



RULEMAKING ISSUE

June 20, 1988

(Information)

SECY-88-169

For: The Commissioners

From: William C. Parler
General Counsel

Subject: RULEMAKING ON STANDARDIZATION
AND LICENSING REFORM

Purpose: To inform the Commissioners about the current rulemaking efforts on standardization of nuclear power plant designs and institution of one-step licensing.

Summary: The attached draft Federal Register Notice of proposed rulemaking on standardization and licensing reform implements the Commission's Policy Statement on Nuclear Power Plant Standardization (52 Fed. Reg. 34884, Sept. 15, 1987) and attempts to embody in procedural regulations as much of the legislation the Commission proposed on these topics in March of last year as the agency's current legislative authority permits.

The draft rule provides for (1) approval of a site in advance of the submission of any application for a construction permit for a power plant on that site, (2) certification, by rulemaking, of reactor designs, including designs which are significantly different from any built and operated thus far, and (3) the issuance of licenses which combine in a single license a construction permit and an operating license which is conditioned on

Contact:
Steven Crockett, OGC
21600

successful completion of construction and testing.

The attached draft Notice responds to written public comments submitted after a public workshop held October 20, 1987 on the Policy Statement on Standardization. The draft has also had the benefit of ACRS and CRGR review. NRR and RES have concurred in it.

The Discussion below highlights certain important policy matters involved in the draft rule. These matters also happen to overlap to a considerable extent with the respects in which the draft rule differs the most from the legislation the NRC proposed last year.

Discussion:

Scope of Design: In keeping with the Policy Statement on standardization, the draft rule says that the NRC will entertain an application for a design of less than full-scope only if the design contains all systems and components that could affect safety and are not site-specific, such as the service water intake structure or the ultimate heat sink. See § 52.45(d) of the draft rule. In this respect the rule represents a compromise between mandating the Commission's preference for full-scope designs and fully implementing the proposed legislation's willingness to accept designs for any "major subsystem" of a plant.

The CRGR recommended that the rule not permit any application for certification of a design that is not essentially complete in scope. See Enclosure 2 to the Minutes of CRGR Meeting No. 137, June 8, 1988, Recommendation 3.a. We have not followed this recommendation but instead have adhered to the Commission's expression, in its Policy Statement on Standardization, of its willingness to consider an application for certification of a design of a major portion of a plant. 52 Fed. Reg. 34884, 34886, col. 3 (September 15, 1987).

If safety is the overriding purpose of standardization, as we believe it is, then the NRC should leave it to market forces to determine whether any part of a design beyond

the parts which significantly affect safety should be standardized. Thus the issue of whether to require full-scope designs comes down to whether the NRC is going to turn down every application for certification of a design which is not essentially complete, without even having considered any prima facie case such an application might make that the proffered design includes within its scope everything which might significantly affect safety. We believe that there may be no good grounds for such a sweeping, before the fact, judgment about such applications.

In permitting such applications to be filed, the proposed rule does not intend to imply that it is possible to leave the balance of plant out of a design and still have within the scope of design every system and component that might significantly affect safety. The rule would only express the agency's willingness to give at least preliminary consideration, under the high standards of §§ 52.45 and 52.47, to designs of incomplete scope. The rule would leave the staff and the Commission free to reject such designs after having reviewed them.

Level of Detail: The draft rule imposes stringent demands on the level of detail required in an application for design certification. The draft requires that the design information provided shall be equivalent to that required for a final design approval under Appendix O, and shall include performance requirements and design specifications sufficient to permit the preparation of procurement specifications. See § 52.47.

Finality: The several finality provisions in the draft rule are designed to make standardization secure by protecting Commission-level resolutions of issues from change except when public health and safety require it. First, while a design certification is in effect, the NRC may not modify the design unless a modification is required for adequate protection of the public health and safety. See § 52.63(a). Only during the proceeding for renewal of the certification may the NRC modify the design

for the sake of a substantial increase beyond adequate protection. This provision is a compromise between the legislation, which would permit only adequate protection modifications, and § 50.109, which permits modifications for the sake of a substantial increase in protection as well as for adequate protection.

Second, the holder of a design certification may seek an admendment of the certification, and the admendment will be granted if it complies with the agency's regulations in effect at the time of the admendment rulemaking. However, the admendment will not be backfitted on plants already referencing the design unless adequate protection of the public health and safety so requires. See § 52.63(b).

Third, an applicant for a combined license which references a certified design, or a licensee for a plant which references a certified design, may ask for an exemption under § 50.12 from some provision of the design rule.

Fourth and last, the draft proposed rule would greatly limit the changes a licensee could make without prior Commission approval to a plant which references a certified design. A licensee could make such changes only if they did not involve changes to the design as described in the rule certifying the design. See § 52.63(d).

Similar restrictions govern changes to early site permits. See §§ 52.39. Taken as a whole, these finality provisions make early site permits and design certifications reasonably secure while at the same time leaving the Commission enough power to assure adequate protection of public health and safety and to require significant improvements in the designs and permits from time to time.

Fees: In keeping with the proposed revisions to Parts 170 and 171 now before the Commission, the draft rule charges the costs of review of applications for site permits and certifications to the holders of the

permits and applications. The proposed legislation would have charged these costs to applicants which referenced the permits or certifications. However, as in the legislation, the fees will be charged on a deferred basis. See §§ 52.19 and 52.49.

Hearings: In keeping with the NRC's current statutory authority, the draft rule provides for mandatory hearings on applications for early site permits and combined construction permits and operating licenses.

The draft rule provides that the proceeding on an application for a design certification will take the form of notice-and-comment rulemaking together with opportunity for an informal hearing before an Atomic Safety and Licensing Board.

Under present statute, the Commission must provide an opportunity for a hearing before operation is authorized under a previously granted combined CP/OL. However, the draft rule limits the contentions that can be made at that stage to those which allege, with basis and specificity, that there has been a material -- and uncorrected -- nonconformance with the license. See § 52.103. Moreover, the rule tries to limit the range of possible dispute over such nonconformances by requiring applicants for combined CP/OLs to propose inspections, tests, analyses and related acceptance criteria which will provide reasonable assurance that the facility has been constructed and will operate in conformity with the license. See § 52.79(b)

Emergency Planning: Several provisions in the draft rule are designed to secure the earliest possible resolution of emergency planning issues. For instance, section § 52.17(c) of the rule requires that the application for an early site permit contain emergency plans which are as fully developed as circumstances permit, and § 52.18 states that the Commission, after consultation with FEMA, will make the appropriate findings on the submitted plans. Section 52.79(c) contains analogous requirements for the application for a combined license. We

believe these provisions fulfill the Commission's commitment to the National Governors' Association to propose for public comment in any licensing reform rulemaking the Commission might conduct provisions for the approval of emergency plans before the grant of a construction permit. See Chairman Zech's October 27, 1987 letters to Governor Sununu (New Hampshire) and others.

Commission Questions: Section VI of the preamble to the draft proposed rule sets forth several questions on which we believe it would be helpful to have public comment. These issues include some of the issues discussed above.

William C. Parler
General Counsel

Attachment:
Draft Federal Register Notice
of Proposed Part 52

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Nuclear Regulatory Commission

10 CFR Part 52

Early Site Permits; Standard Design Certifications; and
Combined Licenses for Nuclear Power Reactors

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is considering adding a new Part to its regulations which would provide for issuance of early site permits, standard design certifications, and combined construction permits and conditional operating licenses for nuclear power reactors. Part 52 sets out the review procedures and licensing requirements for applications for these new licenses and certifications.

DATES: The comment period expires 60 days after publication in the FEDERAL REGISTER. Comments received after [end of comment period] will be considered if practical to do so, but only those comments received on or before this date can be assured of consideration.

ADDRESSES: Comments may be sent to the Secretary of the Commission, Attention: Docketing and Service Branch, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, or may be hand-delivered to One White Flint North, 11555 Rockville Pike, Rockville, MD 20852, between 7:30 a.m. and 4:15 p.m. weekdays. Copies of comments received may be examined at the Commission's Public Document Room at 1717 H St. NW., Washington, D.C., between the hours of 7:45 a.m. and 4:15 p.m. weekdays.

FOR FURTHER INFORMATION CONTACT: Steven Crockett, Attorney, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Telephone: (301) 492-1600.

SUPPLEMENTARY INFORMATION:

Public Meeting

The NRC staff will conduct a public meeting to answer questions on the meaning and intent of the provisions of this proposed rule. It is hoped that such a meeting would be helpful to persons who intend to submit written comments on the proposed rule. The meeting will be held on [a date about midway through the comment period] at [a place to be determined closer to the time the Commission votes to publish the proposed rule]. The meeting will begin at 9:00 a.m.

I. Background

The Nuclear Regulatory Commission has long believed that standardized nuclear power plant designs and other means of achieving early resolution of licensing issues could significantly enhance the safety and reliability of nuclear plants, and could likewise enhance public participation in the licensing process while reducing the complexity and uncertainty of that process. The considerable variation in the design, construction, operation and maintenance of nuclear plants has led to an operating reactor population of great variability and diversity, even among reactors from the same vendor. While giving

freedom to innovation during the early years of the industry, when innovation was most needed, the "one-of-a-kind" approach may also have hindered the growth of significant economies of scale of benefit to safety and to the efficiency and predictability of regulation. Standardization of reactor designs should result in greater accumulation of construction and operating experience with a given design, easier transfer of that experience from one reactor to another, and more easily maintained qualified vendor support, all of which should advance safe and reliable operation. Moreover, by permitting early identification and resolution of safety issues, standardization and other means of achieving early resolution of licensing issues should afford public participants in the licensing process an earlier entry into that process, greatly reduce the number and importance of safety issues which are decided late in the process, and permit a speedy, yet thorough, NRC staff review whenever an application incorporates a certified standardized design. Thus, early resolution of issues should lead to a simpler and more predictable licensing process.

Through such devices as early site reviews, final design approvals, and reviews of duplicate and replicate plants, the NRC has for some time offered applicants the means to achieve a degree of standardization and to reach early resolution of issues. The NRC will continue to offer these means.¹ However, it is the opinion of the Commission that the

¹ The NRC's current policy on replication appears in this Federal Register notice after this Supplementary information. The Commission welcomes comment on this policy, in particular on whether the NRC should continue to offer the option of replication.

nuclear power industry is now sufficiently advanced in technology and organization to enable applicants to submit essentially complete designs or major portions thereof for certification by rulemaking before construction and thus secure the benefits of a greater degree of standardization and early resolution of issues. Moreover, the NRC now has under review several designs which are amenable to standardization, and the industry is showing increasing interest in such designs. For the past several years, the Commission has pursued Congressional affirmation of the goals of standardization in the form of a Nuclear Power Plant Standardization and Licensing Act. However, much of what this proposed legislation would provide can be put into effect now, under the Commission's existing statutory authority. The Commission therefore proposes to add to its regulations a new Part, which is described in Sections II-V below.

