



POLICY ISSUE (Notation Vote)

August 18, 1992

SECY-92-287

For: The Commissioners

From: James M. Taylor
Executive Director for Operations

Subject: FORM AND CONTENT FOR A DESIGN CERTIFICATION RULE

Purpose: To request Commission guidance on various issues related to the form and content for a design certification rule under 10 CFR Part 52. This paper also addresses the treatment of codes and standards as requested in the staff requirements memorandum (SRM) of February 15, 1991, pertaining to SECY-90-377 and the relationship between the design certification rule and the combined license that references the rule, as proposed in SECY-91-178.

Summary: The staff is proposing a format for a design certification rule for standardized plant designs. This proposal includes several staff positions that address issues related to implementing 10 CFR Part 52. The specific issues discussed include (1) the documentation of certified design information; (2) the documentation of the resolution of selected design-specific technical and severe accident issues; (3) the extent of issue resolution provided for design information; (4) the "50.59-like" process to control changes to the Tier 2 design information; and (5) the provisions for updating codes and standards. Enclosure 1 is an example of a format for a design certification rule for a generic evolutionary light water reactor (ELWR) design.

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SECY NOTE: TO BE MADE PUBLICLY AVAILABLE IN 5 WORKING DAYS FROM THE DATE OF THIS PAPER.

Background: Subpart B of Part 52 provides a process for issuing a standard design certification for a nuclear power plant design in the form of a rule. Previous Commission papers have addressed this process, including the required level of design detail (SECY-90-377); the required inspections, tests, analyses, and acceptance criteria (ITAAC) (SECY-91-178, SECY-91-210, and SECY-92-214); and the use of design acceptance criteria (SECY-92-053 and SECY-92-196). The General Counsel has issued SECY-92-170 on rulemaking procedures for design certification.

Discussion: The staff is proposing a design certification rule in accordance with Section 52.54, which implements the intent of Part 52 to provide early resolution of licensing issues and foster standardization. The proposed rule also addresses recent concerns that the design certification rule should allow sufficient flexibility to incorporate advancements in technology and equipment. The design certification rule that the staff proposes calls for each certification of a standard plant design to become a separate appendix to Part 52. The appendix will reference two types of design-related information, which will be identified as Tiers 1 and 2. Both tiers of design-related information will be extracted from the application for design certification, as described in Enclosure 2.

The following items discuss various aspects of the numbered sections (in parentheses) in the proposed design certification rule as shown in Enclosure 1:

(1) The scope of the rule (A.1).

Comment: Identifies the standard design that will be certified by this appendix to 10 CFR Part 52.

(2) Definitions (A.3).

(3) The contents of the standard design certification, including which documents are to be certified by the rule (A.5).

Comment: The proposed design certification rule is a relatively concise rule that would incorporate by reference the two-tiered design-related information that is extracted from the application for design certification. This information will be consolidated into a stand-alone master document called the design control document (DCD). The content of the DCD is described in Enclosure 2.

(4) The approval of the design certification (A.7).

Comment: This section would state the Commission's approval of this rule for the design, and certify the Tier 1 design information identified in Section A.5 of the rule. The specific findings of the administrative review process required by Section 52.51 will be set forth in the statement of considerations for the rule.

(5) The requirements for referencing this rule (A.9).

Comment: This section would describe the requirements that an applicant, for a construction permit or combined license, or a licensee that references this rule must comply with. The documentation of the resolution of selected design-specific technical and severe accident issues (e.g., SECY-90-016 issues) that are considered "applicable regulations" is described in Enclosure 3.

(6) The resolution of issues (A.11).

Comment: This section would identify the scope of matters resolved in connection with the issuance of this rule. These matters would not be subject to litigation in future hearings for issuances of combined licenses (COL), construction permits, operating licenses, or for any hearing before fuel loading as required by Section 52.103. However, any changes to this information would be subject to litigation in the same manner as other issues in the applicable hearing. The extent of issue resolution provided by this rule is discussed in Enclosure 4.

(7) The duration of the certification (A.13).

Comment: This section would establish the effective date and the duration of the certification. It would state that the design certification could be referenced for a period of 15 years from the effective date, unless extended in accordance with Sections 52.55 or 52.57. Beyond this period, the rule would expire and could no longer be referenced by an applicant for a construction permit or combined license.

