RULEMAKING ISSUE
NOTATION VOTE

November 3, 2005 SECY-05-0203

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: REVISED PROPOSED RULE TO UPDATE 10 CFR PART 52, "LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS"

PURPOSE:

To request Commission approval to publish in the *Federal Register* revised proposed revisions 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 to requirements in related sections of the regulations in Title 10 Chapter 1 which would withdraw and supersede the Commission's July 3, 2003 (68 FR 40026), proposed rule on 10 CFR Part 52.

SUMMARY:

The Nuclear Regulatory Commission (NRC) staff is proposing to amend the regulations concerning the licensing and approval processes for nuclear power plants in 10 CFR Part 52. The proposed rule contains a rewrite of 10 CFR Part 52, as well as changes throughout the Commission's regulations to enhance the NRC's regulatory effectiveness and efficiency in implementing the licensing and approval processes in Part 52 and to clarify the applicability of various requirements to each of the regulatory processes in Part 52 (i.e., early site permit, standard design approval, standard design certification, combined license, and manufacturing license). This rulemaking to enhance 10 CFR Part 52 is based on lessons learned during design certification and early site permit (ESP) reviews and on discussions with stakeholders about the ESP, design certification, and combined license (COL) review processes.

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On July 3, 2003 (68 FR 40026), the NRC published a proposed rule to clarify the NRC's regulations related to nuclear power plant licensing under Part 52. Upon further consideration, the staff is proposing to amend the requirements for the licensing and approval processes in the regulations that will withdraw and supersede the 2003 proposed rule. The staff believes that this new rulemaking action will improve the effectiveness and efficiency of the licensing and approval processes in Part 52 for future applicants.

BACKGROUND:

The NRC staff planned to update 10 CFR Part 52 after the first standard design certification reviews. The proposed rulemaking action began with the issuance of SECY-98-282, "Part 52 Rulemaking Plan," on December 4, 1998 (ML032801416). The Commission issued a staff requirements memorandum on January 14, 1999 (ML032801439), approving the NRC staff's plan for revising 10 CFR Part 52. Subsequently, the NRC staff obtained considerable stakeholder comment on its planned action. On July 3, 2003 (68 FR 40026), the NRC published a proposed rule that would clarify miscellaneous parts of the NRC's regulations; update 10 CFR Part 52 in its entirety; and incorporate stakeholder comments.

Following the close of the public comment period on the July 2003 proposed rule, a number of factors led the staff to question whether that proposed rule would meet the Commission's objective of improving the effectiveness of NRC's processes for licensing future nuclear power plants. First, public comments identified several concerns about whether the proposed rule adequately addressed the relationship between Part 50 and Part 52 and clearly specified the applicable regulatory requirements for each of the licensing and approval processes in Part 52. In addition, as a result of the staff's review of the first three ESP applications, the staff gained additional insights into the ESP process. The staff also had the benefit of public meetings with external stakeholders on the development of staff guidance on the ESP and COL processes. As a result, the staff decided that a substantial rewrite and expansion of the original proposed rulemaking to include changes throughout the entire body of NRC regulations in Title 10 Chapter 1 was desirable so that the agency may more effectively and efficiently implement the licensing and approval processes for nuclear power plants in Part 52. The staff again considered previously submitted comments in developing this proposed rule and, on August 25, 2005, posted draft rule language on the rulemaking Web site and published a notice of the availability of the draft rule language in the *Federal Register* (September 6, 2005; 70 FR 52942).

DISCUSSION:

As discussed in the attached *Federal Register* notice, the revised proposed rule contains a rewrite of Part 52, as well as changes throughout the NRC's regulations, to improve the organization, format, and language of Part 52 and to clarify the applicability of various technical and regulatory requirements throughout Title 10 Chapter 1 to each of the processes in Part 52. In light of the substantial rewrite of the July 2003 proposed rule, the expansion of the scope of the rulemaking, and the staff's recommendation to publish the revised proposed rule for public comment, the staff has decided that developing responses to comments received on the 2003 proposed rule is not an effective use of agency resources. The staff recommends that commenters on the 2003 proposed rule who believe that their earlier comments are not addressed in the revised proposed rule (or are not adequately addressed) resubmit their

comments. The staff will provide resolutions for comments received on the revised proposed rule in the statement of considerations for the final rule.

Since the Commission first adopted 10 CFR Part 52 in 1989, the NRC and external stakeholders have identified a number of interrelated issues and concerns. The fundamental concern is that the overall regulatory relationship between Part 50 and Part 52 is not always clear, and it is often difficult to tell whether general regulatory provisions in Part 50 apply to Part 52. A related concern is the current lack of specific delineation of the applicability of NRC requirements throughout Title 10 Chapter 1 to the licensing and approval processes in Part 52. For example, the indemnity and insurance provisions in Part 140 were not revised to address their applicability to applicants for and holders of COLs under Subpart C of Part 52. Even where Part 52 provisions referenced specific requirements in Part 50, it was not always clear from the language of the Part 50 requirements how the requirements applied to the Part 52 processes. For example, current § 52.47(a)(1)(i) provides that a standard design certification application must contain the "technical information which is required of applicants for construction permits and operating licenses by 10 CFR...part 50...and which is technically relevant to the design and not site-specific." The language does not explicitly identify the Part 50 requirements that are "technically relevant to the design." Even where a specific regulation in Part 50 is identified as a requirement, the language of the referenced regulation itself was not changed to reflect that the specific requirements applied to the Part 52 processes. For example, § 52.79(b) provides that the application must contain the "technically relevant information required of applicants for an operating license required by 10 CFR 50.34." Further, § 50.34(b) is based upon the two-step licensing process whereby certain important information is submitted at the construction permit (CP) stage and then supplemented with more detailed information at the operating license stage. Thus, information that must be submitted in the CP application (e.g., the "principal design criteria for the facility" required by § 50.34(a)(3)(i)), may be regarded as not required to be submitted for a COL application under the current version of Part 52.

