TO CONCERTED ACTIVITIES—MINUTES

### Proposed Exclusion of Two Party Rate-Fixing Agreements

Section 537.2 of General Order 18 (46 CFR Part 537) presently requires all pro-