The Commission announced its intention to pursue rulemaking on standardization in its recent Policy Statement on Nuclear Power Plant Standardization, 52 Fed. Reg. 34884 (September 15, 1987). The Policy Statement, now superceded by this proposed rule and preamble, described the Commission's experience with standardization, set out the Commission's reasons for pursuing a greater degree of standardization, and outlined some of the crucial elements the Commission would seek to embody in a rule. The Policy Statement provided for a sixty-day comment period and gave notice that a public workshop would be held during the comment period so that the NRC and interested parties could have a more thorough discussion of the Statement and the pending rulemaking than written comments alone would permit. The workshop was held in Bethesda

on October 20, 1987, with representatives of the NRC staff, the Department of Energy, and the industry participating. During the Workshop, the NRC outlined the proposed rule and answered preliminary questions about it. A transcript of the workshop may be found in the Commission's public document room, 1717 H Street, NW., Washington, D.C. 20555.

During the comment period, the Commission received comments from six organizations and two individuals. Chief among the comments were the highly detailed ones submitted by the Nuclear Management and Resources Council (NUMARC), which were endorsed, or at least reflected to a large degree, by the comments submitted by the other organizations, among them two engineering firms and three reactor manufacturers. These comments also may be found in the Commission's Public Document Room in Washington, D.C. The proposed rule set out below incorporates many of the suggestions made in the comments. For instance, the rule provides for certification of "advanced" designs, establishes a rulemaking process which goes beyond notice and comment, provides that a design certification shall remain in effect during the proceeding on a request for renewal of the certification, and does not make the granting of a combined license dependent upon State and local government certification of willingness to participate in emergency planning, although it does seek the earliest possible resolution of emergency planning issues.

In some instances, the proposed rule does not incorporate suggestions made in the comments. These suggestions and our reasons for not including them are discussed in the appropriate places in Sections

III, IV, and V below. In Section VI we raise certain questions on which we would appreciate comment. Some of these questions have to do with suggestions we have not incorporated in the proposed rule.

Although many intervenors have long supported standardization, even to the point of arguing that the Commission should make standardization mandatory, some of the comments on the Policy Statement opposed standardization. In particular, one individual claimed that standardization will stifle engineering ingenuity, close the public out of the licensing process, spread the safety problems of a given design to a large number of reactors, and eventually meet defeat at the hands of a multitude of site-specific changes to a certified design. This individual also claimed that it was not the proper role of the Commission to "enhance the availability of nuclear plants", as the Commission had put it in its Policy Statement on Standardization, or to "give priority" to standardization rather than the safety problems of present plants.

To the contrary, the Commission believes that competition among designers will more than adequately encourage ingenuity, that the public will be better able to participate in the licensing process if it is given an essentially complete design even before any plant of that design is built, that good design, thorough regulatory review, and long experience with nuclear power should together go a long way to preclude significant safety problems in certified designs, and that the proposed rule's restrictions on changes in certified designs should assure a lasting and high degree of standardization. Under the Energy

Reorganization Act of 1974, the Commission is not permitted to develop nuclear power plants and then regulate what it has developed, but it may nonetheless do what it can by way of sound procedural mechanisms and appropriate distribution of resources to encourage and enable others to develop better designs and build better plants. The principal aim in such "enhancement" is, as always, public health and safety. In the light of this overarching aim, the Commission's statement that it intends to give priority to standardized designs and the like must not be misread to mean that the safety of the presently operating plants will become less important than the review of standardized designs. Such is not the case now and will not become so. The Commission means only to give priority among applicants to those proffering or referencing standardized designs and early site permits.

II. General Scope and Structure

Part 52 is intended to improve the licensing of nuclear power plants by the use of three procedural innovations, two of which have been in partial use by the Commission for several years. The first of these is the early site permit or site-bank concept, already in partial use through the procedures of Appendix Q to 10 CFR Part 50. Subpart A of Part 52 formalizes the early site approval process, allowing a prospective applicant to obtain a permit for one or more pre-approved sites on which future nuclear power stations can be located. Subpart B carries forward the standard design approval process of Appendix O to Part 50 in much the same way, allowing a prospective applicant, vendor, or other interested party to obtain Commission approval of a complete

nuclear power plant design or a major portion thereof. Subpart C establishes procedures for the issuance of a combined construction permit and conditional operating license (hereafter referred to as a combined license) for a nuclear power plant. The combined license is essentially a construction permit which also requires consideration and resolution of many of the issues currently considered at the operating license stage. It does not authorize operation. Operation will be authorized only after the Commission has decided that the relevant license conditions have been met. The procedures also provide an opportunity for a hearing on carefully-defined issues before operation is authorized. Although a pre-approved site and certified standard design need not be referenced for the combined license, maximum efficiency will result if site-related issues, as well as design-related issues, have been resolved before commencement of the combined license proceeding.

This structure reveals the overall purpose of Part 52: to improve reactor safety and to streamline the licensing process by encouraging the use of standard designs and by permitting early resolution of environmental and safety issues related to the reactor site and design. As a result, the scope of the combined license proceeding for a facility can be far more limited than the scope of the two-step licensing process currently in use. Similarly, after the combined license proceeding, the regulatory matters which would remain for resolution before authorization to operate under the combined license would be much more limited and well-defined than are the issues which remain to be resolved in an operating license proceeding under current practice.

All three subparts of the proposed Part 52 draw heavily on existing provisions in 10 CFR Part 50 and its appendices. Reference to pre-existing sections obviates the need to repeat identical provisions. In addition, most of the provisions of Part 50 have been in use for many years and are commonly understood by applicants, intervenors, and the NRC staff. Finally, Part 50 should remain intact because licensing under it may be expected to continue for some time in parallel with licensing under the improved procedures of Part 52. If, in the future, all licensing is conducted under Part 52, the two parts can be combined into a single part containing all provisions applicable to the licensing of production and utilization facilities.

III. Definitions - Section 52.3

This section contains largely self-explanatory definitions of "combined license," "early site permit," "standard design," and "standard design certification". The omnibus provision in paragraph (e) incorporates other useful definitions from Part 50 and the Atomic Energy Act.

IV. Subpart A - Early Site Permits

This subpart allows any prospective applicant for a construction permit or a combined license under Subpart C to apply for an early site permit, notwithstanding the fact that an application for a construction permit or combined license for a facility has not been filed. Filing requirements are set out in §§ 52.15 and 52.17. The application should

describe, among other things, the number, type, and thermal power level of the facilities for which the site may be used. Section 52.17(b) requires that the application contain a plan for redress of the site for use in the event that site preparation activities are performed under the permit and the permit expires without having been referenced in an application for a construction permit or a combined license under Subpart C of Part 52. Finally, § 52.17(c) requires the application to contain emergency plans which are as fully developed as circumstances permit and which show that the area surrounding the site is amenable to emergency planning which would provide reasonable assurance that adequate protective measures could be taken in the event of a radiological emergency at the site. This last paragraph of § 52.17 requires the applicant to make good faith efforts to obtain certifications by the responsible local and State governmental agencies that such agencies will participate in developing emergency plans. The same paragraph provides that if such certifications cannot be obtained, the application shall nonetheless demonstrate that the area surrounding the site is amenable to adequate emergency planning.

Section 52.19, along with conforming amendments to 10 CFR Part 170 which are currently being made as part of a general revision of Part 170, establish a new procedure for collection of fees associated with the review of an application for an early site permit or a renewal thereof. The applicant for the permit will be assessed these fees only when an application referencing the early site permit is filed while the permit is valid. If no application referencing the early site permit is filed, the permit holder must pay these fees at the end of the initial

twenty-year period. Fees for a renewed permit will be assessed in the same manner. However, if an application for an early site permit or renewal is denied or withdrawn, any outstanding fees will be immediately due and payable by the applicant for the permit or renewal.

Section 52.21 states that an early site permit is a Commission license, and is subject to the applicable procedural requirements of 10 CFR Part 2.

The issues presented in an early site permit proceeding are to a considerable extent environmental, but since they also involve significant safety issues, a report by the Advisory Committee on Reactor Safeguards (ACRS) on the permit application is required by § 52.23.

Section 52.25 provides that issuance of an early site permit allows the holder of the permit to conduct site preparation activities without having to seek prior NRC approval. The holder possesses what is commonly referred to as an "LWA-1" for the site and may perform such activities as are permitted in 10 CFR § 50.10(e)(1). Section 52.25 also requires redress of the site if the permit is not renewed and not referenced in an application.

An early site permit is valid for an initial period of twenty years (§ 52.27) and may, upon application, be extended for periods of up to twenty years each (§ 52.29), provided certain criteria are met (§ 52.31). Section 52.29 provides that any person whose interests may be affected by renewal of the permit may request a hearing.

An early site permit for which an application for renewal has been timely filed remains in effect until the Commission has determined whether to renew the permit. If an early site permit is not renewed, it continues to be valid in any proceeding on an application for a construction permit or a combined license which references the early site permit and was docketed prior to the expiration of the early site permit (§ 52.29(c)). An application for renewal must be filed not less than twelve nor more than thirty-six months prior to the expiration date (§ 52.29(a)).

An approved site may be used for purposes not related to the construction of a nuclear power facility (for example, a fossil-fueled station or a park) provided that the Commission is informed of all significant non-nuclear uses prior to actual construction or site modification activities (§ 52.35). A permit may be revoked if a non-nuclear use would interfere with a nuclear use, or would so alter the site that important assumptions underlying issuance of the permit were called into question.

Section 52.39(a) provides that, notwithstanding the provision in 10 CFR § 50.109 for backfits aimed at substantial increases beyond adequate protection, during the initial or renewal period in which an early site permit is in effect the Commission shall not impose more stringent requirements on the early site permit or the site for which the permit was issued unless the Commission determines either that significant new information shows that more stringent requirements are necessary to bring the site or the permit into compliance with the Commission's

regulations and orders in effect at the beginning of the initial or renewal period, or that more stringent requirements are necessary for adequate protection of the public health and safety. Section 52.39(b) provides that an applicant for a construction permit, operating license, or combined license, or an amendment to such a license, who has filed an application referencing an early site permit may request a variance from one or more elements of the permit.

V. Subpart B - Certified Standard Designs

The Commission's existing rules regarding standard designs are found in Appendices M, N, and O, to 10 CFR Part 50. Appendix M concerns licenses to manufacture one or more nuclear power reactors to be installed and operated at sites not identified in the license application. Appendix N concerns licenses to construct and operate nuclear power reactors of duplicate design at multiple sites. Appendix O governs the staff review and approval of standard designs for an entire nuclear power reactor or a major portion thereof, and includes a provision for Commission approval of a standard design in a rulemaking proceeding. This Subpart concerns only the latter provision of Appendix O. Subpart B is intended to set forth the procedures and requirements for Commission approval of standard designs by rulemaking. The term "certification" is used for this approval to distinguish it from the preliminary and final staff approval of standard designs as set forth in Appendix O.

Section 52.43 addresses the relationship of Subpart B to Appendices M, N, and O of 10 CFR Part 50, as described above. These Appendices represent different approaches to standardization and will remain in effect, as will the replicate plant approach to standardization. Appendices M and N may be used independently of Subpart B unless the applicant also wishes to use a certified standard design. A final design approval under Appendix O is a prerequisite for certification of a standard design under this Subpart. An application for a final design approval must state whether the applicant intends to seek certification of the design, since staff review of a design for which certification is sought may be different from staff review of a design for which only a final design approval is sought. For the same reason, anyone who holds a final design approval on the effective date of this rule and wishes to apply for certification of the design must obtain a new final design approval. However, the application in this case may simply update and supplement the application which was filed for the original final design approval, and the staff's review of the new application need not revisit issues settled in the original review.