In the 2003 proposed rule, the NRC proposed several changes that were intended to address some (but not all) of these issues. However, based on comments received on the 2003 proposed rule, the NRC's experience to date with ESP applications, interactions with external stakeholders concerning NRC regulatory guidance for COL applications, and the NRC's screening of Title 10 Chapter 1 requirements following the receipt of public comments on the 2003 proposed rule, the staff concludes that the 2003 proposed rule would not adequately address and resolve these issues. Accordingly, the staff now proposes to take a more comprehensive approach to addressing these issues by reorganizing Part 52, implementing a uniform format and content for each of the subparts in Part 52, using consistent wording and organization of sections in each of the subparts, and making conforming changes throughout Title 10 Chapter 1 to reflect the licensing and approval processes in Part 52. The staff has also attempted to coordinate and reconcile differences in wording among provisions in Parts 2, 50, 51, and 52 to provide consistent terminology throughout the regulations affecting Part 52.

Under the NRC's proposed reorganization of Part 52, the existing Appendices O and M on standard design approvals and manufacturing licenses, respectively, would be redesignated as new subparts in Part 52. Redesignating these appendices as subparts in Part 52 would result in a consistent format and organization of the requirements applicable to each of the licensing and approval processes in Part 52. In addition, the redesignation would clarify that each of the

licensing and approval processes in these appendices are available to potential applicants as an alternative to the licensing and approval processes in Part 50 (construction permit and operating license) and the existing subparts A through C of Part 52. By doing so, the staff is simply attempting to standardize the format and organization of Part 52, and to clarify the full range of licensing and regulatory alternatives that are available under Part 52 for use by potential applicants. Consistent with the broad scope of Part 52, the NRC proposes to retitle 10 CFR Part 52 as "Licenses, Certifications, and Approvals for Nuclear Power Plants." The staff's proposed revision to Part 52 will contain five subparts: one each for ESPs (Subpart A), design certifications (Subpart B), COLs (Subpart C), design approvals (Subpart E), and manufacturing licenses (Subpart F). The staff proposes to reserve Subpart D for possible future use.

The staff also proposes to reorganize and expand the scope of the administrative and general regulatory provisions that precede the Part 52 subparts by adding new sections on written communications (analogous to § 50.4), employee protection (analogous to § 50.7), completeness and accuracy of information (analogous to § 50.9), exemptions (analogous to § 50.12), combining licenses (analogous to § 50.52), jurisdictional limits (analogous to § 50.53), and attacks and destructive acts (analogous to § 50.13). In general, the staff believes that adding the new sections to Part 52 rather than revising the comparable sections in Part 50 is more consistent with the general format and content of the Commission's regulations.

Appendix N, which addresses duplicate design licenses, will be removed from Part 52 and will be retained in Part 50, because the duplicate design license is a Part 50 operating license. Appendix Q, which addresses early staff review of site suitability issues, will also be removed from Part 52 but retained in Part 50. Appendix Q provides for NRC staff issuance of a staff site report on site suitability issues with respect to a specific site for which a potential applicant seeks the NRC staff's views. This early site review process is separate from the ESP process in Subpart A of Part 52. The staff recognizes that there appears to be some redundancy between the early site review process and the ESP process. Accordingly, the staff proposes to remove Appendix Q from Part 52 and retain it only in Part 50.

The staff has reviewed the existing regulations in Title 10 Chapter 1 to determine if they must be modified to reflect the licensing and approval processes in Part 52. This review had two aspects. First, the staff determined whether an existing regulatory provision must, by virtue of a statutory requirement or regulatory necessity, be extended to address a Part 52 process and, if so, how the regulatory provision should apply. Second, in situations where the Commission has some discretion, the staff determined whether there were policy or regulatory reasons to extend the existing regulations to each of the Part 52 processes. Most of the NRC's proposed conforming changes occur in 10 CFR Part 50. In making changes involving 10 CFR Part 50 provisions, the staff adopted the general principle of keeping the technical requirements in 10 CFR Part 50 and maintaining all applicable procedural requirements in 10 CFR Part 52. However, due to the complexity of some provisions in 10 CFR Part 50 (e.g., § 50.34), this principle could not be universally followed. A description of, and bases for, the proposed conforming changes are discussed in the attached *Federal Register* notice for each affected part. Because of the expanded nature of the revised proposed rulemaking, the staff prepared an updated regulatory analysis which is provided as an attachment to this paper (Attachment 2).