Part 52 is not explicit with regard to the effectiveness of a certified design after the license is issued and the design certification expires. The staff believes that the intent of Section 52.63 and the benefits of standardization can only be realized if this rule remains in effect until the facility license expires. Therefore, this proposed rule was drafted to continue the validity, for applicants and licensees, of the certified design until the application is withdrawn or the license expires.

(8) The change process for a certified design (A.15).

Comment: The change process for a certified design is dependent upon three factors: (1) whether the information is in Tier 1 or Tier 2, (2) the entity requesting the change, and (3) the time period relative to the design certification and the subsequent referencing of the certified design. These relationships and the change process is discussed in Enclosure 5.

This section of the rule would also propose a "50.59-like" change process for Tier 2 information. A discussion of this proposed change process is contained in Enclosure 6. In addition, the staff and industry have worked to provide a means for updating certain codes and standards that are identified in the DCD. Enclosure 7 discusses the change process for codes and standards.

In summary, the staff believes that the general approach to the form and content of the design certification rule proposed in this paper, coupled with the proposed staff positions, implements the intent of Part 52 to provide early resolution of licensing issues and to foster standardization and licensing stability, and also addresses how the design certification rule will allow sufficient flexibility to incorporate advancements in technology and equipment.

Recommendations: That the Commission:

- (1) Approve the staff's general approach to the form and content of the standard design certification rule.
- (2) Approve the staff's position that the approved design-related information be consolidated into a single master document (DCD).
- (3) Approve the staff's position that the resolution of selected design-specific technical and severe accident issues be approved in the rule that certifies the design, and be treated as "applicable regulations."
- (4) Approve the staff's position that an applicant or licensee must reference both tiers of information in the DCD.
- (5) Approve the staff's position that Tier 2 information be designated as "resolved in connection with the issuance or renewal of a design certification" within the meaning of Section 52.63(a)(4).

- (6) Approve the staff's position that an otherwise expired design certification remains valid for a license referencing that design certification until the license expires.
- (7) Approve the staff's position that changes to Tier 2 information by the Commission are subject to 10 CFR 50.109.
- (8) Approve the staff's proposed "50.59-like" process, as set forth in A.15(e) of Enclosure 1. This proposal states that the "50.59-like" process is available to control changes to Tier 2 information for both an applicant and a licensee that references the certified standard design.
- (9) Note that the staff intends to make this paper publicly available within 5 working days from the date of this paper.

Coordination:

The Office of the General Counsel has reviewed this paper and has no legal objection to its contents.


James M. Taylor
Executive Director
for Operations

Enclosures:
As stated

DISTRIBUTION:
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Commissioners' comments or consent should be provided directly to SECY by c.o.b. Wednesday, September 2, 1992.

Commission staff office comments, if any, should be submitted to the Commissioners NLT August 26, 1992, with an information copy to SECY. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

PROPOSED PART 52 STANDARD DESIGN CERTIFICATION RULE

10 CFR Part 52, Appendix A

A.1 Scope.

This Appendix constitutes the standard design certification for the Evolutionary Light Water Reactor (ELWR) design, in accordance with 10 CFR Part 52, Subpart B. The applicant for the certification of the ELWR design was _____.

A.3 Definitions.

- (a) *Design control document* (DCD) is the master document that contains the information that is referenced by this design certification rule. The DCD includes the Tier 1 information that is certified by this rule and the Tier 2 information that is approved by this rule. An applicant for a construction permit or combined license that references this design certification must reference both tiers of information.
- (b) *Tier 1* is the portion of the design-related information contained in the DCD that constitutes the certified standard design. This information identifies the scope of the standard design and consists of the Tier 1 design descriptions, the inspections, tests, analyses, and acceptance criteria (ITAAC), the site parameters, and the interface requirements.
- (c) *Tier 2* is the remainder of the design-related information contained in the DCD and it is supportive of the certified standard design. Although Tier 2 information is not certified, it is information that is designated to be "those matters resolved in connection with the issuance or renewal of a design certification" within the meaning of 10 CFR 52.63(a)(4).
- (d) *etc.*

A.5 Contents of the ELWR Certified Standard Design.

This standard design certification incorporates by reference the information set forth in the ELWR DCD dated _____.

A.7 Approval of the ELWR Standard Design Certification.

After conducting a rulemaking proceeding in accordance with 10 CFR 52.51, the Commission approves this rule for the ELWR design, certifies the Tier 1 design-related information, and approves the Tier 2 design-related information. (The required findings will be set forth in the statement of considerations for this rule.)

A.9 Referencing Requirements.