Sections 52.45 and 52.47 contain the requirements for filing and contents of applications for certifications of designs. These sections are drafted in general terms so that Part 52 will not have to be amended every time the information and safety criteria in Parts 20, 50, 73, and 100 of 10 CFR undergo some further development. The NRC staff is currently developing safety criteria for application in the review of advanced reactor designs. These criteria will define minimum safety requirements for such reactors and will provide for assessment and

documentation of the enhanced safety the Commission expects such reactor designs to embody. Part 52 deals only with procedural aspects of the certification of reactor designs. The staff will advise the prospective applicant for certification on precisely what information is required for the staff's consideration of the application.

Certification of a reactor design which differs significantly from a reactor design which has been built and operated may be granted only after the design has been shown to be sufficiently mature. There is a presumption in § 52.45 of the proposed rule that such maturity will have to be demonstrated through comprehensive testing of a prototype. The same section of the rule sets forth the criteria which must be satisfied if the presumption is to be overcome. The same criteria must be satisfied by any applicant proposing to demonstrate the maturity of a design by means of a prototype of only part of the design. If an applicant for a construction permit or combined license under this Part chooses to reference a final design approval for a design whose maturity must be demonstrated by prototype and has not yet been so demonstrated, the applicant will be subject to the requirements of § 50.34(a)(8) regarding research and development to confirm the adequacy of the design.

Ideally, designs for which certification is sought will be for an essentially complete plant. Such designs would make more straight-forward the preparation of a PRA and safety analysis and would help minimize the extent of the staff's review of the license applications which reference a single design. Such designs would also

help assure that no two plants of the same design would vary significantly from each other. For these reasons, the NRC will give priority in allocation of resources to support review and approval to applications for essentially complete designs. However, the NRC will entertain applications for certification of a major portion of a plant if, and only if, that portion contains all buildings, structures, systems, and components that can significantly affect the safe operation of the plant. See § 52.45(d) below.

Applications for certification of any design must contain a level of detail comparable to that required for a final design approval under Appendix O and sufficient to enable the staff to judge the applicant's proposed means of assuring that construction conforms to design, and to reach a final conclusion on all matters which must be decided before the certification can be granted. See § 52.47 below.

Section 52.49 parallels § 52.19 with regard to fees, and conforming amendments are being made to Part 170 as part of the general revision of that Part. One engineering firm argued that fees would be a substantial disincentive to potential applicants for certification. And, of course, any fee the NRC charges is to some degree a disincentive. However, the agency is now legally bound to charge fees which account for a substantial part of its budget. Design review will require substantial resources which, under a series of statutes going back to the Independent Offices Appropriations Act, the agency must recoup at least in part.

However, the Commission is free under current law to lessen the disincentive effect of the fees it must charge for review of standardized designs. Therefore, in addition to not charging an application fee, the NRC will defer any fees associated with review of the application, pending the filing of applications for construction permits or combined licenses referencing the certified standard design. Any outstanding fees will become due and payable by the holder of the design certification at the end of the initial period of the certification. Fees for the renewal of a standard design certification will be assessed in the same manner.

Section 52.51 provides that a standard design certification is a rule that will be issued in accordance with the provisions of Subpart H of 10 CFR Part 2. Subpart H of 10 CFR implements Section 553 of the Administrative Procedure Act for NRC rulemaking proceedings. Section 2.805(b) of 10 CFR provides that the Commission may hold informal hearings and may structure them as the Commission determines will best serve the purposes of the proceeding. In addition to notice of an application for a design certification, and an opportunity to provide written comments on the application, the Commission will provide an opportunity to request an informal hearing on the application before an Atomic Safety and Licensing Board. Any hearing held will provide an opportunity for written presentations made under oath or affirmation, and for oral presentations and questioning if the Board finds them either necessary for the creation of an adequate record, or the most expeditious way to resolve controversies. Ordinarily, the questioning will be done by members of the Board, using the Board's questions or

questions submitted to the Board by the parties. The Board may also request authority to use additional procedures, such as discovery, or may request that the Commission convene a formal adjudication on discrete issues involving substantial disputes of fact, necessary for the Commission's decision, that cannot be resolved with sufficient accuracy except in formal adjudication. The staff will be a party in any informal hearing, and the decision in such a hearing will be based only on information on which all parties to the hearing have had an opportunity to comment.

The major issues associated with the review of an application for a certified standard design concern the safety features of the design. Section 52.53 therefore provides for mandatory ACRS review of the application. Review by the ACRS will be limited to issues on which the ACRS has not made findings and recommendations in any earlier review of the design. The Commission may, of course, ask the ACRS to report on any matter within its expertise.

The certified standard design will initially be valid for ten years (§ 52.55), but it may be renewed, upon application, for periods of an additional five to ten years each (§ 52.57). The procedures to be used for a rulemaking proceeding on the application for renewal shall be those required for rulemakings on applications for initial certification of designs. A design certification for which an application for renewal has been timely filed remains in effect until the Commission has determined whether to renew the certification. If the certification is not renewed, it continues to be valid in any proceeding ultimately based

on an application which references the certified design and was docketed prior to the expiration of the certification (§ 52.57(b)).

Section 52.59 contains the criteria for evaluating an application for renewal. The initial burden is on the applicant to show that the design complies with the Atomic Energy Act and all the Commission's regulations other than the design certification itself. During the rulemaking on the application for renewal, the Commission may, in addition to requiring that the design conform to current regulations and orders, impose more stringent safety requirements on the certification, but only if the Commission determines that there is a substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the more stringent requirements and that the direct and indirect costs of implementation of those requirements are justified in view of this increased protection. If a renewal application is denied, the applicant may revise the design and file a new application for a standard design certification. See § 52.59(b).

The stability of a certified standard design is essential to the concept of standardization. For this purpose, § 52.63 contains provisions whose purpose is to preserve design stability against three possible sources of change. First, § 52.63(a), which parallels § 52.39 for early site permits, provides that, during the initial or renewal period in which a design certification is in effect, the Commission will not require design changes unless the Commission determines in a notice and comment rulemaking that significant new information shows that the

changes are necessary to bring the design or the plants referencing it into compliance with the Commission's regulations and orders in effect when the certification was issued or renewed, or that the changes are necessary for adequate protection of public health and safety. Of course, as the Atomic Energy Act requires, the Commission will make such determinations without regard to economic costs. Modifications to a design certification rule will be applied to all plants referencing the certified design.

The Commission believes that carrying out such modifications by way of rulemaking will not hamper the Commission's ability to act quickly in the event that plants referencing a certified design pose undue risks. There is no reason why such rulemakings should proceed less quickly than license amendment proceedings for the same purpose. Indeed, the procedures for rulemaking would appear to be simpler than those for license amendment. Moreover, the Commission has the authority to issue immediately effective interim rules, pending completion of final rulemaking resolutions of undue risk issues.

Members of the public may challenge a design certification rule by means of petitions for rulemaking and, during licensing proceedings on applications which reference a standardized design, only by claims that adequate protection of public health and safety, or compliance with the Commission's regulations and orders, requires modification of the rule. NUMARC urged that a design certification rule be subject to challenge by a member of the public only in a rulemaking proceeding. However, members of the public cannot be barred from making claims in a proceeding that the criteria by which the Commission is to make its

decision on the application are not met. Moreover, § 7 of Appendix O to 10 CFR Part 50, of which Subpart B of the proposed rule is an elaboration, provides for challenge to the design certification rule outside of rulemaking.

Second among the provisions aimed at maintaining stability for certified designs, § 52.63(b) provides that the holder of a design certification may request an amendment to the design by way of notice and comment rulemaking. The Commission will grant the amendment if it complies with the Atomic Energy Act and the Commission's regulations and orders. An amendment to a design certification initiated by the holder of the certification will be applied to all plants referencing the design only if the amendment is necessary for adequate protection of the public health and safety.

Third and last, § 52.63(c), which parallels § 52.39(b) for early site permits, provides that a licensee or an applicant for a facility license or amendment which references a certified standard design may request an exemption from one or more elements of the design certification rule. The Commission will grant the request if it complies with the requirements of 10 CFR § 50.12(a). NUMARC suggested that a lesser standard than § 50.12 be applied to a request for an exemption, namely, that the request for an exemption simply meet the Commission's regulations (except, of course, for the particular design certification regulation itself). However, the Commission believes that the benefits of standardization will not be fully achieved unless significant site-specific variation among plants referencing a given

certified design is kept to an irreducible minimum. In harmony with the aim of keeping such variation to a minimum, § 52.63(d) permits the licensee of a plant built according to a standardized design to make a change to the standardized portion of the plant, without prior Commission approval, only if the change does not involve changes to the design as described in the rule certifying the design, or in the certifying rule together with any exemption which may have been granted the licensee under § 52.63(c).

V. Subpart C - Combined Construction Permits and Conditional Operating Licenses

Section 161h of the Atomic Energy Act and 10 CFR § 50.52 provide that the Commission may issue a single license for several activities which could otherwise be licensed separately. However, this provision has not been applied to construction permits and operating licenses for nuclear power plants. Indeed, the current licensing process has not changed substantially since it was originally enacted. In the early years of the nuclear power industry, there were many first-time nuclear plant applicants, designers, and consultants, and many novel design concepts. Accordingly, the process was structured to allow licensing decisions to be made while design work was still in progress and to focus on case-specific reviews of individual plant and site considerations. Construction permits were commonly issued with the understanding that open safety issues would be addressed and resolved during construction, and that issuance of a construction permit did not constitute Commission approval of any design feature. Consequently, the

operating license review was very broad in scope. Now that the nuclear industry has matured, it is possible to describe and evaluate plant designs on a generic basis, to have designs essentially complete in scope and level of detail prior to construction, and to propose and evaluate plant sites without plant design details. These circumstances make it possible to combine the construction permit proceeding with much of the operating license proceeding into a single proceeding for the issuance of a combined construction permit and conditional operating license. Full-power operation can then be authorized under the combined license following an opportunity for a hearing on a more limited set of carefully defined issues.

The application for a combined license may, but need not, reference a standard design which has been certified under Subpart B, or a site for which an early site permit has been issued under Subpart A (§ 52.73). If the facility is to be of a design which has been certified, the scope of the proceeding on the application for a facility license is narrowed, the major safety questions having been resolved in the earlier rulemaking on the design. Similarly, if the facility is to be located on a site for which an early site permit has been issued, the scope of the facility license proceeding is further narrowed. If an early site permit is not referenced, the early site review procedures of 10 CFR Part 2 remain available to expedite the environmental review. Obviously, the efficiency and effectiveness of the combined licensing process is maximized if both a certified standard design and a pre-approved site are referenced. For this reason, the Commission anticipates that this will be the preferred approach, particularly with

regard to standard designs. In order to encourage standardization, the Commission will give priority among applications to those which reference certified standard designs and pre-approved sites.