The staff recently sent another paper to the Commission, SECY-05-120, "Security Design Expectations for New Reactor Licensing Activities," (ML051100233) recommending changes to requirements for new reactors in the area of security. In its staff requirements memorandum for SECY-05-120, dated September 9, 2005 (ML052520334), the Commission approved the staff's recommendations to require applicants to submit a safety and security assessment addressing the relevant security requirements which were established for currently operating plants by order,[1] including the requirements for protection against the supplemented design-basis threat and the requirements for enhanced mitigative measures. The staff's implementation of these recommendations will be addressed in a future rulemaking.

The following discussion highlights several staff proposals in the revised proposed rulemaking for Commission consideration:

- Segregation of the Part 50 and Part 52 licensing processes
- Reform of the manufacturing license process
- Emergency preparedness requirements for ESP applicants and COL holders
- Issues affecting ESP finality
- Quality assurance requirements for ESP applicants
- Applicability of 10 CFR Part 21 and 10 CFR 50.55(e)
- Probabilistic Risk Assessment (PRA) requirements

In addition, discussions on three additional issues can be found in SECY-02-0077, "Proposed Rule to Update 10 CFR Part 52, 'Early Site Permits, Standard Design Certifications, and Combined Licenses for Nuclear Power Plants'" (ML021050284). The first issue relates to the Commission's direction in 1994 to impose requirements on future licensees to maintain, update, and use a PRA for the life of a nuclear facility. In SECY-02-0077, the staff stated that it is not necessary in today's regulatory environment to impose requirements that licensees maintain, update, and use a PRA for the life of the facility (i.e., a living PRA). The staff now intends to consider the need for a living PRA as part of its program plan to make risk-informed performance-based revisions to 10 CFR Part 50. Therefore, the staff is not proposing to add a living PRA requirement to 10 CFR Part 52. The second issue discussed in SECY-02-0077 relates to a nuclear industry proposal in 1999 to revise the change criteria in the design certification rule. The third issue is the status of two petitions submitted by the Nuclear Energy Institute (NEI) to revise the requirements in 10 CFR Part 52.

This revised proposed rule retains the changes originally proposed in SECY-02-0077 to resolve these first two issues, with one addition to the PRA requirements as discussed later in this paper. In addition, both the 2003 proposed rule and this revised proposed rule address the Commission's disposition of one of the two NEI petitions (PRM 52-2) discussed in

[1] February 25, 2002, All Operating Reactor Licensees, Order Modifying License (Effective Immediately), EA-02-26, 67 FR 9792 (March 4, 2002); April 29, 2003, All Operating Reactor Licensees, Order Modifying License (Effective Immediately), EA-03-086, 68 FR 24,517 (May 7, 2003).

SECY-02-0077.[2] Resolution of the second petition did not result in any changes to the regulations. Proposals related to the remaining two issues discussed in SECY-02-0077 have been revised in this proposed rule and are discussed below (emergency preparedness requirements and the applicability of Part 21).

Segregation of Part 50 and Part 52 Licensing Processes

Currently, Part 52 allows an applicant for a CP to reference either an ESP under Subpart A or a design certification under Subpart B. The staff proposes that the Commission seek stakeholder feedback on whether the provisions allowing a CP applicant to reference an ESP or a design certification should be removed entirely from 10 CFR Part 52. The staff believes that removing these provisions will ensure the most effective use of agency resources for new reactor licensing activities. The current regulations in 10 CFR Part 50 that address the application for and granting of CPs do not address a CP applicant's ability to reference either an ESP or a design certification and the staff has not developed any guidance on how the CP process would incorporate an ESP or design certification. In addition, the staff proposes that future applicants who want to construct and operate a commercial nuclear power facility use the COL process in Subpart C of Part 52.

Reform of Manufacturing License Process

Appendix M of Part 52 sets forth the Commission's requirements governing manufacturing licenses. Appendix M, which was first adopted by the Commission in 1973, provides for issuance of a license authorizing the manufacture of a nuclear power reactor to be incorporated into a nuclear power plant under a CP and operated under an operating license at a different location from the place of manufacture. Under the current licensing regime in Appendix M, the Commission does not approve a final reactor design to be manufactured prior to issuance of the manufacturing license. Rather, analogous to the two-step process, the Commission issues a manufacturing license based upon the review of a preliminary design equivalent to the design information that is provided in a CP application. Upon approval of the preliminary design and associated information, the Commission issues a manufacturing license authorizing the manufacture—but not the removal from the manufacturing site—of one or more nuclear power reactors. Thereafter, manufacturing can commence, although the Commission must approve the final design of the manufactured reactor by license amendment (see the note in paragraph 7 of Appendix M). Under paragraph 8 of Appendix M, the manufactured reactor may not be removed from the place of manufacture until approval of the final design under paragraph 7.