- (a) An applicant for a construction permit or license, or licensee that references this standard design certification, must reference both tiers of information in the ELWR DCD.
- (b) An applicant for a construction permit or license, or licensee that references this standard design certification, may initiate changes to the ELWR DCD in accordance with Section A.15 of this rule.
- (c) If there is a conflict between the information in the ELWR DCD and the application for design certification or the staff's FSER and supplements thereto, then the ELWR DCD is controlling.
- (d) The technical positions that are identified in the staff's FSER at pp. _____, shall be considered "applicable regulations" for the ELWR design for the purposes of 10 CFR 52.48 and 52.63.

A.11 Issue Resolution.

- (a) All nuclear safety issues arising from the information set forth in the ELWR DCD are "resolved in connection with the issuance or renewal of a design certification" within the meaning of 10 CFR 52.63(a)(4).
- (b) (Insert appropriate provision relating to resolved NEPA issues.)

A.13 Duration of the ELWR Standard Design Certification.

This standard design certification may be referenced for a period of 15 years from [insert date 30 days after publication in the Federal Register], except as provided for in 10 CFR 52.55(b) and 52.57(b). This standard design certification will remain valid for an applicant or licensee that references this standard design certification until their application is withdrawn or license expires.

A.15 Change Process.

- (a) Any person may petition the Commission to modify, amend, or rescind the ELWR standard design certification, including Tier 2 information, in accordance with Subpart H of Part 2. However, except as set forth in 10 CFR 52.63(a)(1), the Commission may not modify, rescind, or impose new requirements on the certified design (Tier 1).
- (b) All modifications to this standard design certification made in accordance with 10 CFR 52.63(a)(1) will be applied to all plants

referencing this standard design certification, except those for which the modification has been rendered technically irrelevant by action taken in accordance with 10 CFR 52.63(a)(3), (a)(4), or (b).

- (c) An applicant for a construction permit or license, or licensee that references this standard design certification may request an exemption from the certified design (Tier 1) in accordance with 10 CFR 52.63(b)(1). The exemption request must address the requirements of 10 CFR 50.12(a), and discuss any decrease in safety that may result from the reduction in standardization caused by the exemption.
- (d) Any modification, rescission, or imposition of new requirements on Tier 2 information by the Commission is subject to 10 CFR 50.109.
- (e) An applicant for a construction permit or license, or licensee that references this standard design certification may make changes to the Tier 2 information, without prior NRC approval, unless the change involves a change to the certified standard design (Tier 1), the technical specifications, or an "unreviewed safety question" as defined in 10 CFR 50.59. The Tier 2 changes will no longer be considered "matters resolved in connection with the issuance or renewal of a design certification" within the meaning of 10 CFR 52.63(a)(4).

A.17 Record Keeping.

- (a) An applicant for a construction permit or license, or licensee that references this standard design certification shall maintain records of all departures from the ELWR DCD. These records must describe the departures, discuss the need for the departure, and, as applicable, discuss any decrease in safety that may result from the reduction in standardization caused by the departure, as required by 10 CFR 52.63 or the factors set forth in A.15(e).
- (b) An applicant for a construction permit or license, or licensee that references this standard design certification shall maintain and submit quarterly reports of all changes to the facility pursuant to Section A.15(e) until the applicant or licensee receives either an operating license under 10 CFR Part 50 or the Commission makes its findings under 10 CFR 52.103. Records shall be maintained and submitted in accordance with the record keeping requirements of 10 CFR 50.59 thereafter.
- (c) The applicant for a construction permit or license, or licensee that references this standard design certification shall maintain all records required by this section in an auditable form and make them available for inspection until after either: (i) the license referencing this standard design certification expires; or (ii) the license application referencing this design certification is withdrawn.

DOCUMENTATION OF CERTIFIED DESIGN INFORMATION

The staff is working closely with industry to identify the two-tiered design-related information that will be consolidated into a single document, called the design control document (DCD). The consolidation of the two-tiered design-related information into this single document will provide an effective means of controlling this information, and will facilitate incorporation of this information into the rule by reference. The applicant for design certification will extract this information from its application, specifically identifying proposed Tier 1 information, and submit it to NRR for review. The staff will review the DCD and provide its evaluation in the FSER and any supplements thereto. The applicant will then revise the DCD, as necessary, and the version that is approved by the staff (master DCD) will be referred to in the proposed standard design certification rule. After completion of the certification rulemaking, the Commission will direct the staff to make any required changes to the master DCD and the applicant will submit necessary page changes for the master DCD. Copies of the master DCD will be provided to the public document room and the Office of the Federal Register. Upon approval by the Office of the Federal Register, the final standard design certification rule will be published in the Federal Register and it will reference the master DCD.

