

THIS PRELIMINARY PROPOSED RULE LANGUAGE AND ACCOMPANYING DISCUSSION IS BEING RELEASED TO SUPPORT INTERACTIONS WITH STAKEHOLDERS AND THE ADVISORY COMMITTEE ON REACTOR SAFEGUARDS (ACRS). THIS LANGUAGE HAS NOT BEEN SUBJECT TO COMPLETE NRC MANAGEMENT OR LEGAL REVIEW, AND ITS CONTENTS SHOULD NOT BE INTERPRETED AS OFFICIAL AGENCY POSITIONS. THE NRC STAFF PLANS TO CONTINUE WORKING ON THE CONCEPTS AND DETAILS PROVIDED IN THIS DOCUMENT AND WILL CONTINUE TO PROVIDE OPPORTUNITIES FOR PUBLIC PARTICIPATION AS PART OF THE RULEMAKING ACTIVITIES.

AN IMPORTANT NOTE FOR THIS ITERATION IS THAT THE STAFF IS ACTIVELY ASSESSING VARIOUS ALTERNATIVE DESIGN/LICENSING APPROACHES TO ADDRESS COMMENTS THAT THE RULEMAKING SHOULD SUPPORT METHODOLOGIES THAT ARE LESS RELIANT ON PROBABILISTIC RISK ASSESSMENTS (PRA). THE DEVELOPMENT OF THIS SUBPART PRIMARILY REFLECTS A RISK-INFORMED OR PRA-CENTERED APPROACH. THE STAFF IS DEVELOPING ALTERNATIVE APPROACHES AND RELATED PRELIMINARY RULE SECTIONS FOR A FUTURE ITERATION THAT CAN BE CONSIDERED BY AND DISCUSSED WITH STAKEHOLDERS, NRC MANAGEMENT, AND THE COMMISSION.

THE STAFF IS PRIMARILY SEEKING INSIGHTS REGARDING THE CONCEPTS IN THIS PRELIMINARY LANGUAGE AND SECONDARILY SEEKING INSIGHTS RELATED TO DETAILS SUCH AS NUMERICAL VALUES FOR VARIOUS CRITERIA.

SUBPART I (Maintaining and Revising Licensing Basis Information) – PRELIMINARY RULE LANGUAGE

(August 2021)

SUBPART I – “Maintaining and Revising Licensing Basis Information”

Preliminary Language	Discussion
<p>§ 53.1300 Licensing Basis Information. Each holder of an early site permit, construction permit, operating license, or combined license for a commercial nuclear plant licensed under this part shall maintain licensing basis information; evaluate changes to site characteristics, plant design features, and programmatic controls to determine needed approvals and revisions; and submit appropriate updates to the NRC in accordance with the requirements in this subpart. As used in this subpart, licensing basis information refers to that information contained in regulations, orders, licenses, certifications, or approvals issued by the NRC for a commercial nuclear plant licensed under this part and that information submitted to the NRC by an applicant or licensee in a safety analysis report, program</p>	<p>Subpart I and some provisions within Subpart H define the requirements and processes for maintaining licensing basis information by holders of early site permits, construction permits, operating licenses and combined licenses. The subpart is generally organized into those sections dealing with (1) licensing basis information that licensees are not authorized to change without NRC approval (e.g., licenses, regulations) and (2) licensing basis documents that licensees may change unless specified criteria are not satisfied (e.g., FSAR, program descriptions).</p>

<p>description, or other information required to be maintained and submitted to the NRC in this part.</p>	
<p>§ 53.1310 Changes to Licensing Basis Information Requiring Prior NRC Approval. (a) Sections 53.1311 through 53.1313 define the process for a licensee to request and the NRC to issue amendments to licenses, which include an early site permit, construction permit, operating license, or combined license and any conditions contained therein, technical specifications or other attachments to a license, and any orders issued by the NRC modifying a license unless the order itself defines another method for controlling revisions to the requirements included in the order or the order is revised or superseded by another order issued by the NRC. (b) A licensee may propose changing licensing basis information established by NRC regulations by requesting an exemption in accordance with § 53.080.</p>	<p>This section introduces the requirements for proposing changes to the licensing basis information defined by licenses, orders, and regulations.</p> <p>Note that changes to standard design certifications are addressed in Subpart H (§ 53.1239) and proposed changes by a licensee to information related to a standard design certification or manufacturing license are addressed in later sections of this subpart.</p>
<p>§ 53.1311 Application for amendment of license. Whenever a holder of an early site permit, construction permit, operating license, or combined license under this part desires to amend the license, an application for an amendment must be filed with the Commission, as specified in § 53.040 of this part, that fully describes the changes desired, and following as far as applicable, the form prescribed for original applications. Applications for amendments involving changes to plant SSCs, programmatic controls, or the role of plant personnel must include an assessment of the changes in relation to the safety requirements in Subpart B, the analyses requirements of § 53.450, its analysis about the issue of no significant hazards consideration using the standards in § 53.1313, and a consideration of environmental factors.</p>	<p>This section provides the equivalent of § 50.90 for applications to amend an early site permit, construction permit, operating license, or combined license issued under Part 53.</p>
<p>§ 53.1312 Public notices; State consultation. The Commission will use the following procedures for an application requesting an amendment to an early site permit, construction permit, operating license, or combined license under this part. (a) <i>Public notices.</i></p>	<p>This section provides the equivalent of § 50.91 for the NRC's processes related to applications to amend an early site permit, construction permit, operating license, or combined license issued under Part 53.</p>