In view of the substantial reorganization and rewriting of Title 10 Chapter 1 the staff has reconsidered the efficacy of the current manufacturing license process in Appendix M and proposes substantial changes to enhance regulatory effectiveness and efficiency. The most important change is that a final reactor design, equivalent to that required for a standard design certification under Part 52 or an operating license under Part 50, must be submitted and approved before issuance of a manufacturing license. There are several reasons for this

[2] The staff discussed its proposed resolution of PRM 52-2 in SECY-02-0175 (September 27, 2002) and of PRM 51-1 in SECY-02-0199 (November 8, 2002).

change. First, the staff's experience with standard design certifications demonstrates that nuclear power plant designers are technically capable of developing a final reactor design for Commission review and approval. Second, approval of a final reactor design removes the current awkward regulatory process of issuing a manufacturing license and then amending the license when a final design is submitted. Approval of a final design ensures early consideration and resolution of technical matters before there is any substantial commitment of resources associated with the actual manufacture of the reactor, which will enhance regulatory stability and reduce financial risk. Finally, Commission approval of standardized manufacturing processes, by promoting workforce stability and manufacturing process feedback, will help maintain and possibly greatly improve the quality and standardization of the manufactured reactors, compared to the traditional construction of reactors on site by numerous contractors and subcontractors.

The proposed requirements for a manufacturing license set forth in proposed Subpart F of Part 52 reflect both the expanded scope of approval to include the final design of the reactor to be manufactured and the lessons learned from the ESP application reviews. Also, in light of the staff's proposal to provide approval of a final design in a manufacturing license, the staff proposes to provide a greater degree of finality for a manufacturing license, comparable to the finality provided for standard design certifications.

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. In preparing the 2003 proposed rule, the staff reviewed the historical record of the requirements for emergency preparedness exercises for COL holders and evaluated whether proposed changes to 10 CFR Part 52 were necessary. SECY-02-0077 contains a summary of the staff's review of the history of this issue. The staff confirmed that a full-participation exercise need not be performed before issuance of a COL. In SECY-02-0077, the staff stated that it had determined that the requirements in 10 CFR Part 52 related to emergency preparedness exercises did not need to be revised, but that the emergency planning regulations in 10 CFR Part 50 needed to be amended in order to incorporate the existing licensing processes in 10 CFR Part 52 for ESPs and COLs. At that time, the staff planned to include conforming administrative changes to 10 CFR Part 50, Appendix E, with an upcoming rulemaking that was outlined in SECY-01-0131, "Rulemaking Plan: 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" (ML011520066).

When the staff began to prepare this revised proposed rule, the conforming changes to Part 50, Appendix E, were not complete. The staff decided to include those changes in this Part 52 rulemaking because the staff had expanded the scope of the Part 52 rulemaking to include conforming changes to Part 50. The major proposed changes regarding emergency preparedness requirements for ESP and COL applicants are provided below.

Emergency Preparedness Requirements for Early Site Permit Applicants

The staff proposes to amend Part 52 to address changes to emergency preparedness requirements for ESP applicants. The staff proposes to amend § 52.17(b)(1), which requires

that an ESP application identify physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans. The staff proposes to add a sentence stating that if physical characteristics that could pose a significant impediment to the development of emergency plans are identified, the application must identify measures that would, when implemented, mitigate or eliminate the significant impediment. The staff believes this addition is necessary to clarify the staff's expectations in cases where a physical characteristic exists that could pose a significant impediment to the development of emergency plans. Identification of such physical characteristics does not provide the staff with sufficient information to determine if such characteristics are likely to pose a significant impediment to the development of emergency plans.

The staff also proposes to add new provisions in § 52.17 to require that complete and integrated emergency plans submitted for review in an ESP application must include the proposed inspections, tests, and analyses that the holder of a COL referencing the ESP must perform and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met, the facility has been constructed and will operate in conformity with the license, the provisions of the Atomic Energy Act, and the NRC's regulations. The staff is proposing these amendments because it believes that its review of complete and integrated plans included in an ESP application should be no different than its review of emergency plans submitted in a COL application given that the Commission must make the same findings in both cases, namely, that the plans submitted by the applicant provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. The Commission will not be able to make the required finding in the absence of proposed inspections, tests, analyses, and acceptance criteria (ITAAC) in an ESP application that includes complete and integrated emergency plans. Also, requiring the inclusion of emergency preparedness ITAAC in the ESP application is consistent with the Commission's goal of resolving siting issues early in the licensing process. Therefore, the staff proposes to require that ESP applicants that submit complete and integrated emergency plans at the ESP stage also be required to include emergency preparedness ITAAC in their ESP application.

Emergency Preparedness Exercise Requirements for COL Holders

Section 50.47 and Appendix E to 10 CFR Part 50 contain emergency planning requirements for nuclear power plants. Because these regulations do not clearly specify their applicability to ESP or COL applicants or holders, the staff is proposing to make a number of clarifying changes in these regulations. Proposed changes related to the conduct of emergency preparedness exercises are discussed below.

The staff proposes modifying Section IV of Appendix E, "Content of Emergency Plans," to require that, for a COL, the first full-participation exercise be conducted within 2 years of the scheduled date for initial loading of fuel and that if the first full-participation exercise is conducted more than 1 year prior to the scheduled date for initial loading of fuel, an exercise which tests the licensee's onsite emergency plans must be conducted no more than 1 year before the scheduled date for initial loading of fuel. These requirements are analogous to those for the operating license process, taking into account the differences in the COL licensing process.

