REGULATORY ANALYSIS FOR REVISED PROPOSED RULE: UPDATE 10 CFR 52, “LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS"

Introduction

The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations by revising the provisions applicable to the licensing and approval processes for nuclear power plants and making necessary conforming amendments throughout the NRC’s regulations to enhance the NRC’s regulatory effectiveness and efficiency in implementing its licensing and approval processes. The proposed changes would clarify the applicability of various requirements to each of the licensing processes (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. The NRC believes that this rulemaking action will improve the effectiveness and efficiency of the licensing and approval processes for future applicants.

This regulatory analysis has been prepared in accordance with the Nuclear Regulatory Commission (NRC) Regulatory Analysis Guidelines (RA Guidelines), NUREG/BR-0058, Revision 4, dated September 2004. The regulatory analysis consists of two parts. The first is an aggregate analysis of the proposed rule. The second part is a screening review for disaggregation to identify any individual provisions whose costs are disproportionate to the potential benefits.

A. Aggregate Analysis- Summary of Results

Consistent with the RA Guidelines, the NRC performed an aggregate analysis of the proposed rule. The analysis is based on a projected business scenario reflecting the NRC's expectations of eight combined license applications (COL) during the next three years and thereafter two COL applications per year would occur over the next 17 years. The provisions of the proposed rule relating to Part 52 are estimated to result in net present value savings to the industry of *$25,886 K*, and *$26,266 K* using a 3-percent and a 7-percent discount rate, respectively. The provisions of the proposed rule relating to Part 21 are estimated to result in net present value cost of $7,550 K and $5,123 K to the industry, using a 3-percent and a 7-percent discount rate, respectively. The net present value of the entire proposed rule is estimated to result in a net savings to the industry of *$18,336 K* and *$21,143 K* at a 3- percent and a 7-percent discount rate, respectively. In addition, the proposed rule is estimated to be a one time net present value savings to the NRC of *$8,336 K*.

The NRC concludes that the costs of the rule are justified in view of the quantitative savings and evaluation and discussion of qualitative benefits in Section 5.1. The analysis measures the incremental value of the proposed rule vis-a-vis the current rule. A summary of the analysis is presented in Section 5.2.

B. Screening Review for Disaggregation

The NRC also performed a screening review for disaggregation in accordance with Section 4.3.2 of the RA Guidelines to determine if there are provisions whose costs are disproportionate to the benefits and whose inclusion in the aggregate analysis could mask the true impact. This

analysis also responds to the Commission's direction in SRM-01-0134, dated July 23, 2001: "If there is a reasonable indication that a proposed change imposes costs disproportionate to the safety benefit attributable to that change, as part of the final rule package the Commission will perform an analysis of that proposed change in addition to the aggregate analysis of the entire rulemaking to determine whether this proposed change should be aggregated with the other proposed changes for the purposes of backfit analysis. That analysis will need to show that the individual change is integral to achieving the purpose of the rule, has costs that are justified in view of the benefits that would be provided or qualifies for one of the exceptions in 10 CFR 50.109(a)(4)." The results of the analysis are documented in Section 5.2.

1. Statement of Problem and Objective

The NRC published 10 CFR Part 52, “Early Site Permits, Standard Design Certifications, and Combined Licenses for Nuclear Power Plants” in April 1989. The NRC now proposes to revise these requirements through a reorganization, clarification and rewrite of Part 52. The staff is also proposing clarification and corrections to 10 CFR Parts 1, 2, 10, 19, 20, 21, 25, 26, 50, 51, 52 (including appendices A, B, and C), 54, 55, 72, 73, 75, 95, 140, and 170. The proposed rule reflects lessons learned from the Commission’s experience in design certification and early site permit reviews, input from stakeholders, as appropriate, on the combined license process, and corrects known errors and omissions. This action is expected to improve the effectiveness and efficiency of Part 52 licensing processes for future applicants. The major objectives of this rulemaking are to —

- increase regulatory efficiency
- reduce unnecessary regulatory burden
- address issues and incorporate lessons learned from the Part 52 licensing processes
- make conforming changes throughout 10 CFR to reflect the revised licensing and regulatory approval processes
- address omissions and errors identified since the promulgation of Part 52
- clarify ambiguities in Part 52 to reflect the original intent of the NRC

This proposed action would be applicable to future applicants for early site permits, design approvals, design certifications, combined license, and manufacturing license applications. It would not affect any current licensee under Part 52 since no license has yet been issued under Part 52. However, the proposed action would affect holders of existing design certifications.

2. Background

A. Original Promulgation of Part 52

The NRC promulgated 10 CFR Part 52 on April 18, 1989 (54 FR 15386), to reform the NRC's licensing process for future nuclear power plants. The rule added alternative licensing processes in 10 CFR Part 52 for early site permits, standard design certifications, and combined licenses. The processes in 10 CFR Part 52 resolve safety and environmental issues early in licensing proceedings and enhance the safety and reliability of nuclear power plants through standardization. The rule also moved the licensing processes in Appendices M, N, O, and Q of 10 CFR Part 50 to 10 CFR Part 52. Subsequently, the NRC certified three nuclear plant designs under Subpart B of 10 CFR Part 52— the U.S. Advanced Boiling Water Reactor (ABWR) Design (62 FR 25827, May 12, 1997), the System 80+ design (62 FR 27867, May 21, 1997), and the AP600 design (64 FR 72015, December 23, 1999) and codified these designs in Appendices A, B, and C of 10 CFR Part 52, respectively.

The regulations in Part 52 provide for the certification of standardized reactor designs, making it possible to use the same design information for the licensing of several plants, and provide for the issuance of a single license for both construction and operation, eliminating the need for two applications and two submittals of design information. Part 52 also provides for the approval of a nuclear power plant site in advance of the submission of any application for a construction permit for that site. The use of standardized designs allows a more focused review and the industry can transfer experience in maintenance and operation from one plant to another more easily. In summary, the principal objective of Part 52 was to increase the effectiveness and efficiency of the licensing process for nuclear power plants by early resolution of issues.

