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36FR06903

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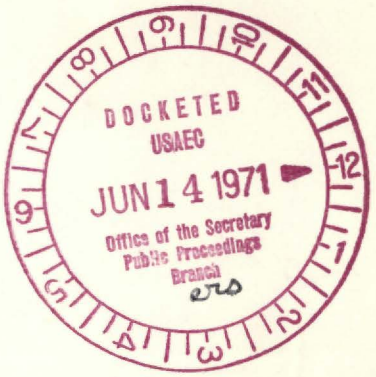
DOCKET NUMBER
PROPOSED RULE PR-50
Quality Assurance

GENERAL ELECTRIC

NUCLEAR ENERGY DIVISION

GENERAL ELECTRIC COMPANY, 175 CURTNER AVE., SAN JOSE, CALIF. 95125
Phone (408) 297-3000, TWX NO. 910-338-0116



June 10, 1971

Secretary of the Commission
United States Atomic Energy Commission
Washington, D.C. 20545

Attention: Chief, Public Proceedings Branch

Subject: PROPOSED AMENDMENT TO 10 CFR 50, MAKING APPENDIX B TO 10 CFR PART 50 APPLICABLE TO FUEL REPROCESSING PLANTS

Gentlemen:

The Reactor Fuels and Reprocessing Department (RF&RD) of the General Electric Company has reviewed the proposed rule making (36 F.R. 6903) whereby Appendix B of 10 CFR Part 50 would be applicable to fuel reprocessing plants, and wishes to make the following comments:

1) RF&RD concurs with the application of Appendix B of 10 CFR Part 50 to fuel reprocessing plants.

2) At the time the MFRP's quality control plans were being formulated, the quality assurance criteria and requirements were not yet published. However, during the preparation of the plans for the MFRP, the AEC issued quality control assurance criteria and requirements for reactors as a proposed Appendix B to 10 CFR 50. We adopted these criteria for guidance in preparing the MFRP quality control plan and, as noted in Supplement 3 to the Safety Analysis Report (Docket 50-268), we feel that the MFRP plan is in substantial compliance with the requirements of 10 CFR 50, Appendix B.

3) We do feel that some clarification of differences in the application of Appendix B to reactors and reprocessing plants is desirable. For example, operating characteristics are inherently different: A fuel reprocessing plant is a passive, low or negative pressure system, designed to prevent criticality with potential corrosion being one of the principal problem areas, whereas a reactor is an active, high pressure, high temperature system designed to achieve criticality with corrosion being a minor problem. Thus, the quality control plans would tend to focus on different problems, such as corrosion testing and design to prevent cracks and crevices that would lead to accelerated corrosion, for a reprocessing plant versus consideration of the high pressures, temperatures and stresses due to thermal cycling in a reactor.

Acknowledged by card 6/14/71 ers

BE SURE TO INCLUDE MAIL CODE ON RETURN CORRESPONDENCE

GENERAL ELECTRIC

We appreciate the opportunity to comment on these changes and would be pleased to clarify or further amplify any of these points.

Respectfully submitted,

GENERAL ELECTRIC COMPANY

L. S. Moody, General Manager
Reactor Fuels & Reprocessing Department

LSM:cws

cc: L. Johnson

GPU SERVICE CORPORATION
(a subsidiary of General Public Utilities Corporation)
260 Cherry Hill Road
Parsippany, New Jersey 07054/201-539-6111

May 3, 1971
File #QA-71/81

Mr. Woodford B. McCool
Secretary
United States Atomic Energy Commission
Washington, D. C. 20545

Dear Mr. McCool:

As you know, during the design and construction phases of a nuclear generating station, an integral part of the owner's responsibility rests in providing assurance that its contractors comply with applicable regulatory and code requirements.

"Compliance", however, cannot always be assured without proper interpretation of an applicable requirement, particularly if one requirement appears to contradict another. We refer to Criteria I and Criteria X of 10CFR Appendix B. It is our view that the regulatory language in Criteria I could be interpreted differently when attempting to enforce control of Criteria X.

Specifically, the following information is offered for your consideration:

CRITERIA I - ORGANIZATION

"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."

CRITERIA X - INSPECTION

"(A program for inspection of activities affecting quality shall be established and executed by or for the organization performing the

. . . / . . .

activity to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity). Such inspection shall be performed by individuals other than those who performed the activity being inspected."

Criteria I (as previously quoted) appears to positively define that a contractor shall have an inspection and product acceptance function separate from its manufacturing or construction group. However, in reading Criteria X (as previously quoted), we have found that this regulatory language could be interpreted to mean that inspections could be performed by persons in the same manufacturing or construction group. An example of such a situation is as follows:

Welding:
According to the wording in Criteria I, a welder's work would have to be inspected, verified, etc. by a person or group independent of the welder's group which is directly responsible for performing the welding. This would mean that another welder or the welding foreman or welding engineer belonging to the same department could not do the *final inspection and document the acceptability of the welder's work. If this is an accurate interpretation of Criteria I, then Criteria X appears to contradict this interpretation, since in the same example the wording in Criteria X could be interpreted to mean that another welder or the welding foreman could inspect, accept and document the welder's work. We refer specifically to the wording: "Such inspection shall be performed by individuals other than those who performed the activity being inspected."

Although there are other cases in which similar problems arise, using this example we respectfully pose the following questions to the AEC and request official response in the form of written comment and/or clarification at your earliest convenience:

Questions:

a) If a contractor allowed his welding foreman, welding engineer or another welder to perform inspection, verification and document acceptance of the welder's work, would the contractor meet the intent of Criteria X?

b) If the contractor meets the intent of Criteria X by implementing the method cited in Question (a), would the contractor be in

* Does not refer to root passes or similar checks

. . . / . . .

violation of Criteria I, in that he did not meet the intent of the organizational requirement cited by this Criteria?

c) How does the AEC interpret the example posed in this letter?

d) Does the AEC agree with our interpretation of Criteria I and X respectively, and does the AEC further agree that these Criteria are contradictory, or could be misinterpreted?

e) If the AEC does agree with us, have they, or will they, take steps to clarify the regulatory language in future as has been done with Criteria III entitled "Design Control" which states: "The verifying or checking process shall be performed by individuals or groups other than those who performed the original design, but who may be from the same organization"?

f) If the AEC does not agree with our interpretation of either or both Criteria I and X, would you please provide official interpretation as to the intent of Criteria I and X?

These questions and an official reading are necessary if we are expected to meet the intent of the regulation. As concerned individuals, we look to the AEC for this information, since your agency is responsible for the enactment and enforcement of 10CFR50 Appendix B and therefore should be able to provide guidance as to how this regulation should be complied with.

Thank you in advance for your assistance.

Very truly yours,

B. G. Avers
Manager Quality Assurance

BGA/ESF:c

CC: Mr. J. G. Miller, V.P.
Metropolitan Edison Company
Mr. W. A. Verrochi (GPU)
Mr. W. H. Hirst (GPU)
Mr. G. F. Bierman (Met-Ed)
Mr. R. W. Heward, Jr. (GPU) FR #1

AUG 6 1970

Mr. Sigmund Kopp
205 Pamela Drive
Warren, Pennsylvania 13635

Dear Mr. Kopp:

Your letter of July 28, 1970, asked whether Section XVIII, Audits, of Appendix B to 10 CFR 50, "Quality Assurance Criteria for Nuclear Power Plants," implies that the facility purchasing or using a component is required to perform an audit of the vendor's or fabricator's quality assurance program.

Section XVIII, Audits, requires that a comprehensive system of audits be carried out to verify compliance with all aspects of the quality assurance program. It does not indicate, in detail, what specifically must be audited and by whom. Included in a comprehensive system of audits, however, should be both internal audits and external audits. Internal audits are those performed within and by the same organization, such as by a supplier, and external audits are those performed by the purchaser to monitor the performance of the supplier. It is neither necessary nor desirable that every supplier be audited by every purchaser, but certainly a supplier furnishing a major component important to safety should normally be audited by the purchaser or its agent.

Sincerely,

Original signed by
E. G. Case

Edson G. Case, Director
Division of Reactor Standards

DRS 9.8

bcc: C. K. Beck, DR
M. M. Mann, DR
L. D. Low, CO
P. A. Morris, DRL
E. G. Case, DRS
R. B. Minogue, DRS
W. M. Morrison, DRS
C. R. Stephens, SECY

(See Previous Concurrences)

OFFICE ▶	DRS:DIR					
SURNAME ▶	Case:jjb					
DATE ▶	8/5/70					

SIGMUND KOPP
205 PAMELA DRIVE
WARREN, PA. 16365

DOCKET NUMBER
PROPOSED RULE PR-50
Quality Assurance

FELLOW ASME
MEMBER NSPE

July 28, 1970

Atomic Energy Commission

Washington, D. C. 20545

Attention: Mr. W. B. McCool, Secretary

Gentlemen:

I have a copy of 10CFR50, Appendix B - "Quality Assurance Criteria for Nuclear Power Plants" as published in the Federal Register June 27, 1970. Section XVIII, Audits, implies that the facility purchasing or using a component is required to perform an audit of the vendor's or fabricator's quality assurance program. Is this interpretation correct?

Very truly yours,

S. Kopp

S. Kopp
Consultant

SK/ml

Acknowledged by card 7/31/70, crs
cy sent to Case's office for reply, 7/31/70

DOCKET NUMBER
PROPOSED RULE PR-2,50
Backfitting

DOCKET NUMBER
PROPOSED RULE PR-50
Quality Assurance

GENERAL ELECTRIC COMPANY
NUCLEAR ENERGY DIVISION

175 CURTNER AVE., SAN JOSE, CALIF. 95125 . . AREA CODE 408, TEL. 297-3000, TWX NO. 910-338-0116

June 30, 1969

Mr. W. B. McCool, Secretary
United States Atomic Energy Commission
Washington, D. C. 20545

Dear Mr. McCool:

Enclosed herewith are the comments of General Electric Company on the proposed amendments to the regulations of the Atomic Energy Commission, 10 CFR Parts 2 and 50, which were published for comment on April 16 and 17, 1969, 34 F.R. Nos. 72 and 73.

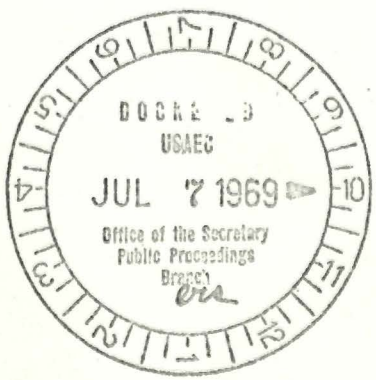
In addition to the specific comments in the enclosed memoranda, we should point out that as a general matter we do not believe that these proposed changes in the regulations represent progress in the direction of stability in the regulatory process which was the subject of the letter of August 26, 1968 from our Dr. A. E. Schubert to the Chairman of the Commission and of my letter of July 3, 1968 to the Director of Regulations. For your information, copies of these letters are enclosed herewith.

Sincerely yours,

G. J. Stathakis
Deputy Division General Manager
Boiling Water Reactor Operations

rk
Enclosures

cc: A. E. Schubert



Acknowledged by card 7/7/69, cys

DOCKET NUMBER
PROPOSED RULE PR-2,50
Backfitting

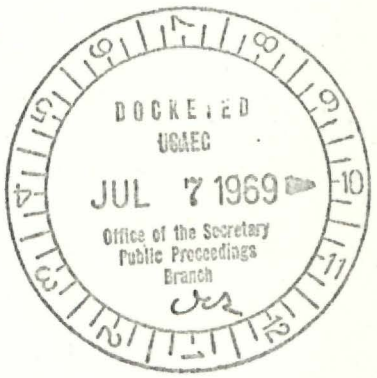
Comments
of
General Electric Company
to
Proposed AEC Amendments
to its rules of practice, 10 CFR Part 2,
and to its regulation,
Licensing of Production and Utilization Facilities,
10 CFR Part 50
[34 F. R. No. 72, April 16, 1969]

Item 1

No comment.

Item 2

No comment.



Item 3

No comment.

Item 4

§ 50.2(w)

Present Language

None

AEC Proposed Change

"Principal architectural and engineering criteria" mean (1) the principal design criteria for the facility; (2) the essential elements of the proposed design of the following structures, systems, and components of the facility: Reactor core, reactivity control systems, protection system, control room, reactor pressure vessel and internals, reactor coolant system and associated auxiliary systems,

reactor coolant makeup system, decay heat removal system, cooling water system, fuel storage and handling system, radioactive waste system, emergency power systems, primary reactor containment, containment isolation system, secondary reactor containment, auxiliary buildings, emergency core cooling system, containment heat removal system, containment atmosphere cleanup systems, and such other structures, systems and components as may be specified by the Commission; (3) the design bases for protection against natural phenomena such as earthquakes, tornadoes, hurricanes, floods, tsunamis, and seiches; and (4) the essential elements of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility.

G.E. Proposed Change

"Principal architectural and engineering criteria" mean those principal criteria relating to the design, fabrication, construction, testing and operation of the facility against which an assessment may be made respecting the protection of the health and safety of the public.

Reasons for G.E. Proposed Change

We are in general accord with the principle that the applicant should be required to submit essentially the same information contemplated by the Commission's version of § 50.2(w), but suggest that it might be more appropriately included in the Preliminary Safety Analysis Report required by § 50.34. Accordingly, we have suggested revisions to § 50.34 incorporating this concept.

The definition of "principal architectural and engineering criteria" is of course important because in the amendment

to § 50.35(a) proposed by the Commission the applicant would be required to describe the principal architectural and engineering criteria of the facility prior to the issuance of the construction permit.

§ 50.35(b), if amended, would provide that the applicant could not depart from such criteria without the approval of the Commission, although the applicant could make such changes in the facility without the Commission's prior approval as do not conflict with the criteria, subject to the risk of disapproval of those changes by the Commission at any time prior to the issuance of the operating license. Obviously, the more detailed these criteria as defined by § 50.2(w), the more onerous the burden on the applicant.

Although we concur in the proposed amendments to § 50.35, the definition of "principal architectural and engineering criteria" in § 50.2(w) could, we believe, cause some serious problems.

First, the dictionary definition of criteria is "standards on which a judgment or decision can be based." Thus the very specific details with respect to design features and a quality assurance program described in § 50.2(w) as proposed by the AEC are in fact not criteria.

Second, under § 50.35(b) if after the issuance of the construction permit the applicant desired to make changes in the design of the facility he would have to obtain the approval

of the Commission if such changes involved a departure from or a conflict with the criteria. Consequently, the design at the construction permit stage must be virtually complete to avoid further time consuming regulatory submittals, reviews and approvals, or the applicant must take the substantial risk of Commission disapproval after the change already has been made. If the changes proposed by the AEC in § 50.2(w) and § 50.35 are adopted, there would be no reason why a finding could not be made for an operating license at the construction permit stage, since if the applicant deviates from the principal design criteria, the essential elements of the design, the design bases for protection against natural phenomena, and quality assurance procedures as earlier presented in the PSAR and approved by the AEC, the applicant would be required by § 50.35(b) to return to the AEC for further approval of such changes, no matter how small.

In summary, it is essential at the issuance of a construction permit that the applicant and the AEC have a mutual understanding of the level of plant definition and acceptance for which the permit is being granted. This is best achieved on a practical basis by addressing the AEC approvals to the criteria level rather than to the level of design details, quality assurance requirements or design bases. Specific design bases and other details of the design and engineering of the facility associated with the various activities of design, procurement, fabrication, construction, testing, and operation, are subject to

review, change or supplement as a project progresses. The applicant and his contractors must be given the latitude to make necessary detail changes without returning to the Commission for approval.

Item 5

No comment.

Item 6

§ 50.57(a)

AEC Proposed Change

(3) There is reasonable assurance (i) that the activities authorized by the operating license can be conducted without endangering the health and safety of the public, and (ii) that such activities will be conducted in compliance with the regulations in this chapter; and

G.E. Proposed Change

"(3) There is reasonable assurance (i) that the activities authorized by the operating license can be conducted without undue risk to the health and safety of the public, and (ii) that such activities will be conducted in compliance with the regulations in this chapter; and"

Reason for G.E. Proposed Change

With regard to the issuance of construction permits in both the present and proposed § 50.35(a)(4)(ii) the Commission has used the words "the proposed facility can be constructed and operated at the proposed location without undue risk to the health and safety to the public." It would

appear that to be consistent the same standard of protection of the health and safety of the public should be applied at both the construction permit and operating license stages, and that "without undue risk" is the proper test.

AEC Proposed Change

(6) The issuance of the license will not be inimical to the common defense and security or to the health and safety of the public.

G.E. Proposed Change

The proposed § 50.57(a)(6) should be deleted.