The staff is also proposing changes in § 50.47. Section 50.47(d) currently provides that no NRC or Federal Emergency Management Agency (FEMA) review, findings, or determinations concerning the state of offsite emergency preparedness or the adequacy of and capability to implement State, local, or utility offsite emergency plans are required prior to issuance of an operating license authorizing only fuel loading or low-power testing and training (up to 5 percent of the rated power) provided the NRC makes a finding that the state of onsite emergency preparedness provides reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. Providing parallel provisions to § 50.47(d) for COL holders has proven complicated. To do so, the staff has proposed to add a new § 50.47(e), and because of the nature of the COL process, the staff has also proposed a coordinated revision to § 50.54, "Conditions of licenses," to provide a condition to be added to all COLs allowing operation at up to 5 percent power with deficiencies identified by FEMA. This is necessary to account for the fact that the COL will already be issued at the time of the first full- or partial-participation exercise and that it will contain ITAAC requiring that there be no offsite emergency preparedness deficiencies.

Although the staff believes that the regulatory scheme provided by its proposed revisions to the emergency preparedness requirements in 10 CFR Part 50 is consistent with the current operating license process, the staff is concerned that allowing COL holders to operate at up to 5 percent power with offsite emergency preparedness deficiencies could result in consequent contamination of the reactor with no assurance that the plant will ever operate at full power. The staff will consider this issue as part of its overall review of the emergency preparedness regulations in accordance with the Commission's December 20, 2004 Staff Requirements Memorandum on the Briefing on Emergency Preparedness Program Initiatives (ML043550354).

The staff also proposes to add new requirements to Appendix E to Part 50 that, if the applicant has an operating reactor at the site, an exercise, either full- or partial-participation, be conducted for each subsequent reactor constructed on the site. This new provision is desirable because of the nature of ITAAC for emergency preparedness requirements. The emergency preparedness ITAAC, specifically ITAAC that will be demonstrated through an exercise, provide the necessary reasonable assurance for programs and facilities associated with the yet-unbuilt reactor. Recent agreements between the NRC and external stakeholders on emergency preparedness ITAAC are based on the understanding that ITAAC for the emergency preparedness exercise will demonstrate various aspects of emergency preparedness (e.g., programs and facilities) that do not need specific, detailed ITAAC. For example, there is no ITAAC for determining whether an adequate staffing roster exists for the technical support center or emergency operations facility, but the adequacy of staffing could be demonstrated during an exercise. Therefore, Appendix E requirements for emergency preparedness exercises must be included for the current concepts of emergency preparedness ITAAC to be valid. With regard to subsequent reactors, those aspects of an exercise which address currently untested (i.e., unexercised) aspects of emergency preparedness for the proposed new reactor must be addressed in new emergency preparedness ITAAC. If various generic exercise-related elements of emergency preparedness for the site have been previously addressed and satisfied, no ITAAC will be required for those elements of emergency preparedness for subsequent reactors.

Issues Affecting ESP Finality

Emergency Preparedness Requirements for a COL Applicant Referencing an Early Site Permit

The staff proposes to modify §§ 52.39 and 52.79 to require a license applicant referencing an ESP to update and correct the emergency preparedness information provided under § 52.17(b). The issue of updating an ESP was first raised by the Illinois Department of Nuclear Safety, which suggested in a September 28, 1994, letter that emergency plans and/or offsite certifications approved as part of an ESP review be kept up to date throughout the duration of an ESP and the construction phase of a COL.

The staff agrees in part with the Illinois Department of Nuclear Safety. However, the staff believes that there is no need to update the emergency plans approved in an ESP until the permit is referenced in a COL or CP application. At that time, the emergency plans will have to be reviewed to confirm that they are up to date and to provide new information that may materially affect the Commission's earlier determination on emergency preparedness or that is needed to correct inaccuracies in the emergency preparedness information approved in the ESP to support a reasonable assurance determination. Accordingly, the staff is proposing that §§ 52.39 and 52.79 contain an updating requirement to be imposed upon the applicant referencing an ESP.

In addition, the staff is proposing that the applicant must discuss whether the new information could materially change the bases for compliance with the applicable NRC requirements. New information which materially changes the bases for compliance includes (1) information which substantially alters the bases for a previous NRC conclusion with respect to the acceptability of a material aspect of emergency preparedness or an emergency preparedness plan and (2) information which constitutes a sufficient basis for the Commission to modify or impose new terms and conditions related to emergency preparedness in accordance with § 52.39(a)(1). New information which materially changes the Commission's determination on emergency preparedness matters or results in modifications of existing terms and conditions of the ESP will be subject to litigation during the CP or COL proceedings in accordance with § 52.39(c).

In a related matter, the staff proposes to accord finality to changes to an ESP emergency plan (or major features thereof) that are made after the issuance of the ESP if (1) the approved ESP emergency plan (or major feature) is based upon an emergency plan in use by a licensee of a nuclear power plant; (2) the changes to the ESP emergency plan are identical to the changes in the referenced licensee's plan; and (3) the changes in the referenced licensee's emergency plan are in compliance with § 50.54(q). The staff's proposal is based on the position that changes to emergency plans which are properly implemented under § 50.54(q) do not require NRC review and approval before implementation; therefore similar changes to an ESP's emergency preparedness plan made under similar controls should not require NRC review and approval as part of the new licensing process.

Requirements for Staff Review of New and Significant Environmental Information at the COL Stage

Currently, 10 CFR Part 51 does not reference the Part 52 licensing and approval processes. The staff is proposing conforming changes to Part 51 to address this lack of specific reference.