B. July 2003 Proposed Rulemaking

The NRC planned to revise 10 CFR Part 52 after the first standard design certification reviews. In SECY-98-282, "Part 52 Rulemaking Plan", dated December 4, 1998, the staff proposed to initiate a rulemaking to revise Part 52. In a staff requirements memorandum issued on January 14, 1999, the Commission approved the NRC staff's plan for revising 10 CFR Part 52. After the issuance of SECY-00-0092, Combined License Review Process, dated April 20, 2000, stakeholders at public meetings raised other licensing issues with 10 CFR Part 52 Subparts A and C (early site permits and combined licenses, respectively). The NRC obtained considerable stakeholder comments on its planned action through three public meetings on the proposed rulemaking, and two postings of draft rule language on the NRC's rulemaking Website. On July 3, 2003, (68 FR 40026) the NRC published a proposed rule that would clarify and/or correct 10 CFR Parts 1, 2, 10, 19, 20, 21, 25, 26, 50, 51, 52 (including appendices A, B, and C), 54, 55, 72, 73, 140, 170, 171, and revise portions of 10 CFR Part 52, and incorporate stakeholders comments.

3.0 Revised Proposed Rulemaking

Following the close of the public comment period on the July 2003 proposed rule, the NRC re-evaluated whether the 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 July 2003 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, during the public comment period and thereafter, the NRC gained additional insights about early site permits as a result of the NRC's review of the first three early site permit applications. The NRC also had the benefit of public meetings with external stakeholders on

the development of NRC staff guidance on early site permits and combined licenses. The NRC therefore 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.

Accordingly, the NRC decided to develop a revised proposed rule for public comment that will supersede the July 2003 proposed rule. The revised proposed rule contains a reorganization and virtually complete rewriting of Part 52, and conforming 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 (early site permit, standard design approval, standard design certification, combined license, and manufacturing license).

4. Identification and Discussion of the Alternative Approaches

4.1 Alternative 1 - Take No Action

The no-action alternative is not to revise 10 CFR Part 52 and not to make conforming changes throughout 10 CFR. This action would not support the original intent of the Commission to revisit and update the rulemaking after gaining some experience with its use. Since the promulgation of 10 CFR Part 52 in April 1989, the NRC has approved three design certifications, issued a final design approval for a fourth design, and began reviewing three early site permit applications. In addition, the Commission has held numerous public meetings to obtain input from stakeholders on the Part 52 regulatory processes.

The pros and cons of Alternative 1 are as follows:

Pros:

- The NRC would not incur the cost of the final rulemaking.

Cons:

- would not increase regulatory efficiency.
- would not reduce unnecessary regulatory burden.
- would not address issues and incorporate lessons learned from the Part 52 licensing processes.
- would not make conforming changes throughout 10 CFR to reflect the revised licensing and regulatory approval processes.
- would not address errors identified since the promulgation of Part 52.
- would not clarify ambiguities in Part 52 to reflect the original intent of the NRC.

4.2 Alternative 2 - Publish Proposed Revisions to Part 52

Alternative 2 would reorganize and rewrite Part 52 to incorporate lessons learned about Part 52 licensing and regulatory processes from reviewing design certification and early site permit applications, and from interactions with stakeholders on Part 52, including the combined license process. This rewrite would include conforming changes throughout 10 CFR to reflect the adoption of licensing and regulatory- approval processes in Part 52 and to clarify the relationship between requirements in Part 52 and other regulatory requirements in the regulations. Although the rule is mainly focused on Part 52, the NRC is proposing changes in many other parts of the regulations to clarify ambiguities and maintain consistency between the various licensing processes.

The pros and cons of Alternative 2 are as follows:

Pros

- would increase regulatory efficiency
- would reduce unnecessary regulatory burden
- would address issues and incorporate lessons learned from the Part 52 licensing processes
- would make conforming changes throughout 10 CFR to reflect the revised licensing and regulatory approval processes
- would address errors identified since the promulgation of Part 52
- would clarify ambiguities in Part 52 to reflect the original intent of the NRC

Cons

- NRC would incur the cost of the final rulemaking.

The proposed changes in this rulemaking can loosely be grouped in three categories, (i) conforming changes, format changes, reorganiztion and clarifications that do not impose additional regulatory requirements, (ii) corrections, omissions and additions that conform to the current NRC policy, and hence are not additional requirements, and (iii) changes that impose additional regulatory requirements that represent a departure from the current NRC policy. A regulatory analysis addresses only the incremental changes for measuring the impact of a rule. Accordingly, this regulatory analysis addresses the changes described in the last group (iii). The proposed rule contains four changes that represent a departure from the current NRC policy. The four proposed changes that require further analysis are—

(1) update emergency preparedness requirements for a COL applicant referencing an ESP,

(2) change the manufacturing licensing process concept; and require the development of

inspection, testing, analyses and acceptance criteria (ITAAC) for the manufacturing licensing application,

(3) implement quality assurance requirements per 10 CFR Part 50, Appendix B, for ESP applicants, and

(4) implement reporting of defects requirements under Part 21 and Section 50.55(e) for referenced ESP applicants and design certification applicants.

Detailed discussion of these four proposed changes are described below:

4.2.1 Update emergency preparedness requirements for a COL Applicant referencing an ESP

This amendment pertains to a COL applicant referencing an ESP. It requires the applicant to update and correct emergency preparedness information of the site conditions and to discuss whether the new information may materially change the bases for compliance with the applicable NRC requirement. New information which materially changes the bases for compliance includes (1) information which substantially alters the bases for a previous NRC conclusion on the acceptability of a material aspect of emergency preparedness or an emergency preparedness plan, and (2) information which would constitute a sufficient basis for the Commission to modify or impose new terms and conditions for emergency preparedness.