Sections 52.75 through 52.79 contain the requirements for filing and contents of applications. It should be noted that an environmental report is not required if a pre-approved site is proposed for the facility (§ 52.77). The applicant must make good faith efforts to obtain certifications from responsible State and local governmental agencies that the proposed emergency plans are practicable and that the responsible agencies are committed to execution of their responsibilities under the plans. If such certifications cannot be obtained, the applicant must nonetheless demonstrate that the proposed plans provide reasonable assurance that adequate protective measures will be taken in the event of a radiological emergency at the plant (52.79(d)). The antitrust review will be conducted as it has been done in the past for construction permit applications. Because the antitrust review can proceed in parallel with the technical review, the antitrust review should not affect the efficiency of the combined license proceeding.

Sections 52.81 and 52.83 incorporate, where appropriate, the technical standards and requirements of Part 50 as they would be applied to power plant license applicants and licensees under the existing system. That is, applications for a combined license will be reviewed according to the Part 50 standards for construction permits and operating licenses, where appropriate (§ 52.81), and holders of Part 52

combined licenses will be held to the appropriate Part 50 standards for plants under construction or, upon conversion to an operating license, in operation (§ 52.83). All limitations contained in the Part 50 provisions (for example, requirements for plants receiving operating licenses after a certain date) carry forward to Part 52.

The combined license hearing will be governed by the appropriate sections of 10 CFR Part 2 (§ 52.85). ACRS review of the application is mandatory (§ 52.87), although the scope of the report will be much narrower if the application references a certified standard design or a pre-approved site that the ACRS has previously reviewed. Section 52.89 provides that, if the application references an approved site or a certified standard design, the environmental review shall focus on the suitability of the site for the design and any other significant environmental issue not considered in any previous proceeding on the site or the design. It should be noted that since both the early site permit and the standard design certification require the preparation of an environmental impact statement, only an environmental assessment need be prepared in connection with the application for a combined license. If the application does not reference a pre-approved site, the usual Part 51 procedures must be followed for review of the environmental part of the application.

As noted above in the discussion of Subpart A, once the application for a combined license has been docketed, an applicant who plans to use a site for which an early site permit has been issued may perform "LWA-1" activities (see § 50.10(e)(1)) without prior NRC approval. If

the application does not reference an approved site, the applicant must request such authorization before performing "LWA-1" activities (§ 52.91). If such activities are carried out and the application is withdrawn or denied, redress of the site will, in some cases, be required. To perform "LWA-2" activities, all applicants must seek authorization from the Licensing Board under § 50.10(e)(3)(i), which allows further construction activities at the site prior to issuance of a construction permit or combined license.

Section 52.93 governs the extent to which a certified standard design or an early site permit may be modified by the applicant during a proceeding on an application for a combined license. As provided in § 52.93(a), the applicant may request an exemption from one or more elements of the design for that particular facility. The Commission will grant the request if it complies with the requirements of 10 CFR § 50.12(a). As provided in § 52.93(b), if the application for the combined license references an early site permit, the applicant may also request a variance from some element of the permit.

Section 52.97 provides that the Commission may issue a combined license for a facility if the applicable requirements of §§ 50.40, 50.42, 50.43 and 50.50 have been met and there is reasonable assurance that the facility will be constructed and operated in conformity with the license, the provisions of the Atomic Energy Act, and the Commission's regulations. In addition to technical specifications, the license will include the inspections, tests, and analyses that the licensee shall perform and the acceptance criteria therefor which will

provide reasonable assurance that the facility has been constructed and will be operated in accordance with those requirements. The Commission will verify the licensee's compliance those requirements through its inspection program (§ 52.99).

Section 105c. of the Atomic Energy Act requires that the Commission determine whether "significant changes" have taken place with respect to the antitrust situation during the review of an application for an operating license. This is done because the competitive circumstances could alter markedly between the issuance of the construction permit and the completion of the facility. The proceeding on the application for a combined license includes consideration of the antitrust situation. However, since operation under a combined license cannot be authorized until the plant is constructed, § 52.101 provides for possible further antitrust review at the stage when authorization of operation is being considered. If significant changes have occurred since issuance of the combined license, the statutory antitrust review must precede commercial operation of the facility and could result in the imposition of additional license conditions. However, because most issues will be decided prior to issuance of a combined license, and because the scope of the proceeding authorizing operation under the license will be correspondingly narrowed, the time between issuance of the combined license and the authorization of operation should be short enough to make significant changes in the antitrust situation unlikely.

Before the facility may operate, the holder of the combined license must apply for authorization of operation under the combined license.

The Commission will publish a notice of the proposed authorization in the Federal Register pursuant to 10 CFR § 2.105. Within 30 days, any person whose interests may be affected by the authorization may request a hearing on the basis (1) that there has been a nonconformance with the license, the licensee's written commitments, the Atomic Energy Act, or the Commission's regulations and orders, which has not been corrected and which could materially and adversely affect the safe operation of the facility; or (2) that some modification to the site or the design is necessary to assure adequate protection of public health and safety or the common defense and security. The petitioner must set forth with reasonable specificity the facts and arguments which form the basis for the request. These provisions are designed to accord finality to the Commission's earlier decisions regarding the facility and to assure that the operating license proceeding is focused on significant safety issues.

VI. Commission Questions

The Commission will, of course, appreciate receiving comment on any aspect of this proposed rule. However, the Commission will be particularly appreciative of comment on the following questions:

1. In implementing by rulemaking the Commission's legislative proposals on standardization, does this proposed rule take full advantage of the Commission's authority under the Atomic Energy Act? Does it in any way exceed the Commission's authority?

2. Should a design certification take the form of a license rather than a rule? Does the Commission have the authority under existing law to license a design? NUMARC believes that the rights and obligations which attach to a license may be more clearly understood than those which would attach to a certification which took the form of a rule. The proposed rule accords with § 7 of Appendix O to 10 CFR Part 50 in treating the certification as a rule. Rulemaking may provide greater procedural flexibility than a license proceeding does, and certification by rule would be open to a wider pool of applicants than certification by license (see 10 CFR § 50.38).

3. What procedures are appropriate for design certification by rulemaking?

4. Should the Commission require as part of a certified standard design the standardization of construction practices, operation and maintenance practices, quality assurance, and personnel training?

5. The proposed rule says that the NRC will entertain an application for certification of a design of only a major portion of a plant if that portion contains all buildings, structures, systems, and components that "significantly affect the safe operation of the plant". The Commission's intent here is to rule out of consideration for certification any incomplete design in which events in the balance of plant could have an adverse impact on the safety of that portion of the plant for which certification is sought. Would some phrase other than "significantly affect the safe operation of the plant" better serve as a

standard by which to determine whether to accept an application for certification of an incomplete design? Should the NRC, in addition, require of any such application a showing of good cause, or the like, for seeking certification of a design of less than full scope?

6. What are the appropriate standards to apply to a request by a holder of a design certification to amend the certification? If the amendment is granted, should all plants which reference the certification be required to backfit to comply with the amended certification, or only some, as required by the proposed rule?

7. In order to prevent continual regression from standardization among plants initially built according to the same design, should stricter standards than those in 10 CFR § 50.12 be applied to requests for exemptions from a design certification rule?

8. The proposed rule generally permits the NRC to impose modifications on site permits and design certifications only for the sake of compliance or adequate protection. Under the proposed rule, only when an early site permit or a design certification comes up for renewal would the NRC be able to impose modifications which went beyond requiring adequate protection. Does the proposed rule provide a reasonable degree of finality to early site permits and design certifications?

9. The proposed rule places a term of twenty years on early site permits and allows for an unlimited number of renewals of up to twenty

years each. Should a longer or shorter term be placed on the permit? What should the respective burdens of the permit holder and the NRC be at renewal?

10. How might the proposed rule provide for a "sign-as-you-go" process of NRC inspection of a plant being constructed according to a certified design? NUMARC suggested instituting such a process in order to secure the earliest possible resolution of quality assurance and design conformance questions. The NRC encourages the earliest possible resolution of such questions. To this end, the rule requires applications for design certifications and combined licenses to propose for inclusion in the certification or license inspections, tests, analyses, and related acceptance criteria which will help provide reasonable assurance that the facility has been well constructed. See §§ 52.47 and 52.79 of the proposed rule. Moreover, the NRC would, during construction authorized by this part, devote the resources necessary to achieve the earliest possible staff-level identification and resolution of quality assurance and design conformance questions. However, the NRC does not see how Commission-level finality can be afforded the resolution of such questions without risking an almost continual hearing on the construction of the plant.

11. The National Governors' Association adopted the following Recommendation, among others, at its 79th annual meeting, July 26-28, 1987: "In the future, emergency plans should be approved by the NRC before it issues the construction permit for any new nuclear power plant." To what extent should approval of emergency plans be required

before an early site permit or a combined license is issued? Are the provisions of the proposed rule adequate in this regard? See §§ 52.17(c) and 52.79(d).

12. The staff is considering whether there is a need for further rulemaking or guidance for future reactors, both light-water reactors and other types, to assure that future license applications adequately address the Commission's Safety Goal Policy Statement, 51 Fed. Reg. 28044 (August 21, 1986), and the licensing criteria set forth in the Commission's Severe Accident Policy Statement, 50 Fed. Reg. 32138 (August 8, 1985), particularly the criteria that call for demonstration of compliance with the applicable parts of 10 CFR § 50.34(f) and completion of a probabilistic risk assessment (PRA) together with a systematic consideration of any severe accident vulnerabilities the PRA might expose. Is the language in §§ 52.47(a) and 52.47(b) sufficient to assure that future applications adequately address these matters?

REPLICATE PLANT CONCEPT

The replicate plant concept involves an application by a utility for a license to construct or operate one or more nuclear power plants of essentially the same design as one already licensed.

The design of the plant already licensed (termed the base plant design) may be replicated at both the construction permit and operating license stages, and in applications for combined construction permits and operating licenses in a one-step licensing process. Replication of an approved base plant design at the construction permit stage is a

prerequisite for its replication at the operating license stage. Although replication of the base plant design at the operating license stage is not mandatory, that is, the operating license application may be submitted as a custom plant application, it is strongly recommended.

An application for a replicate plant must demonstrate compliance with the four licensing requirements for new plant designs as set forth in the Commission's Severe Accident Policy Statement, 50 Fed. Reg. 32138 (August 8, 1985).

Each application proposing to replicate a previously licensed plant will be subjected to a qualification review to determine the acceptability of the base plant for replication and to define specific matters that must be addressed in the application for the replicate plant. A further requirement for qualification is that the application for a replicate plant must be submitted within five years of the date of issuance of the staff safety evaluation report for the base plant. The qualification review will consider the following information:

- (1) The arrangement made with the developers of the base plant design for its replication;
- (2) The compatibility of the base plant design with the characteristics of the site proposed for the replicate plant;
- (3) A description of any changes to the base plant design, with justification for the changes;
- (4) The status of any matters identified for the base plant design in the safety evaluation report, or subsequently identified by the ACRS or during the public hearings on the base plant application as requiring later resolution;

(5) Identification of the major contractors, with justification for the acceptability of any that are different than those used by the base plant applicant; and

(6) A discussion of how the replicate plant design will conform to any changes to the Commission's regulations which have become effective since the issuance of the license for the base plant.