Reasons for G.E. Proposed Change

The source of the proposed § 50.57(a)(6) apparently is § 103d and § 104d of the Atomic Energy Act of 1954, as amended, which both provide (in part):

> "In any event, no license may be issued to any person within the United States if, in the opinion of the Commission, the issuance of a license to such a person would be inimical to the common defense and security or to the health and safety of the public."
>
> (Emphasis added.)

It is clear that the thrust of § 103d and § 104d is directed towards the qualifications of the applicant, not the safety of the facility. In the Commission's regulations the question of protection of the health and safety of the public at the operating license stage has already been covered in the proposed § 50.57(a)(3) above. Accordingly, the proposed § 50.57(a)(6) should either be deleted or rewritten so that it is clear that it refers only to the

qualifications of the applicant and not to the safety of the facility.

§ 50.57(b)

AEC Proposed Change

Each operating license will include appropriate provisions with respect to any uncompleted items of construction and such limitations or conditions as are required to assure that operations during the period of the completion of such items will not endanger public health and safety.

G.E. Proposed Change

(b) Each operating license will include appropriate provisions with respect to any uncompleted items of construction and such limitations or conditions as are required to assure that operations during the period of the completion of such items will not result in undue risk to the health and safety of the public.

Reason for G.E. Proposed Change

As has been noted in regard to the proposed § 50.57(a)(3) above, the standard of protection of the health and safety of the public should be the same at all stages of the proceedings, and accordingly the same test, "without undue risk," should be used.

Item 7

§ 50.109 Backfitting

Present Language

None

AEC Proposed Language

(a) The Commission may, in accordance with the procedures specified in this chapter, require the backfitting of a facility if it finds that such action will provide substantial, additional protection which is required for the public health and safety or the common defense and security. As used in this section, "backfitting" of a production or utilization facility means the addition or modification of structures, systems or components of the facility after the construction permit has been issued.

G.E. Proposed Change

(a) The Commission may, in accordance with the procedures specified in this chapter, require the backfitting of a facility if it finds that operation of the facility without the identified backfitting would result in undue risk to the health and safety of the public as measured against applicable AEC regulations at the time the construction permit was issued. As used in this section, "backfitting" of a production or utilization facility means the addition or modification of structures, systems or components of the facility after the construction permit has been issued.

Reason for G.E. Proposed Change

The requirements by the Commission for backfitting must be consistent with other rules established by the Commission regarding findings which must be made by the Commission and the hearing boards. The wording of § 50.109(a) proposed by the AEC is open-ended since it

does not offer a base point against which to measure adequacy or need for the backfitting. Under the proposed AEC wording, the Commission could require backfitting by adopting a sliding scale for "substantial, additional protection," even if there were no evidence that the facility could not already operate without undue risk to the health and safety of the public.

The applicant must be given some protection regarding status of the Commission's safety related requirements for his plant at the time the construction permit is issued. This protection cannot be achieved unless the Commission is required to make a finding that there is an overriding need for the backfitting in terms of undue risk to the health and safety of the public.

As has been discussed in the G.E. comment to the proposed § 50.57(a)(6), references to the common defense and security should be limited to areas involving the qualifications of the applicant and are not relevant to the safety of the plant.

In addition, we suggest that the definition of "backfitting" may be more appropriately included with the other definitions in § 50.2.

AEC Proposed Language

(c) The Commission may at any time require a holder of a construction permit or a license to submit such information concerning the addition or proposed addition, the elimination

of proposed elimination, or the modification or proposed modification of structures, systems or components of a facility as it deems appropriate.

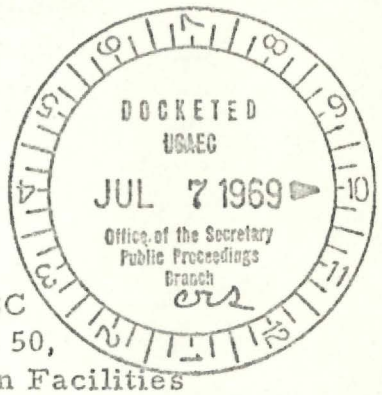
G.E. Proposed Change

(c) The Commission may at any time require a holder of a construction permit or a license to submit such information concerning the addition or proposed addition, the elimination or proposed elimination, or the modification or proposed modification of structures, systems or components of a facility as it deems appropriate. A request for such information will be made only after the Commission has made a preliminary, independent finding that construction or operation of the facility in the absence of such information will result in undue risk to the health and safety of the public.

Reason for G.E. Proposed Change

The proposed AEC wording of § 50.109(c) guarantees an unknown and undeterminable potential liability to the applicant with respect to his obligation to develop information and analysis required to determine the need for and the extent of any backfitting. The AEC could at any time--from construction permit to plant deactivation--require the holder of a construction permit or operating license to review the current status of technology to determine if application of such technology would result in additional safety. Thus the AEC could conduct fishing expeditions

by requiring the submittal of information by the utility at his time and expense regarding the sufficiency and adequacy of existing equipment and the need for additional safety features without the AEC having previously passed judgment on the safety issue involved. We believe that it should be incumbent upon the Commission to make such safety-related findings before requesting an applicant to provide the additional information. The applicant should not be required to spend considerable effort to obtain and evaluate development information and convert it into design requirements for his particular facility until after the Commission has made a finding regarding the need for such information.



Comments
of
General Electric Company
to
Amendments Proposed by AEC
to its regulation, 10 CFR Part 50,
Licensing of Production and Utilization Facilities
[34 F.R. No. 73, April 17, 1969]

Item 1

§ 50.34

AEC Proposed Change

(a) Preliminary Safety Analysis Report. Each application for a construction permit shall include a Preliminary Safety Analysis Report. The minimum information[2] to be included shall consist of the following:

G.E. Proposed Change

(a) Preliminary Safety Analysis Report. Each application for a construction permit shall include a Preliminary Safety Analysis Report which, as amended, will be utilized by the Commission as a technical basis for evaluation of the facility and issuance of the construction permit. The minimum information[2] to be included shall consist of the following:

Reason for G. E. Proposed Change

§ 50.34(a) should be expanded to indicate that the Preliminary Safety Analysis Report and its amendments will be utilized as the technical basis for the construction permit. It would justify the need for the PSAR.

G. E. Proposed Change

(1) Same as present § 50.34 (a)(1).

(2) The principal architectural and engineering criteria for the facility.

Reason for G. E. Proposed Change

Neither the current wording of § 50.34(a) nor the proposed AEC changes require the applicant to identify or provide a set of "principal architectural and engineering criteria," yet the findings to be made by the AEC are based, in part, upon such criteria. Thus, G. E. proposed that the principal architectural and engineering criteria, as G. E. suggests that they be defined in § 50.2(w), be identified in the PSAR.

(3) A summary description and discussion of the facility including: (i) the principal design characteristics of the following safety related structures, systems and components where appropriate: Reactor core, reactivity control systems, protection systems, control room, reactor pressure vessel and internals, reactor coolant system and associated auxiliary systems, reactor coolant makeup system, decay heat removal

system, cooling water system, fuel storage and handling system, radioactive waste systems, emergency power systems, reactor primary containment, reactor secondary containment, containment isolation systems, auxiliary buildings, emergency core cooling systems, containment heat removal systems, containment atmosphere cleanup systems, and such other structures, systems, and components primarily provided for the protection of the health and safety of the public.

Reason for G. E. Proposed Change

The "summary description and discussion of the facility" presently required by § 50.34(a)(2) to be included in the application for a construction permit should be expanded to include identification of the systems noted in the Commission's proposed wording of § 50.2(w). Since under the G. E. proposed changes these systems are not defined as "principal architectural and engineering criteria," they would be subject to change by the applicant after the issuance of the construction permit without prior approval by the Commission required by the proposed § 50.35(b). The list of items is also restricted to those primarily provided for health and safety of the public.

(4) Identification and qualification of principal contractors.

Reason for G. E. Proposed Change

The AEC requires identification of principal contractors, and this has been added.

(5) The preliminary design of the facility, including:

(i) The design bases for the specific structures, systems, and components related to safety, including design bases for protection against natural phenomena such as earthquakes, tornadoes, hurricanes, floods, tsunamis, and seiches.

(ii) Same as § 50.34(a)(3)(iii)

Reason for G.E. Proposed Change

The "principal design criteria" are deleted from § 50.34(a)(3)(i) since those criteria, which define the functional requirements of structures, systems, and components of the facility related to the protection of public health and safety, are included in our proposed definition of "principal architectural and engineering criteria" in § 50.2(w) which we believe should be required to be included in the PSAR under § 50.34(a)(2).

The preliminary design of the facility has been expanded to include identification of design bases for protection against natural phenomena as used in the Commission's proposed wording of § 50.2(w). As above, these would not appear in "principal architectural and engineering criteria."

(6) Same as present § 50.34(a)(5).

(7) Same as present § 50.34(a)(6).

(8) A description of the quality assurance program to be applied to the safety-related functions of those 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. Appendix B, "Quality Assurance Requirements for Nuclear Power Plants," sets forth the requirements for quality assurance programs for nuclear power plants.

(9) Same as present § 50.34(a)(8).

Reason for G.E. Proposed Change

The Commission's proposed wording of § 50.34(a)(7) refers to Appendix B as "Quality Assurance Criteria." An inspection of Appendix B reveals that those items are detailed requirements, not criteria. As above, these requirements would not appear in "principal architectural and engineering criteria."

§ 50.34

AEC Proposed Change

(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:

G.E. Proposed Change

(b) Final Safety Analysis Report. Each application for a license to operate a facility shall include a final safety analysis report. Engineering, design, technical and other information presented in the Preliminary Safety Analysis Report which remains unchanged need not be resubmitted in the Final Safety Analysis Report, but may be incorporated by reference. The Final Safety Analysis Report shall include the the following:

Reasons for G.E. Proposed Change

Experience in the total licensing process is showing that a large amount of the technical information which is required at the construction permit stage is not of a preliminary nature. For example, heat transfer correlations, principal architectural and engineering criteria, descriptions, control rod designs, accident dose calculations, quality assurance requirements, and results of previous R&D programs are typical of subject which need not be repeated again in the Final Safety Analysis Report. Of course if any substantive changes have occurred in such items, then they should be repeated and explained. However, many of these

page-consuming topics could merely be referenced from earlier documentation for use in the FSAR. As currently written, § 50.34(b) does not provide for such incorporation by reference. Much paper work could be eliminated if this procedure were adopted.

AEC Proposed Change

(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.

G. E. Proposed Change

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

Reasons for G. E. Proposed Change

As noted in the comment to proposed § 50.34(a)(7), these matters are in the nature of requirements, not criteria.

Item 2

Proposed G. E. Change

Appendix B--Quality Assurance Requirements for Nuclear Power Plants

Introduction. Every applicant for a construction permit for a nuclear power plant is required by the provisions of § 50. 34 to include in its Preliminary Safety Analysis Report a description of the quality assurance program to be applied to the design, fabrication, construction, and pre-operational and startup testing of the structures, systems, and components of the facility 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 safety related functions of such structures, systems, and components.

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. 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.

Reason for G. E. Proposed Change

We believe that the definitions in the introduction are made more precise, that redundancy of wording is eliminated, and that the Scope of Appendix B is directed to safety related items through the proposed G. E. changes.

In particular, we believe that evaluation of the quality assurance program will best be accomplished on a continuing basis as the program is put into effect on the project, and it is not appropriate for the applicant to evaluate his own quality assurance program in the Preliminary Safety Analysis Report.

Proposed G. E. Change

III. DESIGN CONTROL

Measures shall be established to assure that applicable regulatory requirements and the design bases, as defined in § 50.2 and as specified in the Preliminary Safety Analysis Report, 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 be conducted by the design organizations to assure that design requirements are met throughout the various phases of design, procurement, fabrication, installation and preoperational testing. Reports of in-process and final design reviews shall be reviewed by management of the responsible design organizations. Design changes, including field changes during the design, construction, and startup of the nuclear power plant shall be approved by the organization that performed the original design. After the startup of the nuclear power plant, design changes shall be approved by a responsible organization designated by the applicant. Procedures shall be established among participating design organizations for the review, approval, release, distribution and revision of documents involving design interfaces.

Reason for G. E. Proposed Change

It is important that design changes and implementation of design changes be consistent with established design bases. This is best accomplished by the original design organization.

Proposed G. E. Change

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 or drawings shall include appropriate quantitative or qualitative means for determining that important operations have been satisfactorily accomplished.

Reason for G. E. Proposed Change

The means of conveying the information is through a composite of instructions, specifications, procedures, drawings, etc.; and all necessary information is not complete in any one vehicle. Thus the language should permit the composite approach rather than requiring total information in each document or drawing.

Proposed G. E. Change

VI. DOCUMENT CONTROL

Measures shall be established to control the issuance of documents, such as instructions, procedures, and drawings, including changes thereto, which prescribe the controlling activities affecting quality. These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and that the authorized revisions of documents are distributed to and used

at the location where the prescribed activity is performed. During the design, construction, and startup of the nuclear power plant, changes to documents shall be reviewed and approved by the same organizations that performed the original review and approval. After startup of the nuclear power plant, changes to documents shall be performed, reviewed, and approved by an organization designated by the applicant.

Reason for G. E. Proposed Change

The word "all" has been deleted since on a practical basis it is not meaningful to prescribe all activities, and in addition emphasis is to be placed on safety-related activities and not all plant related activities.

Changes in last paragraph are consistent with those made in Article III above.

G.E. Proposed Change

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 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.

Reasons for G.E. Proposed Change

It is suggested that the last sentence be removed from this section since "audit" and "corrective action" are covered in other sections.

G. E. Proposed Change

X. INSPECTION

A program for in-process and final inspection shall be established to assure that the end product is in conformance with documented instructions, procedures, and drawings. Examinations, measurements, or tests of material or products 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.

Reasons for G. E. Proposed Change

We believe that emphasis should be placed on inspection of the quality itself of the end product rather than inspection of the activities which may affect quality.

G. E. Proposed Change

XI. TEST CONTROL

A test program shall be established to assure that all required testing, including proof testing, acceptance testing, and pre-operational and startup 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.

Reasons for G. E. Proposed Change

We believe that this change clarifies the meaning of "operational" by clearly defining it as applying to the operation of the component during the preoperational and startup phase, rather than to the operation of the entire nuclear power plant.

G. E. Proposed Change

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 the nuclear power 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.

Reasons for G. E. Proposed Change

This addition is to distinguish a power plant from a manufacturing plant.

G. E. Proposed Change

XVI. CORRECTIVE ACTION

Measures shall be established to assure that 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 provide for ascertaining the cause of conditions adverse to quality and determining the corrective action required. The corrective action measures shall extend to the performance of all contractors and subcontractors as necessary. The identification of serious conditions adverse to quality, the cause of the condition, and the corrective action shall be documented.

Reasons for G. E. Proposed Change

We believe that the revised wording more closely describes good quality control practice regarding corrective action. The need for corrective action should be brought to management attention, but no system can absolutely preclude repetition. For example, controlling and sorting defective material may be more economical than developing a process which will yield a 100% acceptable product.

Please be assured that we are prepared to assign senior management and technical personnel to work with your staff in implementing these suggestions, or any similar actions that you may propose.

Sincerely yours,

G. J. Stathakis

GJS:dms

cc: A. E. Schubert
T. R. Clark

Further, we suggest that this activity be carried on through a steering group which would give the program direction and keep it on schedule. The steering group would appoint joint working groups as required, and would delineate their memberships and scope. In doing this, a relevant consideration for the steering group would be whether the issue is specific to a particular reactor design or applicable across the entire industry.

It should be made clear that it would not be for the steering and working groups to make final judgments on licensability. This decision clearly rests with the AEC and ACRS. The recommendations of the steering and working groups would, however, greatly facilitate license reviews and, we believe, would make such reviews much more effective than if the entire task were to be done on a project-by-project basis. Moreover, as such new considerations are considered, recommendations on them would be made by the joint groups to the Regulatory Staff and the ACRS. After such resolution as may be required, the new items or modifications would be added to the appropriate ASDB.

We believe that this approach would provide an appropriate balance of incentives for both stability in the design phase of current plants, and for innovation. Applications meeting the requirements of the then-current ASDB could be reviewed on a highly expedited basis. Similarily, the opportunity for joint review of new design features apart from the review of specific applications should tend to stimulate innovation.

IV. Our fourth suggestion was concerned with developing general safety criteria and standards. Such criteria and standards are needed in the long term as the basis for assured stability in the licensing process. Our recommendation here was principally to accelerate the current efforts. We noted that it would be desirable to increase the AEC and ACRS participation in industry code effort. Similarly, working sessions with the industry would help in finalizing the general and supplementary safety criteria now being developed by the AEC.

As we noted at our meeting, the objective of these suggestions is to provide a structure which would permit the regulatory process to identify and commit to the licensability of currently acceptable designs, and to systematize the introduction of new considerations. This would be the function and value of the ASDB.