This amendment to update the ESP's emergency preparedness information and the corresponding discussion of bases of compliance in the combined license application constitutes a change from the existing rule. The detailed cost-benefit analysis of this proposed amendment is provided in Section 5.1.1.

4.2.2 Change the manufacturing licensing process concept, require the development of ITAAC for the manufacturing license application *and mandatory hearing*.

Appendix M of Part 52 currently sets forth the NRC's requirements for manufacturing licenses. Appendix M, which was first adopted by the NRC 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 construction permit and operated under an operating license at a different location from the place of manufacture. Under the current licensing regime in Appendix M, the NRC does not approve a final reactor design to be manufactured before issuing the manufacturing license. Rather, as in the Part 50 two-step licensing process, the NRC issues a manufacturing license based upon the review of a preliminary design equivalent to that provided in a construction permit application. Upon approval of the preliminary design and associated information, the NRC 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 begin, although the NRC must approve the final design of the manufactured reactor by license amendment.

In view of the substantial re-organization and rewriting of 10 CFR generally, the NRC 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 in the manufacturing license concept proposed by the NRC is that a final reactor design must be submitted and approved before issuance of a manufacturing license. This approval of a final reactor design eliminates one step from the current two-step process of issuing a manufacturing license, and amending the license when a final design is submitted. The technical information required to be included in an application for a manufacturing license,

as set forth in proposed §§ 52.157 and 52.158, reflects both the expanded scope of approval to include the final design of the reactor to be manufactured, as well as lessons learned with respect to early site permits. Section 52.157 specifies the standard information required to be submitted in support of the design of a reactor. In addition, the application must address the provisions with respect to the demonstration by test, analysis, experience or a combination thereof of simplified, inherent, passive, or other innovative means to accomplish safety functions, or the results of testing of a prototype plant, as set forth in proposed revisions to § 50.40. Information which must be submitted as part of an application, but is not typically considered part of a final safety analysis report, is identified in § 52.158. This includes a PRA, proposed ITAAC to be used by the licensee that will construct and operate a nuclear power plant at its site using the manufactured reactor, and an environmental report for the manufactured reactor. The environmental report must address severe accident mitigation design alternatives (SAMDAs), since the design approval phase is usually the most cost-effective stage for incorporating design features for addressing severe accidents.
The NRC is approving a reactor design for manufacture and the ITAAC for verifying that it has been acceptably manufactured and integrated into a nuclear power facility such that it can be safely operated in accordance with the approved manufactured reactor design, the NRC's regulations, and the requirements of the AEA.

The NRC also proposes to provide a mandatory hearing as a matter of discretion, in large part because the NRC has never issued a manufacturing license of the type contemplated in the proposed subpart F of Part 52, even though a mandatory hearing is not required under Section 189.a.(1)(A) of the AEA.

The proposed changes to the current Appendix M constitutes a change from the existing rule.

The detailed cost-benefit analysis of this proposed amendment is provided in Section 5.1.2.

4.2.3 Implement quality assurance requirements per 10 CFR Part 50, Appendix B for ESP applicants

The current regulations do not explicitly require implementing a Part 50 Appendix B program in support of an ESP application, and there is no current requirement to describe the applicant's quality assurance program in an ESP application. However, under the current Part 52 regulatory process, activities associated with site safety must be controlled by QA measures sufficient to provide reasonable assurance that future safety-related systems, structures, and components (SSC) of a nuclear power plant that might be constructed on the site will perform adequately in service. The regulations in 10 CFR 52.39, with certain specific exceptions, require the NRC to treat matters resolved in an ESP proceeding as resolved in making findings for issuance of a construction permit, operating license, or combined license. 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 level of quality used to control activities related to safety-related SSCs should be equivalent in substance in the ESP and COL phases. For these reasons, applications must apply quality controls to each ESP activity associated with the generation of design information for safety-related SSCs that are equivalent to those specified in Appendix B for similar activities.

The proposed rulemaking eliminates this ambiguity by the explicit requirement for an ESP applicant to establish and use quality control processes in accordance with 10 CFR Part 50 Appendix B, to conduct activities associated with an ESP. This constitutes a change from the

existing rule. A detailed cost-benefit analysis of this proposed amendment is provided in Section 5.1.3.

4.2.4 Implement reporting of defects requirements under Part 21 for ESP applicants and design certification applicants under Part 52

The reporting requirements in Section 206 of the Energy Reorganization Act of 1974 (ERA), as amended (1974 ERA) are incorporated in 10 CFR Part 21 and § 50. 55(e). Section 50.55(e) sets forth the Section 206 reporting requirements applicable to holders of a construction permit. The proposed rule sets forth the NRC's proposals on how reporting requirements to implement Section 206 should be applied to applicants for ESPs and design certifications.

The NRC believes that the extensions of NRC's reporting requirements implementing Section 206 of the ERA to Part 52 licensing and approval processes should be consistent with three key principles. First, the requirements should be legal obligations throughout the entire regulatory life of an NRC license, or a standard design certification. Second, defects must 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. Third, each entity conducting activities within the scope of Part 52 must develop and implement procedures and practices to ensure that it fulfills its Section 206 reporting obligations in an accurate and timely manner.

Reporting requirements for early site permits

The NRC proposes that Part 21 apply to early site permit applicants and holders. In order for

the applicant for an early site permit to have the capability to report to the NRC any known significant safety concerns with respect to its site, or any safety concerns of which it may subsequently become aware (i.e., to be able to report any defects or failures associated with substantial safety hazards under Part 21) the early site permit applicant would have to have a program in place for implementing the requirements of 10 CFR Part 21. The applicant's program may be inspected by the NRC as Part of the application review and approval of the early site permit application would be subject to approval of the Part 21 program.