ENVIRONMENTAL IMPACT -- CATEGORICAL EXCLUSION

The proposed rules would amend the procedures currently found in Part 50 and its appendices for the filing and reviewing of applications for construction permits, operating licenses, early site reviews, and standard design approvals. As such they meet the eligibility criteria for the categorical exclusion set forth in 10 CFR § 51.22(c)(3). That section applies to "[a]mendments to ... Part[] 50 ... which relate to (i) procedures for filing and reviewing applications for licenses or construction permits or other forms of permission" As the Commission explained in promulgating this exclusion, "[a]lthough amendments of this type affect substantive parts of the Commission's regulations, the amendments themselves relate solely to matters of procedure. [They] ... do not have an effect on the environment." 49 Fed. Reg. 9352, 9371, col. 3 (March 12, 1984) (final environmental protection regulations).¹ Accordingly, pursuant to 10 CFR § 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with these proposed rules.²

¹It makes no substantive difference for the purpose of the categorical exclusion that the proposed amendments will be placed in Part 52 rather than in Part 50. The amendments are, in fact, amendments to the Part 50 procedures and could have been placed in that Part.

²The requirements concerning testing of full-size prototypes of advanced reactors, see § 52.45(c) of the proposed rule, may appear not to fit into the category excluded by § 51.22(c)(3), since to comply with the requirement, an applicant most likely will have to build and test a prototype plant, an act clearly with an environmental impact. Nonetheless, § 52.45(c) is eligible for exclusion under § 51.22(c)(3). Unlike, for instance, the promulgation of

(Footnote Continued)

PAPERWORK REDUCTION ACT STATEMENT

The proposed rule contains information requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. § 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

BACKFIT ANALYSIS

If this proposed rule becomes final, it will not modify or add to the systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to construct or operate a facility. However, it could be argued that this rule will modify and add to the procedures or organization required to design a facility, since the rule would add to, or else at least spell out, the requirements for applicants for design certifications. Moreover, the rule, if made final, will, at the very least, substantially modify the expectations of

(Footnote Continued)

a safety rule which applies to operating plants, the formal action of promulgating § 52.45(c) will have only a potential impact on the environment. That impact becomes actual only if a designer chooses to pursue certification of an advanced design. Under the present circumstances, no meaningful environmental assessment or impact statement can be made. Cf. 49 Fed. Reg. at 9372, cols. 2-3 (entering into an agreement with a State under Section 274 of the Atomic Energy Act has no immediate or measurable environmental impact and therefore warrants a categorical exclusion). The issuance of the construction permit and operating license for a prototype plant would, of course, be a major federal action with a significant impact on the environment, and would entail the preparation of an environmental impact statement. Cf. id., col. 3 (the States must prepare detailed environmental analyses before they license certain activities).

anyone who had hoped to apply for a design certification under the existing section 7 of Appendix 0, particularly of any such who presently hold preliminary or final design approvals under that Appendix.

Nonetheless, the Commission believes that the backfit rule does not apply to this proposed rule and, therefore, that no backfit analysis pursuant to 10 CFR § 50.109(c) is required for this proposed rule. The backfit rule was not intended to apply to every action which substantially changes settled expectations. Clearly, the backfit rule would not apply to a rule which would impose more stringent requirements on all future applicants for construction permits, even though such a rule arguably might have an adverse impact on a person who was considering applying for a permit but had not done so yet. In this latter case, the backfit rule protects the construction permit holder, not the prospective applicant, or even the present applicant. The proposed rule below is of the character of such a hypothetical rule. The proposed rule arguably imposes more stringent requirements for design certification and thereby may have an adverse impact on some persons. However, the effects of any final rule based on this proposed rule will be largely prospective, and such a final rule will not require any present holder of a design approval (no person holds a design certification) to meet new standards in order to remain in possession of such an approval.

REGULATORY FLEXIBILITY ACT CERTIFICATION

The proposed rule will not have a significant impact on a substantial number of small entities. The proposed rule will reduce the procedural burden on NRC licensees by improving the reactor licensing process. Nuclear power plant licensees do not fall within the definition of small businesses in section 3 of the Small Business Act, 15 U.S.C. § 632, the Small Business Size Standards of the Small Business Administration in 13 CFR Part 121, or the Commission's Size Standards published at 50 FR 50241 (Dec. 9, 1985). The impact on intervenors or potential intervenors will be neutral. For the most part, the proposed rules will affect the timing of hearings rather than the scope of issues to be heard. For example, many site and design issues will be considered earlier, in connection with the issuance of an early site permit or standard design certification, rather than later, in connection with a facility licensing proceeding. Similarly, a combined license proceeding will include consideration of many of the issues that would ordinarily be deferred until the operating license proceeding. Thus, the timing rather than the cost of participating in NRC licensing proceedings will be affected. Intervenors may experience some increased preparation costs if they seek to reopen previously decided issues because of the increased showing that will be required. Once a hearing commences, however, an intervenor's costs should be decreased because the issues will be more clearly defined than under existing practice. Therefore, in accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. § 605(b), the Commission hereby certifies that the proposed rule, if promulgated, will not have a significant economic impact on a

substantial number of small entities and that, therefore, a regulatory flexibility analysis need not be prepared.

REGULATORY ANALYSIS

As presently constituted, the American population of nuclear power reactors consists largely of one-of-a-kind designs. Experience has shown that the highly individualistic character of this population has consumed enormous resources in the processes of design, construction, and safety review. Since, typically, design of a plant was not complete when construction of it began, many safety questions were not resolved until late in the licensing proceeding for that plant. Such late resolution of questions introduced great uncertainty into proceedings, since the process of resolution often entailed lengthy safety reviews, construction delays, and backfits. Moreover, the low incidence of duplication among designs has meant that experience gained in the construction and operation of a given plant has often not been useful in the construction and operation of any other plant, and has made the generic resolution of continuing safety issues more complicated.

In the face of this experience with a population of unique plants, there have long been fundamentally only three alternatives for Commission action, the last two of them not mutually exclusive: either make no effort to bring about an increased degree of standardization, or propose legislation on standardization, or enact by rulemaking as much of a scheme for promoting standardization as the Commission's current statutory authority permits. The Commission has for some time concluded

against the first alternative, having decided that a substantial increase in standardization would enhance the safety and reliability of nuclear power plants and require fewer resources in safety reviews of plants, and that the Commission should have in place provisions for the review of standardized designs and other devices for assuring early resolution of safety questions. The Commission has therefore pursued standardization both by proposing legislation -- without success -- and by promulgating rules, in particular Appendices M, N, and O to Part 50 of 10 CFR. Lacking legislation on standardization, the Commission believes that the most suitable alternative for encouraging further standardization is to fill out and expand the Commission's regulatory scheme for standardization and early resolution of safety issues.

Therefore, the Commission now proposes to promulgate a new set of regulations, to be placed in a new Part in 10 CFR, Part 52. This new Part facilitates the early resolution of safety issues by providing for pre-construction-permit approval of power plant sites, Commission certification of standardized designs, and the issuance of licenses which combine permission to construct a plant with a conditional permission to operate it once construction of it has been successfully completed. Ideally, a future applicant will reference an approved site and a certified design in an application for a combined license, thus obviating the need for an extensive review of the application and construction. The provision in Part 52 for Commission certification of designs has the additional objective of encouraging the use of standardized designs, thereby adding to the benefits of early resolution

the safety benefits of accumulated experience and the economic benefits of economies of scale and transferable experience.

Quantification of the costs and benefits of this rulemaking is probably not possible. Much depends on the extent to which the industry pursues standardization. Clearly, if the Commission and the industry spend the resources necessary to certify a score of designs and then no applicant references any of them, those resources will have been largely wasted. On the other hand, it is just as clear that if a score of plants uses a single certified design, there will have been a great saving of the resources of the industry, the agency, and the interested public alike. To be added to the uncertainties surrounding the industry's response, there are also uncertainties concerning the costs of the certification process, and the costs of developing the designs themselves, especially the advanced designs, which, it is presumed, will require testing of prototypes. However, if the industry finds it in its interest to proceed with the development of nuclear power, there is every reason to expect that the safety and economic benefits of standardization will far outweigh the upfront costs of design and Commission certification: Review time for applications for licenses will be drastically reduced, the public brought in to the process before construction, construction times shortened, economies of scale created, reliability of plant performance increased, maintenance made easier, qualified vendor support made easier to maintain, and, most important, safety enhanced.

Thus, the rationale for proceeding with this rulemaking: There is no absolute assurance that certified designs will in fact be used by the utilities; however, it is certain that if the reasonably expected benefits of standardization are to be gained, then the Commission must have the procedural mechanisms in place for review of applications for early site approvals, design certifications, and combined licenses. The most fundamental choice is, of course, the industry's, to proceed or not with standardization, according to its own weighing of costs and benefits. But the Commission must be ready to perform its review responsibilities if the industry chooses standardization.

LIST OF SUBJECTS IN 10 CFR PART 52

Administrative practice and procedure, Antitrust, Backfitting, Combined license, Early site permit, Emergency planning, Fees, Inspection, Limited work authorization, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Reporting and recordkeeping requirements, Standard design, Standard design certification.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. § 553, the Commission is proposing to add to 10 CFR Chapter 1 a new Part 52:

PART 52 - EARLY SITE PERMITS; STANDARD DESIGN CERTIFICATIONS;
AND COMBINED LICENSES FOR NUCLEAR POWER PLANTS

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- 52.99 Inspection During Construction.
- 52.101 Pre-Operational Antitrust Review.
- 52.103 Authorization to Operate under a Combined License.

Authority: Secs. 103, 161, 182, 183, 186, 189, 68 Stat. 936, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2133, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846).

GENERAL PROVISIONS

§ 52.1 Scope.

This Part governs the issuance of early site permits, standard design certifications, and combined construction permits and conditional operating licenses for nuclear power facilities under the Atomic Energy Act of 1954, as amended (68 Stat. 919), and Title II of the Energy Reorganization Act of 1974 (88 Stat. 1242).

§ 52.3 Definitions.

As used in this Part,

(a) "Combined license" means a combined construction permit and conditional operating license for a nuclear power facility issued pursuant to Subpart C of this Part.

(b) "Early site permit" means a Commission approval, issued pursuant to Subpart A of this Part, for a site or sites for one or more nuclear power facilities.

(c) "Standard design" means a design which is sufficiently detailed and complete to support licensing of a nuclear power facility or approval of a major portion of such a facility when referenced in an application for a construction permit, combined construction and conditional operating license, or standard design certification, as appropriate, and which is usable for a multiple number of units or at a multiple number of sites without reopening or repeating the review.

(d) "Standard design certification" means a Commission approval, issued pursuant to Subpart B of this Part, of a standard design for a nuclear power facility, or a major portion of such a facility. A design so approved may be referred to as a "certified standard design".