The DCD includes the Tier 1 information that is certified by this rule and the Tier 2 information that is approved by this rule. An applicant for a construction permit or combined license that references a standard design certification must reference both tiers of information. The Tier 1 information will identify the scope of the certified standard design and will consist of the design descriptions, the inspections, tests, analyses, and acceptance criteria (ITAAC), the site parameters, and the interface requirements. The level of design detail that is extracted from the SSAR to become the Tier 1 design descriptions will include the important design information that was relied upon as the fundamental bases for the staff's safety review, such as the key assumptions in the safety analyses and in the bases for the technical specifications.

The Tier 2 information is the remainder of the design-related information contained in the DCD and it is supportive of the certified standard design. Although Tier 2 information is not certified, it is information that is approved by the certification rule. All nuclear safety issues arising from the information contained in the DCD will be designated as "resolved in connection with the issuance or renewal of a design certification" within the meaning of 10 CFR 52.63(a)(4). The Tier 2 information will be based upon the application for design certification with modifications, as necessary, to conform with the requirements of the Office of the Federal Register for publishing a rule. The staff is currently working with OGC and NUMARC on the treatment of proprietary information and secondary references in a rule that can be approved by the Office of the Federal Register.

The process for developing the DCD involves a number of steps and will require careful review of the initial DCD and the revised DCD incorporating staff

changes to minimize the potential for ambiguities or inconsistencies, since the final DCD as approved by the Commission and referenced in the published rule will be the controlling document. Integrating the proposed design as set forth in the application, the staff positions reflected in the FSER, and the changes directed by the Commission on the basis of the rulemaking record will require substantial effort to assure consistency. However, the staff believes that the value of having a single integrated design document, rather than a series of documents (application, FSER and Commission Order) each containing some portion of the certified design, is worth the effort involved.

The decisions on how to bifurcate the DCD into Tier 1 and Tier 2 are currently part of the ongoing design review process. These decisions will be based primarily on the importance of the design-related information to the staff's review and the different change standards for an applicant or licensee that references the rule, as described in Enclosure 5.

THE DOCUMENTATION OF SELECTED TECHNICAL AND SEVERE ACCIDENT ISSUES

In the SRM pertaining to SECY-91-262, "Resolution of Selected Technical and Severe Accident Issues for Evolutionary Light Water Reactor Designs," the Commission approved the staff's recommendation to proceed with design-specific rulemakings through individual design certifications to resolve selected technical and severe accident issues for the GE ABWR and ABB-CE System 80+ designs. These matters include staff positions that deviate from or are not embodied in current regulations, but were approved by the Commission and will be clearly identified and evaluated in the staff's FSER and supplements thereto. These matters would include: (1) selected technical and severe accident issues, (2) other resolutions of issues that deviate from current regulations, and (3) any issues resolved in the certification rulemaking under the National Environmental Policy Act. Examples include issues discussed in SECY-90-016, "Evolutionary Light Water Reactor (LWR) Certification Issues and their Relationship to Current Regulatory Requirements;" SECY-91-078, "Chapter 11 of the Electric Power Research Institute's (EPRI's) Requirements Document and Additional Evolutionary Light Water Reactor (LWR) Certification Issues;" and SECY-91-229, "Severe Accident Mitigation Design Alternatives for Certified Standard Designs."

Since agency positions on the above issues were identified and incorporated into the designs during the staff's design review based on Commission guidance rather than specific regulations, the certification rule will approve the resolutions for the specific designs. These resolutions will be incorporated into the DCD by the applicant for design certification. The agency positions will be explicitly specified in the form of design-specific requirements in the staff's FSER and any supplements thereto. The explicit documentation of these agency positions will provide a clear regulatory basis for these issues, as well as any additional issues that may be considered and incorporated during the certification rulemaking. The completed standard design certification rule will then designate these agency positions, which are identified in the FSER and supplements thereto, as "applicable regulations" for the specific design for the purposes of 10 CFR 52.48 and 52.63.