As was indicated at the meeting, we believe that the current boiling water reactor designs have progressed to the point where such an ASDB could be developed on a reasonably prompt schedule. It would be primarily a matter of recording the basis which is being employed for reviewing current plants. We suggested the third quarter of 1968 as a target for the completion of the BWR ASDB.

II. There are certain questions concerning current reactor designs which have been identified at the construction permit stage as requiring resolution prior to the issuance of an operating license. Our second suggestion was that the joint teams have as a further objective the identification and listing in detail of all such unresolved questions. For example, for BWRs, not only would the specific project be listed, but also the design item (i.e., jet pumps), the area of concern (i.e., stress analysis), and the specific requirement for information (i.e., stresses at identified points).

Once these check lists are formulated, the resolution of the items with the AEC and ACRS would be carried out on a generic basis and in accordance with an agreed-upon early schedule. As the action to be taken on each item is agreed upon and concluded, the written basis of the resolution would be appended to the ASDB. With time, therefore, the ASDB would provide a description of the safety features of a reactor which would be acceptable both at the construction permit and operating license stages without a necessity for further safety review.

We believe that this work could develop a proposed schedule for the resolution of open questions by the end of 1968.

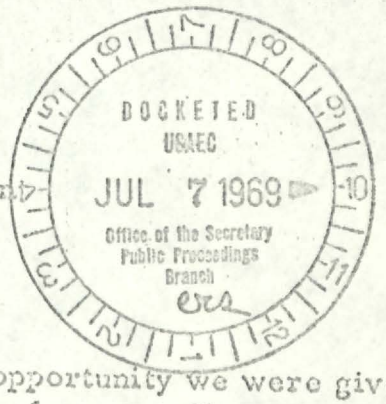
III. Our third suggestion would provide a mechanism for accommodating new considerations and data which will be relevant in safety evaluation. New considerations and data will be evolved from new designs, as well as from reactor operating experience, development programs presently in progress, and improved methods of analysis.

We believe the regulatory process can best adjust to all such new considerations by a procedure which would identify them and determine their safety relevance on a general basis apart from specific license applications. To this end, we recommended that a joint AEC, ACRS, and industry group be set up to evaluate all such new considerations.

DOCKET NUMBER
PROPOSED RULE PR-2, 50
Backfitting

DOCKET NUMBER
PROPOSED RULE PR-50
Quality Assurance

July 3, 1968



Mr. Harold L. Price
Director of Regulations
U. S. Atomic Energy Commission
Washington, D. C. 20545

Dear Mr. Price:

I wish again to thank you for the opportunity we were given on June 13 to discuss with you and members of your staff our suggestions for ways of implementing the recommendations concerning the power reactor regulatory process which were made by Dr. A. E. Schubert to the Commission in his letter of April 26, 1968. We agreed at the conclusion of our meeting that it would be helpful for us to document the principal points of our presentation.

Our suggestions were as follows:

I. Our first suggestion was concerned with plants of current design for which construction permits have been and are being issued. We proposed that a joint AEC - General Electric group be established, apart from any license application proceeding, to identify the accepted safety design features of these boiling water reactors. Similar teams could be established for reactors of other manufacturers. Each team would define all of the characteristics and bases important to safety that are employed in the respective reactor designs.

The objective of each team would be to prepare an agreed-upon document with enough details so that the reactor design of a proposed nuclear power plant could be accepted without further review as to these features at the construction permit stage if it included all of the agreed characteristics and bases. Such a document, an "Agreed Safety Design Basis" (ASDB), would be most valuable in reducing the work that is now required in preparing for and carrying out regulatory reviews. The ASDB would not only define the basis of what is accepted for the purpose of the construction permit, but it would also be used at the operating license stage to qualify a design if it is shown that the reactor has been built in accordance with its provisions.

the elimination of mandatory ACRS review of license applications when the Commission and the ACRS deem it warranted. We support that proposal. We urge, however, that, to the maximum extent it can within the limits of its existing authority, the Commission proceed now with the policy we have suggested.

Sincerely,

A. E. Schubert

case-by-case development of such requirements, which is the present regulatory practice.

4. Finally, we believe the Commission's policy should make provision for active pursuit of the work on more general safety standards and criteria. You will recall that this was the subject of my letter of December 5, 1967. I should point out, however, that we are convinced that the initial step in the policy we have recommended, that of determining that plants of current design represent in effect currently acceptable, de facto safety standards and criteria, is essential for the development of more generalized safety standards.

We believe that this affirmative determination of policy by the Commission would be a major step forward in attainment of the level of stability in the regulatory process which is an urgent necessity for the industry. It seems to us that the arguments for taking this action now basically are twofold.

(a) The policy is fully justified. Plant designs have been analyzed and evaluated many times over. In successive licensing proceedings, on the basis of detailed information, regulatory groups have come to the conclusion that plants of current design can be constructed and operated without undue risk to public health and safety. We believe this record fully warrants the Commission determination that plants of such design need not be required to include additional or different safety features except on the basis of further developments which would support joint government-industry recommendations arrived at and documented as the policy would provide.

(b) Given the justification for this action, taking it is an essential step in the interests of the government and of industry alike. The stabilization of the regulatory program will be a very valuable aid to the objective evaluation in the marketplace of the competitive status of nuclear and fossil-fueled power.

Further, for the government this action would go far toward establishing control over the case load and procedural complexities which threaten to seriously interfere with the orderly dispatch of the business of the regulatory groups.

We have noted with interest the Commission's recent proposal to the Joint Committee on Atomic Energy that the Atomic Energy Act be amended to authorize

construction. This feature of the policy would eliminate the open-ended safety requirements problem that has proved particularly troublesome. This step would also provide maximum incentives to all of the participants in the industry, utilities, architect-engineers and principal suppliers alike, to accept the commitment on their part to complete plant construction in accordance with the construction permit design basis.

3. The policy we believe should also formally establish systematic procedures, independent of the processing of individual applications, for the review and evaluation of new data accumulated from research and development activity, and from operating experience, as the basis for new safety requirements.

More specifically, we recommend that under this policy the Commission establish joint government-industry groups to perform this review function. These groups should also conduct systematic reviews and engineering analyses of designs of current plants to evaluate the cumulative effect of safety requirements and safety systems that have been added in the past.

On the basis of such reviews and evaluation, these groups would make recommendations to the Commission as to whether and in what manner different or additional safety requirements or licensing reviews should be adopted in the licensing process.

In most cases the adoption of new safety requirements or analyses would be applied only to applications filed after the date of adoption. This has been the practice in this country with industrial codes. However, it is recognized that there may be cases where retrofit to plants being built or in operation would be necessary. It seems to us, however, that such a requirement should be limited to those cases in which confirmed data clearly proves that critical safety assumptions or design bases for these plants were erroneous.

Further, in light of the proprietary nature of much of the information that might be reviewed by the joint government-industry groups, it is probably appropriate that separate groups be established with each of the equipment manufacturers.

The important point here is that a formal procedure be established for the systematic introduction of new requirements as opposed to the

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Backfitting

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DOCKET NUMBER
PROPOSED RULE PR-50
Quality Assurance

A. EUGENE SCHUBERT
VICE PRESIDENT
NUCLEAR ENERGY DIVISION

April 26, 1968

Dr. Glenn T. Seaborg, Chairman
United States Atomic Energy Commission
Washington, D. C. 20545

Dear Dr. Seaborg:

This letter is to confirm the suggestions concerning the regulatory program that General Electric made in our discussion on April 16.

As we indicated at that time, it seems to us that the principal problem with the nuclear power reactor licensing program at the present time is the lack of stability in the area of safety requirements. Instability is evident both from application to application, and, with individual applications, from construction permit to operating license. We believe that action by the Commission to correct this condition is available, and that such action would be timely now - particularly in view of the progress that has been made toward the standardization of plant designs in the manufacturer segment of the industry.

It seems to us that the present situation could be greatly improved by the adoption by the Commission of a regulatory policy, with appropriate implementation, which would have four principal features. These would be:

1. The Commission would find, as a matter of policy, that the level of safety features provided in plants which are currently being authorized for construction is sufficient. This policy would declare that, site considerations aside, additional safety features could be required in future plants of like design only as specifically authorized (Point 3, below). Moreover, the policy would also limit design reviews and analyses in the licensing process so that repetitive, de novo examinations of plants of like design would not be required.

2. As a concomitant point, the Commission's policy would make it clear that the issuance of a construction permit would represent a commitment by the Commission to the issuance of an operating license for plants that are built in conformity with the design basis authorized for

Quality Assurance

PROPOSED RULE PR-50

Southern California Edison Company

P. O. BOX 351

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JERRY A. BRODY
ASSISTANT COUNSEL

June 24, 1969

Secretary
U.S. Atomic Energy Commission
Washington, D.C. 20545

Attention: Chief, Public Proceedings Branch

Re: Quality Assurance Criteria for Nuclear Powerplants

On April 17, 1969, the Atomic Energy Commission published a proposed 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."

On behalf of Southern California Edison Company, I submit the following comments concerning the proposed amendment:

1. Our major comment is that the guide is written in very general language. As a result, it will be subject to a great deal of interpretation. If the Atomic Energy Commission wishes to interpret it in a liberal manner, the requirements to meet the intent of this guide would be extremely difficult to fulfill. It is conceivable that the time and manpower required to administer the program under a liberal interpretation could double Edison engineering costs for administering a nuclear plant project.

   The proposed guide utilizes quality assurance in its broadest meaning, and establishes criteria not only for quality assurance during plant construction but also for design, start-up, and plant operation. This broad interpretation appears to overlap to some degree on matters

Acknowledged by card 6/26/69/pk

previously covered in Technical Specifications. It is therefore suggested that the amendment be more specific in its requirements.

2. In the introduction of the proposed guide, as well as later in the guide, it is indicated that the guide covers only "structures, systems, and components that prevent or mitigate the consequences of postulated accidents." This statement requires considerable interpretation to decide which specific portions of a nuclear facility should be included. It could be inferred that only safety feature systems, the major vessels, and other similar equipment are covered. Since we believe the criteria are intended to encompass more of a facility, this statement should be clarified to be more explicit.

3. The first sentence under II., together with the footnote under I, essentially establishes that nuclear plants which already have operating licenses will have to "backfit" some sort of quality assurance program. It would be desirable for the guide to include specific exemptions for previously licensed plants. As a minimum, the guide should only require licensed plants to establish a program in the operational area. As the guide is presently written, it is conceivable that licensed plants would have to document items that were not required to be documented during the original design and construction.

4. Under III., Design Control, the guide requires "design reviews by individuals or groups other than those who performed the original design." In some instances, this requirement could be extremely difficult and expensive to meet. This same section indicates that these design reviews will verify and assure the adequacy of the design. The words "verify" and "assure" can be interpreted to mean a complete check of the original design. This could result in essentially doubling

the engineering design time. It is suggested that this section be clarified to make periodic audits of the design acceptable.

5. Section XIV., Inspection Test and Operating Status, states that procedures shall be provided for tagging equipment when necessary to prevent inadvertent operation. This statement is delineating plant operating procedures, and outlines requirements that should be left to the determination of the operating organization. It is suggested, therefore, that the last sentence in Section XIV. be eliminated.

6. Section XVI., Corrective Action, requires that the cause of any condition adverse to quality be determined and corrected. This statement could require that the cause be determined and a proposed solution be developed to prevent recurrence of any condition that is found during inspection not to meet the required standards. Such a requirement is unreasonable from the standpoint of the effort involved and the returns to be realized.

I hope that you will accept the late submission of these comments.

Thank you very much.

Very truly yours,

David N. Barry, III

David N. Barry, III
Assistant Counsel
Southern California Edison Co.

DNB:bjs

P.O. BOX 3100 MIAMI, FLORIDA 33101

DOCKET NUMBER
PROD. AND UTIL. FACILITIES RULE PR 50

Quality Assurance

FPL
FLORIDA POWER & LIGHT COMPANY

June 24, 1969

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USAEC
JUN 26 1969
OFFICE OF THE SECRETARY
PUBLIC PROCEEDINGS BRANCH

U. S. Atomic Energy Commission
Washington
D. C. 20545

Attention: Chief, Public Proceedings Branch

Gentlemen:

Pursuant to notice given in 34 Federal Register 73, we hereby forward comments on a proposed new Appendix B "Quality Assurance Criteria for Nuclear Power Plants". We would appreciate it if these comments can be accepted even though the sixty-day period has expired.

Our comments are directed principally at that sentence in Section III of the proposed criteria which reads "These measures shall provide for the performance of design reviews by individuals or groups other than those who performed the original design...." This requirement by itself is unobjectionable since it reflects existing and long-established practice in experienced and knowledgeable design organizations serving the electric utility industry. Our concern is that persons responsible for applying the criteria consider that the above design review requirement is further modified by the fifth sentence of Section I of the criteria: "In general, assurance of quality requires management measures which provide that the individual or group....is independent of the individual or group directly responsible for performing the specific activity." We object to the further imposition upon the design review process that it be by an "independent person or group".

Design organizations serving the electric utility industry (whether professional engineering concerns or in-house organizations) are characterized by experience, technical attainment and professionalism. The industry utilizes relatively mature technologies which are intensively diffused throughout the organizations responsible for their application. We believe that such organizations contrast with ad hoc design organizations concerned with frontier technologies. Further, our design organizations, for sixty years or more, have had their structure and practices shaped by the utility's requirement

Acknowledged by ltr 6/26/69, pk

for high availability, long-life power plants. We believe these organizations have been and are now completely cognizant of the requirement that the integrity of their designs be motivated by the need for prevention of harm to the public. We further believe this added motive is only a modest extension of the existing motives to protect plant employees from the effects of large amounts of contained energy and to prevent untold hardship upon the public as a result of interruption of power supplies. We believe that little or no adjustment of organizational structure or practices in the name of providing "independent" review, whatever that means, is now necessary for the achievement of design integrity commensurate with the objectives of public safety which we seek.

The difficulty lies not so much in the ideal of "independent" review as in its application. The design process of a large power plant is a complex process taking place in large, organizationally sophisticated, and highly integrated organizations. Each facet of the design receives a complex of multiple considerations distinct from other facets. To attempt to submit this complex process to regulatory scrutiny for the purpose of ultimately permitting it to be stamped with the label of "independent" defeats both the regulatory process and the design process. The standard of "independence" is simply inapplicable to a complex process such as design. The mold of "independence" is too vague in its outline and the design process will suffer from being forced into it.

It is an extremely formidable task to consider even the detailed description of a design organization to a regulatory reviewer necessary to adequately convey the complex of organizational arrangements which assure design integrity. Should such a task be undertaken, the reviewer would of necessity have to be a person of stature and experience in the administration of large and complex designs by means of a large organization. Consider also that one month after the expenditure of a great deal of effort on the part of our staff and yours, the organization will have changed. So large and complex a human structure must constantly change to remain responsive to its technological enviroment. What could be the result of such a review? We would both deplore the imposition of any structural or procedural rigidities in any viable organization charged with such sensitive responsibilities. Our experience has been that excessively rigid organizational requirements can only lead to dilution of individual responsibility and creativity, overburden technical brilliance with administrative detail, and produce results by rote instead of reason.

In summary, a regulatory inquiry into structure of a design organization in the name of imposing some form of structure known as independence will not yield desirable results. On the contrary, the process of inquiry can only lead to an extension of the licensing process, and the process of regulation can only lead to decline in the efficiency of the design organization.

The gravity of a potential extension of regulation into the internal structure and practices of a professional organization is sufficiently great for us to urge that its consideration be divorced from any licensing proceedings. If there is concern on the part of the Commission as to whether our design organizations are properly motivated, organized or administered, let this be the subject of a mutual industry-AEC exchange in a task-force setup. The management and administration of complex technical application required in serving the public can best be served by voluntary and evolutionary adjustment to meet any changed needs, rather than by the imposition of formal regulatory requirements.

Our final comment is to observe that like many preceding criteria, the quality assurance criteria are of necessity general. The ultimate import of these criteria will be determined by the manner in which they are applied by both applicants and those involved in the regulatory process. We propose that the criteria remain tentative for two years, and that following this, an additional period for comment be established. In this way, concrete experience can be incorporated into the final revision.

We are grateful for the opportunity to express our views.