(1)(i) The Commission may publish in the *Federal Register* under § 2.105 an individual notice of proposed action for an amendment for which it makes a proposed determination that no significant hazards consideration is involved, or, at least once every 30 days, publish a periodic *Federal Register* notice of proposed actions, which identifies each amendment issued and each amendment proposed to be issued since the last such periodic notice, or it may publish both such notices.

(ii) For each amendment proposed to be issued, the notice will (A) contain the staff's proposed determination, under the standards in § 50.92, (B) provide a brief description of the amendment and of the facility involved, (C) solicit public comments on the proposed determination, and (D) provide for a 30-day comment period.

(iii) The comment period will begin on the day after the date of the publication of the first notice, and, normally, the amendment will not be granted until after this comment period expires.

(2) The Commission may inform the public about the final disposition of an amendment request for which it has made a proposed determination of no significant hazards consideration either by issuing an individual notice of issuance under § 2.106 of this chapter or by publishing such a notice in its periodic system of Federal Register notices. In either event, it will not make and will not publish a final determination on no significant hazards consideration, unless it receives a request for a hearing on that amendment request.

(3) Where the Commission makes a final determination that no significant hazards consideration is involved and that the amendment should be issued, the amendment will be effective on issuance, even if adverse public comments have been received and even if an interested person meeting the provisions for intervention called for in § 2.309 of this chapter has filed a request for a hearing. The Commission need hold any required hearing only after it issues an amendment, unless it determines that a significant hazards consideration is involved, in which case the Commission will provide an opportunity for a prior hearing.

(4) Where the Commission finds that an emergency situation exists, in that failure to act in a timely way would result in derating or shutdown of a nuclear power plant, or in prevention of either resumption of operation or of increase in power output up to the plant's licensed

power level, it may issue a license amendment involving no significant hazards consideration without prior notice and opportunity for a hearing or for public comment. In such a situation, the Commission will not publish a notice of proposed determination on no significant hazards consideration, but will publish a notice of issuance under § 2.106 of this chapter, providing for opportunity for a hearing and for public comment after issuance. The Commission expects its licensees to apply for license amendments in timely fashion. It will decline to dispense with notice and comment on the determination of no significant hazards consideration if it determines that the licensee has abused the emergency provision by failing to make timely application for the amendment and thus itself creating the emergency. Whenever an emergency situation exists, a licensee requesting an amendment must explain why this emergency situation occurred and why it could not avoid this situation, and the Commission will assess the licensee's reasons for failing to file an application sufficiently in advance of that event.

(5) Where the Commission finds that exigent circumstances exist, in that a licensee and the Commission must act quickly and that time does not permit the Commission to publish a Federal Register notice allowing 30 days for prior public comment, and it also determines that the amendment involves no significant hazards considerations, it:

(i)(A) Will either issue a Federal Register notice providing notice of an opportunity for hearing and allowing at least two weeks from the date of the notice for prior public comment; or

(B) Will use local media to provide reasonable notice to the public in the area surrounding a licensee's facility of the licensee's amendment and of its proposed determination as described in paragraph (a)(2) of this section, consulting with the licensee on the proposed media release and on the geographical area of its coverage;

(ii) Will provide for a reasonable opportunity for the public to comment, using its best efforts to make available to the public whatever means of communication it can for the public to respond quickly, and, in the case of telephone comments, have these comments recorded or transcribed, as necessary and appropriate;

(iii) When it has issued a local media release, may inform the

licensee of the public's comments, as necessary and appropriate;

(iv) Will publish a notice of issuance under § 2.106;

(v) Will provide a hearing after issuance, if one has been requested by a person who satisfies the provisions for intervention specified in § 2.309 of this chapter;

(vi) Will require the licensee to explain the exigency and why the licensee cannot avoid it, and use its normal public notice and comment procedures in paragraph (a)(2) of this section if it determines that the licensee has failed to use its best efforts to make a timely application for the amendment in order to create the exigency and to take advantage of this procedure.