THE EXTENT OF ISSUE RESOLUTION

Section 52.63(a)(4) of Part 52 states that "...the Commission shall treat as resolved those matters resolved in connection with the issuance or renewal of a design certification." Subsequently, in the SRM for SECY-90-377, "Requirements for Design Certification Under 10 CFR Part 52," dated February 15, 1991, the Commission stated that "...the process provides issue finality on all information provided in the application that is reviewed and approved in the design certification rulemaking. Information obtained during the staff's review process that forms the basis for a safety decision should be formally docketed as part of the application. Only this information will have regulatory significance for the design certification process." Based upon this guidance, the staff is proposing that the design-related information in the DCD be designated as "resolved in connection with the issuance or renewal of a design certification" within the meaning of 10 CFR 52.63(a)(4).

The Tier 1 information will be certified by the design certification rule, and therefore, issue resolution is provided for this information in accordance with 10 CFR 52.63(a)(4). The staff will explicitly review and approve the Tier 1 information in the FSER and supplements thereto. The status of Tier 2 information, which is not completely approved in the FSER, is less clear. For example, the staff may indicate that its review was conducted in accordance with a particular section of the Standard Review Plan (SRP) and, thereby, indicate by reference the scope of the material reviewed and found acceptable. Since the public will have been afforded the opportunity to review this information during the design certification rulemaking, and since the staff treated the Tier 2 information as part of the supporting basis for their safety findings for the certified design, it is the staff's position that Tier 2 information, whether it is explicitly cited or not in the FSER or SRP, is approved by the rule and designated as "those matters resolved in connection with the issuance or renewal of a design certification" within the meaning of 10 CFR 52.63(a)(4).

It is important to recognize that the proposed rule treats as "resolved" not only those matters specifically addressed in Tier 1 and Tier 2 of the DCD (which will reflect staff positions set forth in the FSER), but also all matters "related" to such information, including issues that could have been raised but were not. For example, if Tier 2 information indicated that the design employs two, 1000 GPM reciprocating pumps, issues regarding the number of the pumps, the flow rate of the pumps, and the nature of the pumps (reciprocating, centrifugal, proportioning, etc.) would all be treated as "resolved."

Information that is removed from Tier 2 because it cannot be published or referenced in the Federal Register, possibly including proprietary information, will not have issue preclusion in accordance with 10 CFR 52.63(a)(4). Also, an applicant or licensee that references a design certification rule and makes changes to either Tier 1 or Tier 2 information would lose issue preclusion for the changed information.

CHANGE PROCESS FOR A CERTIFIED DESIGN

Changes to Tier 1 information are limited to rulemaking under 10 CFR 52.63(a)(1), plant-specific order under 10 CFR 52.63(a)(3), or exemption under 10 CFR 52.63(b)(1). Section 52.63(a)(1) states that rulemaking can only be initiated by the Commission, either on its own, or in response to a petition from the public, the design certification holder, or an applicant or licensee. The Commission must determine that the change is necessary either to bring the certification into compliance with the Commission's regulations applicable and in effect at the time the certification was issued, or to assure adequate protection of the public health and safety or the common defense and security. Any rulemakings under 10 CFR 52.63(a)(1) would then be applicable to all plants referencing the rule, which would include those plants in operation at the time, as well as any future plants, as stated in 10 CFR 52.63(a)(2). Under 10 CFR 52.63(a)(3), the Commission may impose plant specific orders to assure compliance with regulations in effect at the time the design certification was issued, or to assure adequate protection, provided there are special circumstances as defined in 10 CFR 50.12(a). Such orders would apply to the specific plant to which they were directed and not to the design certification itself. Under 10 CFR 52.63(b)(1), an applicant (for a combined license or a construction permit) or a licensee who references a standard design certification may request exemptions from the elements of the design certification, provided there are special circumstances as set forth in 10 CFR 50.12(a). If granted, then the exemption would also be plant specific and the changed information would be subject to litigation in the same manner as other issues in a licensing proceeding.

For Tier 2 information, which is not certified but is "resolved" by the rule, a lower threshold for change is appropriate in order to accommodate changes in technology, to incorporate lessons learned from construction and operating experience, and to accommodate necessary changes to a facility or application for a facility. The change process found in 10 CFR 50.59 for similar information for plants currently in operation has proven to be an effective tool to manage change. Further, in 10 CFR 52.63(b)(2) the Commission explicitly provided that subject to 10 CFR 50.59, holders of licenses based on a design certification may make changes in the design without prior Commission approval unless the change involves a change in the design as described in the rule certifying the design. Although this explicit provision is applicable only to licensees, a similar process is appropriate for applicants for a combined license. Such a process has been incorporated into the proposed rule, permitting applicants and licensees to make changes in Tier 2 information, provided that such change does not involve a change in the Tier 1 information. This process is discussed in more detail in Enclosure 6. Since the Tier 2 information is approved in the rule certifying the standard design, any changes to Tier 2 that are requested by the staff or the public will require rulemaking, and are governed by the backfit standard in 10 CFR 50.109, "... substantial increase in the overall protection".