Yours very truly,

George Kinsman

George Kinsman
Senior Vice President

GK:dt

CC: Dr. Peter A. Morris

DOCKET NUMBER
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Quality Assurance

Babcock & Wilcox

Power Generation Division

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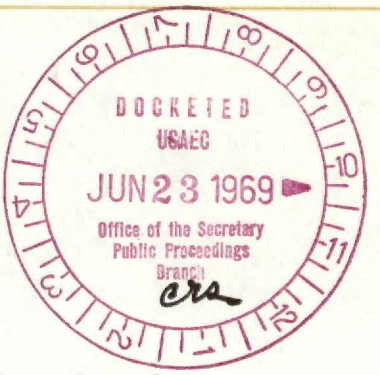
June 17, 1969



The Secretary
U.S. Atomic Energy Commission
Washington, D. C. 20545

Attention: Chief, Public Proceedings Branch

Gentlemen:

This letter is to comment on the AEC's proposed revision to 10 CFR 50 as published in the Federal Register of April 17, 1969, titled "Quality Assurance Criteria for Nuclear Power Plants". Due to the detailed nature of the proposed revision, we have a number of specific comments to offer. It is appropriate, however, to note the major areas in which improvements seem necessary. For this reason, specific comments have been categorized.

The Babcock & Wilcox Company has for many years past recognized the benefit, and subscribed to the philosophy, of a thoroughgoing quality assurance program. We therefore are in sympathy with the Commission's desire to set forth adequate criteria and bases for establishing such a program throughout the nuclear industry. It is with this basic support of such a program in mind that we offer the following comments:

(1) Documentation. We believe that the scope of the proposed documentation and record keeping in the amendment is so broad that it may impose real inconvenience, and in some instances hardships, in operation without always significantly improving quality. A real danger exists that the proposed regulation may actually result in the accumulation of very detailed records, but only at the expense of the time senior engineers, inspectors, and supervisors could be devoting to more significant quality control activities. We suggest that the proposed rule should be critically reviewed once again prior to issuance to assure that only the necessary and required records are maintained, and that thus greater emphasis will be placed on records deemed essential consistent with safety.

(2) Design Control. Section III of Appendix B, Design Control, specifies 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". The scope of effort required in such reviews is not specified. It should at least be made clear that experienced engineers reviewing and checking the original work for method, input, and accuracy are adequate to fulfill the requirement, and that original work or independent repetition of engineering effort is not required.

Acknowledged by card 6/23/69, crs

(3) Amendment Scope. We believe that the scope of the proposed rule is too all-encompassing, leading to inflexible, detailed, specific regulating requirements, where in many instances more general criteria would be appropriate. More general criteria would also afford needed flexibility to the many different organizations and quality assurance program formats which will utilize these regulations. If quality assurance requirements are to be set forth, then a critical review of the regulation should be made to assure that they are limited in number so as to identify the essential elements of the QA program. Such a limitation in scope would permit participating organizations to detail and extend the basic requirements, but would place added emphasis and importance on the specified requirements. The scope of the proposed amendment is enlarged also by the fact that no recognition is given to the degree to which structures, systems, and components are related to safety importance or to their degree of redundancy. Rather, in such areas as documentation and materials traceability, all requirements are applied with equal emphasis to all components having any safety-related function. The detailed new Appendix B which is proposed is thus often confusing and repetitive, and as a result, is open to uneven and arbitrary interpretation. Some specific examples are:

(a) In the revised Par. 50.34 (a) (7), and in the first sentence of the Introduction to Appendix B, a "description and evaluation of the quality assurance program to be applied to the design, fabrication, etc. ---" is required of applicants in their PSAR's. In view of the very detailed requirements set forth in the proposed Appendix B, a statement of compliance would seem more appropriate than an evaluation. We agree that an evaluation would be appropriate if the regulation established general criteria for quality assurance and the manner of implementing these were left to the applicant.

(b) In 50.34 (b) (6) (ii), Managerial and Administrative Controls to assure safe operation are referred to as a requirement of Appendix B. While we recognize the necessity for documenting the QA program in the application, it is not evident that requiring such controls falls within the purview of the quality assurance program. We believe this is an unnecessary complication in the Quality Assurance Criteria and, since Section 50.34 (b) (6) presently requires information concerning managerial controls as written, it should remain unchanged, and the second sentence in the proposed 50.34 (b) (6) (ii) should be deleted. There is no real relationship between the quality assurance program and the requirement for such controls. Correspondingly, the second sentence in the Introduction to Appendix B should be deleted.

(c) The last sentence of Section I, Organization, of Appendix B specifies "regular review" of the status and adequacy of their part of the quality assurance program by management of other organization (than the applicant) participating in the program. This is open to definition of "regular review" and "review" as a minimum, and all that need be specified is that cognizant management remain informed of status and adequacy.

(d) In Section II, Quality Assurance Program, of Appendix B, the phrase "consistent with the progress of the work" should be added in the first sentence after the words, "The applicant shall establish at the earliest practical time". In this section the intent of the second and last sentences is covered elsewhere in the regulations, (e.g., in many of the following sections of this proposed amendment and in the proposed 50.2 (w) and revised 50.34), and these sentences should be deleted except for the portion of the last sentence referring to training.

(e) In Section III, Design Control of Appendix B, the intent of the third sentence seems to be covered adequately in Section VI, and the sentence, modified as necessary, seems more appropriate to that Section than to its present location. That portion of the fifth sentence specifying management review of reports of in-process design reviews seems much too specific and inconsequential a requirement for inclusion in these criteria.

(f) In Section VIII of Appendix B, Identification and Control of Materials, Parts, and Components, a requirement is stated for establishing measures for the identification and control of materials, parts and components, including partially fabricated assemblies. The proposed regulation states, "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 scope of this statement leaves it open to all components in all systems having any (unspecified) degree of safety-related function and does not limit these requirements to the manufacturers of major components. We believe that retaining this degree of traceability would be unrealistic and that this requirement should be restricted to pressure-containing parts of safety-related systems.

We have no further comments to offer at this time, but we will be happy to discuss the concerns which have been expressed here with the Commission's staff at any suitable time.

Sincerely yours,

W. H. Rowand

W. H. Rowand
Vice President

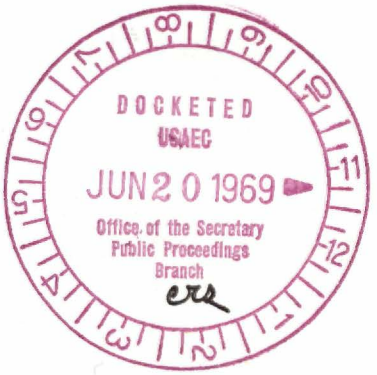
WHR/db

DOCKET NUMBER
PROPOSED RULE PR-50
Quality Assurance

ATOMIC INDUSTRIAL FORUM INC.

850 THIRD AVENUE · NEW YORK, N.Y. 10022 · PLAZA 4-1075

June 18, 1969



Secretary
U. S. Atomic Energy Commission
Washington, D. C. 20545

Attention: Chief, Public Proceedings Branch

Dear Sir:

This letter is in response to a Federal Register notice of April 17 inviting public comment on a proposed amendment to 10 CFR Part 50 which would add an Appendix B, "Quality Assurance Criteria for Nuclear Power Plants."

To review this proposed amendment, the Forum convened on June 3 the following ad hoc group of knowledgeable and interested members:

Harvey F. Brush	Bechtel Corporation
W. A. Carbiener	Battelle Memorial Institute
Paul Dragoumis	American Electric Power Service Corporation
J. P. Gibbons	Philadelphia Electric Company
Sherman D. Goodman	Gilbert Associates, Inc.
Stanley K. Hellman	The Ralph M. Parsons Company
Murray Joslin	Consultant
C. Rogers McCullough	Southern Nuclear Engineering, Inc.
R. J. McWhorter	S. M. Stoller Associates
Lawrence E. Minnick	Yankee Atomic Electric Company
Harold Oslick	Ebasco Services Incorporated
Francis J. Patti	Burns & Roe, Inc.
E. J. Sack	Consolidated Edison Company of New York, Inc.
Kenneth W. Sieving	Stone & Webster Engineering Corp.
W. R. Smith	The Babcock & Wilcox Company
John J. Taylor	Westinghouse Electric Corporation
Edwin A. Wiggin	Atomic Industrial Forum, Inc.

The comments which follow represent a consensus of the above listed individuals.

Acknowledged by card 6/20/69, crs

The group concurs with the Commission that the establishment of quality assurance criteria is both necessary and desirable. Notwithstanding this agreement, we believe the criteria as proposed include detailed requirements which will place heavy demands on the time and efforts of highly trained specialists which will not necessarily be translated into attainment of the quality which should be incorporated in safety related structures, systems, and components. In fact, some portions of the proposed criteria are presented in such minuscule detail as to comprise a constraint on activities rather than serving as guidelines for directing attention to matters of importance.

Specifically, much of our concern can be attributed to three major criticisms which respectively deal with the over-extended scope of the criteria, the inflexibility of certain of the criteria, and an over-emphasis on documentation. In addition, there are a number of instances where ambiguity and redundancy may lead to confusion and unintended non-conformity with the criteria.

The balance of our comments are directed to the three major criticisms cited above.

Scope: Both the preamble and introduction to the proposed rule amendment state that its purpose is to provide quality assurance requirements for "the design, construction, and operation" of "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."

We do not believe it necessary or desirable to extend the proposed quality assurance criteria to facility operations. Limitations on operations are adequately covered in technical specifications and operator qualification requirements. And for the same reason, we do not believe that these criteria should be generally applied to "maintaining, repairing, and refueling" a facility as indicated in the introduction. Excepted, of course, are those aspects of maintenance and repair involving replacement of or modification to structures, systems and components originally covered by the quality assurance program.

On the other hand, we do agree that quality assurance criteria of a performance type should be applied to "designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, and modifying safety related structures, systems, and components. In this connection, Section 50.34(a)(7) should make clear that the quality assurance program is to be applied to the design, fabrication, construction and testing of structures, systems, and components of the facility which have a significant, direct bearing on plant safety - not to all structures, systems and components of the facility. It should also be made clear that the degree of detail and complexity of the required quality assurance program should be directly related to the safety risks associated with a malfunction or failure of said structure, system or component.

Inflexibility: We question the need to spell out a quality assurance program "at the earliest practical time" in the detail called for in Section II. It would provide much more flexibility to the applicant, without compromising the purview of the Commission, to call for a quality assurance program of the requisite detail to be developed in stages, consistent with the scheduled progress of the construction program. If this is what is intended, it would prove helpful to make the language more explicit.

In a number of instances, the criteria extend beyond performance requirements and attempt to spell out how these requirements are to be met. For example, Section III indicates that "design reviews" will be the means by which the applicant assures that applicable regulatory requirements and the design basis are correctly translated into specifications, drawings, procedures, and instructions. If design review is intended to mean duplication of design activities, we would submit that the objective of design control could be as well served by conservative design practices set forth in written procedures so that implementation could be readily checked. The problem here stems in part from a lack of definition of "design review."

Another example of where the criteria extend beyond performance requirements is to be found in Section X calling for the designation of "mandatory inspection hold points." Depending on the type of quality assurance program being followed, identifying such hold points in appropriate documents and employing them to monitor and control the progress of the work may or may not prove a useful procedure.

Documentation: The proposed criteria could go far beyond what appears to the group as necessary or reasonable in their requirements for documentation and document control, depending on the interpretation given to individual requirements by the AEC staff. For example:

> Section III refers to procedures which are to be established "for the review, approval, release, distribution, and revision of documents involving design interfaces;"
>
> Section IV calls for "documents for procurement of material equipment, and services, whether purchased by the applicant or by its contractors or subcontractors;"
>
> Section V provides that "activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances;"
>
> Section VI indicated that "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;"

Section VII provides that "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 product or services /and/ test reports, inspection records, audit reports, certificates, and other evidence of quality shall be used in this assessment;"

Section VIII indicates that measures established for the identification and control of materials, parts, and components, including partially fabricated assemblies "shall assure that identification is maintained, either on the item or on records traceable to the item...;"

Section X provides that "a program for in-process and final inspection of activities affecting quality shall be established to assure conformance with documented instructions, procedures, and drawings;"

Section XI calls for a test program "to assure that all required testing, including proof testing, acceptance testing, and operational testing, is identified and performed in accordance with written test procedures..." This same Section states that "test results shall be documented...;"

Section XV deals with measures to control material, parts, or components which do not conform to requirements and states that these measures "shall include procedures for identification, documentation, segregation...;"

Section XVI which treats on corrective action states that "the identification of conditions adverse to quality, the cause of the condition, and the corrective action taken shall be documented;"

Section XVII states that "records shall be maintained sufficient to furnish documentary evidence of activities affecting quality for use in the management of the program;" and

Section XVIII dealing with audits points out that "audit results shall be documented..."

Clearly, some of the above documentation is necessary, but it seems equally clear that the indicated superfluity of documentation requirements will only serve to divert the attention of the limited

number of personnel qualified in the quality assurance area to non-productive efforts and thereby risk attainment of the real objectives of the program envisioned.

Closing Comment: We have not attempted to modify the proposed Appendix B to make it conform with the criticisms and suggestions cited above. We believe that such an effort would prove of only limited value prior to a detailed discussion with the AEC regulatory staff. In view of the potential impact of the proposed criteria on the industry and the number of questions raised during our discussion on June 3, we would hope to be given an opportunity to meet with appropriate representatives of the AEC regulatory staff at their convenience to discuss this matter in further detail.

Sincerely yours,

Edwin A. Wiggin
Secretary, Reactor Safety Committee

EAW:jr

YANKEE ATOMIC ELECTRIC COMPANY

441 STUART STREET, BOSTON, MASSACHUSETTS 02116

June 18, 1969

YA-2772

Secretary
U. S. Atomic Energy Commission
Washington, D. C. 20545

Attention: Chief, Public Proceedings Branch

Gentlemen:

This letter is in response to the Commission's invitation for comment on the proposed amendment to Part 50 of the Commission's regulations published in the Federal Register for April 17, 1969 and having to do with Quality Assurance Criteria.

We found the proposed criteria to be a well-stated, complete and generally exemplary listing of useful methods for attaining quality assurance in the design and construction of a nuclear power station. We feel further that the issuance of this listing is appropriate and helpful in serving to emphasize the desirability and necessity for a well-planned and effective quality assurance program. We also feel, however, that the actual definition of such a program is still largely a matter of judgement as to the extent to which the various methods available and delineated in the criteria shall be applied.

To be somewhat more explicit we feel that essentially every proposed requirement has an appropriate application on at least selected "structures, systems and components", but we also feel that there are many plant items which by no means merit the exhaustive approach delineated in the proposed criteria taken as a whole. Perhaps it is too obvious even to state, but the quality assurance program appropriate for a reactor pressure vessel is so vastly different than that necessary for a transistor in a control circuit that it would seem desirable for such differences to be clearly recognized in the preparation of an all-inclusive set of criteria.

This general line of thought is occasionally apparent in the text of the proposed criteria through the use of qualifying words such as "suitably", "to the extent necessary", and "as appropriate". Many of the requirements, however, seem to be tempered only by the general qualifying statement in Section II, QUALITY ASSURANCE PROGRAM to the

6/20/69, era

effect that "The quality assurance program shall provide control - - - over activities affecting the quality of identified structures, systems, and components, to an extent consistent with their importance to safety." (Emphasis added.)

Actually, we feel that there are a variety of considerations in addition to "importance to safety" which must be evaluated in determining the level of quality assurance effort to be devoted to a specific area. Among these are the complexity of the item from the standpoint of design and fabrication; the relative difficulty or simplicity of testing the item to demonstrate its functional condition; and the general state of the art in terms of experience, competence, design methods and process control.

We recognize the difficulties involved in developing criteria in such a broad field which would be completely explicit without being unduly voluminous and probably burdensome. Yet reasonable consistency of approach between various projects is certainly desirable, if not essential from the point of view of both the applicant and the AEC staff. We suggest that a discussion type meeting or meetings composed of representatives from all segments of the industry and based on the comments received on these criteria would serve a useful purpose in this regard.

Very truly yours,

L. E. Minnick

L. E. Minnick
Vice President

LEM/aj

UNITED STATES
ATOMIC ENERGY COMMISSION
RICHLAND OPERATIONS OFFICE
P. O. BOX 550
RICHLAND, WASHINGTON 99352

IN REPLY REFER TO:

June 11, 1969

Mayhue A. Bell
Division of Operational Safety, HQ

PROPOSED AMENDMENT TO 10 CFR 50 - QUALITY ASSURANCE REQUIREMENTS FOR NUCLEAR POWER PLANTS

The subject guidance has been reviewed and discussed informally with our contractors. We have the following comments:

a. Page 1 - Revise to read: ". . . Nuclear power plants include reactor 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. Fuels preparation, handling, storage, and reprocessing facilities as well as waste management facilities are not included in this criteria. This appendix establishes . . ."

b. Page 3 - The organization as described in the third and fourth sentences indicates that the auditors and the "doers" may be the same people. These functions should probably be separated. Statements following appear to conform generally to this separation of responsibilities idea, but are not clear.

c. Page 3 - The last sentence on the page is weak. It seems to indicate a self-audit but the wording does not make that clear.

d. Page 4 - It would seem wise to have a "Management" quality assurance program since the total quality of a plant is not related to just the physical aspects.

e. Page 5 - In the first sentence, "Management" could be added to the list.

f. Page 5 - There appears to be an inconsistency or an omission in this requirement. In the first part, design reviews must be performed by individuals or groups other than those who performed the original design. Later in the requirement, it is stated that design changes and field changes shall be approved by the organization that performed the original design.