(e) All other terms in this Part have the meaning set out in 10 CFR § 50.2, or Section 11 of the Atomic Energy Act, as applicable.

SUBPART A - EARLY SITE PERMITS

§ 52.11 Scope of Subpart.

This Subpart sets out the requirements and procedures applicable to Commission issuance of early site permits for approval of a site or sites for one or more nuclear power facilities separate from and prior to the filing of an application for a construction permit or combined license for such a facility.

§ 52.13 Relationship to Subpart F of 10 CFR Part 2.

The procedures of this Subpart do not replace those set out in Subpart F of 10 CFR Part 2. Subpart F applies only when early review of site suitability issues is sought in connection with a forthcoming application for a permit to construct certain power facilities. This Subpart applies when any person which may apply for a construction permit under Part 50 of 10 CFR, or for a combined license under Part 52 of 10 CFR, seeks an early site permit separately from and prior to an application for a construction permit for a facility; this Subpart may not be used once an application has been docketed pursuant to § 2.603.

§ 52.15 Filing of Applications.

(a) Any person which may apply for a construction permit under Part 50 of 10 CFR, or for a combined license under Part 52 of 10 CFR, may file with the Director of Nuclear Reactor Regulation an application

for an early site permit. Such an application may be filed notwithstanding the fact that no application for a construction permit or a combined license has been filed in connection with the site or sites for which a permit is sought.

(b) The application shall comply with the filing requirements of 10 CFR §§ 50.30(a), (b), and (f).

§ 52.17 Contents of Applications.

(a) The application shall contain the information required by 10 CFR §§ 50.33(a)-(d) and 50.34(a)(1). In particular, the application should describe the following: (1) the number, type, and thermal power level of the facilities for which the site may be used; (2) the boundaries of the site; (3) the proposed general location of each facility on the site; (4) the anticipated maximum levels of radiological and thermal effluents each such facility will produce; (5) the type of cooling systems, intakes, and outflows that may be associated with each facility; (6) the seismic, meteorological, hydrologic, and geologic characteristics of the proposed site (see Appendix A to 10 CFR Part 100); and (7) the existing and projected future population profile of the area surrounding the site. A complete environmental report as required by 10 CFR §§ 51.45 and 51.50 shall be included in the application.

(b) The application shall propose a plan for redress of the site in the event that the activities permitted by § 52.25(a) are performed and the site permit expires before it is referenced in an application for a construction permit or a combined license issued under Subpart C

of this Part. The application shall demonstrate that there is reasonable assurance that redress carried out under the plan will achieve a self-maintaining, environmentally stable, and aesthetically acceptable site suitable for whatever non-nuclear use may conform with local zoning laws.

(c) The application shall contain emergency plans which are as fully developed as circumstances permit and which show that the area surrounding the site is amenable to emergency planning which would provide reasonable assurance that adequate protective measures could be taken in the event of a radiological emergency at the site. The applicant shall make good faith efforts to obtain certifications by the responsible local and State governmental agencies (1) that the proposed emergency plans are practicable, (2) that these agencies are committed to participating in any further development of the plans, including any required field demonstrations, and (3) that these agencies are committed to executing their responsibilities under the plans in the event of an emergency. The application shall contain any such certifications obtained. If any such certifications cannot be obtained, the application shall nonetheless demonstrate that the area surrounding the site is amenable to emergency planning which would nonetheless provide reasonable assurance that adequate protective measures could be taken in the event of a radiological emergency at the site.

§ 52.18 Standards for Review of Applications.

Applications filed under this Subpart will be reviewed according to the applicable standards set out in 10 CFR Part 50 and its appendices as they apply to applications for construction permits for nuclear power plants. In particular, the Commission shall prepare an environmental

impact statement during review of the application, and the Commission shall determine, after consultation with the Federal Emergency Management Agency in accord with the applicable portions of 10 CFR § 50.47(a)(2), whether the information required of the applicant by § 52.17(c) demonstrates that the area surrounding the site is amenable to emergency planning which would provide reasonable assurance that adequate protective measures could be taken in the event of a radiological emergency at the site.

§ 52.19 Permit and Renewal Fees.

The fees charged for the review of an application for the initial issuance or renewal of an early site permit are those for special projects, as defined in 10 CFR § 170.3 and set forth in 10 CFR § 170.21. There is no application fee. All fees for the review of an application shall be deferred as follows:

(a) If an application is filed for a construction permit or combined license for a facility to be located at a site for which an early site permit has been issued, the permit holder shall pay the applicable fees for the permit at the time the facility application referencing the early site permit is filed. If, at the end of the initial period of the permit, no facility application referencing the early site permit has been docketed, the permit holder shall pay any outstanding fees for the permit.

(b) If the permit is renewed, the permit holder shall pay any outstanding fees for the renewal at the time a facility application referencing the early site permit is filed. If, at the end of the

renewal period, no facility application referencing the permit has been filed, the permit holder shall pay any outstanding fees for the renewal.

(c) If an application for the issuance or renewal of an early site permit is denied or withdrawn, any outstanding fees associated with the review of the application shall be immediately due and payable by the applicant for the permit or renewal.

§ 52.21 Hearings.

An early site permit is a partial construction permit and is therefore subject to all procedural requirements in 10 CFR Part 2 which are applicable to construction permits, including the requirements for docketing in §§ 2.101(a)(1)-(4), and the requirements for issuance of a notice of hearing in §§ 2.104(a), (b)(1)(iv) and (v), (b)(2) to the extent it runs parallel to (b)(1)(iv) and (v), and (b)(3). All hearings conducted on applications for early site permits filed pursuant to this part will be governed by the procedures contained in Part 2.

§ 52.23 Referral to the ACRS.

A copy of the application shall be referred to the Advisory Committee on Reactor Safeguards (ACRS). The ACRS shall report on those portions of the application which concern safety.

§ 52.25 Extent of Activities Permitted.

(a) The holder of an early site permit may perform the activities at the site allowed by 10 CFR § 50.10(e)(1) without first obtaining the separate authorization required by that section.

(b) If the activities permitted by paragraph (a) of this section are performed at a given site, and the permit is not renewed for that site and not referenced in an application for a construction permit or a combined license issued under Subpart C of this Part, then the permit remains in effect solely for the purpose of site redress, and the holder of the permit must redress the site in accord with the terms of the site redress plan required by § 52.17(b). If, before redress is complete, a use not envisaged in the redress plan is found for the site or parts thereof, the holder of the permit shall carry out the redress plan to the greatest extent possible consistent with the alternate use.

§ 52.27 Duration of Permit.

An early site permit issued pursuant to this Subpart shall be valid for twenty years from the date of issuance. An applicant for a construction permit or combined license may, at its own risk, reference in its application a site for which an early site permit application has been docketed but not granted.

§ 52.29 Application for Renewal.

(a) Not less than twelve nor more than thirty-six months prior to the end of the initial twenty-year period, or any later renewal period, the permit holder may apply for a renewal of the permit. An application for renewal shall contain all information necessary to bring up to date the information and data contained in the previous application.

(b) Any person whose interests may be affected by renewal of the permit may request a hearing on the application for renewal. The request for a hearing must comply with 10 CFR § 2.714. If a hearing is granted, notice of the hearing will be published in accord with 10 CFR § 2.703.

(c) An early site permit, either original or renewed, for which an application for renewal has been timely filed remains in effect until the Commission has determined whether to renew the permit. If the permit is not renewed, it continues to be valid in proceedings on an application for a construction permit or combined license referencing the permit and docketed before the end of the initial period of the permit, or a later renewal period. An unrenewed permit also continues to be valid in proceedings on an application for an operating license which is based on a construction permit referencing the permit and docketed prior to expiration of the permit or renewal.

(d) The application for renewal shall be forwarded to the Advisory Committee on Reactor Safeguards (ACRS), which shall review the application and report its findings and recommendations to the Commission. The ACRS need not reconsider issues on which it has made

findings and recommendations in any earlier review of the site which is the subject of the application.

§ 52.31 Criteria for Renewal.

(a) The Commission shall grant the renewal if the Commission determines that the site complies with the Atomic Energy Act and the Commission's regulations and orders in effect at the time of the renewal, and any more stringent requirements the Commission may wish to impose after a determination that there is a substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the more stringent requirements and that the direct and indirect costs of implementation of those requirements are justified in view of this increased protection.

(b) A denial of renewal on this basis does not bar the permit holder or another applicant from filing a new application for the site which proposes changes to the site or the way in which it is used which correct the deficiencies cited in the denial of the renewal.

§ 52.33 Duration of Renewal.

Each renewal of an early site permit shall be for not less than ten nor more than twenty years.

§ 52.35 Use of Site for Other Purposes.

A site for which an early site permit has been issued under this Subpart may be used for purposes other than those described in the permit, including the location of other types of energy facilities. The permit holder shall inform the Director of Nuclear Reactor Regulation of any significant non-nuclear activities for which the site is to be used. The information about such activities shall be given to the Director in advance of any actual construction or site modification for such activities. If the Director finds that a particular non-nuclear use may have a significant adverse effect on the suitability of the site for the purposes described in the early site permit, the Director may issue an order to show cause why the permit should not be revoked or modified.

§ 52.37 Reporting of Defects and Noncompliance; Revocation, Suspension, Modification of Permits For Cause.

For purposes of Part 21 and § 50.100 of 10 CFR, an early site permit is a construction permit.

§ 52.39 Finality of Early Site Permit Determinations.

(a)(1) Notwithstanding anything in 10 CFR § 50.109, during the initial period in which a permit issued under this Subpart is in effect, the Commission shall not impose more stringent requirements, including more stringent emergency planning requirements, on the early site permit or the site for which it was issued, unless the Commission determines either that significant new information shows that a modification is

necessary to bring the permit or the site into compliance with the Commission's regulations and orders in effect at the time the permit was issued, or that a modification is necessary to assure adequate protection of the public health and safety or the common defense and security.

(2) Similarly, notwithstanding anything in 10 CFR § 50.109, during any renewal period in which an early site permit issued under this Subpart is in effect, the Commission shall not impose more stringent requirements, including more stringent emergency planning requirements, on the permit or the site for which it was issued, unless the Commission determines either that significant new information shows that a modification is necessary to bring the permit or the site into compliance with the Commission's regulations and orders in effect at the time the permit was renewed, or that a modification is necessary to assure adequate protection of the public health and safety or the common defense and security.

(b) An applicant for a construction permit, operating license, or combined license, or any amendment to such license, who has filed an application referencing an early site permit issued under this Subpart may include in the application a request for a variance from one or more elements of the permit. In determining whether to grant the variance, the Commission will be guided by the considerations set forth in 10 CFR § 50.92, which guide the Commission's determinations on applications for amendments to construction permits.

SUBPART B - STANDARD DESIGN CERTIFICATIONS

§ 52.41 Scope of Subpart.

This Subpart sets out the requirements and procedures applicable to Commission issuance of rules granting standard design certifications for nuclear power facilities, or major portions thereof, separate from the filing of an application for a construction permit or combined license for such a facility.

§ 52.43 Relationship to 10 CFR Part 50, Appendices M, N and O.