Reporting requirements for standard design certification

A standard design certification represents the NRC's approval by rulemaking of an acceptable nuclear power reactor design, which may then be referenced in a subsequent construction permit, operating license, combined license, or manufacturing license application. The NRC proposes to impose requirements to implement Section 206 on applicants for standard design certification.

5.1 Regulatory Impact —Cost-benefit of the proposed action

Discussion in Section 4.2 identified four changes that represent a departure from the current NRC policy. These changes would not affect any current licensees under Part 52 since no license has yet been issued under Part 52, and would be applicable to future applicants. The cost-benefit analysis of the regulatory requirements associated with these four changes are based upon the NRC's assessment of the future business scenario as described below.

- Eight COL applications during the next 3 years and thereafter two COL applications per year would be submitted over the next 17 years. It is assumed that 3 of those

anticipated COL's would be referencing an ESP during the next 3 years, and half of them would be referencing i.e.;1 COL = (2 x 0.5) would be referencing an ESP annually for the next 17 years.

- One ESP application would be submitted over the next 3 years and thereafter one application would be submitted annually over the next 17 years.
- Four design certifications would be submitted over the next 4 years.
- Two manufacturing licenses would be submitted in the next 20 years.

5.1.1 Update emergency preparedness requirements for a COL applicant referencing an ESP

A combined license applicant referencing an early site permit must include an update of the emergency preparedness information and a discussion of whether the new information materially alters the basis for compliance with the relevant requirements. This additional requirement constitutes a change from the current rule. The cost-benefit analysis of this proposed amendment using the above mentioned assumptions is as follows:

Costs to Applicant

The NRC assumed that *three* COL applications referencing an ESP would be submitted over the next 3 years, and thereafter one COL application referencing an ESP would be submitted annually for the next 17 years.

The NRC estimates that it will take an applicant approximately 4 staff-months for a one-time cost of $64 K (4 staff-months x 4 weeks/month x 40 hrs/week x $100/hr) per application for updating the emergency preparedness information of an ESP.

The business scenario discussed above would result in a present value of approximately $*926 K* at a 3-percent discount rate. With a 7-percent discount rate, the estimate would be $*633 K.*

Costs to NRC

NRC would not incur additional costs for reviewing the updated emergency preparedness of a referenced early site permit, since the NRC would have to review the updated information anyway, Particularly considering possibilities of significant lapse of time between the issuance of an ESP and the submittal of a COL.

Benefits to Applicant

The NRC believes that this proposed amendment would reduce the overall regulatory burden of an applicant referencing an early site permit when reviewed in the context of the entire license review process, even though inclusion of the updated emergency preparedness information in the referencing license application is an additional burden on the applicant. The NRC, in absence of the updated information, can not adequately assess the state of emergency preparedness of the COL application referencing an ESP. To determine the adequacy of the state of emergency preparedness, the NRC, would have to request the information of the applicant. The applicant would spend considerable more resources to compile, analyze and submit the information at a later date as compared to providing the information in the referencing application. This delayed submittal would also prolong the license review time. It is estimated that it will take at least 50 percent more effort to submit the information after issuance of the referencing license application, since the submittal would necessitate reassembly of the

team, require review of the existing documents and then update potentially large number of changes to the original submittal.

Using the above business scenario, updating of the emergency preparedness information during the license review phase would increase the applicant's effort by 50 percent, or $96 K (4 NRC-months x 4 weeks/month x 40 hr/week x 1.5 x $100/hr) per application. The same business scenario, at a 3-percent discount rate would result in a present value of approximately $1,390 K. With a 7-percent discount rate, the estimate would be $950 K.

Benefits to NRC

The review of the submittal would have no additional impact on the NRC for the reasons discussed in the cost section, but the schedule delays might have an impact. No efforts have made to quantify the impact of potential schedule delay.

5.1.2 Changes in manufacturing licensing process concept require the development of ITAAC for the manufacturing license application and a mandatory hearing.

This proposed amendment requires that a final reactor design be submitted and approved before issuance of a manufacturing license. The approval of a final reactor design eliminates the current two-step regulatory process of issuing a manufacturing license based on preliminary design information and 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 to manufacturing the reactor. The technical information that must be included in an application for a manufacturing license reflects both the expanded

scope of approval to include the final design of the reactor to be manufactured and the lessons learned during the ESP applications reviews.

The proposed amendment would eliminate preparation and agency review of the preliminary license application, but would require an expanded license application that would include additional technical information, namely a PRA, proposed ITAAC to be used by the licensee that will construct and operate a nuclear power plant at the site using the manufactured reactor, and an environmental report. Under the current regulatory process, the PRA and the Environmental Report are integral Parts of the license application, and hence inclusion of these in the final safety analysis report (FSAR), a Part of the license application under the proposed rulemaking, though not typical, are not considered additional burden on the applicant. However, the development of ITAAC would be an additional burden. Under the proposed rulemaking elimination of the preliminary license application in itself would be a reduction in regulatory burden on both the applicant and the NRC.

The proposed amendment requires that a mandatory hearing be held for a manufacturing license. This provision would impose additional burden both on the applicant and on the NRC.

The cost-benefit analysis of these proposed amendments is as follows:

Cost to Applicant

It is assumed that an application for a manufacturing license under the proposed rulemaking is equivalent to the first step of the existing process (i.e., license application and corresponding design report except for the development of ITAAC). In other words, the preparation of a

manufacturing license application under the proposed rule would involve the same amount of work as for the first step under the existing regulatory regime except for developing ITAAC. The proposed requirement for developing ITAAC as a Part of the manufacturing license application constitutes a change to the existing regulations and would impose additional regulatory burden on applicants for a manufacturing license.

Using the business scenario of two applications for manufacturing license, the NRC estimates that the applicant would incur a one time cost of $4,160 K (10 staff-years x 2080 hr/year x $ 100/hr x 2 applications) for the development of ITAAC.

