

RULEMAKING ISSUE NOTATION VOTE

May 8, 2002

SECY-02-0077

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: PROPOSED RULE TO UPDATE 10 CFR PART 52, "EARLY SITE PERMITS, STANDARD DESIGN CERTIFICATIONS, AND COMBINED LICENSES FOR NUCLEAR POWER PLANTS"

PURPOSE:

To request Commission approval to publish in the *Federal Register* a proposed revision to the requirements in Part 52 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 52), "Early Site Permits, Standard Design Certifications, and Combined Licenses for Nuclear Power Plants," and proposed revisions to other related sections of the regulations in Title 10.

SUMMARY:

This rulemaking to enhance 10 CFR Part 52 is based on lessons learned during previous design certification reviews and on discussions with stakeholders about the early site permit, design certification, and combined license review processes. The rulemaking also makes conforming changes to related sections of the regulations and addresses comments received on the draft rule language that was made available for comment on the NRC's rulemaking Web site on September 27, 2001.

The NRC staff is proposing some significant changes which are discussed in Section III of the attached *Federal Register* notice. Five issues related to this rulemaking are addressed below. The first issue relates to the Commission's direction in 1994 to impose requirements on future licensees to maintain, update, and use a probabilistic risk assessment for the life of a nuclear facility. The second issue relates to a nuclear industry proposal in 1999 to revise the change criteria in the design certification rules. The third

issue relates to emergency preparedness requirements for a combined license. The fourth issue involves the status of two petitions submitted by the Nuclear Energy Institute (NEI) to revise the requirements in 10 CFR Part 52. The fifth issue involves conforming changes to clarify the applicability of 10 CFR Part 21.

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The NRC staff recommends that the Commission approve the attached notice of proposed rulemaking for publication and certify that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities. This certification is needed to satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

BACKGROUND:

On December 4, 1998, the NRC staff submitted SECY-98-282, "Part 52 Rulemaking Plan," to implement part of Direction Setting Issue #10, "Reactor Licensing for Future Applicants." This rulemaking plan to enhance 10 CFR Part 52 was based on lessons learned during the previous design certification reviews and on discussions with nuclear industry representatives about the 10 CFR Part 52 licensing processes. In a January 14, 1999, staff requirements memorandum (SRM), the Commission approved the rulemaking plan and directed the staff to seek involvement of stakeholders before proposing the rule to the Commission. A notice of the rulemaking plan was added to the NRC's rulemaking Web site on June 16, 1999. On September 3, 1999, letters were sent to 10 external stakeholders informing them of this rulemaking and soliciting comments. NEI submitted comments on April 3, 2001, and the NRC staff considered those comments in developing this proposed rule.

On August 2, 2001, the Commission issued an SRM following a briefing on risk-informing special treatment requirements and stated that the NRC staff should engage stakeholders early in the process of rulemaking for 10 CFR Part 52. The Commission also stated that the staff could share draft rule language with all stakeholders in advance of the proposed rule. In response to this SRM, the staff posted draft rule language on the rulemaking Web site and published notification of the availability of the draft rule language in the *Federal Register* on September 27, 2001. Subsequently, General Electric, Entergy, NEI, Westinghouse Electric, and Exelon Generation submitted comments on the draft language. The staff considered their comments in the development of this proposed rule and posted revised draft rule language on the NRC's rulemaking Web site on February 28, 2002.

DISCUSSION:

This proposed rule revises 10 CFR Part 52 and related sections of 10 CFR Parts 2, 20, 21, 50, 51, 72, 73, 140, and 170. In a significant change to the structure of 10 CFR Part 52, the NRC staff is proposing that each licensing process in 10 CFR Part 52 have

its own subpart. The purpose of this change is for consistency with other parts and to show that each of the licensing processes has equal standing. The staff also proposes to retitle 10 CFR Part 52 as “Additional Licensing Processes for Nuclear Power Plants,” because the licensing processes in 10 CFR Part 52 are in addition to the two-step process in 10 CFR Part 50 and the license renewal process in 10 CFR Part 54. Several subparts will be reserved for future licensing processes. Other changes address issues identified during the design certification reviews and during discussions with external stakeholders on the 10 CFR Part 52 licensing processes. The reasons for all of the substantive changes are described in Section III of the attached *Federal Register* notice.