(a) Appendix M to 10 CFR Part 50 governs the issuance of licenses to manufacture nuclear power reactors to be installed and operated at sites not identified in the manufacturing license application. Appendix N governs licenses to construct and operate nuclear power reactors of duplicate design at multiple sites. These appendices may be used independently of the provisions in this Subpart unless the applicant also wishes to use a certified standard design approved under this Subpart.

(b) Appendix O governs the staff review and approval of preliminary and final standard designs. Such designs may be challenged in individual licensing proceedings. This Subpart governs Commission approval, or certification, of standard designs by rulemaking, as set forth in paragraph 7 of Appendix O. A final design approval under Appendix O is a prerequisite for certification of a standard design under this Subpart. An application for a final design approval shall

state whether the applicant intends to seek certification of the design. If the applicant does so intend, the application for the final design approval must, in addition to containing the information required by Appendix O, comply with the applicable requirements of 10 CFR, particularly §§ 52.45 and 52.47 of this Part.

§ 52.45 Filing of Applications.

(a)(1) Any person may seek a standard design certification for an essentially complete nuclear power facility, or a major portion of such a facility. An application for certification may be filed notwithstanding the fact that no application for a construction permit or combined license for such a facility has been filed. Applications for certification of less than a complete facility must meet the criteria set forth in paragraph (d) of this section.

(2) Since a final design approval under Appendix O of Part 50 of 10 CFR is a prerequisite for certification of a standard design, a person which seeks such a certification and does not hold, or has not applied for, a final design approval, shall file with the Director of Nuclear Reactor Regulation an application for certification. Any person which seeks certification but already holds, or has applied for, a final design approval, also shall file with the Director of Nuclear Reactor Regulation an application for certification, since the NRC staff may require that the information before the staff in connection with the review for the final design approval be supplemented for the review for certification.

(b) The applicant shall comply with the filing requirements of 10 CFR §§ 50.30(a) and (b) as they would apply to an application for a nuclear power plant construction permit.

(c) The NRC will entertain an application for certification of a reactor design which differs significantly from reactor designs which have been built and operated. However, certification of such a design will be given only after the design has been shown to be sufficiently mature. The maturity of such a design shall be demonstrated by means of an appropriately sited, full-size, prototype reactor, unless the following criteria are satisfied:

(1) The performance of each safety feature of the design has been demonstrated through either previous experience or full-scale testing;

(2) Interdependent effects among the safety features of the plant have been found acceptable by analysis, testing, or previous experience; and

(3) There exist sufficient data on the performance of the safety features of the plant to assess analytical tools used for safety analyses over a full range of operating and accident conditions, including the response of the safety features over the lifetime of the plant.

The Appendix O final design approval of such a design will identify the specific testing required for certification of the design.

(d) Designs should be essentially complete in scope. The NRC will entertain an application for certification of a design of only a major portion of a plant only if that portion contains all buildings, structures, systems, and components that can significantly affect the safe operation of the plant and are not fixed by site-specific

considerations or parameters. In any case, site-specific elements, such as the service water intake structure or the ultimate heat sink, may be excluded from the scope of the design. However, excluded site-specific elements that can significantly affect safe operation must be addressed by the application in the technical information which §§ 52.47(b) and 52.47(d) require the application to provide on the site parameters and interface requirements for the design.

§ 52.47 Contents of Applications.

The application shall contain a level of design information equivalent to that required for a final design approval under Appendix O. The information submitted for a design certification must include performance requirements and design specifications sufficiently detailed to permit the preparation of procurement specifications and acceptance and inspection requirements. The information must also be sufficient to enable the staff to judge the applicant's proposed means of assuring that construction conforms to design and to reach a final conclusion on all matters which must be decided before the certification can be granted. In particular,

(a) The application shall contain the technical information which is required of applicants for construction permits or operating licenses by Part 20, Part 50 and its appendices, and Parts 73 and 100, and which is not site-specific or irrelevant to the design for which the applicant is seeking certification. In particular, the application shall demonstrate compliance with any applicable portions of the Three Mile Island requirements set forth in 10 CFR § 50.34(f). The staff will

advise the prospective applicant for certification on whether the information required by the listed portions of 10 CFR is appropriate to the staff's consideration of the application, and on whether any additional technical information on the design is required.

(b) The application shall also include (1) the site parameters postulated for the design, and an analysis and evaluation of the design in terms of such parameters; (2) proposed technical resolutions of the Unresolved Safety Issues and medium- and high-priority Generic Safety Issues applicable to the design; (3) a design-specific probabilistic risk assessment (PRA), together with a consideration of any severe accident vulnerabilities that the PRA exposes and a realistic assessment of the degree to which the design conforms to the Commission's Safety Goals for plant operations; and (4) proposed tests, analyses, inspections and acceptance criteria which are necessary to provide reasonable assurance that a plant which references the design is built and operated within the specifications of the design.

(c) An application seeking certification of a modular design shall describe the various options for the configuration of the plant and site, including variations in common systems, interface requirements, and system interactions. The final safety analysis and the probabilistic risk assessment should, when necessary, take into account differences among the various options, and the analysis should set forth any restrictions which will be necessary during the construction and startup of a given module to ensure the safe operation of any module already on line.

(d) An application for a design certification shall meet the following criteria:

(1) The application shall contain interface requirements to be met by those portions of the plant for which the application does not seek certification. These requirements must be sufficiently detailed to allow completion of the final safety analysis and design-specific probabilistic risk assessment required by paragraph (b) of this section.

(2) The application shall demonstrate that compliance with these interface requirements is verifiable through inspection, testing (either in the plant or elsewhere), previous experience, or analysis. Compliance with interface requirements dealing with reliability of components shall be verifiable through previous experience or testing.

(3) The application shall also contain a representative design for those portions of the plant for which the application does not seek certification. Such a representative design shall illustrate how the interface requirements can be met, so as to aid the staff in its review of the final safety analysis and probabilistic risk assessment required by paragraph (b) of this section.

§ 52.49 Fees for Design Certification and Certification Renewal.

The fees charged for the review of an application for the initial issuance or renewal of a standard design certification are set out in 10 CFR Part 170, together with a schedule for their phased recovery as the certified standard design is referenced. There is no application fee. All fees for review of an application shall be deferred as follows:

(a) Each time an application is filed for a construction permit or combined license for a facility referencing the design for which a

standard design certification has been issued, the holder of the design certification shall pay the specified portion of the applicable fees for the approval at the time the facility application referencing the certified standard design is filed. If, at the end of the initial period of the certification, no facility application referencing the certified standard design has been filed, the holder of the design certification shall pay any outstanding fees for the certification.

(b) If the standard design certification is renewed, the holder of the design certification shall pay the specified portion of any outstanding fees for the renewal each time a facility application referencing the certified standard design is filed. If, at the end of the renewal period, no facility application referencing the certified standard design has been filed, the holder of the design certification shall pay any outstanding fees for the renewal.

(c) If an application for the issuance or renewal of a certified standard design is denied or withdrawn, any fees associated with the review of the application shall be immediately due and payable by the applicant for the design certification or renewal.

§ 52.51 Administrative Review of Applications.

A standard design certification is a rule that will be issued in accordance with the provisions of Subpart H of 10 CFR Part 2. The Commission shall initiate the rulemaking after an application has been filed under § 52.(a) of this Subpart and shall specify in detail the procedures to be used for the rulemaking. Such procedures shall include notice and comment coupled with an informal hearing before an Atomic

Safety and Licensing Board. The procedures for the hearing shall include opportunity for written presentations made under oath or affirmation, and for oral presentations and questioning if the Board finds them either necessary for the creation of an adequate record, or the most expeditious way to resolve controversies. Ordinarily, the questioning will be done by members of the Board, using either the Board's questions or questions submitted to the Board by the parties. The Board may also request authority to use additional procedures, such as discovery, or may request that the Commission convene a formal adjudication on discrete issues involving substantial disputes of fact, necessary for the Commission's decision, that cannot be resolved with sufficient accuracy except in formal adjudication. The staff will be a party in the hearing. During the rulemaking, the treatment of proprietary information will be governed by 10 CFR § 2.790 and applicable Commission case law. The decision in such a hearing will be based only on information on which all parties have had an opportunity to comment.

§ 52.53 Referral to the ACRS.

The application shall be forwarded to the Advisory Committee on Reactor Safeguards (ACRS), which shall review the application and report its findings and recommendations to the Commission. The ACRS need not reconsider issues on which it has made findings and recommendations in any earlier review of the design which is the subject of the application.

§ 52.55 Duration of Certification.

A standard design certification issued pursuant to this Subpart shall be valid for ten years from the date of issuance. An applicant for a construction permit or combined license may, at its own risk, reference in its application a design for which a design certification application has been docketed but not granted.

§ 52.57 Application for Renewal.

(a) Not less than twelve nor more than thirty-six months prior to expiration of the initial ten-year period, or any later renewal period, the holder of the design certification may apply for renewal of the certification. An application for renewal shall contain all information necessary to bring up to date the information and data contained in the previous application. The procedures to be used for a rulemaking proceeding on the application for renewal shall be those required by § 52.51 for rulemakings on applications for initial certification of a design.

(b) A design certification, either original or renewed, for which an application for renewal has been timely filed remains in effect until the Commission has determined whether to renew the certification. If the certification is not renewed, it continues to be valid in proceedings on an application for a construction permit, combined license, or operating license referencing the certified design and docketed prior to expiration of the certification or renewal.

(c) The application for renewal shall be forwarded to the Advisory Committee on Reactor Safeguards (ACRS), which shall review the application and report its findings and recommendations to the Commission. The ACRS need not reconsider issues on which it has made findings and recommendations in any earlier review of the design which is the subject of the application.

§ 52.59 Criteria for Renewal.

(a) The Commission shall issue a rule granting the renewal if the design, either as originally certified or as modified during the rulemaking on the renewal, complies with the Atomic Energy Act and the Commission's regulations and orders in effect at the time of the renewal, and any more stringent safety requirements the Commission may wish to impose after a determination that there is a substantial increase in overall protection of the public health and safety or the common defense and security to be derived from the more stringent requirements and that the direct and indirect costs of implementation of those requirements are justified in view of this increased protection.

(b) Denial of renewal does not bar the holder of the design certification or another applicant from filing a new application for certification of the design which proposes design changes which correct the deficiencies cited in the denial of the renewal.

§ 52.61 Duration of Renewal.

Each renewal of certification for a standard design shall be for not less than five nor more than ten years.

§ 52.63 Finality of Standard Design Certifications.

(a)(1) Notwithstanding anything in 10 CFR § 50.109, during the initial period in which a design certification issued under this Subpart is in effect, the Commission shall not impose more stringent safety requirements on the certification unless the Commission determines in a rulemaking either that significant new information shows that a modification is necessary to bring the certification or the referencing plants into compliance with the Commission's regulations and orders in effect at the time the certification was issued, or that a modification is necessary to assure adequate protection of the public health and safety or the common defense and security.