The NRC estimates that the applicant would incur a one time cost of $100 K (500 staff-hours x $100/hr x 2 applications) to prepare for and to participate in the mandatory hearing.

In total, applicants would incur a one time costs of $4,260 K (4160+100).

Cost to NRC

The NRC estimates that the agency would incur a one time cost for reviewing the ITAAC $625 K (2 staff-years x 1776 hr/year x $ 88/hr x 2 applications).

The NRC estimates that the agency would incur a one time cost for holding a mandatory hearing $88 K (500 staff-hours x $88/ hr. x 2 applications).

In total, the agency would incur a one-time cost of $713 K (625+88).

Benefit to Applicant

The applicant would not be required to prepare and submit an amendment of a manufacturing license under the proposed rule, reduce regulatory burden compared to the two-step licensing process of the existing regulations. The NRC estimates that the elimination of one step would result in a one-time reduction of $31,200 K (75 staff-years x 2080 hr/year x $100/hr x 2 applications).

Benefit to NRC

The NRC estimates that the agency would avoid the one-time cost of reviewing the license application $9,377 K (30 staff-years x 1776 hr/year x $88/hr x 2 applications). The NRC rate is based on estimated in-house data.

It should be noted, developing ITAAC adds burden for the manufacturing license applicant, it does not add burden to the ultimate operator of a nuclear power generating facility since the ITAAC are developed before the issuance of the operating license and included in the operating license costs. Put another way, the additional burden of ITTAC actually shifts the burden from one phase to another; i.e., from operating license phase to the manufacturing license phase.

5.1.3 Implement Quality Assurance (QA) requirements per 10 CFR Part 50, Appendix B for ESP applicants

The proposed rulemaking requires an ESP applicant to implement a QA program pursuant to Part 50 Appendix B to control ESP activities. The incremental burden of using Part 50

Appendix B program is shown below.

Costs to Applicant

The NRC estimates that the applicant would incur a one-time costs of establishing a Part 50 Appendix B QA program of $48 K (3 staff-months x 4 weeks/month x 40 hr/week x $100/hr) per applicant, and $72 K (40 hr/month x 18 months x $100/hr) per applicant to implement the QA program for the ESP activities or for a total of $120 K per applicant.

Assuming the above business scenario of 1 ESP application in the next 3 years, and thereafter 1 ESP application per year for the next 17 years at a 3-percent discount rate would result in a present value of approximately $1,518 K. With a 7-percent discount rate, the estimate would be $991 K.

Costs to NRC

The NRC would not incur any additional costs.

5.1.4 Implement reporting of defects requirements under Part 21 for ESP applicants and Design Certification applicants under Part 52

Part 21 implements the reporting requirements in Section 206 of the Energy Reorganization Act of 1974, as amended (1974 ERA). The proposed Part 52 rule sets forth the Commission's proposals for applying reporting requirements implementing Section 206 of the 1974 ERA be applied to Part 52 licensing processes. The NRC's three key principles of reporting under

Section 206 of the ERA are (i) a legal obligation exists throughout the entire regulatory life of a NRC license or a Part 52 regulatory approval, (ii) defects should be reported whenever the information on potential defects would be most “effective”, and (iii) each entity conducting activities within the scope of Part 52 should develop and implement procedures and practices to ensure that it accurately and timely meets its Section 206 reporting obligations.

This proposed amendment requires that applicants for ESPs and standard design certifications make contractual agreements with contractors, subcontractors, consultants and other suppliers of goods and services to notify them that they are subject to the NRC’s regulatory requirements for reporting, and developing and implementing reporting requirements. These requirements would impose additional regulatory burden on applicants and their contractors, subcontractors, consultants, and other suppliers of goods and services.

Each entity conducting activities under Part 52, would have a quality assurance (QA) program in place to control their specific activities. The QA programs of applicants and their contractors, subcontractors, consultants, and other suppliers must be modified to include procedures and practices for timely and accurate reporting of any defects that they become aware of during and after completion of their scope of work. These programs must be capable of being implemented later when a product is referenced in a subsequent construction permit, an operating license, or a COL. The programs for reporting must also continue throughout the regulatory life of the referenced license. In addition, for holders of combined licenses and manufacturing licenses, the records regarding reporting of defects must be kept for the duration of the regulatory life. These requirements would impose additional regulatory burden on the future applicants.

The cost-benefit analysis of this proposed amendment is as shown below :

Costs to Applicant

ESP Applicants

The NRC estimates that the one-time cost for setting up the procedures for reporting of defects would be $96 K (320 hr x 3 vendors x $100/hr) per ESP applicant.

Per the business scenario assumption of 1 referenced ESP applicant during the next 3 years, thereafter 1 referenced ESP applicant annually for the next 17 years would occur. This would result, at a discount rate of 3-percent in a cost of $1,214 K, and $793 K at a discount rate of 7-percent.

Also, the NRC estimates that it would require 180 hr/year for an estimated three contractors to report defects and maintain records for the regulatory life of an ESP, and it is assumed that 4 ESP applicants would be affected for a cost $216 K (180 hr/year x 3 vendors x $100/hr x 4 ESP applicants) annually for the next 20 years for a net present value of $3,218 K at a 3-percent discount rate and $2,290 K at a 7-percent discount rate.

Design Certification Applicants

In addition, 4 design certification applications during the next 4 years are estimated to be referenced by COL applicants. Setting up the procedures for reporting of defects would incur a one-time cost of $96 K (320 hr x 3 vendors x $100/hr) per applicant. Per the business scenario

of 4 design certifications it would result in a net present value of $341 K at a 3-percent discount rate $293 K and at a discount rate of 7-percent.

Also, for 4 design certification applicants, it would cost $216 K (180 hr/year x 3 vendors x $100/hr x 4 applicants) annually for the next 16 years starting from the fourth year for a net present value of $2,777 K at a 3-percent discount rate and $1,747 K at a 7-percent discount rate.