The NRC staff also considered whether it should address the renewal of combined licenses in this rulemaking and has determined that this issue should be deferred to a future rulemaking after the staff has gained some experience with the combined license process under 10 CFR Part 52. The staff believes that lessons learned during the licensing process under 10 CFR Part 52 could be directly applicable to the combined license renewal process. For this reason, the staff has not proposed any changes related to renewal of a combined license in this rulemaking.

Probabilistic Risk Assessment

Current Subpart B to 10 CFR Part 52 sets out the requirements and procedures applicable to Commission issuance of rules granting certification of nuclear power plant designs. Section 52.47 sets forth the requirements for the contents of design certification applications. Paragraph 52.47(a)(1)(v) requires an application for design certification to contain a design-specific probabilistic risk assessment (PRA).

Subpart C to 10 CFR Part 52 sets out the requirements and procedures applicable to Commission issuance of combined licenses for nuclear power facilities. Section 52.79 sets forth the requirements for the contents of combined license applications. Paragraph 52.79(b) sets out the technically relevant information required of applicants for combined licenses and requires an application that does not reference a certified design to comply with the requirements of § 52.47(a)(1)(v) to provide a design-specific PRA.

One of the proposed changes to 10 CFR Part 52 is a revision to the current § 52.79(b) (proposed § 52.211(b)) to state that a combined license application that does reference a certified design must include a plant-specific PRA based on the design-specific PRA that is updated to account for site-specific design information and any design changes. In addition, the proposed rule revises § 52.211(b)(2) to explicitly state that an application not referencing a certified design must contain a plant-specific PRA, rather than referencing the requirement in § 52.47(a)(1)(v). The NRC staff proposes no further changes or additions to PRA requirements in 10 CFR Part 52.

In SECY-94-182, “Probabilistic Risk Assessment (PRA) Beyond Design Certification,” dated July 11, 1994, the NRC staff provided the Commission with its proposal for using PRAs after the NRC issues a design certification in accordance with 10 CFR Part 52 and asked the Commission for guidance on this subject. The staff concluded that there were significant benefits to maintaining a living PRA and that a living PRA, properly used during the advanced design life cycle (design, construction, and operation), could (1) improve safety by providing a tool to separate the more important safety aspects from the less important; (2) aid in determining priorities and resource allocations; and (3) estimate the sources and magnitude of risk. The staff proposed that licensees be required to maintain, update, and use a PRA for the life of the facility and outlined three options for establishing this requirement. In an SRM dated July 27, 1994, the Commission approved Option 2, development of a generic “operational rule” applicable to all applicants for and holders of combined licenses. The NRC staff deferred development of this rule because, until recently, it was considered a low priority. In 2000, this action was subsumed into the Part 52 rulemaking.

External stakeholders raised this issue again during a February 16, 2001, meeting on 10 CFR Part 52 and, in a November 13, 2001, letter, NEI provided comments on the draft proposed rule language. NEI stated in comment 11.1b that . . . “no such requirement is appropriate in Part 52. SOC [statements of consideration] and guidance could identify the expectation that future licensees will update and maintain their plant-specific PRAs.”

Since 1994, the NRC has made significant progress toward risk-informed regulation. The NRC staff has implemented the revised reactor oversight process and the revised maintenance rule, including the requirement that licensees assess and manage the increase in risk from proposed maintenance activities. Industry PRA standards and a peer review process have been developed. Licensees have substantially improved their PRAs to take advantage of risk-informed regulation. The above events have combined to provide (1) improved safety by focusing attention on the more important safety aspects; (2) improved methods for determining priorities and allocating resources; and (3) improved ability to estimate the sources and magnitude of risk. Therefore, the staff does not believe that it is necessary in today’s regulatory environment to impose requirements that licensees maintain, update, and use a PRA for the life of the facility. If, in the future, the staff considers recommending that the Commission impose a living PRA requirement on licensees of operating plants, then the staff will consider a similar requirement for future applicants. For these reasons, the staff proposes not to add a living PRA requirement to 10 CFR Part 52.