One of the proposals has been the subject of much discussion between the NRC staff and nuclear industry stakeholders, namely, the staff's proposal to add a requirement in § 51.50 that the applicant's environmental report for a COL application referencing an ESP must contain any new and significant information on the site or design to the extent that the information differs from, or is in addition to, the information discussed in the ESP environmental impact statement (EIS). The staff is also proposing to add a requirement that the applicant must have an acceptable process for identifying any new and significant information regarding the NRC's conclusions in the ESP EIS.

The NRC's regulations and the applicable case law interpreting the National Environment Policy Act of 1969 (NEPA), as amended, support the staff's belief that, inasmuch as an ESP and a COL are major Federal actions significantly affecting the quality of the human environment, both actions require the preparation of an EIS. However, 10 CFR Part 52 provides finality for previously resolved issues. Under NEPA, the COL environmental review is informed by the EIS prepared at the ESP stage, and the NRC staff intends to use tiering and incorporation by reference whenever it is appropriate to do so. The COL applicant must address any other significant environmental issues not considered in any previous proceeding, such as issues deferred from the ESP stage to the COL stage (e.g., the benefits assessment).

For an ESP, the NRC prepares an EIS that resolves numerous issues within certain bounding conditions. These issues are candidates for issue preclusion at the COL, CP, or operating license stage. While the NRC is ultimately responsible for completing any required NEPA review, including ensuring that the conclusions for a resolved ESP environmental issue remain valid for a COL action, the NRC staff proposes that a COL applicant must identify whether there is new and significant information on the issue. A COL applicant should have a reasonable process to ensure it becomes aware of new and significant information that may have a bearing on the earlier NRC conclusion, and should document the results of this process in an auditable form for issues for which the COL applicant does not identify any new and significant information. The NRC will independently evaluate and be responsible for the reliability of all information used in the EIS prepared for a COL. In carrying out its responsibilities, the staff may (1) inquire into the continued validity of information disclosed in an EIS for an ESP that is referenced in a COL application and (2) look for any new information that may affect the assumptions, analysis, or conclusions in the ESP EIS.

In conclusion, the NRC staff has determined that the issuance of a COL is a major Federal action significantly affecting the quality of the human environment and, in accordance with 10 CFR 51.20, the NRC must prepare an EIS for the action. For matters resolved at the ESP stage, if there is no new and significant information that materially differs from that discussed in the ESP EIS, then the staff will rely upon ("tier off") the ESP EIS and disclose the NRC conclusion for matters covered in the ESP review. Such matters will not be subject to litigation at the COL stage.

Revision to the ESP Finality Provisions

The staff proposes to make changes to § 52.39 to address the finality of an ESP. With the benefit of hindsight and experience gained in reviewing the first three ESP applications and recognizing the industry's preference to provide less detail in an ESP application than was

originally envisioned by the Commission, the staff believes that most issues concerning a referenced ESP may be characterized as:

(1) Questions about whether the site characteristics, design parameters, or terms and conditions specified in the ESP have been met;

(2) Significant new emergency preparedness or environmental information not considered for the ESP; or

(3) Questions regarding whether the early site permit should be modified, suspended, or revoked.

Questions about whether the referencing application demonstrates compliance with the ESP are fundamentally questions of compliance with the ESP. Such compliance matters are specific to the proceeding for the referencing application, and the staff concludes that such matters about whether the referencing application complies with the ESP should be regarded as questions material to the proceeding and admissible as contentions in the referencing application proceeding if the usual requirements for timely admitted contentions in 10 CFR Part 2 are met.

The staff also regards new emergency preparedness information submitted in the referencing application which materially changes the Commission's determination on emergency preparedness matters as an issue material to the proceeding and admissible as a contention in the referencing application proceeding. Likewise, any significant environmental issue not considered for the ESP is also subject to litigation during the proceeding on the referencing application to the extent the issue differs from issues discussed or reflects significant new information. Because new emergency preparedness or environmental information will be identified only at the time a license application referencing the early site permit is submitted to the NRC, the staff believes it is appropriate to address such issues in the proceeding on the referencing application.

Other questions regarding whether the permit should be modified, suspended, or revoked equate to challenges to the validity of the ESP. The Commission's process for challenges to the validity of a license is given in 10 CFR 2.206. Accordingly, the staff concludes that challenges to the validity of an ESP should be processed in accordance with § 2.206.

OGC has advised the staff that other alternatives are available that would provide for the updating of emergency preparedness and environmental information to occur outside of the referencing COL proceeding. The staff does not consider the alternatives to be an efficient or effective use of agency resources, especially in light of the manner in which early site permit applicants have chosen to pursue an early site permit (e.g., use of a plant parameter envelope), deferring resolution of many issues until the COL stage. The staff believes it is most efficient to expend resources to update early site permit issues only when the early site permit is referenced in a COL application and to address early site permit updating issues in the COL proceeding, as opposed to updating the early site permit in a proceeding separate from the COL proceeding. Under this approach, all issues affecting the COL are addressed in one proceeding.