(2) Similarly, notwithstanding anything in 10 CFR § 50.109, during any renewal period in which a design certification issued under this Subpart is in effect, the Commission shall not impose more stringent safety requirements on the certification unless the Commission determines in a rulemaking either that significant new information shows that a modification is necessary to bring the certification or the referencing plants into compliance with the Commission's regulations and orders in effect at the time the certification was renewed, or that a modification is necessary to assure adequate protection of the public health and safety or the common defense and security.

(3) Any modification the NRC imposes on a design certification rule under paragraphs (a)(1) and (a)(2) of this section will be applied to all plants referencing the certified design.

(b) The holder of a standard design certification issued under this Subpart may file a request for an amendment to the design certification by way of notice and comment rulemaking. The Commission shall grant the amendment request if it determines that the amendment will comply with the Atomic Energy Act and the Commission's regulations. The amendment will be applied to all plants referencing the design only if the amendment is necessary for adequate protection of the public health and safety or the common defense and security. Any other amendment will apply only to plants referencing the design after the amendment is granted.

(c) An applicant for a construction permit, operating license, or combined license, or a licensee whose license references a certified standard design issued under this Subpart, may request an exemption from one or more elements of the design certification. The Commission shall grant such a request if it determines that the exemption will comply with the Atomic Energy Act, the Commission's regulations and orders, and the requirements of 10 CFR § 50.12(a). Exemptions will apply only to the license for which the exemption was requested.

(d) The licensee of a plant built according to a standardized design may make a change to the standardized portion of the plant, without prior Commission approval, only if the change does not involve changes to the design as described in the rule certifying the design, or in the certifying rule together with any exemption which may have been granted the licensee under § 52.63(c).

SUBPART C - COMBINED LICENSES

§ 52.71 Scope of Subpart.

This Subpart sets out the requirements and procedures applicable to Commission issuance of combined construction permits and conditional operating licenses (hereinafter referred to as "combined licenses") for nuclear power facilities.

§ 52.73 Relationship to Subparts A and B.

An application for a combined license under this Subpart may, but need not, reference a standard design certification issued under Subpart B of this part or an early site permit issued under Subpart A of this part.

§ 52.75 Filing of Applications.

Any person except one excluded by 10 CFR § 50.38 may file with the Director of Nuclear Reactor Regulation an application for a combined license for a nuclear power facility. The applicant shall comply with the filing requirements of 10 CFR §§ 50.4 and 50.30(a) and (b) as they would apply to an application for a nuclear power plant construction permit. The fees associated with the filing and review of the application are set out in 10 CFR Part 170. The applicant shall include an environmental report with the application if it does not reference an early site permit.

§ 52.77 Contents of Applications; General Information.

The application shall contain all of the information required by 10 CFR §§ 50.33 and 50.33a as those sections would apply to an applicant for a nuclear power plant construction permit. In particular, the applicant shall comply with the requirement of § 50.33a(b) regarding the submission of antitrust information.

§ 52.79 Contents of Applications; Technical Information.

(a) The application shall contain the final safety analysis report required by 10 CFR § 50.34(b). The report may incorporate by reference the final safety analysis report for a certified standard design, but must be supplemented to include, as appropriate, the information required of applicants for operating licenses by 10 CFR Part 50. In particular, an application referencing a certified design shall describe those portions of the design which are site-specific, such as the service water intake structure or the ultimate heat sink. An application referencing a certified design must also demonstrate compliance with the interface requirements established for the design under § 52.47(d) of this Subpart. If the application does not reference a certified design, the application shall comply with the requirements of § 52.47 of this Part for level of design information, and shall contain the technical information required by §§ 52.47(a), 52.47(b)(2) and (3), and, if the design is modular, 52.47(c). The application shall also include proposed technical specifications prepared in accordance with the requirements of 10 CFR Part 50.

(b) The application for a combined license shall include the proposed inspections, tests, and analyses which the licensee shall perform and the acceptance criteria therefor which will provide reasonable assurance that the facility has been constructed and will operate in conformity with the application, the provisions of the Atomic Energy Act, and the Commission's regulations.

(c) If the application references an early site permit, the application shall demonstrate the suitability of the site for the design and shall discuss any other significant environmental issue not considered in any previous proceeding on the site or the design. If the application does not reference an early site permit, then the application shall contain the information required by § 52.17(b) of Subpart A of this Part on redress of the site in the event that the activities permitted by § 52.91(a) of this Subpart are performed.

(d) The application shall contain emergency plans which provide reasonable assurance that adequate protective measures can be taken in the event of a radiological emergency at the site. The applicant shall make good faith efforts to obtain certifications by the responsible local and State governmental agencies (1) that the proposed emergency plans are practicable, (2) that these agencies are committed to participating in any further development of the plans, including any required field demonstrations, and 3) that these agencies are committed to executing their responsibilities under the plans in the event of an emergency. The application shall contain any such certifications obtained. If any such certifications cannot be obtained, the application shall demonstrate that the proposed plans nonetheless

provide reasonable assurance that adequate protective measures can be taken in the event of a radiological emergency at the site.

§ 52.81 Standards for Review of Applications.

Applications filed under this Subpart will be reviewed according to, as appropriate, the pertinent standards set out in 10 CFR Part 50 and its appendices as they apply to applications for construction permits and operating licenses for nuclear power plants.

§ 52.83 Applicability of Part 50 Provisions.

Unless otherwise specifically provided in this Subpart, all provisions of 10 CFR Part 50 and its appendices applicable to holders of construction permits for nuclear power reactors also apply to holders of combined licenses issued under this Subpart. Similarly, all provisions of 10 CFR Part 50 and its appendices applicable to holders of operating licenses also apply to holders of combined licenses issued under this Subpart who have received written authorization for full-power operation under § 52.103. However, any limitations contained in Part 50 regarding applicability of the provisions to certain classes of facilities continue to apply.

§ 52.85 Administrative Review of Applications.

A combined license is subject to all applicable procedural requirements contained in 10 CFR Part 2, including the requirements for

docketing (§ 2.101) and issuance of a notice of hearing (§ 2.104). All hearings on combined licenses will be governed by the procedures contained in Part 2.

§ 52.87 Referral to the ACRS.

The application shall be forwarded to the Advisory Committee on Reactor Safeguards (ACRS), which shall review the application and report its findings and recommendations to the Commission. The ACRS need not reconsider issues on which it has made findings and recommendations in any earlier review of the site or the design which is the subject of the application.

§ 52.89 Environmental Review.

If the application references an early site permit or a certified standard design, the environmental review shall focus on the suitability of the site for the design and any other significant environmental issue not considered in any previous proceeding on the site or the design. The results of this limited review shall be presented at the hearing on the application. However, the Commission will not modify any final determination on an issue that has been considered and decided in such earlier proceedings except as provided in §§ 52.39 and 52.63 regarding finality of early site permit determinations and finality of standard design certifications, respectively. If the application does not reference an early site permit or a certified standard design, all of

the environmental review procedures set out in 10 CFR Part 51 shall be followed, including issuance of a final environmental impact statement.

§ 52.91 Authorization to Conduct Site Activities.

(a) If the application references an early site permit, the applicant may perform the site preparation activities authorized in § 52.25 after the application for a combined license has been docketed. Otherwise, the applicant must request authorization to conduct site preparation activities pursuant to 10 CFR §§ 50.10(e)(1) and (2). In either case, authorization to conduct the activities described in 10 CFR § 50.10(e)(3)(i) may be granted only after the presiding officer in the combined license proceeding makes the additional finding required by 10 CFR § 50.10(e)(3)(ii).

(b) If, after an applicant for a combined license has performed the activities permitted by paragraph (a) of this section, the application for the license is withdrawn or denied, and the early site permit referenced by the application expires or the holder of the early site permit so requests, then the applicant must redress the site in accord with the terms of the site redress plan required by § 52.17(b). If, before redress is complete, a use not envisaged in the redress plan is found for the site or parts thereof, the applicant shall carry out the redress plan to the greatest extent possible consistent with the alternate use.

§ 52.93 Exemptions and Variances.

(a) Applicants for a combined license under this Subpart, or any amendment to such license, may include in the application a request, pursuant to 10 CFR § 50.12, for an exemption from one or more of the Commission's regulations, including any part of a design certification rule. The Commission shall grant such a request if it determines that the exemption will comply with the Atomic Energy Act, the Commission's regulations, and the requirements of 10 CFR § 50.12(a).

(b) An applicant for a combined license, or any amendment to such license, who has filed an application referencing an early site permit issued under this Subpart may include in the application a request for a variance from one or more elements of the permit. In determining whether to grant the variance, the Commission will be guided by the considerations set forth in 10 CFR § 50.92, which guide the Commission's determinations on applications for amendments to construction permits.

§ 52.97 Issuance of Combined Licenses.

(a) The Commission may issue a combined license for a nuclear power facility upon finding that the applicable requirements of §§ 50.40, 50.42, 50.43, 50.47, and 50.50 have been met, and that there is reasonable assurance that the facility will be constructed and operated in conformity with the license, the provisions of the Atomic Energy Act, and the Commission's regulations.

(b) The Commission will identify in the license the inspections, tests, and analyses that the licensee shall perform and the acceptance

criteria therefor which will provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the Atomic Energy Act, and the Commission's regulations.

§ 52.99 Inspection During Construction.

After issuance of a combined license, the Commission shall assure through inspections, tests, and analyses that construction of the facility is completed in conformity with the combined license, the provisions of the Atomic Energy Act, and the Commission's regulations. The Commission shall apply to holders of combined licenses the same inspection program applied to holders of nuclear power plant construction permits. Holders of combined licenses shall comply with the provisions of §§ 50.70 and 50.71.

§ 52.101 Pre-Operational Antitrust Review.

Prior to conversion of a combined license to an operating license, the NRC staff shall conduct an antitrust review pursuant to § 50.42(b) to determine whether significant changes in the licensee's activities or proposed activities have occurred subsequent to the previous review by the Attorney General and the Commission in connection with the issuance of the combined license. If the Commission determines that significant changes have occurred, the antitrust review required by Section 105c(1) of the Atomic Energy Act must be completed prior to commencement of commercial operation of the facility. Upon completion of this review,

and following receipt of the advice of the Attorney General, the Director of Nuclear Reactor Regulation may impose such additional license conditions as may be needed to avoid creating or maintaining a situation inconsistent with the antitrust laws as specified in Section 105a of the Atomic Energy Act.

§ 52.103 Authorization to Operate under a Combined License.

(a) Before the facility may operate, the holder of the combined license must apply for authorization of operation under the combined license. If the combined license is for a modular design, each module will be the subject of a separate authorization. The Commission will publish a notice of the proposed authorization in the Federal Register pursuant to 10 CFR § 2.105. Within 30 days, any person whose interests may be affected may request a hearing on the basis either (1) that there has been a nonconformance with the license, the licensee's written commitments, the Atomic Energy Act, or the Commission's regulations and orders, which has not been corrected and which could materially and adversely affect the safe operation of the facility; or (2) that significant new information shows that some modification to the site or the design is necessary to assure adequate protection of public health and safety or the common defense and security. The petitioner must set forth with reasonable specificity the facts and arguments which form the basis for the request.

(b) If no hearing is requested, or if all requests are denied, the Commission may authorize operation under the combined license, as provided in § 50.56, upon making the findings in § 50.57.