10 CFR 50.59 Change Criteria

In SECY-99-130, “Final Rule – Revisions to Requirements of 10 CFR Parts 50 and 72 Concerning Changes, Tests, and Experiments,” dated May 12, 1999, the NRC staff requested the Commission’s approval to publish a final rule revising 10 CFR 50.59 and related requirements. Section 50.59 concerns licensees’ authority to make changes to their facilities and procedures or to conduct tests and experiments without prior NRC approval. The revisions to § 50.59 were published in the *Federal Register* on October 4, 1999 (64 FR 53582). During the preparation of the § 50.59 rulemaking, nuclear industry commenters proposed that each

of the three design certification rules (Appendices A, B, and C) in 10 CFR Part 52 be amended to incorporate the revised change criteria in § 50.59. SECY-99-054, "Plans for Final Rule – Revisions to 10 CFR Parts 50, 52, and 72: Requirements Concerning Changes, Tests, and Experiments," dated February 22, 1999, included draft final rule revisions to the design certification rules for the Advanced Boiling Water Reactor and System 80+ designs. However, in SECY-99-130, the staff noted that a rulemaking was planned to update 10 CFR Part 52 for areas of improvement. The staff stated that it would consider the final revisions to § 50.59 during the rulemaking to update 10 CFR Part 52 and, therefore, would defer incorporating the revised § 50.59 criteria into the design certification rules.

In developing the proposed rule changes to 10 CFR Part 52, the NRC staff posted draft rule language on the NRC's rulemaking Web site on September 27, 2001, that included revisions to Appendices A, B, and C to incorporate the revised § 50.59 change criteria. The staff believed it would be beneficial to have a change process for Tier 2 information that conforms with the § 50.59 process for nuclear power plant licensees. The staff has incorporated the new criteria into the § 50.59-like change process in each of the three design certification rules in Appendices A, B and C of 10 CFR Part 52. In addition, the staff has prepared, after consulting with the Office of the General Counsel (OGC), a proposed change to current § 52.63(a)(1) (proposed § 52.127(a)(1)), which would permit the Commission to modify design certification rules by notice and comment rulemaking by adding a new criterion to that allows changes that reduce unnecessary regulatory burden and maintain protection to public health and safety and the common defense and security. The purpose of the proposed change is two-fold: (1) to allow the Commission to adopt in the final 10 CFR Part 52 rulemaking the proposed new criteria for the § 50.59-like change process into the three design certification rules¹; and (2) in the future to allow the Commission to modify design certification rules to reduce unnecessary regulatory burden, so long as protection to public health and safety and common defense and security are maintained.

Emergency Preparedness

Issues regarding the review and verification of emergency preparedness for nuclear power plants have been the subject of much correspondence between the NRC staff and Commission from 1989 to the present. The staff reviewed the historical record regarding the requirements for emergency preparedness exercises for combined license holders to evaluate whether proposed changes to 10 CFR Part 52 were necessary at this time. The staff has confirmed that the full-participation exercise does not need to be performed before issuance of a combined license. The staff has also determined that the requirements in 10 CFR Part 52 related to emergency preparedness exercises do not need to be revised at this time. However, the staff has determined that the emergency planning regulations in 10 CFR Part 50 may need to be amended in order to incorporate the licensing processes that

¹OGC has advised that the current language of 10 CFR 52.63(a)(1) appears to restrict the agency from modifying the § 50.59-like change process in the current design certification rules to incorporate the new § 50.59 criteria.

now exist in 10 CFR Part 52 for early site permits and combined licenses. In light of its recent review, the staff now plans to include conforming administrative changes to 10 CFR Part 50 Appendix E with the upcoming rulemaking that was outlined in SECY-01-0131, "Revision of Appendix E, Section IV.F.2 to 10 CFR Part 50, Concerning Clarification of Emergency Preparedness Exercise Participation Requirements of Co-Located Licensees." The following discussion summarizes the staff's review of the history of this issue.