It is obvious that design changes and field changes can be as important as the original design and hence deserve the same type of impartial review. This may not be accomplished by simply requiring approval by original designers.

g. Page 6 - In section V, a formal definition of "important operations" should be established; setting up such a definition should be part of this procedure.

h. Page 7 - In section VI, there should be some statement that material and so forth will be checked for conformance to specifications before the equipment, etc., is used or installed.

i. Page 7 - Section VIII seems to be fine in concept but application to each nut and bolt would be unrealistic.

j. Page 9 - Section XII indicates that calibration shall be accomplished at regular intervals, but gives no instructions as to action required when out of adjustment conditions are identified. It would seem reasonable to inspect again or take other appropriate action when conditions such as this have been found.

k. Page 10 - Section XIV. A procedure should be approved for removal of stamps, tags, etc., after completion of inspections and other requirements.

l. Page 10 - Section XIV. There should be provisions for establishing inspection norms for systems, subsystems, parts, etc.; an inspection is meaningless without well based measurement criteria.

General

The opinion has been expressed that the criteria are not sufficiently specific and that an applicant will have difficulty in defining an acceptable quality assurance program. There is a feeling that these criteria will not speed up the regulatory process and may discourage an applicant. If possible, it would be better to state: "here are the standards you must meet." This would eliminate much trial and error.

We note that the criteria are addressed to "the health and safety of the public." We who are under the General Manager also have to consider property safety and effect on programs.

Your transmittal refers to the proposed Part 50 amendment as quality assurance requirements for Nuclear Power Plants. The news release refers to the amendment as guidance while the amendment wording is quality assurance criteria. We would want specific definition of the wording in the event this document becomes applicable to Commission-owned reactors.

W. E. Lotz, Director
Health and Safety Division

HN:AB

DOCKET NUMBER
PROPOSED RULE PR-50
Quality Assurance

GILBERT ASSOCIATES, INC.

ENGINEERS AND CONSULTANTS

June 16, 1969

GILBERT ASSOCIATES, INC.
P. O. BOX 1498
525 LANCASTER AVE.
READING, PA. 19603

DOCKETED
USAEC
JUN 19 1969
Office of the Secretary
Public Proceedings
Branch
crs

Secretary
U. S. Atomic Energy Commission
Washington, D. C. 20545

Attention: Chief Public Proceedings Branch

Dear Sir:

This letter is in response to the Commission's invitation for comments or suggestions for consideration in connection with proposed amendments to 10 CFR Part 50 of the Commission's regulations published in the Federal Register on April 17, 1969.

We completely agree with the need to establish criteria or requirements which cover the essential elements of a quality assurance program. Furthermore, the expressed intent to provide a quality program covering "- - - identified structures, systems and components, to an extent consistent with their importance to safety." is excellent. Therefore our comments are limited to the applicability and extent of these requirements so as to clarify the upper limit beyond which it is unnecessary to go in order to satisfy the intent of the proposed amendment.

We have essentially four comments or suggestions as follows:

1. We feel that the intent of Section III, Design Control is "to assure that applicable regulatory requirements and the design basis - - - are correctly translated into specifications, drawings, procedures and instructions". The design basis itself is adequately reviewed in the licensing process and adopted from the application of the 70 general design criteria. Its adoption should represent the starting point in the project for the application of the provisions of the quality program. The use of the words "design review" throughout the proposed amendment should only be used in the context of the first statement of this paragraph. Therefore, in order to avoid mis-interpretation we suggest that the design basis itself be explicitly excluded from the provisions of this amendment and that all reference to design review apply only to the above statement of intent. Furthermore, the extent of the design review should be established so as to avoid duplicate calculations and duplicate engineering.

Acknowledged by card 6/19/69, crs

GILBERT ASSOCIATES, INC.

ENGINEERS AND CONSULTANTS

2. The proposed amendment to paragraph (a)(7) requires that the preliminary safety analysis report include "a description and evaluation of the quality assurance program to be applied to the design, fabrication, construction and testing of the - - -". We suggest that it is more practical for the quality program details to be established in stages that are consistent with the progress of design, construction and the selection of sub-contractors and vendors, since the program itself is based on these factors to a large extent. The PSAR should include only the essential parts of the quality program.

3. We have two suggestions aimed at minimizing the paper work required to achieve a given set of objectives. The first concerns a clarification of Section IV Procurement Document control. If a contractor or sub-contractor conforms in all respects with the provisions of the proposed amendment (Appendix B, 10 CFR 50) as evidenced by a quality assurance evaluation survey, we feel that routine in-situ inspection and reporting by the applicant or his representative is not required. This would mean that once a vendor or sub-contractor has been qualified as to method, equipment and procedures by actual inspection, then subsequent inspections can be minimized without loss of quality.

   The second concerns Section VIII, Identification and Control of Materials, Parts and Components. During the fabrication of components consisting of many parts, piece numbers change as sub-assemblies are completed; consequently, partial assemblies are given new piece numbers and the original identification is lost. Since traceability is cumbersome and documentation is heavy, material approvals by heat number or batch number (rather than by individual piece, welding rod or insert) would be more desirable where applicable. This would offer considerable simplification of paper work without loss of quality.

4. The Introduction to Appendix B as proposed states that the quality assurance program "- - -applies to all activities affecting the safety related functions - - - these activities include design, purchasing, fabricating, handling, shipping, storing, cleaning, erection, installing, inspections, testing, operating, maintaining, repairing, refueling and modifying". We feel that the quality assurance provisions of Appendix B should not apply to operation,

GILBERT ASSOCIATES, INC.

ENGINEERS AND CONSULTANTS

Secretary
USAEC
Washington, D. C.

June 16, 1969

maintenance and refueling since these functions are covered by other reviews associated with the regulatory process, such as technical specifications, schedules of maintenance and refueling, fuel management programs and programs for operator training and qualification.

In general, the interests of quality and safety can best be served if qualified Engineers (who are in short supply) spend their time on design problems rather than excessive documentation. Therefore, it is essential to have a clarification of intent for all parties involved in the licensing process even though the general language of the proposed amendment is good. By so doing, applicants, compliance people and members of DRL will be pulling in the same general direction.

Very truly yours,

S. D. Goodman
Chief Nuclear Engineer

W. H. Traffas
Manager Quality Assurance

SDG:C

cc: Harold L. Price
Director of Regulation
U. S. AEC
Washington, D. C.

AMERICAN ELECTRIC POWER *Service Corporation*

AEP

2 Broadway, New York, N. Y. 10004
(212) 422-4800

June 13, 1969

Mr. W. B. McCool, Secretary
U. S. Atomic Energy Commission
Washington, D. C. 20545

Attention: Chief, Public Proceedings Branch

Dear Sir:

This is in response to the Commission's invitation for comments on proposed amendments to 10 CFR Part 50, labelled "Quality Assurance Criteria for Nuclear Power Plants."

Our comments on the proposed changes fall into two categories, the first covering the 18 criteria themselves, and the second being a general concern over the proposed application of these criteria to the operating and refueling stages. Each of these categories is discussed separately below.

With respect to the Quality Assurance Criteria themselves, the major item for concern is criterion III "Design Control" which requires verification of design by individuals or groups other than those who perform the original design. If this is intended to express a need for a second party check limited to perusal of the design approach and results obtained by the original designer, it seems a reasonable and acceptable requirement. If, on the other hand, the "design review" requested intends a recalculation or total re-engineering by a second party, this requirement is both unreasonable and unworkable. This is especially true if one recognizes the unavailability of highly qualified people to duplicate design work.

There is no doubt that documentation is required to assure both the Permittee's managers and the Commission that the agreed upon Quality Assurance Program is, in fact, being effected. We are, however, concerned that the requirements for exhaustive documentation may result in overattention to establishing a record, to the detriment of performance. Inasmuch as literal application of the 18 criteria could result in such a problem, we suggest incorporation in the introduction of a statement of Commission philosophy on the limits of reasonableness in requirement for documentation.

The second major category in which we have a concern, as stated above, is the application of the 18 criteria to the operations and refueling phases. The criteria are properly applicable to the safety related functions of structures, systems, and components during the design, purchasing, construction, and testing stages. They should also govern certain aspects of maintenance and modifications that might be made in the plant. However, neither the wording of many of the criteria, nor the requirements of the operating license phase (technical specifications training and qualification programs) indicate any need or value in extending the Quality Assurance Criteria to cover operations and refueling.

Sincerely yours,

Paul Dragoumis/mem

Paul Dragoumis
Assistant Vice President and
Chief Nuclear Engineer

PD mem

cc: G. Charnoff

DOCKET NUMBER
PROPOSED RULE PR-50
Quality Assurance

PACIFIC GAS AND ELECTRIC COMPANY

245 MARKET STREET • SAN FRANCISCO, CALIFORNIA 94106 • (415) 781-4211

RICHARD H. PETERSON
SENIOR VICE PRESIDENT
AND GENERAL COUNSEL

FREDERICK T. SEARLS
GENERAL ATTORNEY

June 13, 1969

Secretary
U. S. Atomic Energy Commission
Washington, D. C. 20545

Attention: Chief, Public Proceedings Branch

Gentlemen:

This concerns the Notice of Proposed Rulemaking published by the Commission on April 16, 1969 (34 F. R. 6540) and the Quality Assurance Criteria published in 34 F. R. 6599 on April 17, 1969. We believe the Commission is to be commended for attempting to develop regulations in the areas covered in the proposals. For the sake of brevity we will confine our comments to what we conceive to be the problems in the approaches followed in the proposals.

With regard to the addition of paragraph (w) to 10 CFR 50.2 defining "principal architectural and engineering criteria", we believe that the proposed definition goes beyond what is implied in the term defined, which speaks in terms of criteria. The proposed definition establishes not only criteria but goes one step further and requires details as to how the criteria are to be met. We believe this is more than should be required at the construction permit stage.

Under proposed 10 CFR 50.35(b) construction permit holders are forbidden to depart from the "principal architectural and engineering criteria" without the approval of the Commission. The mechanics of obtaining this approval are not spelled out. However, in a job as large and complex as the construction of a nuclear power plant there are bound to be a number of changes as the design progresses. This is desirable in order that the latest technological developments may be incorporated in the work. However, given the very detailed proposed definition of "principal architectural and engineering criteria", the requirement that Commission approval be obtained for any changes therein would create an impossible situation as far as the construction schedule is concerned. The only alternative would be to "freeze" the design very early in the proceedings, which is undesirable.

Acknowledged by card 6/18/69 crs

As stated previously, if the definition of "principal architectural and engineering criteria" were limited to criteria, then changes could be made in the details without the delays caused by the need for obtaining approval of the Commission. Any such changes would be subject to the risk of subsequent Commission disapproval unless Commission approval had been sought and obtained. The Commission would not lose anything by this procedure because it has a second, plenary review of the application prior to issuance of the operating license.

As an alternative, though less desirable, we suggest that the procedures for post license changes in 10 CFR 50.59 be utilized, which would limit Commission approval to changes which involve an "unreviewed safety question" as defined in the regulation. This would give the applicant more flexibility by limiting the number of changes required to be referred to the Commission. The Commission would, of course, have the opportunity to review all changes at the time of its second complete review of the application at the operating license stage.

With regard to the Quality Assurance Criteria proposed, we can add little to what has already been said by the Westinghouse Electric Corporation in its comments to the Commission on this subject dated June 9, 1969. We believe these comments are well taken and urge the Commission to give them favorable consideration.

Very truly yours,

Richard H. Peterson

PAC:TC

DOCKET NUMBER
PROPOSED RULE PR-50
Quality Assurance

The Ralph M. Parsons Company

Engineers · Constructors

617 WEST SEVENTH STREET, LOS ANGELES 17, CALIFORNIA

PLEASE REPLY TO
26 BROADWAY
NEW YORK, N. Y. 10004

June 16, 1969

DOCKETED
USAEC
JUN 17 1969
Office of the Secretary
Public Proceedings
Branch
ers

Secretary,
U. S. Atomic Energy Commission
Washington, D. C. 20545

ATTENTION of Chief, Public Proceedings Branch

Dear Sir:

In response to the proposed issuance of Federal Regulations governing Quality Assurance Criteria for Nuclear Power Plants, Appendix B of paragraph 50.34 of 10 CFR Part 50, we herewith submit the comments of The Ralph M. Parsons Company. These comments supplement those issued by the Atomic Industrial Committee's Reactor Safety Committee, since our personnel participated in the review on these proposed rule changes by that group.

In general, our comments primarily reflect the feeling that many of the elements of the criteria overlap each other and consequently are not clearly defined. In addition, there appears to be an overemphasis placed on the mechanics and techniques of meeting the criteria, as opposed to just defining criteria and philosophy; i.e., Design Control - Section III. We also believe that this criteria should not reflect commercial operation of the plant since this phase of the project is better covered by the Technical Specifications and the Quality Assurance Program personnel are probably not as qualified as the operating staff to perform this function.

Detailed comments on each section of proposed Appendix B are attached. We hope that you give serious consideration to these, and all comments that you receive, and we would be happy to answer any questions you have.

Very truly yours,

THE RALPH M. PARSONS COMPANY

S. K. Hellman

S. K. Hellman
Chief Nuclear Engineer

W. A. Kalk

W. A. Kalk
Manager - Quality Assurance

SKH/WAK/db
Attch.
As above

Acknowledged by card 6/17/69 ers

DETAIL COMMENTS ON APPENDIX B

INTRODUCTION

It is recommended that the introduction state that the quality assurance program, as submitted by the applicant, define the timing for the implementation of all elements of quality assurance. This would then define, at the PSAR submittal stage, the schedule for quality assurance activities on the part of the applicant and contractors. Since the PSAR will define the quality assurance program, the FSAR should indicate the deviations from that program.

SECTION I - ORGANIZATION

This section should request the submittal of a complete Q. A. organization by the applicant. Where a multi-organization approach is selected by the applicant, the method of coordination between elements, organizations and people should be outlined in the PSAR.

SECTION II - QUALITY ASSURANCE PROGRAM

This section should indicate that the specific elements delineated in Appendix B, commencing with Section II are the guidelines to be used for the applicant's Q. A. program. The last two sentences of the section should be deleted because they reflect method and mechanics, and not criteria. Where the specific elements of an applicant's program are combined or modified from elements contained herein, the applicant should outline his criteria.

SECTION III - DESIGN CONTROL

There should be a separation between the area of design reviews and design changes. With respect to design changes, procedures should be established by the applicant for defining the method of review and approval. Release, distribution, and revision are subjects related to Section VI, Document Control. Delineation of specific areas of design reviews, as included in the middle of this section should be deleted.

SECTION IV - PROCUREMENT DOCUMENT CONTROL

This section should be included as part of Section VI, Document Control. One system covering all project documents provides a better method for control, retrievability, and traceability for all design and construction information. The criteria for documentation required for all procured items can be better outlined in Section VII.

SECTION V - INSTRUCTIONS, PROCEDURES AND DRAWINGS

This section could be better deleted and combined with Section VI.

SECTION VI - DOCUMENT CONTROL

All project documentation should be covered in this section. The applicant should outline the groups or individuals who will be responsible for controlling all documentation and generally define the methods to be utilized.

SECTION VII - CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

Final disposition of all documentation should fall under Section VI.

SECTION VIII - IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

No comments.

SECTION IX - CONTROL OF SPECIAL PROCESSES

This section could be deleted because it is covered by Section VII, X, XI, etc. Much of this criteria will be incorporated into the basic design, fabrication and construction specifications. In any case, what constitutes qualified personnel and procedures?

SECTION X - INSPECTION

This section is too detailed and incorporates information on required techniques and mechanics of inspection. Perhaps it would be better to only include the first few sentences in this section and state that the results of all inspections should be filed under Section VI.

SECTION XI - TEST CONTROL

What type of testing is referred to and what is meant by "all testing"? In line with our introduction statements in this letter, we question the advisability of covering "operational testing".

SECTION XII - CALIBRATION OF MEASUREMENT AND TEST EQUIPMENT

This section should accept certification of calibration, rather than requiring individual checking of all equipment. An example of this philosophy would be an equipment vendor's shop.

SECTION XIII - HANDLING, STORAGE, SHIPPING AND PRESERVATION

This section should cover the site requirements; similar requirements on procured items should be covered under Section VII.