In summary, at a 3-percent discount rate it would cost $7,550 K (1,214+3,218+341+2,777), and $5,123 K (793+2,290+293+1,747) at a 7-percent discount rate.

5.1.5 Final Rulemaking costs:

NRC

The NRC estimates that completing the final rulemaking would require a one-time cost of $328 K (2.1 staff-years x 1776 hr/year x $ 88/hr).

5.2 Aggregate Analysis

In accordance with the RA Guidelines, an aggregate analysis of all the significant provisions is shown in table below.

Provisions	Impact Type	Monetary Impact	
		Applicant	NRC
		All Costs in Thousand $'s	
		3%/7% @	3%/7% @
(1) Update of emergency preparedness for an ESP	Costs	-926/-633	0
	Savings	1,390/950	0
(2) Manufacturing license concept change, development of ITAAC, & mandatory hearing	Costs	*-4,260**	*-713**
	Savings	31,200/31,200*	9,377/9,377*
(3) Implement QA program for ESP applicant	Costs	-1518/-991	0
	Savings	0	0
(4) Implement reporting of defects (Part 21)	Costs	-7,550/-5,123	0
	Savings	0	
Total Part 21 amendments		-7,550/-5,123	0
Total Part 52 rulemaking amendments		*25,886/26,266*	*8,664**
Total All Parts rulemaking amendments		*18,336/21,143**	*8,664**
NRC Final rulemaking Cost	Costs	0	-328*
Net monetary impact at (3%/7% discount rate)		*26,672/29,479*	

Costs are negative, savings are positive.

@ Discount Rate

* Indicates One-time Occurrence

5.3 Disaggregation Analysis

The NRC has prepared an analysis of the impact of the proposed changes (Attachment A) that identifies each provision affected by the rulemaking and determines whether it is appropriate to include each proposed change in the rule. This attachment details an analysis of each proposed change and whether it is needed for the regulatory initiative to resolve the concerns and meet the stated objectives that are the focus of the regulatory initiative. The NRC also performed an analysis to identify any individual provision that could impose cost disproportionate to the benefits attributable to each provision. The NRC has concluded that there are no provision whose costs are disproportionate to the benefits and whose inclusion in the aggregate analysis could mask the impact of this rulemaking.

6. Decision Rationale

The NRC proposes to adopt Alternative 2. The basis for this proposed rulemaking is regulatory efficiency. Alternative 2 meets the objectives as stated in the Section 1- Statement of Objectives. A few salient features of the objectives are cited below.

Regulatory efficiency

- The regulatory requirements for license applications and supporting documents have been organized for consistency between the various licensing and regulatory processes of 10 CFR Part 52.
- The interconnection with other Parts of Title 10 Chapter 1 are clearly described.
- Regulatory requirements for information for regulatory approval are clearly expressed enabling applicants to address relevant issues completely, and provide sufficient

information in license application and avoiding burdensome and costly resubmittals of information during the license review.

Reduction of unnecessary regulatory burden

- Regulatory burden reduction of $*26,672* K at a 3-percent discount rate and *$29,479* K at a 7-percent discount rate

Address issues and lessons learned with respect to the Part 52 licensing process:

- Applicants resolve design development issues early in the process ensuring early considerations and resolution of technical matters before a substantial commitment of resources.
- Increases regulatory stability and predictability, saving resources.
- Facilitates regulatory process of standardization of nuclear power plants.

Make conforming changes throughout 10 CFR to reflect the revised licensing and regulatory approval processes.

Address errors identified since the promulgation of Part 52.

Clarify ambiguities in Part 52 to reflect the original intent of the NRC.

7. Implementation Schedule

This rule will become effective 30 days after publication of the final rule in the *Federal Register*.

Attachment A

Disaggregation Analysis

Section/Description	RE	RB	LL	CC	OR	CA
10 CFR Part 1						
1.4.3 Office of nuclear reactor regulation				x		
10 CFR Part 2						
Subpart A						
2.1 Scope				x		
2.4 Definitions				x		
2.100 Scope of parts				x		
2.101 Filing of applications	x			x		x
2.102 Administrative review of application				x		
2.104 Notice of hearing	x			x		
2.105 Notice of proposed action	x			x		
2.106 Notice of issuances				x		
2.109 Effect of timely renewal application	x			x		
2.110 Filing and administrative action on submittals for standard design approval or early review of site suitability issues				x		
2.111 Prohibition of sex discrimination				x		
Subpart B						
2.2 Scope of subpart				x		
2.202 Orders	x			x		
Subpart C						
2.390 Public inspections, exemptions, requests for withholding				x		
Subpart E						
2.500 Scope of subpart				x		
2.501 Notice of hearing on application pursuant to Subpart F of Part 52 for a license to manufacture nuclear power reactors	x	x		x		
2.502 Notice of hearing on application under a construction permit for nuclear power reactor manufactured at the site at which the reactor to be operated-**Deleted**	x	x		x		
2.503 Finality of decision	x	x		x		
2.504 Applicability of other sections				x		
Subpart H						
2.800 Scope and applicability	x			x		x
2.801 Initiation of rulemaking	x			x		x

Legend: RE - Increase Regulatory Efficiency; RB - Reduce Regulatory Burden; LL - Lesson Learned; CC - Conforming Changes throughout 10 CFR; OR - Correct Omissions and Error; CA - Clarify Ambiguous Language