In a February 17, 1989, memorandum from the Executive Director for Operations, the staff alerted the Commission to an issue associated with emergency planning requirements as they related to the combined license process in Subpart C of 10 CFR Part 52. The staff stated that 10 CFR Part 52 would require that complete emergency plans be approved and exercised before the combined license was issued. In accordance with 10 CFR 52.97(a), the Commission must find that the applicable requirements of 10 CFR 50.47, among others, have been met before issuance of a combined license. It was stated in the memorandum that an initial exercise would be held before issuance of the combined license and exercises would be held every two years thereafter until operation. In a June 29, 1989, memorandum, the staff indicated to the Commission that although a pre-licensing exercise could be developed, some aspects of the plans would be difficult to demonstrate prior to construction of the facility (e.g. the control room and emergency response facilities). Additionally, if portions of the plans were exercised for the first time in post-licensing tests, the results might be subject to an opportunity for hearing relatively late in the process. On September 11, 1989, the Commission (COMKC-89-9, "Review of the Emergency Preparedness Regulations (Memorandum from the Executive Director for Operations to the Commissioners, dated June 29, 1989)) requested that the staff update 10 CFR Part 50 emergency planning requirements to better reflect the goals of 10 CFR Part 52 with respect to, in part, review of the safety basis of the regulatory requirement for a full participation exercise with the objective of determining whether exercise timing and frequency can be detached from the authorization to operate under a combined license or the permissible timing of the exercise extended, and address the extent to which exercise results would be litigated in NRC hearings under 10 CFR Part 52.

In 1992, the Energy Policy Act of 1992 was enacted. Among other things, the new legislation specified that inspections, tests, analyses, and acceptance criteria (ITAAC) in combined licenses must include those applicable to emergency planning. The new legislation also allowed interim plant operation prior to completion of a hearing on whether the acceptance criteria had been met. Therefore, such a hearing would not delay operation of the plant if the Commission were to find, after consideration of petitioners' prima facie showing, that there is reasonable assurance of adequate protection of public health and safety.

Considering the language in this new legislation and the difficulties with the staff's 1989 position requiring that an initial exercise be held before issuance of a combined license, the NRC staff developed SECY-95-090, "Emergency Planning Under 10 CFR Part 52," dated April 11, 1995. SECY-95-090 was developed to inform the Commission of the staff's views on how emergency planning requirements, including exercise requirements, would be addressed at each phase of nuclear power plant licensing under 10 CFR Part 52. The staff stated that an application for a combined license must include proposed ITAAC, including those applicable to

emergency preparedness (current §52.79(c)). These ITAAC are to be those that are necessary and sufficient to demonstrate compliance with 10 CFR 50.47(b), or any acceptable alternatives as provided for in 10 CFR 50.47(c). The staff recognized that a reasonable assurance finding would have to be made before plant features required for emergency response were completed. However, the staff noted that the establishment of and the requirement to meet these ITAAC in the combined license would enable the NRC, in consultation with the Federal Emergency Management Agency (FEMA), to make a predictive regulatory finding of reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

Because the initial full-participation exercise required by Section IV.F.2.a² of Appendix E to 10 CFR Part 50 would be a combined license ITAAC, it would have to be conducted along with other inspections, tests, and analyses, and meet the acceptance criteria before fuel is loaded. The ITAAC for this initial exercise would necessarily be the last emergency preparedness ITAAC completed and it would be necessary for both FEMA and NRC to evaluate that exercise. In that all other ITAAC related to both onsite and offsite emergency preparedness would have been met prior to the conduct of the full participation exercise, all the necessary onsite and offsite plans, procedures, personnel, equipment, etc. would be in place to allow for the testing of both the licensee's and State and local emergency response plans³ as required by Appendix E. The periodic exercises required by 10 CFR 50.47(b)(14) and 10 CFR Part 50 Appendix E, Section IV.F.2 would be conducted after the initial full-participation exercise, as part of the licensee's emergency plan.