After completion of construction in accordance with a combined license, the authorization to operate hinges on a Commission finding that the acceptance

criteria in the combined license have been met (10 CFR 52.103(c)). Non-compliance with other aspects of the combined license, such as Tier 2 issues or other conditions of the combined license, might result in enforcement actions, but would not be the basis for denial of authority to operate unless:

- (a) the matter affected compliance with an acceptance criteria.
- (b) the matter was of such vital safety significance as to warrant an order prohibiting operation; such an order would in effect be a modification of the design certification pursuant to 10 CFR 52.63(a) to impose an additional acceptance criteria, with which the facility did not comply.

It is also important to note that non-conformance with the DCD would involve the enforcement process in accordance with Appendix C to 10 CFR Part 2.

In summary, the change process for a standard design certification is dependent upon three factors: (1) whether the information is in Tier 1 or Tier 2, (2) the entity initiating the change, and (3) the stage in the lifetime of the certification rule or the combined license that references the rule. These relationships and their change process are discussed below and are also presented in the attached table:

- (a) Following design certification rulemaking but before COL application. During this period the NRC will be limited to the rulemaking process, with the standards set forth in 10 CFR 52.63(a)(1), for all changes to Tier 1 information. The public and the certification holder can petition the NRC under 10 CFR 2.802 to change Tier 1 in accordance with 10 CFR 52.63(a)(1). A similar rulemaking process will be used to change Tier 2 information, except the standard for justifying changes is 10 CFR 50.109.
- (b) After license application but before COL issuance. Changes to Tier 1 would be limited to rulemaking per 10 CFR 52.63(a)(1), or exemptions per 10 CFR 52.63(b)(1). Changes to Tier 2 information could be requested by rulemaking as stated above or via Section A.15(e) of Enclosure 1 (the "50.59-like" process), for an applicant for a construction permit or combined license (Enclosure 6). Changes to the information in the remainder of the combined license application can be handled during the review or the hearing for the combined license.
- (c) Following COL issuance. For Tier 1 information, the NRC can impose changes by amendment rulemaking or plant-specific order under 10 CFR 52.63(a) and the licensee may also submit an exemption request per 10 CFR 52.63(b)(1). Tier 2 information can be changed by rulemaking as stated above or via Section A.15(e) of Enclosure 1 by a licensee. Changes to the remainder of the information in the combined license application could be made under 10 CFR 2.204 or 50.109 for the NRC, 10 CFR 50.90 or 52.63(b)(2) for the licensee, and 10 CFR 2.206 for the public. If anyone wishes to modify or prohibit operation of the facility, they need to demonstrate that one or more of the acceptance criteria have not been met in accordance with 10 CFR 52.103(b).

PROCEDURES FOR CHANGING DESIGN-RELATED INFORMATION

MILESTONES:	DESIGN CERTIFIED	APPLICATION FOR COMBINED LICENSE	ISSUANCE OF COMBINED LICENSE	LICENSE EXPIRES
NRC	TIER 1	•Rulemaking - 52.63(a)(1)	•Rulemaking - 52.63(a)(1)	•Rulemaking - 52.63(a)
	TIER 2	•Rulemaking - with 50.109 standard	•Rulemaking - with 50.109 standard	•Rulemaking - with 50.109 standard
	COL	•N/A	•Application review	•Backfit - 50.109 or 2.204
PUBLIC AND CERTIFICATION HOLDER	TIER 1	•Rulemaking - 52.63(a)(1) (Petition per 2.802)	•Rulemaking - 52.63(a)(1) (Petition per 2.802)	•Rulemaking - 52.63(a) (Petition per 2.802)
	TIER 2	•Rulemaking (Petition per 2.802)	•Rulemaking (Petition per 2.802)	•Rulemaking (Petition per 2.802)
	COL	•N/A	•Combined license hearing	•Petition-52.103(b) or 2.206
UTILITY	TIER 1	•N/A	•Exemption - 52.63(b)(1)	•Exemption - 52.63(b)(1)
	TIER 2	•N/A	•A.15(e) "50.59-like" or application review	•A.15(e) "50.59-like" or a license amendment
	COL	•N/A	•Application review	•License amendment - 50.90 or 52.63(b)(2)