SECTION XIV - INSPECTION; TEST AND OPERATING STATUS

No comment.

SECTION XV - NONCONFORMING MATERIALS, PARTS OR COMPONENTS

Based on above comments, this can be covered in Section XIII.

SECTION XVI - CORRECTIVE ACTION

We believe that this section should be deleted and the criteria covered under Sections I and II. In addition, we question the advisability of delineating the degree of control on the vendor's shop as opposed to control and justification of the part being procured. This detail gets beyond the delineation of "criteria".

SECTION XVII - QUALITY ASSURANCE RECORDS

This section should be deleted and covered in one statement under Section VI. The statement should reflect the fact that all records, documentation, data, etc., covering the elements of the Q.A. program as outlined herein, shall be filed under Document Control.

SECTION XVIII - AUDITS

The degree of auditing reviews should be minimized. Specifically the sentence dealing with the review of audit results, the third sentence in the section, should be deleted.

Quality Assurance, Backfitting

DOCKET NUMBER
PROPOSED PR 2,50 50

B-427

TWX INCOMING

RECEIVED
HEADQUARTERS
MAIL SERVICE SECTION

2\58PM 910-338-0116 SAN JOSE CALIF 6/16/69 1969 JUN 16 PM 6 04

1969 JUN 17 AM 8 47

U.S. ATOMIC ENERGY COMMISSION WASHINGTON, D.C.

U.S. ATOMIC ENERGY COMM.
TWX UNIT

W.B. MC COOL, SECRETARY
UNITED STATES ATOMIC ENERGY COMMISSION
WASHINGTON, D.C.

THIS IS TO ADVISE YOU THAT BY MONDAY, JUNE 23, 1969, YOU WILL RECEIVE COMMENTS OF GENERAL ELECTRIC COMPANY TO AMENDMENTS PROPOSED BY AEC TO ITS REGULATIONS AND RULES OF PRACTICE, PUBLISHED IN THE FEDERAL REGISTER ON APRIL 16 AND 17, 1969, CONCERNING LICENSING OF PRODUCTION AND UTILIZATION FACILITIES, BECAUSE OF THE COMPLEXITY AND FAR-REACHING EFFECTS OF THESE PROPOSED AMENDMENTS, IT HAS NOT BEEN POSSIBLE TO COMPLETE OUR COMMENTS AT THIS TIME. WE BELIEVE GE\S COMMENTS ARE IMPORTANT AND CONSTRUCTIVE, AND WE TRUST THAT THE COMMISSION WILL BEAR WITH THIS SLIGHT DELAY.

E.T. MAHER-COUNSEL
NUCLEAR ENERGY DIVISION-
GENERAL ELECTRIC CO.

DOCKETED
JUN 17 1969
Office of the Secretary

END

TWX INCOMING

HOW MSG.RECD
R OK TNX END

Gulf General Atomic
Incorporated

P. O. Box 608
San Diego, California 92112
Tel: (714) 453-1000

June 14, 1969

Secretary
U. S. Atomic Energy Commission
Washington, D. C. 20545

Attention: Chief, Public Proceedings Branch

Dear Sir:

Gulf General Atomic Incorporated has made a careful review of your proposed additional criteria for quality assurance programs in the construction and operation of nuclear power plants published in the Federal Register on April 17, 1969.

While we at Gulf General Atomic feel that in our nuclear power plant design and construction activities we fully comply in principle with the proposed addition, we are quite concerned that the government may by virtue of this regulation go beyond broad principles and impose through implementation restrictive practices. It has been our experience that there is nearly always more than one way to organize and successfully administer these important programs. The reactor industry, because of its relative newness, is constantly changing. These changes exhibit themselves in the form of new codes, new construction methods and materials and a wide variety of contracting methods. For this reason we believe the industry needs the freedom to adjust its administrative and technical procedures to always be the most efficient and effective for the current conditions.

We see two highly detrimental results from regulations which ultimately may go beyond the overall concept and attempt to regulate at the detailed level. First, it destroys initiative. People tend to be content to accept the situation and hence fail to push obvious improvements because of the inherent resistance of the system to change. Second, it tends to abrogate responsibility. Individuals usually exhibit a pride in their procedure or system that strongly motivates them to make it work. A too detailed and restrictive procedure will destroy this motivation, and the individual will let the regulation assume the responsibility.

Acknowledged by card 6/17/69, ors

We have one specific concern with the proposed additional criteria and that is the association of quality assurance with design review. Part II, page 4, and Part III, page 5, imply a significantly broadened scope for a normal quality assurance organization. This aspect of the proposed addition needs further clarification.

In summary, we feel that any proposed regulation should be limited to stating the broad requirements for quality assurance associated with nuclear power plants and leave the details of the implementation and the defense of such implementation to the industry.

Very truly yours,

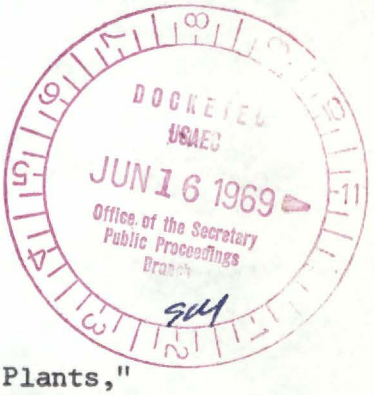
C. A. Rolander

C. A. Rolander
Vice President

Quality Assurance

DOCKET NUMBER
PROPOSED RULE PR - 50

3611 Maplevue Drive
Bethel Park, Pennsylvania 15102
June 11, 1969



Secretary, United States Atomic Energy Commission
Washington, D. C. 20545

Attention: Chief, Public Proceedings Branch

Subject: "Quality Assurance Criteria for Nuclear Power Plants," Appendix B of AEC Regulation 10 CFR Part 50; "Licensing of Production and Utilization Facilities," published in The Federal Register, Vol. 34, No. 73, Thursday, April 17, 1969

Dear Sir:

This letter submits my comments and suggestions on the "Quality Assurance Criteria for Nuclear Power Plants," published in The Federal Register April 17, 1969.

The new Criteria appear to be well thought out and comprehensive. They can represent a significant step forward in efforts to insure public safety in a complex new technology, where official estimates of what could result from an "incident" at a large urban power plant refer to deaths in the thousands, injuries in the tens of thousands and losses in the billions of dollars. While much can be said in praise of the proposed Criteria, this letter focuses on the loopholes and ambiguities which tend to destroy their effectiveness.

In my judgment the requirement for an adequate independent design review constitutes the most important part of the proposed Criteria from a public safety point of view. The Government has always insisted on independent checking for its own nuclear plants and has found such checking to be an indispensable part of insuring safety and reliability. In the Naval Reactors Program, for example, the independent design reviews performed by the Westinghouse Plant Apparatus Department and Bettis Atomic Power Laboratory, and by General Electric's Machinery Apparatus Operation and Knolls Atomic Power Laboratory have uncovered many deficiencies in manufacturer's designs which compromised structural integrity. These findings have resulted in major design changes and operational restrictions.

Acknowledged by card 6/16/69. CJD

Current practice in the commercial atomic power industry includes little comparable independent checking. Although the ASME Code for Nuclear Vessels covers the design requirements for reactor vessels, steam generators, pressurizers and heat exchangers, there is no provision for even a cursory review of the required stress reports. Neither is there any such provision in the Draft ASME Code for Pumps and Valves for Nuclear Power issued for trial use and comment in November of 1968. The USAS B 31.7 Code for Nuclear Power Piping issued for trial use and comment in February of 1968 also contains no review provisions. It is, therefore, essential that an independent review be specifically required in the Government regulations.

Design calculations crucial to public safety are now being performed by a myriad of proprietary and publically available computer programs used for the thermal, stress and dynamic analysis of nuclear components. Each of these computer programs contains numerous simplifications, approximations and assumptions. Many of them were "verified" by comparing specific calculated results with experimental results, but were later found to give incorrect results for somewhat different geometries or loading conditions. Often the range of applicability of a given program depends on very subtle mathematical considerations seldom understood by the user. The results obtained from these programs usually constitute the only basis for evaluating resistance to catastrophic failure, structural stability, fatigue life and seismic shock resistance of critical components. Calculations so crucial to public safety should not be accepted without being checked by an independent computer program or analytical method.

The need for such an independent check is compounded by the dilution of liability for nuclear accidents that now exists in the commercial nuclear power industry. Utilities continue to rely on manufacturers in questions of public safety. However, the manufacturers have not accepted the liability. Neither have the inspection agencies who disclaim legal liability for the structural adequacy of the vessel or for any failures which may subsequently occur. The insurance companies are, it is clear, relying upon the Government. The Atomic Energy Indemnity Act, extended for another ten years in 1965, provides for an insurance subsidy up to 500 million dollars out of the Federal Treasury to compensate for part of the loss of life and property possible in a nuclear accident. Homeowners insurance policies generally contain a Nuclear Clause which excludes damages due to nuclear incidents. With this dilution of responsibility, an independent design review is absolutely essential.

I have contributed a great deal of personal effort to the formulation of Code rules which are intended to protect the public and I agree that the considerable efforts being put into this work by industry and Government are worthwhile. However, experience has shown that structurally inadequate designs almost always violate Code rules. Such designs are usually the result of oversights or the use of inappropriate methods of analysis. This conclusion is based on more than ten years experience in the Naval

Reactors Program at the Bettis Atomic Power Laboratory where I reviewed Stress Reports prepared by many consultants and manufacturers. I am convinced that the requirement for an independent design review is more important to public safety than any improvements that could possibly be made in the Code Criteria themselves.

The belief that a truly independent review can be performed by individuals or groups "who may be from the same organization" as those who performed the original design is unrealistic. Given the best intentions, no organization should be relied upon to police itself when public safety is so intimately involved as it is in the nuclear industry. It is the duty of Government to insure that the safety of the public is not jeopardized.

The loophole described above very seriously compromises the effectiveness of the proposed new Quality Assurance Criteria and it must be removed. However, an equally serious deficiency lies in the ambiguity of the wording contained in the proposed new Criteria. I have talked to utility executives who have studied the new Criteria and who have concluded that it contains no new design review requirements. This state of affairs can only be corrected by clearly spelling out the responsibilities of the license applicant. It must be specifically stated in the regulations that the applicant is responsible for independent design reviews for all Class A vessels as defined in Section III of the ASME Boiler and Pressure Vessel Code and for all pumps, valves and piping which contain reactor coolant and/or moderator, and which are relied upon to the extent that the loss of their service or function may impair the safety of the system.* (A modification of footnote 2 of the proposed Quality Assurance Criteria can be used to avoid a requirement for duplicate independent reviews for components of similar design and operating history.)

Finally, in order to avoid ambiguities which could make the Criteria virtually ineffective, the applicant must be required to obtain these independent design reviews at his own expense. This should be clearly and specifically spelled out in the regulations.

I have heard only two objections to the urgent recommendations outlined herein. The first objection is that there are too few independent individuals or groups capable of performing the required design checks. This objection does not square with the facts. There are many individual independent consultants available with experience in the design and analysis of pressure vessels and related equipment. In addition, there are several non-profit institutions capable of performing the desired design checks. These include the Southwest Research Institute, Battelle Memorial Institute and The Franklin Institute. Further, there are several

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* This is the definition used to define Class A vessels in the ASME Code.

independent consulting firms who offer such services. These include: Dynatech; KPA Nuclear, Inc.; MPR Associates; NUS Corporation and Teledyne Materials Research Company. Since these independent organizations are currently being relied upon to perform the original design analyses, they should be capable of performing a competent review.

The second objection is that meaningful independent design reviews would not be worth the cost. This argument admittedly introduces the need to make value judgments, but such judgments are not difficult in this case. The independent structural design reviews which experience has shown to be so essential to safety can be performed for all critical parts of the system for well under one percent of the total cost of the plant. Can the industry afford to neglect such reviews?

Nuclear power offers great potential benefits to mankind and should be developed on a priority basis even where it is not currently the most economical source of power. The nuclear industry is now in a crucial development period and cannot afford an "incident." Highly vocal critics of nuclear power must not be allowed to shake public confidence during this period. By emphasizing that checks and rechecks of structural integrity are required by law for all nuclear plants, the AEC can maintain the public confidence necessary to achieve one of its primary objectives--rapid progress in the development of nuclear power.

Very truly yours,

William J. O'Donnell

William J. O'Donnell, Ph.D., P. E.

WJO/ket

DOCKET NUMBER
PROPOSED RULE PR-50
Quality Assurance

Westinghouse Electric Corporation **Power Systems**

Joseph C Rengel
Executive Vice President
Nuclear Energy Systems

Penn Center
Box 355
Pittsburgh Pennsylvania 15230

June 9, 1969

Secretary
U. S. Atomic Energy Commission
Washington, D.C. 20545

Attention: Chief, Public Proceedings Branch

Dear Sir:

In response to the invitation for comments or suggestions in connection with the proposed amendment to 10CFR50, concerning a new Appendix B entitled "Quality Assurance Criteria for Nuclear Power Plants", Westinghouse Nuclear Energy Systems is pleased to forward comments. The proposed rulemaking was published in the Federal Register on April 17, 1969.

Westinghouse agrees with the intent of the subject rulemaking in that an effective quality assurance program is necessary in the design and construction of nuclear power plants. We also feel that all the elements of a good program are embodied in the major section headings of the proposed Appendix B, and these are in line with the elements of our own program. We are concerned, however, that the proposed amendment is not appropriate in scope or definition of detail. Also, it appears that Appendix B establishes specific requirements rather than criteria for general guidance as the title would indicate. In general, we believe the Commission has properly identified the essential elements of a quality assurance program which the nuclear industry will endorse. However, to a large degree, the requirements as written are confusing and easily misinterpreted which leads us to take exception or suggest changes to the amendment before it becomes a regulation.

There are several areas of major concern to us. These are summarized below. Also, attached to this letter are specific comments on the proposed regulations.

Acknowledged by card 6/16/69 ero

SUMMARY

1. The scope of the Criteria as stated is too broad to be effective. Reference is made in the Introduction, and elsewhere, to plant operation and other later activities such as refueling and maintenance. Although there is no question that quality assurance principles apply through the operating life of a plant, it is apparent that the body of the Criteria was not written with the post-startup phase in mind. The text as written is ambiguous, since many of the requirements do not apply in the context of the operational phase. Furthermore, there already exist quality-governing controls in the operational phase, such as Technical Specifications and other references of the Operating License. If additional controls are needed, they should be considered separately.

2. The section on Design Control should not single out design reviews as a specific means to assure that applicable regulatory requirements and the design bases are correctly translated into specifications, drawings, procedures and instructions. The term "design review" should be deleted to avoid any implication that duplication of design activities must be performed. The criterion could appropriately state that conservative design practices should be followed, and that these practices should be set forth in written procedures so that implementation can be readily measured. The final wording should be checked carefully to assure that no intent of double effort can be inferred.

3. Undue emphasis is placed on documentation, without stated regard to importance of the activity involved. Certainly, good procedures are a key element of an effective quality assurance program. Documentation that the important actions were in fact taken is necessary to provide objective evidence of compliance. These principles must be applied with good judgment, however, to prevent a program of paperwork for its own sake, which would weaken an otherwise good program and unnecessarily increase costs to the industry and to the public.

4. The document makes many inappropriate references to specific methods and techniques of quality assurance rather than stating criteria, objectives and end results which must be met by some suitable means of the Applicant's (or Manufacturer's) choice. For example, in-process and final inspections, audits and mandatory hold points are just some of many suitable techniques that can be used to assure quality. The document should avoid implying that the use of these specific techniques is mandatory when others would serve as well. Otherwise, these specific techniques will become fixed requirements whether or not they are effective and applicable to the particular situation.

5. The document invites demands for information which the designer or manufacturer considers proprietary. It should allow for the withholding of proprietary information, where appropriate, by suitable substitution of non-proprietary evidence of compliance.

Our comments and suggestions are given in the belief that constructive changes can and should be incorporated in the proposed rulemaking to reflect a cooperative AEC-Industry effort to develop clear criteria appropriate to nuclear power plants. We are prepared to work with the AEC to resolve any questions or differences arising from these comments. To this end, we will meet with you at your convenience to discuss our comments at greater length. Development of quality assurance criteria understood and accepted by both AEC and Industry will benefit all of us.

Sincerely yours,

Joseph C. Rengel

Joseph C. Rengel

Attachment

6/11/69

DETAILED COMMENTS ON PROPOSED AEC QUALITY ASSURANCE CRITERIA

Reference: AEC (10 CFR Part 50), "Licensing of Production and Utilization Facilities, Quality Assurance Criteria for Nuclear Power Plants," paragraphs 50.34(a) (7) and (b) (6), and Appendix B, published in Federal Register, Vol. 34, No. 73, Thursday, April 17, 1969.