Industry Petitions on 10 CFR Part 52

In two separate submittals on July 18, 2001, NEI petitioned the NRC for changes to 10 CFR Part 52 early site permit and combined license requirements. The first petition (Docket No. PRM 52-1) sought to modify 10 CFR Part 52 to avoid duplicative NRC reviews

²Section IV.F.2.a of Appendix E to 10 CFR Part 50 requires a full participation exercise to be conducted within two years before the issuance of the first operating license for full power (one authorizing operation above 5% of rated power) of the first reactor and shall include participation by each State and local government within the plume exposure pathway Emergency Planning Zone (EPZ) and each state within the ingestion exposure pathway EPZ. If the full participation exercise is conducted more than one year prior to issuance of an operating license for full power, an exercise which tests the licensee's onsite emergency plans shall be conducted within one year before the issuance of an operating license for full power. This exercise need not have State or local government participation.

³10 CFR 52.79(d) and 50.47(c)(1) allow for licensee plans for situations where State or local governments decline or fail to participate in offsite radiological emergency planning and preparedness. In determining adequacy of such a plan, the NRC will recognize that, in an actual emergency, State and local government officials will take actions to protect the health and safety of the public.

of valid, existing site and facility information that was previously approved by the NRC and subject to public hearing. The petition asked that the proposed 10 CFR Part 52 changes be merged into this 10 CFR Part 52 update rulemaking.

The second petition (Docket No. PRM-52-2) requested that requirements to consider alternate sites in early site permit applications, and NRC reviews thereof, be eliminated. The petitioner also asked NRC to revise 10 CFR Part 51 to reflect that NRC review of alternatives under the National Environmental Policy Act need not, and thus should not, consider need for power, alternate sources, or alternate sites. The petitioner stated that these matters are best determined by State and local governments, the applicant, and the marketplace. The petitioner requested that the proposed 10 CFR Part 52 changes be merged into this 10 CFR Part 52 update rulemaking. The petitioner also asked that the Commission initiate a rulemaking to amend 10 CFR Part 51 and related provisions in 10 CFR Parts 2 and 50.

The two NEI petitions were published in the *Federal Register* for comment on September 24, 2001. Nine comments were received on the PRM 52-1 and eleven comments were received on PRM 52-2.

The NRC staff is currently preparing its recommendations on these two petitions for submittal to the Commission. Because the staff has not completed drafting its recommendations, the attached proposed rule does not address the petitions. The staff concluded that it would not be prudent to delay the 10 CFR Part 52 proposed rulemaking further until completion of action on these two petitions. The staff expects to submit its recommendations on the petitions to the Commission by September 2002.

10 CFR Part 21

The proposed rule includes a number of conforming changes to clarify the applicability of 10 CFR Part 21 to individuals, corporations, partnerships, or other entities doing business within the United States, and directors and responsible officers of such organizations, that hold a permit or license under 10 CFR Part 52. These conforming changes would correct an oversight when the Commission first adopted 10 CFR Part 52, to ensure that the requirements in 10 CFR Part 21 apply to applicants for and holders of combined licenses, manufacturing licenses, and duplicate design licenses, and suppliers of basic components to such holders.

For applicants and holders of an early site permit, and the applicant/vendor of a design certification rule, the NRC staff proposes a different approach. The staff believes that 10 CFR Part 21 should apply only after an early site permit has been referenced by the holder in a license application, and only after a design certification rule has been first referenced in a license application. Although OGC has advised the staff that there is legal authority to apply 10 CFR Part 21 to a design certification applicant/vendor upon Commission adoption of a design certification rule, and (with appropriate rule changes redefining the term "supplies" in the context of an early site permit) to an early site permit holder once an early site permit is issued, the staff recommends a different course. As explained in more detail in the *Federal Register* notice, the staff believes that there is no reasonable concern about safety unless

either the early site permit or design certification is referenced in a license application. Moreover, requiring the early site permit holder to comply with 10 CFR Part 21 notification requirements is inconsistent with the staff's proposal that, with the exception of emergency preparedness information, the early site permit holder should not have to update the information for the permit (see discussion in section III.A.8 of the *Federal Register* notice). The staff has included a question in section IV of the *Federal Register* notice seeking public comments on this matter.