Section/Description	RE	RB	LL	CC	OR	CA
2.811 Filing of standard design certification application; required copies	x			x		x
2.813 Written communications	x			x		x
2.815 Docketing and acceptance review	x			x		x
2.817 Withdrawal of application				x		x
2.819 Denial of application for failure to supply information	x			x		x
10 CFR Part 10						
10.1 Purpose				x		
10.2 Scope				x		
10 CFR Part 19						
19.1 Purpose				x		
19.2 Scope	x			x		
19.3 Definition	x			x		
19.11 Posting of notices to workers	x			x		x
19.14 Presence of representatives of licensees and regulated entities, and workers during inspections	x			x		x
19.20 Employee protection				x		
19.31 Application for exemptions				x		
19.32 Discrimination prohibited				x		
10 CFR Part 20						
20.1002 Scope				x		
20.1401 General provisions and scope-**Deleted**				x		
20.2203 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits				x		
10 CFR Part 21						
21.2 Scope				x		
21.3 Definitions			x	x		
21.5 Communications				x		
21.21 Notification of failure to comply or existence of a defect and its evaluation				x		
21.51 Maintenance and inspections of records	x		x	x		
21.61 Failure to notify	x		x	x		
10 CFR Part 25						
25.35 Classified visits				x		
25.5 Definitions				x		
10 CFR Part 26						
26.2 Scope				x		
26.10 General performance objectives				x		
10 CFR Part 50						
50.2 Definitions	x		x	x		x

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Section/Description	RE	RB	LL	CC	OR	CA
50.10 License required	x		x	x		x
50.23 Construction permits				x		
50.30 Filing of application; oath or affirmation	x			x		
50.33 Contents of applications; general information.	x			x	x	
50.34 Contents of construction permits and operating license applications; technical information	x			x	x	x
50.34a Design objectives for equipment to control releases of radioactive material in effluents - nuclear power reactors				x		
50.36a Technical Specifications on effluents from nuclear power reactors	x		x	x		
50.37 Agreement limiting access to classified information				x		
50.40 Common standards	x			x		
50.43 Additional standards and provisions affecting class 103 licenses for commercial power	x			x		
50.45 Standards for construction permit, combined operating license				x		
50.46 Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors				x		
50.47 Emergency plans	x		x	x		x
50.48 Fire protection				x		
50.49 Environmental qualification of electric equipment important to safety for nuclear power plants				x		
50.54 Conditions of licenses	x		x	x		
50.55 Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses	x		x	x		x
50.55a Codes and standards				x		
50.59 Changes, tests, and experiments				x		
50.61 Fracture toughness requirements for protection against pressurized thermal shock events				x		
50.63 Loss of all alternating current power				x		
50.65 Requirements for monitoring effectiveness of maintenance at nuclear power plants				x		
50.70 Inspections applicability to early site permit holders				x		
50.71 Maintenance of records, making of reports	x			x		

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Section/Description	RE	RB	LL	CC	OR	CA
50.73 License event report system				x		
50.75 Decommissioning funding assurance		x		x		
50.78 Installation information and verification				x		
50.80 Transfer of license				x		
50.81 Creditor regulations				x		
50.90 Application for amendment of license or construction permit				x		
50.91 Notice for public comment; state consultation				x		
50.92 Issuance of amendment				x		
50.100 Revocation, suspension, modification of licenses, permits, and approvals for cause				x		
50.109 Backfitting				x		
50.120 Training and qualification of nuclear power plant personnel	x			x		
Appendix A to Part 50-general design criteria-nuclear power plants				x		
Appendix B to Part 50-Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants	x		x	x		x
Appendix C to Part 50-A guide for the financial data and related information required to establish financial qualifications for construction permits and combined licenses				x		
Appendix E to Part 50- Emergency planning and preparedness for production & utilization facilities	x		x	x		x
Appendix I to Part 50- Numerical guides for design objectives and limiting conditions for operation to use the criterion “As low as is reasonably achievable” for radioactive material in nuclear light-water-cooled nuclear power reactors effluents				x		
Appendix J to Part 50-Primary reactor containment leakage testing for water-cooled reactors				x		
Appendices M and O to Part 50-Moved to Part 52				x		
Appendices S to Part 50- Earthquake Engineering Criteria for Nuclear power plants				x		
10 CFR Part 51						
51.17 Deleted				x		
51.20 Criteria for and identification of licensing and regulatory actions requiring environmental impact statements	x			x		
51.22 Criteria for categorical exclusion	x		x	x		

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Section/Description	RE	RB	LL	CC	OR	CA
51.23 Temporary storage of spent fuel after cessation of reactor operation-generic determination of no significant environmental impact				x		
51.30 Environmental assessment	x	x		x		
51.31 Determinations based upon environmental assessment.	x	x	x	x		
51.32 Finding of no significant impact	x	x	x	x		
51.45 Environmental report	x		x	x		
51.50 Environmental report -construction permit, early site permit, or combined license stage	x		x	x		
51.51 Uranium fuel cycle environmental data - Table S				x		
51.52 Environmental effects of transportation of fuel and waste-Table S-4.				x		
51.53 Post construction environmental reports	x			x		
51.54 Environmental report-manufacturing license	x	x		x		
51.55 Environmental report-design certification	x		x	x		
51.58 Environmental report-number of copies; distribution	x			x		
51.66 Deleted				x		
51.71 Draft environmental impact statement-contents	x			x		
51.75 Draft environmental impact statement-construction permit, early site permit, or combined license				x		
51.95 Deleted	x			x		
51.105 Public hearings in proceedings for issuance of construction permits or early site permits	x	x	x	x		
51.105a Public hearings in proceedings for issuance of manufacturing licenses	x	x		x		
51.108 Deleted	x		x	x		
10 CFR Part 52						
52.0 Scope; applicability of 10 CFR Chapter 1 provisions	x		x	x		x
52.1 Definitions	x		x	x	x	
52.2 Interpretations	x			x		
52.3 Written communications				x		
52.4 Deliberate misconduct	x			x		
52.7 Specific exemptions	x			x		
52.8 Combining licenses	x			x		
52.9 Jurisdictional limits	x			x		
52.10 Attacks and destructive acts	x			x		