1. INTRODUCTORY REMARKS, PARAGRAPH (d)

We consider that specific references to operating, refueling, repairing, maintaining, scheduling, fuel management, and operator training or qualification are inappropriate in these criteria. These functions are adequately covered in other Commission regulations. Consideration should be given, however, to applying these criteria to major plant modifications which change the basic design in such a way as to potentially affect the risk to the health and safety of the public.

2. CONTENTS OF APPLICATIONS: TECHNICAL INFORMATION (50.34(a) (7))

The word "evaluation" is inappropriate and unclear. It should be eliminated from both paragraph 50.34(a) (7) and Appendix B, Introduction.

3. TITLE OF APPENDIX B

The definition of criterion is "a standard on which a judgment or decision may be based." Because of the details given in Appendix B, it is no longer a general guideline or criteria.

As discussed elsewhere, the requirements as written throughout the document describe specific techniques of quality assurance, when many equally satisfactory alternate techniques and methods exist. What techniques are employed to meet a standard or objective can and should vary among manufacturing and design organizations. Rigid, specific requirements will tend to inhibit advances in technology.

4. SCOPE OF THE INTRODUCTION SECTION (APPENDIX B)

As we indicated in the remarks on the introductory paragraph (d), above, all post-startup operations such as operating, maintaining, repairing and refueling are adequately covered in other Commission regulations and should not be listed in or controlled by these criteria.

5. "EVALUATION" IN THE INTRODUCTION SECTION (APPENDIX B)

As in item 2 above, the words "and evaluation" in the fourth line of the Introduction appear to be both inappropriate and confusing. The word

"evaluation" should be eliminated. If it must be retained, its meaning in this context should be defined.

6. REDUNDANCY IN SECTIONS I and XVIII (APPENDIX B)

The last two sentences of Section I (Organization) read: "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." First, these two sentences describe only one of many specific elements of a good quality program, viz., audits, and therefore these references to audits are not appropriate in a section on "Organization". Second, these sentences are redundant with Section XVIII (Audits) which is a slight amplification of the audit function referred to in the last two sentences of Section I (Organization).

If the audit function must be included in some summary of the overall quality assurance program, it would be better to include it as one element of those listed in Section II (Quality Assurance Program).

7. WORKING ENVIRONMENT (SECTION II, APPENDIX B)

The reference to "suitable working environment" is misleading in quality assurance criteria in that it could be inferred to refer to the personal comfort of the operators. What is really important is the proper control of the process variables. A suggested substitute is "suitable process conditions (or controls)".

In the same section, the phrase "program shall establish at the earliest practical time" should be modified to allow establishment of the program in stages. Suggested rewording is: "The program may be established in stages consistent with the scheduled progress of the work."

8. QUALITY ASSURANCE PROGRAM (SECTION II, APPENDIX B)

To avoid misinterpretation, this section should specifically state that the written quality assurance program required of the applicant is intended to establish only policies and guidelines and is not expected to include in the document the detailed procedures and instructions needed to implement the program.

9. DESIGN CONTROL (SECTION III, APPENDIX B)

The section as currently written can be interpreted to require a duplicate engineering effort in many areas, and therefore should be changed.

The specific danger is that "design review" as used in this section will be interpreted to require a series of full-dress, "in-process" and "final" design reviews on each and every system and component, new or old, small or large, critical or non-critical. The words "design review" should be eliminated from the text and replaced with the title words "design control" or other terminology to clearly preclude the doubling of effort from being inferred.

It is appropriate to indicate that there will be suitable organization and documentation of all the current intra and inter-organization checks and reviews , as fitting, that constitute good, conservative, but standard, engineering practices. If duplicative design reviews are not intended, then documentation of standard good engineering practices should suffice so that implementation can be audited against the written procedures.

We interpret the "individuals or groups other than those who performed the original design" as meaning individuals or groups who may report to the same first line management but who are not actively involved in that particular design.

The third from the last sentence in this section should be omitted: "Reports of in-process and final design reviews shall be reviewed by management...." First of all, this sentence could be interpreted to mean that all equipment designs, including all the possible alternative ideas, both must get a design review and a report of that review. Second, only on formal design review are design review reports written. These reports and the reviews required on all equipment would be prohibitively costly.

10. DOCUMENT CONTROL (SECTION VI, APPENDIX B)

The word "all" in the first sentence should be changed to read "significant", in order to avoid an excessively broad interpretation.

11. CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES (SECTION VII, APPENDIX B)

The word "all" should be eliminated from the first sentence, so that a scope broader than that of Appendix B is not inferred.

The last sentence should be eliminated because both "audits" (Section XVIII, Appendix B) and "corrective action" (Section XVI) are adequately covered in other sections. The redundancy is unncessary and confusing.

12. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS (SECTIONS VIII, XIV, AND XV, APPENDIX B)

A. Redundancy

The Sections VIII and XV should be combined to avoid confusion. Note that the last sentence of Section VIII, outlining what one does with nonconforming materials, etc., is merely a summary of the four sentences of Section XV which expands on what must be done on nonconforming material. Thus, as it stands, redundancy exists. Both sections obviously refer to the same identification and control systems with Section XV telling what is done with the exceptions.

Note also that Section XIV (Inspection, Test and Operating Status) states: "These measures shall provide for the identification of those items that conform to inspection and test requirements; nonconforming items shall be clearly marked...." This is clearly redundant with Section VIII (Identification and Control of Materials, Parts and Components) which states: "Measures shall be established for the identification and control of materials, parts,...." and Section XV (Nonconforming Material, Parts or Components) which states: "Measures shall be established to control materials, parts, or components which do not conform...."

B. Universal Pedigreeing of all Material or Components

The Commission should modify VIII to avoid implication that all equipment, regardless of effect upon the health and safety of the public, needs to be pedigreed. It is sufficient to state that appropriate measures shall be provided to see that proper material is used and that defective items, or those not having received required inspections and tests, are not used.

13. CONTROL OF SPECIAL PROCESSES (SECTION IX, APPENDIX B)

The clause "....and are accomplished by qualified personnel using qualified procedures" is redundant, since the "applicable codes", etc., are requirements enough.

14. INSPECTION (SECTIONS X AND IX, APPENDIX B)

A. Redundancy

There is redundancy between sections. Section IX (Control of Special Processes) is one element of Section X (Inspection). Note the reference in sentences three and four of Section X to "monitoring processing methods" and "Process Monitoring", respectively. Also note that references to "monitoring personnel" are made in both sections.

The important elements of Section IX should be included in Section X as one element of the overall "inspection" program.

B. Hold Points

"Mandatory inspection hold points", while an appropriate element of some surveillance or inspection plans, are not appropriately applied universally to all equipment or materials in a nuclear power plant. Hold points are just one of innumerable quality assurance techniques used as elements of a quality assurance program. The reference to hold points should be eliminated.

C. In-Process Inspections

While in-process inspection is one of countless good quality assurance tools used in quality programs, the implication in the first sentence that "in-process" inspection must be universally applied is inappropriate in these regulatory criteria. Therefore, reference to in-process inspection should be eliminated.

15. TEST CONTROL (SECTIONS XI AND XII, APPENDIX B)

There is redundancy in that "calibration of measurement and test equipment" (Section XII) is merely one element of a good overall test control (Section XI) Program. Note Section XI states that "adequate test instrumentation is available and used". Sections XI and X should be combined into one section.

16. INSPECTION, TEST, AND OPERATING STATUS (SECTION XIV, APPENDIX B)

The last sentence of this section, "Procedures shall be provided for tagging equipment such as valves and switches when necessary to prevent inadvertent operation", is inappropriate in a listing of quality assurance criteria for two reasons. First, such matters are appropriately covered in Commission criteria relating to plant operation. Second, tagging out valves and switches is only one of innumerable, detailed administrative procedures used in ensuring the safe operation of a plant and, as such, is inappropriate in any criteria document.

17. NONCONFORMING MATERIAL, PARTS, OR COMPONENTS (SECTION XV, APPENDIX B)

The policy described in the phrase and sentence, "....disposition and notification to affected organizations....Ultimate disposition of nonconforming items shall be documented," while important to a supplier or contractor in the economic management of his operation, do not affect the quality of his conforming product and therefore is inappropriate in regulatory criteria.

18. CORRECTIVE ACTION, (SECTION XVI, APPENDIX B)

The practice described in the sentence, "The measures shall also assure that the cause of the condition adverse to quality be determined and corrected to preclude", while important to economic management, does not affect the quality of the product and therefore the sentence is inappropriate as a regulatory criterion.

19. QUALITY ASSURANCE RECORDS (SECTION XVII, APPENDIX B)

In the last sentence the word "requirements" is used as opposed to the term "criteria". As indicated previously, the word "requirements" is inconsistent with the term "criteria" used in the title of this regulation.

Further, the last sentence should not imply that the applicant "establishes" requirements. The record requirements are "established" by applicable regulations, codes and contracts. Reference to "location" of records should be deleted from the regulation, since that has no bearing on safety.

20. AUDITS (SECTION XVIII, APPENDIX B)

We interpret "appropriately qualified personnel not having direct responsibilities in the area being audited" as meaning appropriately qualified personnel who do not report to the first line manager in the area being audited. This should be made clear.

UNITED STATES ATOMIC ENERGY COMMISSION
IDAHO OPERATIONS OFFICE
P. O. BOX 2108
IDAHO FALLS, IDAHO 83401

JUN 11 1969

M. A. Bell, Chief, Reactor Safety Branch
Division of Operational Safety, AEC Hq.

COMMENTS ON PROPOSED AMENDMENT TO 10 CFR 50 - QUALITY ASSURANCE REQUIREMENTS FOR NUCLEAR POWER PLANTS

Reference: Letter, M. A. Bell to E. K. Loop, transmitting Proposed Amendment to 10 CFR 50, Dated April 23, 1969

The reference solicited comments upon the proposed amendment to 10 CFR 50 transmitted therewith. We have received comments from the quality assurance group of Idaho Nuclear Corporation and we are transmitting a copy herewith.

Based upon our recent experience of having to apply portions of 10 CFR 50 to the ATR, we feel it is important that these comments be forwarded to the Public Proceedings Branch for consideration.

R. E. Tiller

R. E. Tiller, Acting Director
Nuclear Safety Division

Enclosure:
Comments on 10 CFR 50, Weber to Tiller dtd 5-28-69

Quality Assurance

DOCKET NUMBER
PROPOSED RULE PR-50

IDAHO NUCLEAR CORPORATION

P.O. BOX 1845 IDAHO FALLS, IDAHO 83401

208—522-6640

May 28, 1969

Review of Proposed Amendment to
10 CFR 50, Quality Assurance
Requirements for Nuclear Power Plants
We-272-69

Mr. R. E. Tiller, Acting Director
Nuclear Safety Division
Idaho Operations Office
U.S. Atomic Energy Commission
Idaho Falls, Idaho 83401

Reference: ID Letter, R. E. Tiller to S. R. Knight, dated May 5, 1969

Dear Mr. Tiller:

The following comments regarding subject document are submitted in response to the referenced letter:

1. We believe that the subject document is an improvement over those drafts that have preceded it. However, we also feel that the document still leaves much to be desired regarding the definition of basic quality assurance program elements. We therefore find that a number of the comments that we have made previously (We-566-68) still apply.

2. We again suggest that the following quality assurance program elements be described in a more specific manner:

   a. Quality Assurance review and input during design phase.

   b. The role of Quality Assurance during construction phase; indication of responsibility for interface coordination; disposition of nonconformances and preoperation checks and testing.

   c. Operation, maintenance and modification -- procedures, instructions, testing, as-built configuration and in-service inspection.

3. We also note that the importance of management and its relationship to quality assurance programs is not indicated. If a quality assurance program is to be effective and economical, it must be established, funded and maintained by and through management.

4. The introduction lists a number of activities in which Quality Assurance is involved. However, the text does not contain any further mention of areas

such as: "fabricating", "erection", "operating", "maintaining", "refueling" or "modifying".

5. Many of the quality assurance program requirements are considered ambiguous. Such terms as "appropriate", "to the extent necessary", "reviewed for adequacy", "where necessary", "suitable conditions" and "sufficient to", used throughout the text, indicate generalities rather than specifics. Implementation of the quality assurance elements is therefore most difficult for the contractor. Who decides what is "adequate", "necessary", "suitable", etc.? We do not contend that the document must be detailed in the form of an instruction; however, if it is to be used by industry, the requirements must be specific, reference to documents that indicate specifics must be made, or someone must explain the requirements. In the interests of facility adequacy with economy, we suggest that the document be worded in a manner that will provide positive direction for the "applicant's" management regarding quality assurance program requirements for all phases from design through operation, maintenance and modification.

Very truly yours,

L. J. Weber

Manager, Engineering Division

LJWeber:tw

cc: R. E. Tiller
C. M. Rice

William J. Cahill, Jr.
Assistant Vice President

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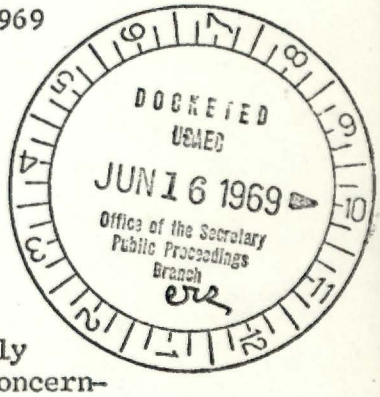
DOCKET NUMBER
PROPOSED RULE PR-2,50
Backfitting
DOCKET NUMBER
PROPOSED RULE PR-50
Quality Assurance

June 13, 1969



Secretary,
U. S. Atomic Energy Commission
Washington, D. C. 20545

Dear Sir

Consolidated Edison Company of New York, Inc. respectfully submits the following comments on proposed regulations concerning the licensing of production and utilization facilities, pursuant to notices of proposed rulemaking published in the Federal Register on April 16 and 17, 1969.

This Company presently operates a nuclear powered electric generating facility, known as Indian Point No. 1, at Buchanan, New York, is constructing Indian Point No. 2 and has recently completed a hearing before the Atomic Safety and Licensing Board for a construction permit for Indian Point No. 3. The Company has also filed an application for construction permits for two additional nuclear units.

1. Definition of "Principal architectural and engineering criteria" - § 50.2(w)

The Commission proposes to add to its regulations a definition of the term "principal architectural and engineering criteria". The proposed definition includes (1) principal design criteria, (2) essential elements of the proposed design of many specified structures, systems and components, (3) the design bases for protection against specified natural phenomena and (4) essential elements of the quality assurance program.

Our principal comment on this proposal, and the others discussed below, is that the Commission should make it clear whether it is simply conforming the regulations to current practices which have evolved through the licensing procedure, or whether it is requiring any changes in current practice. Our understanding of the proposed definition is that it coincides with current practice in the Commission's processing of applications for construction permits. Accordingly, we consider it helpful for the regulations to set forth the Commission's interpretation of the defined phrase. It might be possible, however, to interpret this detailed definition as requiring more data on these criteria than has been required in the past. If our understanding is correct, it would be helpful if the Commission clarified this point with a statement to the effect that

Acknowledged by card 6/16/69, cvs

the purpose of this change is to set forth the Commission's interpretation of this phrase as it is currently being applied, and the Commission does not intend to require any additional data. If our understanding is not correct, then clarification by the Commission would appear to be necessary.

2. Deletion of Concept of Provisional Construction Permit - § 50.35

The Commission proposes to eliminate the provisional construction permit and authorize the issuance of a construction permit upon essentially the same findings as are presently required for a provisional construction permit. The stated purpose is to conform the regulations with practice since almost all construction permits have been "provisional" and have never been converted into "final" construction permits.

We agree that this is a desirable purpose, but, as noted above, it would be helpful if the Commission eliminated possible ambiguities by making it clear that the same degree of proof now required for a provisional construction permit will entitle an applicant to a construction permit under the revised regulations. Because of the similarity in names of the permits, some might think that a construction permit under the revised regulations will require a showing similar to what is now required for a "final" construction permit. This does not appear to be the Commission's intention. If we should be in error as to the Commission's intentions, we would then believe that this change would be undesirable because it would result in an unnecessary delay in starting construction.

3. Deletion of Concept of Provisional Operating License - § 50.57

The Commission proposes to simplify licensing procedures by deleting the provisional operating license and substituting an operating license with temporary limitations on operations, if necessary. We think this is a highly desirable change.

As noted above, this change permits a possible interpretation that a new operating license requires more proof than is presently required for a provisional operating license. It would be useful if the Commission's intentions in this regard were stated explicitly.

4. Backfitting - § 50.109

The Commission proposes to add a new regulation on backfitting because, "Concern has been expressed as to the circumstances under which the Commission will require backfitting of facilities". The proposal is to require backfitting only when the Commission finds "that such action will provide substantial, additional protection which is required for the public health and safety or the common defense and security".