RESOURCES:

The FY 2002 budget includes a total of 1.2 FTE to finalize, publish, issue, and implement the proposed rulemaking and start the final rulemaking. No resources were originally included in the FY 2003 budget for this effort because the final rule was to have been completed in FY 2002. However, extending the completion of the final rule to late in 2002 (FY 2003) requires that approximately 0.3 FTE will be reprogrammed in FY 2003 to complete the final rule, including resolution of public comments.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The Chief Financial Officer concurs in the proposed changes to 10 CFR Part 170. The Office of the Chief Financial Officer has also reviewed this paper for resource implications and has no objections.

The staff briefed the Advisory Committee on Reactor Safeguards (ACRS) on the draft proposed rule language for 10 CFR Part 52 on November 8, 2001. In a letter dated November 14, 2001, the ACRS stated that it planned to review the proposed final version of 10 CFR Part 52 following the reconciliation of public comments. The Committee To Review Generic Requirements will also review the proposed final version of 10 CFR Part 52 following the reconciliation of public comments.

RECOMMENDATION:

That the Commission:

1. *Approve* the notice of proposed rulemaking for publication (Attachment).
2. *Certify* that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities in order to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).
3. *Note* –

- a. The rulemaking will be published in the *Federal Register* with a 75-day public comment period.
- b. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the basis for it, as required by the Regulatory Flexibility Act.
- c. The appropriate congressional committees will be informed.
- d. The proposed rule does not impose requirements that future licensees maintain, update, and use a PRA for the life of the facility.
- e. The NRC staff has determined that the emergency planning regulations in 10 CFR Part 50 may need to be amended in order to incorporate the licensing concepts that now exist in 10 CFR Part 52 for early site permits and combined licenses and that the NRC staff plans to include conforming administrative changes to Appendix E of 10 CFR Part 50 with the upcoming rulemaking that was outlined in SECY-01-0131.

/RA/

William D. Travers
Executive Director
for Operations

Attachment: *Federal Register* Notice

2. *Certify* that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities in order to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

3. *Note* –
 - a. The rulemaking will be published in the *Federal Register* with a 75-day public comment period.
 - b. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the basis for it, as required by the Regulatory Flexibility Act.
 - c. The appropriate congressional committees will be informed.
 - d. Contrary to the Commission’s direction in 1994, the proposed rule does not impose requirements, at this time, that future licensees maintain, update, and use a PRA for the life of the facility.
 - e. The NRC staff has determined that the emergency planning regulations in 10 CFR Part 50 may need to be amended in order to incorporate the licensing concepts that now exist in 10 CFR Part 52 for early site permits and combined licenses and that the NRC staff plans to include conforming administrative changes to Appendix E of 10 CFR Part 50 with the upcoming rulemaking that was outlined in SECY-01-0131.

/RA/

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 Executive Director
 for Operations

Attachment: *Federal Register* Notice

DISTRIBUTION: See attached.

SECY ML021040009 Attachment ML021040011 Package ML021050284

OFC	PM:NRLPO/NRR	NRLPO/NRR	Tech Ed	DD:NRLPO/NRR	D:NRLPO/NRR
NAME	NGilles NVG	JWilson JNW	PKleene PK	MGamberoni NVG for	JLyons JEL
DATE	2/12/02	2/13/02	2/19/02	2/12/02	2/15/02
OFC	DSSA/NRR	DIPM/NRR	RDB/ADM	DSARE/RES	DRAA/RES
NAME	GHolahan GMH	BBoger BB	MLesar MTL	FEltawila FE	SNewberry SN
DATE	03/08/02	3 / 04 /02	03/25/02	2/19/02	3 / 06 /02
OFC	DRIP/NRR	OGC	DO:RES	OCIO	OCFO PJR for
NAME	DMatthews DM	STreby J. Gray for	ATHadani SN for	BShelton BJS	JFunches
DATE	3 / 07 /02	04 / 19 /02	03/07/02	04/17/02	04/17/02
OFC	NRR ET RWB	DEDRP	EDO		
NAME	RBorchardt	WKane	WTravers		
DATE	4/19/02	5 /2/02	5/8/02		