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Section/Description	RE	RB	LL	CC	OR	CA
52.10a Information collection requirements-OMB Approval				x		
Subpart A Early Site Permits						
52.11 Scope of subpart				x		
52.13 Relationship to other subparts	x			x		x
52.15 Filing of application	x		x	x		x
52.16 Contents of application-general information	x			x		
52.17 Contents of application-technical information	x		x	x	x	x
52.18 Standard for review of application	x			x		
52.21 Administrative review of application; hearings				x		
52.24 Issuance of early site permits	x		x	x		
52.25 Extent of activities permitted	x			x		
52.28 Transfer of early site permits	x		x			
52.29 Application for renewal					x	
52.31 Criteria for renewal	x				x	
52.39 Finality of early site permit determination	x			x		
Subpart B Standard Design Certification						
52.41 Scope	x			x		
52.43 Relationship to Others	x		x	x		
52.45 Filing of application	x		x	x		x
52.46 Contents of application; general information	x			x		
52.47 Contents of application; technical information	x		x			x
52.48 Standards for review of applications	x		x			x
52.54 Issuance of standard design certification	x		x			x
52.59 Criteria for renewal	x				x	
52.63 Finality of standard design certifications	x	x			x	
Subpart C Combined License						
52.73 Relationship to other subparts	x			x		
52.77 Contents of application; general information	x				x	
52.79 Contents of applications; technical information in final safety analysis report	x		x		x	x
52.83 Finality of referenced NRC approvals	x		x			x
52.85 Administrative review of applications; hearings	x					
52.87 Referral to the ACRS						
52.89 Environmental review- deleted & reserved	x					x
52.91 Authorization to conduct site activities	x					
52.97 Issuance of combined licenses.			x			
52.98 Finality of combined license; information requests.	x					
52.99 Inspection during construction.	X					x

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Section/Description	RE	RB	LL	CC	OR	CA
52.103 Operation under a combined license	x					x
52.104 Duration of combined license	x					
52.105 Transfer of combined license	x					
52.107 Application for renewal	x					
52.109 Continuation of combined license	x					
52.110 Termination of license	x					
Subpart E Standard Design Approvals						
52.131 Scope of subpart	x					
52.133 Relationship to other subparts	x					
52.135 Filling of applications	x					
52.136 Contents of application; general information	x					
52.137 Contents of application; technical information	x					x
52.139 Standards for review of applications	x					x
52.141 Referral to the ACRS	x					
52.143 Staff approval of design	x					
52.145 Finality of the design approval	x					x
52.147 Duration of design approval	x					
Subpart F- Manufacturing Licenses						
52.151 Scope of subpart	x					
52.153 Relationship to other subparts	x					
52.155 Filling of applications	x	x				
52.156 Contents of applications; general information	x	x				
52.157 Contents of applications; technical information	x	x				
52.157 Contents of applications; technical information in FSAR	x					
52.163 Administrative review of applications; hearings	x					
52.165 Referral to the ACRS	x					
52.167 Issuance of manufacturing license	x					
52.171 Finality of the manufacturing license; information requests	x	x				
52.173 Duration of manufacturing license	x					
52.175 Transfer of manufacturing license	x					
52.177 Application for renewal	x					
52.179 Criteria for renewal	x					
52.181 Duration of renewal	x					
Subpart H- Violations						
52.301 Violations				x		

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Section/Description	RE	RB	LL	CC	OR	CA
52.303 Criminal penalties				x		
Appendices A,B & C Design Certifications for ABWR, System 80+, and AP600	x			x	x	x
Appendix O -Moved processes of Appendix O to Subpart E.				x		
Appendix M- Moved Processes of Appendix M to Subpart F				x		
10 CFR Part 54						
54.1 Purpose				x		
54.3 Definition				x		
54.17 Filing of application				x		
54.31 Issuance of review license				x		
54.37 Additional records and record keeping requirement				x		
54.35 Requirements during term of renewed license				x		
10 CFR Part 55						
55.1 Purpose				x		
55.2 Scope				x		
55.5 Communication				x		
10 CFR Part 72						
72.210 General license required				x		
72.218 Termination of license				x		
10 CFR Part 73						
73.1 Purpose and scope				x		
73.50 Requirements for physical protection of licensed activities				x		
73.56 Personnel access authorization requirements for nuclear power plants				x		
73.57 Requirements for criminal history checks of individuals granted unescorted access to a nuclear power facility or access to safeguards information by power reactor licensees.				x		
Appendix C				x		
10 CFR Part 75						
75.6 Maintenance of record and delivery of information, report, and other comments				x	x	
10 CFR Part 95						
95.5 Definition				x		
95.13 Maintenance of records				x		
95.19 Changes to security practices				x		
95.20 Grant, denial, or termination of facility clearance				x		

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Section/Description	RE	RB	LL	CC	OR	CA
95.23 Termination of facility clearance				x		
95.31 Protective personnel				x		
95.33 Security education				x		
95.34 Control of visitors				x		
95.35 Access to matters classified as national security information and restricted data				x		
95.36 Access by representatives of the international atomic energy commission or participants in other international agreements				x		
95.37 Classification and preparation of documents				x		
95.39 External transmission of documents and material				x		
95.43 Authorized to reproduce				x		
95.45 Changes in classification				x		
95.49 Security of automatic data processing systems				x		
95.51 Retrieval of classified material following suspension or revocation of access authorization				x		
95.53 Termination of facility clearance				x		
95.57 Reports				x		
95.59 Inspections				x		
10 CFR Part 140				x		
140.2 Scope				x	x	
140.10 Scope				x		
140.11 Amounts of financial protection for certain reactors				x		
140.12 Amount of financial protection required for other reactors				x		
140.13 Amount of financial protection required of certain holders of construction permits and combined licenses under Part 52.				x		
140.20 Indemnity agreements and liens				x		
140.31 Scope				x		
140.93 Appendix C				x		
140.96 Appendix F				x		
10 CFR Part 170				x		
170.2 Scope				x		

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