COL - REMAINDER OF COMBINED LICENSE APPLICATION, INCLUDING SITE-SPECIFIC DESIGN FEATURES AND RESPECTIVE ITAAC, PROPRIETARY INFORMATION, EMERGENCY PLAN, SECURITY PLAN, TRAINING, ETC., AND SUPPLEMENTARY DESIGN INFORMATION FROM DAC/ITAAC

THE "50.59-LIKE" CHANGE PROCESS

As outlined in Enclosure 5, 10 CFR 52.63(b)(2) states that subject to 10 CFR 50.59, holders of licenses based upon a standard design certification may make changes in the design without prior Commission approval unless the change involves a change in the design as described in the rule certifying the design. Although this explicit provision is applicable only to licensees, the staff believes that a similar process is appropriate for applicants for a combined license. Such a process has been incorporated into the proposed rule.

The staff's proposed "50.59 like process" is set forth in Section A.15(e) of Enclosure 1. This proposal provides for a systematic change process for Tier 2 information, while maintaining the integrity of the bases for the findings in 10 CFR 52.103(c) to authorize fuel loading. Applicants and licensees would be permitted to make changes to Tier 2 information without prior NRC approval unless the change involved a change to the Tier 1 information, the technical specifications, or involved an "unreviewed safety question" as defined in 10 CFR 50.59. It is the staff's position that changes to staff positions or the basis for staff positions on specific elements of the design set forth in the staff's FSER and supplements thereto would involve an "unreviewed safety question" requiring prior NRC approval.

In the SRM on SECY-90-377, "Requirements for Design Certification under 10 CFR Part 52," the Commission directed the staff to ensure that the "50.59-like" process considered preservation of the severe accident, human factors, and operating experience insights that are part of the staff's review. The proposed "50.59-like" process will ensure preservation of these insights. The process invokes the definition of an "unreviewed safety question" as defined in 10 CFR 50.59, which refers to an increase in the probability of occurrence or consequence of an accident previously evaluated in the SSAR, creation of an accident of a different type than any previously evaluated, or a reduction in the margin of safety as defined in the basis for any technical specification. Insights on severe accident and selected technical issues have been incorporated into the specific designs in both the DCD and FSER based on guidance from previous SRMs and SECY papers. Additionally, insights on these and other issues have been addressed as part of the review of generic safety issues (GSIs) that were required by 10 CFR 52.47(a)(1)(iv). The resolutions of the GSIs will be explicitly documented in the DCD and FSER. Where appropriate, operating experience and other significant issues have also been incorporated into both the DCD and FSER. Changes to the Tier 1 certified design or changes that involve an "unreviewed safety question," including changes to positions set forth in the staff's FSER, would not be permitted without NRC approval.

Insights from safety analyses are being incorporated into the Tier 1 design descriptions and the corresponding ITAAC and staff positions in the FSER will be incorporated into the SSAR. A cross reference from the safety analyses to the Tier 1 design information will be provided as part of the SSAR. Also, where Tier 2 information directly supports Tier 1 information, such as

enveloping analyses to justify a particular acceptance criteria, the SSAR would reference the applicable Tier 1 information. Thus, the proposed "50.59-like" process, set forth in Section A.15(e) of Enclosure 1, will require review of these insights in order to determine if a change is acceptable.

Records documenting changes under the proposed "50.59-like" process prior to and after the issuance of a combined license would be submitted quarterly to the NRC until the findings for authorization to load fuel under 10 CFR 52.103(c) have been made, and would be submitted in accordance with the requirements of 10 CFR 50.59 thereafter (typically annually). Records from these changes also would be maintained in accordance with the provisions of 10 CFR 50.59 (typically until the date the license is terminated), or the license application is withdrawn.

Tier 2 changes which affected Tier 1 information could be made only if the applicant or licensee submitted a request for an exemption, under 10 CFR 52.63(b)(1), or a petition for rulemaking, under 10 CFR 52.63(a)(1) in order to change the Tier 1 information. These changes would then be included as part of the certified design information contained in the plant-specific DCD and referenced in the combined license. Tier 2 changes which involved an "unreviewed safety question," but which did not change Tier 1 information, would be addressed as part of the application for a combined license, or as a license amendment after issuance of the combined license.