QA Requirements for ESP Applicants

The subject of quality assurance requirements for the first three ESP applications (submitted in late 2003) was addressed in an NRC letter to Mr. Ronald Simard of the Nuclear Energy Institute on February 3, 2003 (ML030160555). In that letter, the NRC staff stated that the current regulations in 10 CFR Part 52 did not require that a 10 CFR Part 50, Appendix B, program be implemented in support of ESP applications. However, the staff further stated that ESP activities associated with site safety must be controlled by QA measures sufficient to provide reasonable assurance that future safety-related systems, structures, and components (SSCs) of a nuclear power plant or plants that might be constructed on the site will perform adequately. Implementation of this guidance for the first three ESP applications proved challenging and the staff believes that future ESP reviews will be significantly improved by the addition of an explicit QA requirement for ESP applicants.

With certain exceptions, the regulations in § 52.39 require the Commission to treat matters resolved in an ESP proceeding as resolved in making findings for issuance of a CP, operating license, or COL. Because of this finality, conclusions made during the ESP phase will be relied upon for use in subsequent design, construction, fabrication, and operation of a reactor that might be constructed on the site for which an ESP is issued. Therefore, the staff believes that the level of quality used to control activities related to safety-related SSCs should be equivalent in the ESP and COL phases. Applicants must apply quality controls to each ESP activity associated with the generation of design information for safety-related SSCs that meet the criteria in Appendix B. Therefore, the staff proposes to modify 10 CFR 50.55(f), Appendix B, and § 52.17 to make these QA requirements applicable to ESPs.

Applicability of 10 CFR Part 21 and 10 CFR 50.55(e)

The proposed rule includes a number of conforming changes to clarify the applicability of 10 CFR Part 21 and equivalent requirements in 10 CFR 50.55(e) to individuals, corporations, partnerships, or other entities doing business within the United States (as well as directors and responsible officers of such organizations), that hold a permit or license under 10 CFR Part 52. These conforming changes will address an omission in the existing regulations and ensure that the requirements in 10 CFR Part 21 or § 50.55(e) apply to applicants for and holders of ESPs, design approvals, design certifications, COLs, and manufacturing licenses and suppliers of basic components to such applicants or holders. Note that the staff's current proposals regarding the applicability of Part 21 or § 50.55(e) to applicants for and holders of ESPs and design certifications are different from the staff's positions in the 2003 proposed rulemaking. The changes are mainly the result of the staff's experience in reviewing ESPs and design certification applications since the earlier proposed rule was developed.

The staff's proposal is based on the belief that the extension of NRC's reporting requirements implementing Section 206 to Part 52 licensing and approval processes should be consistent with three key principles. First, NRC regulatory requirements implementing Section 206 should be a legal obligation throughout the entire "regulatory life" of a NRC license, standard design approval, or standard design certification. Second, defects should be reported whenever the information on potential defects will be most effective in ensuring the integrity and adequacy of the NRC's regulatory activities under Part 52 and the activities of entities subject to the Part 52

regulatory regime.[3] Third, each entity conducting activities within the scope of Part 52 should develop and implement procedures and practices to ensure that it accurately and timely fulfills its Section 206 reporting obligations. The application of these three principles to each of the Part 52 licensing and approval processes is described in detail in the attached *Federal Register* notice.

Section 50.55(e) addresses the obligation of holders of CPs and their contractors and subcontractors to report defects constituting a substantial safety hazard. These requirements, which implement Section 206 of the Energy Reorganization Act (ERA) of 1974, as amended, are comparable to the requirements set forth in 10 CFR Part 21. The staff proposes to retain the current regulatory structure, whereby persons and entities engaged in construction activities (and their contractors and subcontractors) are subject to § 50.55(e), and persons and licensees who are authorized to operate a nuclear power plant (and their contractors and subcontractors) are subject to Part 21. Inasmuch as a COL under Part 52 authorizes both construction and operation, a COL holder is subject to the reporting requirements in § 50.55(e) from the date of issuance of the COL until the date that the Commission makes the finding under § 52.103(g). Thereafter, the COL holder will be governed by the reporting requirements in Part 21. The manufacture of a nuclear power reactor under a manufacturing license is the functional equivalent of construction (though only for the reactor, not for the entire facility as in the case of a CP or COL). Accordingly, the staff's view is that the holder of a manufacturing license should be subject to reporting under § 50.55(e). ESPs precede construction and are considered partial CPs; hence the staff believes that they should be subject to reporting under § 50.55(e). Standard design approvals under proposed Subpart E and design certifications under Subpart B of Part 52 are not directly associated with construction, and the staff believes that their reporting should be addressed under Part 21.

Probabilistic Risk Assessment Requirements

The revised proposed rule amends the requirement in proposed § 52.47(b)(1) for a design-specific PRA to clarify that the PRA must be full scope and account for all modes of plant operation (including shutdown) and initiating events. This proposed clarification is intended to indicate that the PRA submitted in a design certification application must be a full-scope PRA that comprises three sequential levels, including an evaluation of core damage frequency, followed by an evaluation of accident releases, and ending with an evaluation of radiological consequences. In addition, the PRA must account for internal events (e.g., loss-of-coolant accident and loss of offsite power) and external events (e.g., flooding, seismic events, and fire) for all modes of plant operation. The staff is proposing this clarification to provide additional guidance to applicants on the scope of the PRA that must be submitted with the design certification application.