We agree that the requirement for a Commission finding is a desirable improvement over existing procedures. However, the proposed language is so vague that it does little to allay the "concern" referred to by the Commission. More detailed criteria than "substantial, additional protection" is necessary if the owner of a facility is to have any comprehension of when backfitting might be required.

We suggest that the regulations provide that backfitting should only be required as a result of the development of new information. This would arise either as a result of the invention of new equipment or the discovery of new phenomena, by research or at operating reactors, and the Commission finds that the use of such new equipment, or protection against such phenomena, results in a substantial improvement in safety. This type of regulation would preclude backfitting to accommodate an extremely remote contingency which the Commission had previously determined to be incredible, in the absence of any new information concerning that contingency.

We believe that this "new information" standard is sound particularly in view of the fact that the question of backfitting only arises when the Commission has previously made a finding that the facility in question can be constructed and operated without undue risk to the health and safety of the public.

5. Quality Assurance Criteria - Appendix B to Part 50

The Commission proposes a new Appendix B to Part 50 to set forth in detail the requirements for a quality assurance program. We would like to comment on Article III entitled "Design Control", which requires design review for all structures, systems and components to which the appendix applies.

Design review can be an extremely time consuming undertaking and obviously can require a substantial increase in the lead time necessary to construct essential facilities. Also there is a great variation in the quantity of work which could be called "design review". Design review should, therefore, be required only where necessary and only to the extent necessary. We do not believe that a full review is necessary for all structures, systems and components covered by Appendix B.

The best confirmation of design is experience. If a structure, system or component is of standard design and has standard design requirements comparable to those already in use, which are operating satisfactorily, design review should be unnecessary. Design review is appropriate for new design procedures or new design requirements for structures, systems and components.

When independent design review is required, this should in most cases be a review of system diagrams to verify that the system adequately meets the concept and a review of specifications to see that material and components are compatible with system requirements. Calculations should only be reviewed to the extent of reviewing the mathematical models used and observation of the results of calculations using judgment and sometimes simple check calculations as a guide to see if the results appear reasonable. Should new or unusual design techniques and calculational models be employed, an independent check should only be made of the technological logic usedto justify them.

Physical drawings need not be independently reviewed since there is much internal checking of them by normal design practice. Independent repetition of calculations appears to be needless once a review of the calculational model is made. In many cases the calculational model has been standardized and is contained in codes and standards or can be referred to by the name of the method, and a reviewer need determine only that the standard calculational model referred to is applicable.

Independent design review of design interfaces should be no more than an observation that the designers on each side of the interface have given their limits and requirements to each other.

No other steps involving independent review would appear to be warranted except when the design approach and methods are new. When only the concept is new, complete checking in those areas where standard design techniques and calculations are applicable should not be required.

There would not appear to be any need to duplicate experiments or tests used for design. When the experiments and tests are unusual, it might be desirable to have an independent analysis of techniques and results.

We appreciate the opportunity for making these comments and hope they may be of use to you in formulating final regulations.

Very truly yours

William J. Cahill, Jr.

NUCLEAR POWER
DEPARTMENT

COMBUSTION ENGINEERING, INC.
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June 12, 1969

The Secretary
U. S. Atomic Energy Commission
Washington, D. C. 20545

Attention: Chief, Public Proceedings Branch

Dear Sir:

The attached comments are submitted in response to proposed amendments to the regulations in 10 CFR Part 50 concerning quality assurance criteria for nuclear power plants. The proposed amendments were published in the Federal Register on April 17, 1969, for public comment.

Sincerely yours,

J. M. West
Vice President

JMW:mes

Acknowledged by card 6/16/69, crs

NUCLEAR POWER DEPARTMENT COMBUSTION ENGINEERING, INC.

COMMENTS SUBMITTED BY
COMBUSTION ENGINEERING, INC., WITH REGARD TO
THE PROPOSED AMENDMENT TO 10 CFR PART 50
CONCERNING QUALITY ASSURANCE CRITERIA FOR
NUCLEAR POWER PLANTS, PUBLISHED IN THE
FEDERAL REGISTER ON APRIL 17, 1969

The preliminary statement, and the "Introduction" to Appendix B, limit the applicability of the proposed quality assurance criteria to "safety-related functions of those structures, systems and components" which "prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public".

We are pleased that the extent of AEC's official concern about quality assurance programs has been defined in a way which limits this concern to safety matters. To make the definition more specific, we suggest deletion of the word "-related" from the phrase "safety-related". We believe that a similar change should be made in the last paragraph on page 2 to make it clear that the regulation applies only to safety functions. As thus revised, the definition of "quality assurance" would read as follows:

> "Quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform its safety functions satisfactorily in service. As used in this definition, "structure, system, or component" means structures, systems and components which prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public.

It would be desirable to amend Section "III. DESIGN CONTROL" so as to clarify or eliminate provisions which now might be interpreted as establishing organizational or procedural requirements with regard to design control within a particular organization. The requirement that "design reviews" be performed by "individuals or groups other than those who performed the original design, but who may be from the same organization" should, we think, be eliminated. Similarly, we believe that the requirement that "reports of in-process and final design reviews shall be reviewed by management of the responsible design organizations." should also be eliminated. In making these suggestions, we do not wish to be understood as suggesting that design reviews or other means of verifying the adequacy of design, are unnecessary, or that it is unnecessary for management

of the responsible design organization to assure itself that adequate design efforts and reviews are being conducted. Rather, we believe that the proposed quality assurance criteria should be amended so as to require the applicant and his contractors to have a design control program, the essential elements of which should be set forth in the PSAR. These programs should be evaluated from the standpoint of whether the safety objectives with regard to design control are likely to be achieved, rather than whether a predetermined format for organizational surveillance is met.

Development of optimum organization and methods for assuring proper control of design work, and for verifying the reliability and accuracy of design, is a responsibility and function of the management of the company involved. Depending on the nature and organizational structure of the company, the nature of the subject matter of the design effort, the availability of qualified personnel, the characteristics of the particular individuals involved, and many other factors, establishment of design reviews in accordance with the organizational concepts of the proposed quality assurance criteria may or may not be a desirable means of accomplishing the objectives of those criteria.

The use of alternate calculational methods and analyses to verify the earlier work; the application of "consistency checks" to confirm the reliability and accuracy of prior design work; the use of failure mode, reliability and accident analyses; prototype and model testing, and various experimental programs; as well as other techniques, may provide the independent design verification which is the objective of the proposed quality assurance criteria in a more effective manner than the independent design reviews referred to therein.

In cases where an independent design review is desirable, the scope and content of such review, and the competence of the reviewer, will be far more meaningful than the reviewer's organizational status.

For similar reasons we believe that the requirement that "reports of in-process and final design reviews shall be reviewed by management of the responsible design organizations" should be eliminated. As noted above, we suggest deletion, because the provision oversimplifies and overformalizes management's all-encompassing responsibility. The objective of the regulations should be to require that applicants and their contractors describe methods to accomplish the objectives of the proposed amendments; the regulations should not prescribe specific organizational or procedural techniques for accomplishing them.

We suggest also that the phrase "principal architectural and design criteria" be substituted for "the design basis" in the first sentence of "III. DESIGN CONTROL".

Many questions can be raised about the detailed nature and extent of independent design reviews and the AEC's role in verifying these reviews. In implementing the proposed criteria, we urge that the AEC assess each measure objectively to assure that unduly onerous requirements are not set up which would have substantial adverse effects on schedules and costs without accomplishing any real improvement in safety.

In addition to the foregoing general comments, we have specific suggestions regarding certain sections as follows:

VIII. Identification and Control of Material, Parts and Components

In the statement which now reads "These measures shall assure that identification is maintained, either on the item or on records traceable to the item", we suggest that the term "item" is too restrictive. This sentence should be changed to the following: "These measures shall assure that identification is retained as required to prevent discrepant material from further processing throughout...." The reason for this suggestion is that material may be accepted for use on a lot basis and it may be impractical to retain the traceability to the individual item; this would include such "items" as fuel pellets, fuel tubing and fuel cladding.

X. Inspection

A portion of this paragraph now reads "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." This may be acceptable for a non-production run product. However, this statement is inappropriate to a continuous, mass production process. An appropriate quality control system's audit would provide better quality assurance in this case than an inspection hold point system.

XII. Calibration of Measurement and Test Equipment

We suggest that the phrase "where such standards exist" be added to the end of the last sentence.

UNITED ENGINEERS & CONSTRUCTORS INC.
1401 ARCH STREET
PHILADELPHIA, PA. 19105

June 11, 1969

Secretary
United States Atomic Energy Commission
Washington, D.C. 20545

Att: Chief, Public Proceedings Branch

Quality Assurance Criteria
for
Nuclear Power Plants

Gentlemen:

As an active Architect-Engineer-Construction Manager of nuclear power plants, United Engineers & Constructors Inc. is vitally concerned with activities relating to the public welfare and the safe operation of these facilities.

In this regard, we respectfully submit for your consideration, the following comments on your "Quality Assurance Criteria for Nuclear Power Plants," released April 17, 1969:

General Comments

1. Appendix B - "Quality Assurance Criteria for Nuclear Power Plants" Introduction, stipulates that:

   A. An applicant's PSAR for a construction permit contains a description of his Quality Assurance Program as applied to the design, fabrication, construction, and testing of the facility.

   B. An applicant's FSAR for an operating license is to include information pertaining to the managerial and administrative controls to be used to assure safe operation (which includes maintenance, repair, refueling, and modifications).

   Comment:

   The quality assurance requirements identified in the criteria intermingle these areas, and in many cases, tend to confuse specific area application of the criteria. Since participating organizations vary from plant to plant, it is incumbent upon an applicant, as his prime responsibility, to provide separate Quality Assurance Programs for construction and operation phases.

We believe it would serve a more useful purpose if the quality assurance criteria could be specifically oriented towards providing separate requirements in the areas of construction and operation. This clarification would aid an applicant in his Quality Assurance Program preparations and simplify those programs to permit ready evaluation and audit actions by regulatory agencies.

2. Following is our general comment reflected by an over-all evaluation of the specific requirements of the criteria (I through XVIII).

Comment:

It appears that the generalizations identified in Sections I through XVIII have been adapted from a manufacturing oriented approach to a total quality control effort. It is difficult for an applicant to interpret these requirements and incorporate them into a simple format in accordance with the proposed headings or sections for evaluation purposes and subsequent implementation.

Because of the interfaces of the participating organizations involved in the building of a nuclear power generating facility, and the necessity of developing an over-all Quality Assurance Program at an early stage for inclusion in the PSAR, the format of the Quality Assurance Program should not be rigidly tied to the section headings for the specifics, but rather prepared to demonstrate an organized approach based on organizational responsibilities.

We believe that the following suggested format would include all the presently identified criteria requirements as applicable under these sections:

1. Organization and Administration
2. Design and Engineering Control
3. Drawing, Specification, and Procedure Control
4. Control of Purchased Material (including Vendor Surveillance)
5. Quality Records
6. NSSS Quality Control
7. Site Quality Control
8. Nonconforming Conditions (including Work Stoppage)
9. Audits

This format generally conforms with most of the organizational approaches now being proposed by applicants. One company has recognized the need for this organizational type of approach and is preparing a report outlining their standardized quality assurance and quality control program on the nuclear portions of the power plant being supplied as part of their contracted services.

Many of the detailed criteria requirements (e.g., identification and control of materials, parts, and components; inspections; test control; calibration of test equipment; control of special processes; inspection status; handling, storage, and preservation; etc.) can be covered under the appropriate headings above, since they are common to most organizational responsibilities and are interrelated in providing a satisfactory achievement for control of quality throughout that phase of responsibility.

Specific Comments

1. Section II - Quality Assurance Program

A. "The applicant shall establish at the earliest practical time a quality assurance program which complies with the requirements of this appendix."

Comment:

Recommendation - revise to read: "....complies with the intent of this appendix." We believe that the applicant should be allowed the flexibility of complying with the intent and varying the level of effort applied to each section of the Criteria.

B. "This program shall be documented by written policies, procedures, and instructions, and shall be carried out throughout plant life."

Comment:

Recommendation - revise to read: "....shall be carried out throughout design, construction, and start-up, prior to receiving operating license." We feel that a separate "Quality Assurance Criteria for Operating Nuclear Power Plants" should be issued as explained in our general comment No. 1 above.

2. Section III - Design Control

A. "Design reviews shall cover items such as the following: reactor physics; .....; accessibility for inservice inspection."

Comment:

Recommendation - delete: "....accessibility for inservice inspection." We feel this requirement should not appear in the Criteria until the ASME has voted on the N45 Committee's "Inservice Inspection Requirements."

Comment:

Suggest rewording starting on line 6.

"These measures shall provide for the performance of design reviews to verify that the actual design satisfactorily meets the intent and broad criteria described in the SAR. Any changes in design from that spelled out in the SAR, shall be immediately brought to the attention of the AEC. Reports....."

One could infer from Section III that the major criteria for a successful design review would be agreement with the SAR. Design adequacy should be the major criteria of a design review.

3. Section IV - Procurement Document Control

A. "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."

Comment:

Recommendation - revise to read: "....to provide a quality assurance program consistent with the appropriate provisions of this appendix." We feel this clarification would be helpful in indicating that all sections of the criteria may not be applicable to all subcontractors or vendors.

4. Section X - Inspection

A. "A program for in-process and final inspection of activities..."

Comment:

Recommendation - insert "by the supplier or contractor" - i.e., "A program for in-process and final inspection of activities affecting quality shall be established by the supplier or contractor....."

We strongly feel that in no way should the applicant or his designated representative relieve any supplier of his primary responsibility for the quality of his product. This comment applies to the entire Section X.

We will be happy to discuss with you, at your convenience, any questions you may have concerning the above comments.

Very truly yours,

J. B. Silverwood, Manager
Reliability and Quality Assurance

RJV/rmd

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CONSULTING
ENGINEERING

June 9, 1969

Secretary,
U.S. Atomic Energy Commission
Washington, D.C. 20545

Attention Chief, Public Proceedings Branch

Dear Sir:

PROPOSED APPENDIX B, 10CFR50
QUALITY ASSURANCE CRITERIA FOR NUCLEAR POWER PLANT

Stone & Webster wishes to take this opportunity to submit its comments prior to the contemplated adoption of Appendix B, 10CFR50, as it appeared in the April 17, 1969 edition of the Federal Register.

First, we wish to lend our support to the issuance of such a quality assurance criteria since it establishes requirements in advance of design, construction and operation of nuclear power plants. It is noticed that Appendix B is an expanded evolution of the quality assurance criteria developed by the USASI/N45 Ad Hoc Planning Committee on Quality Assurance which Stone & Webster actively participated in.

However, as one reviews the proposed criteria, it appears as if the pendulum is swinging from one extreme of vagueness to the other extreme of minute detail and then recycling again. It is believed that Federal regulations should state requirements in definitive terms while allowing the applicant certain maneuverability in methods of compliance without becoming involved in lengthy interpretations or time-consuming explanations/justifications. Examples of the above are:

A. Section III "Design Control" - it is assumed that design reviews include the checking of analyses by another competent person without that person actually doing an independent computation. It must also be assumed that the application of a Professional Engineer's seal on a drawing constitutes a design review in as much as the Professional Engineer has a legal obligation, to the State in which the plant is being constructed, for that drawing being complete and accurate.

B. SectionV "Instructions, Procedures and Drawings" - it is not clear what is meant by ....."shall include appropriate quantitative or qualitative means for determining that important operations have been satisfactorily accomplished."

C. Section X "Inspection" - the intent of this section, that of assuring conformance with appropriate documents, is well understood. However, requiring the use of mandatory inspection hold points is prescribing <u>how</u> a program is to function and not <u>what</u> the program is designed to produce. It is recommended that the last sentence of Section X be deleted.

D. Section XI "Test Control" - it must be assumed that the word "required" in the first sentence pertains to those tests that are delineated in the PSAR.

E. Section XIV "Inspection, Test and Operating Status" - the words "individual items" in the first sentence should be clarified as it must be assumed to mean "components" rather than nuts, bolts, O-rings, etc. that may be subject to inspection witnessing.

F. Section XV "Nonconforming Material, Parts or Components" - the intent of this section is to prevent the use of nonconforming material; and, it is well understood. The second sentence of Section XV is too restrictive; it is recommended that it be reworded as "these measures shall include, <u>as appropriate</u>, procedures...."

G. Section XVI "Corrective Action" - the intent of this section is understood and agreed with; however, the corrective action taken to preclude repetition can only be taken within the bounds of the procurement contract. There can be no authority to correct an action that is inherent in the vendor affecting other customers.

We would be pleased to discuss the above comments with your personnel at your convenience.

Yours very truly,

J. R. Chapman
Senior Vice President

AB:KK