Although the standard design certification will provide issue resolution for both tiers of information in the DCD in accordance with 10 CFR 52.63(a)(4), applicants and licensees may make changes to the DCD as discussed above. If changes are made to the DCD, then the changed information will lose issue preclusion. Examples include changes to the editions of industry codes and standards, revised or updated analytical methods, new technology, or design enhancements. Industry will bear the burden of analyzing these changes to maintain the economic benefits of standardization. Industry has described its intent to do this in the Nuclear Power Oversight Committee (NPOC), "Position Paper on Standardization," of April 1991, which discussed several levels of standardization among plants.

UPDATES OF CODES AND STANDARDS

The process for updating codes and standards in a standard design certification is dependent upon whether the information resides in Tier 1 or Tier 2. The update of the codes and standards in either tier would be accomplished using the same change process for other design-related information, as discussed in Enclosures 5 and 6. In the event that a specific revision, edition, or date of a code or standard is referenced in Tier 1, a combined license applicant or licensee who references the certified design could request an exemption from one or more elements of the Tier 1 information under 10 CFR 52.63(b)(1). This provision was placed in Part 52 to allow an applicant or licensee to seek updates to the design-related information and it should be relatively easy to justify an update to a code or standard, provided that the update is acceptable to the staff. If the exemption is granted, it would lose issue preclusion as required by 10 CFR 52.63(b)(1).

The staff and industry are working to minimize the use of codes and standards in Tier 1. This is being accomplished in two ways. First, only those provisions from codes or standards that are necessary for the staff's safety findings (and that are appropriate for inclusion in Tier 1), rather than all provisions of the codes or standards, are being incorporated. Second, references to a particular code or standard in Tier 1 may not include a specific revision, edition, or date, unless that information is of particular importance for verification of some aspect of the design. If the specific revision, edition, or date is not specified in Tier 1, then it will be identified in Tier 2.

In the event that a particular code or standard is identified in Tier 1, but the specific revision, edition, or date of the code or standard is specified in Tier 2, an applicant or licensee could seek an update under the "50.59-like" process specified in Section A.15(e) of Enclosure 1. If the proposed change affected the Tier 1 information, this would result in a review to determine its acceptability as part of a request for exemption under 10 CFR 52.63(b)(1). If the reference to a particular code or standard appeared only in the Tier 2 information, then the change would be controlled under the proposed "50.59-like" process in Section A.15(e) of Enclosure 1. The Commission is limited to rulemaking in making any changes to Tier 2, and these changes are governed by the backfit standard in 10 CFR 50.109. An applicant or licensee would bear the risk of the increased potential for litigation resulting from the change to the code or standard in either the licensing review or license amendment process.

The design certification will identify the specific editions, revisions, or dates of all codes and standards to establish the basis for approval of the design. The staff's review of the design certification application is based upon the criteria in the specified editions of the codes and standards, and these editions are part of the bases of the staff's findings in the FSER. Certain codes and standards must be met by an applicant for a facility, such as those listed in 10 CFR 50.55a and 10 CFR Part 100, in addition to those codes and standards listed in the certified design. Although reference to

codes and standards in Tier 1 has been minimized, changes to the above regulations may affect the specific editions of codes and standards, as well as related codes and standards, listed in the SSAR and the staff's FSER. The staff will bear an increased burden to consider the potential impacts of changes to 10 CFR 50.55a on a certified design. In the case of a potential conflict in regulations, an applicant for a license would utilize the change process discussed in Enclosures 5 and 6 during the application process to meet the appropriate requirements of those regulations.

For the systems and components that must meet the editions of codes and standards that are approved in 10 CFR 50.55a, the staff's approval will be based upon the editions of the codes that are acceptable at the time of design certification, except for specific editions of the ASME Code relating to inservice inspection (ISI) and inservice testing (IST). Section 50.55a(g) requires ISI and IST conducted during the initial 10-year interval to meet the edition of the ASME Code depending on the date of issuance of the operating license. Further, 10 CFR 50.55a(g) requires the updating editions of the ASME Code every ten years for subsequent ISI and IST programs to incorporate operating experience and development of inspection technology. Therefore, the design certification will specify the requirement to perform ISI and IST in accordance with 10 CFR 50.55a(g). An applicant for a combined license will identify the applicable ISI and IST code editions and submit the corresponding ISI and IST programs for staff review and approval in accordance with 10 CFR 50.55a(g).