Similarly, the staff is proposing changes to current § 52.79(b) (proposed § 52.80(a)), proposed § 52.137, and proposed § 52.158 to require that applications contain a PRA. This amendment would require that if an application for a COL references a standard design certification or standard design approval or if the application proposes to use a nuclear power reactor

[3]Throughout this discussion, reference to entities, licensees, and/or applicants includes the contractors and subcontractors of those entities, licensees, and/or applicants.

manufactured pursuant to a manufacturing license under Subpart F of Part 52, the plant-specific PRA must use the PRA for the design certification, design approval, or manufactured reactor, as applicable, and must be updated to account for site-specific design information and any design changes, departures, or variances. The staff also proposes to include a requirement that a COL application that does not reference a certified design, design approval, or manufactured reactor must contain a plant-specific PRA. Like the requirements for a design certification applicant, the proposed § 52.80(a) requires that the plant-specific PRA be full scope and account for the operating modes and initiating events. The *Federal Register* notice states that the initiating events addressed should include internal and external events that account for site-specific characteristics.

In summary, the staff recommends that the Commission approve issuance of the attached revised notice of proposed rulemaking for public comment that will withdraw and supersede the July 2003 notice of proposed rulemaking.

RECOMMENDATION:

That the Commission:

1. Approve withdrawal of the previously published proposed rule and publication of the attached revised notice of proposed rulemaking.

2. Certify that this rule, if promulgated, will not have a significant 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. This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). This rule will be submitted to the Office of Management and Budget (OMB) for review and approval of the paperwork requirements.

    c. 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 the certification, as required by the Regulatory Flexibility Act.

    d. The appropriate congressional committees will be informed.

RESOURCES:

In the fiscal year (FY) 2007 budget submission, the staff estimated 1.3 FTE in FY 2006 to complete the rulemaking. Based on the current status of this rulemaking, the staff now estimates a total of 1.5 FTE in FY 2006 (1.0 FTE for the Office of Nuclear Reactor Regulation (NRR), 0.3 FTE for OGC, and 0.2 for the Office of Nuclear Security and Incident Response

(NSIR)) and 0.6 FTE in FY 2007 (0.5 FTE for NRR and 0.1 FTE for OGC). These resources have been included in the budgets for NRR, NSIR, and OGC for FY 2006 and FY 2007.

COORDINATION:

The staff provided the Advisory Committee on Reactor Safeguards (ACRS) with a draft proposed rulemaking package for 10 CFR Part 52 on August 10, 2005. In a letter dated September 20, 2005, the ACRS stated that it planned to review the draft final version of the rulemaking following the reconciliation of public comments. The Committee To Review Generic Requirements will also review the draft final version of the rulemaking following the reconciliation of public comments.

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. In addition, the Office of Nuclear Security and Incident Response coordinated offsite emergency preparedness related changes with the Department of Homeland Security/Federal Emergency Management Agency.

/RA Martin J. Virgilio Acting For/

Luis A. Reyes
Executive Director
for Operations

Attachments: 1. *Federal Register* Notice
2. Regulatory Analysis

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for Operations

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2. Regulatory Analysis

SECY ML052300372 **Attachment 1 ML051310208** **Attachment 2 ML052840320**
Package ML052920505
concurrence: * via email ** via memo **WITS 199700060**

OFC	PM:RNRP/NRR	RNRP/NRR	LA:RNRP	Tech Ed	SC/RNRP/DRIP/NRR	PD/RNRP/DRIP/NRR
NAME	NGilles	JWilson	PMagnanelli	PKleene	LDudes (WBeckner for)	WBeckner
DATE	08/26/05	08/26/05	08/26/05	09/05/05	08/26/05	08/26/05
OFC	PM/RPRP/DRIP/NRR	SC/RPRP/DRIP/NRR	PD/RPRP/DRIP/NRR	DE/NRR	DLPM/NRR	PMAS/NRR
NAME	HTovmassian	SCoffin	EMcKenna	MMayfield**	TMarsh**	CCarpenter**
DATE	9/19/05	09/19/05	09/19/05	09/09/05	09/06/05	09/12/05
OFC	DSSA/NRR	DIPM/NRR	DRIP/NRR	DNS/NSIR	DPR/NSIR	DFM/OCFO
NAME	JLyons**	BBoger**	DMatthews	GTracy** (SMorris for)	ELeeds**	TCroote*
DATE	9/21/05	09/09/05	09/22/05	09/09/05	09/09/05	09/01/05
OFC	DFO/OCFO	SFPO/NMSS	DAS/ADM	DO/NSIR	DO/NMSS	DO/RES
NAME	MGivvines* (TCroote for)	WBrach*	MFlynn* (MLesar for)	RZimmerman**	JStrosnider (MFederline for)	CPaperiello** (RBarrett for)
DATE	09/01/05	09/16/05	09/09/05	10/13/05	10/14/05	10/05/05
OFC	OE	OIS	OGC	OCFO	RDB/ADM	OSTP
NAME	MJohnson (RArrighi for)	BJShelton*	STreby	JFunches* (TCroote for)	MLesar**	PLohaus* (CMaupin for)
DATE	09/14/05	10/13/05	10/19/05	10/07/05	10/12/05	10/20/05
OFC	D/NRR	EDO				
NAME	JDyer	M. Virgilio for LAReyes				
DATE	10 /21 /05	11/03/05				

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