(6) Where the Commission finds that significant hazards considerations are involved, it will issue a *Federal Register* notice providing an opportunity for a prior hearing even in an emergency situation, unless it finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

(b) *State consultation.*

(1) At the time a licensee requests an amendment, it must notify the State in which its facility is located of its request by providing that State with a copy of its application and its reasoned analysis about no significant hazards considerations and indicate on the application that it has done so.

(2) The Commission will advise the State of its proposed determination about no significant hazards consideration normally by sending it a copy of the *Federal Register* notice.

(3) The Commission will make available to the State official designated to consult with it about its proposed determination the names of the Project Manager or other NRC personnel it designated to consult with the State. The Commission will consider any comments of that State official. If it does not hear from the State in a timely manner, it will consider that the State has no interest in its determination; nonetheless, to ensure that the State is aware of the application, before it issues the amendment, it will make a good faith effort to communicate directly with that official.

(4) The Commission will make a good faith attempt to consult

<p>with the State before it issues a license amendment involving no significant hazards consideration. If, however, it does not have time to use its normal consultation procedures because of an emergency situation, it will attempt to communicate directly with the appropriate State official.</p> <p>(5) After the Commission issues the requested amendment, it will send a copy of its determination to the State.</p> <p>(c) <i>Caveats about State consultation.</i></p> <p>(1) The State consultation procedures in paragraph (b) of this section do not give the State a right:</p> <p>(i) To veto the Commission's proposed or final determination;</p> <p>(ii) To a hearing on the determination before the amendment becomes effective; or</p> <p>(iii) To insist upon a postponement of the determination or upon issuance of the amendment.</p> <p>(2) These procedures do not alter present provisions of law that reserve to the Commission exclusive responsibility for setting and enforcing radiological health and safety requirements for nuclear power plants.</p>	
<p>§ 53.1313 Issuance of amendment.</p> <p>(a) In determining whether an amendment to a permit or license will be issued to the applicant, the Commission will be guided by the considerations which govern the issuance of initial licenses or permits to the extent applicable and appropriate. If the application involves the material alteration of a licensed facility, a construction permit will be issued before the issuance of the amendment to the license, provided however, that if the application involves a material alteration to a nuclear power reactor manufactured under § 53.xxxx before its installation at a site, or a combined license before the date that the Commission makes the finding under § 53.xxxx [52.103(g)], no application for a construction permit is required. If the amendment involves a significant hazards consideration, the Commission will give notice of its proposed action:</p> <p>(1) Under § 2.105 of this chapter before acting thereon; and</p> <p>(2) As soon as practicable after the application has been docketed.</p> <p>(b) The Commission will be particularly sensitive to a license</p>	<p>This section provides the equivalent of § 50.92 for the NRC's processes related to applications to amend an early site permit, construction permit, operating license, or combined license issued under Part 53. Except for minor wording changes (e.g., event sequence instead of event), the criteria are the same as those used in § 50.92.</p>

<p>amendment request that involves irreversible consequences (such as one that permits a significant increase in the amount of effluents or radiation emitted by a nuclear power plant).</p> <p>(c) The Commission may make a final determination, under the procedures in § 53.1312, that a proposed amendment to an operating license or a combined license for a facility license under this part involves no significant hazards consideration, if operation of the facility in accordance with the proposed amendment would not:</p> <ol style="list-style-type: none"> (1) Involve a significant increase in the probability or consequences of an event sequence previously evaluated; or (2) Create the possibility of a new or different kind of an event sequence from any accident previously evaluated; or (3) Involve a significant reduction in a margin of safety. 	
<p>§ 53.1315 Revising certification information within a design certification rule.</p> <p>(a) A holder of an operating license or combined license who references a design certification rule issued under this part must request an exemption if proposing to change one or more elements of the certification information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 53.080.</p> <p>(b) The request for an exemption will be included with the associated proposed changes to the license, which will be requested and processed in accordance with §§ 53.1311, 15.1312, and 53.1313.</p> <p>(c) Licensees must evaluate changes to the facility as described in the final safety analysis not involving changes to the certification information using the criteria in § 53.1322.</p>	<p>This section provides the requirements for the holder of an operating license or combined license issued under Part 53 that references a design certification rule to propose an exemption from the specified characteristics of the certified design. Other requirements related to design certification and changes to the DC by parties other than the holder of an operating license or combined license is included in Subpart H.</p>
<p>§ 53.1316 Revising design information within a manufacturing license</p> <p>The holder of an operating or combined license under this part who references or uses a nuclear power reactor manufactured under a manufacturing license under this part must request approval for a departure from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The application for such departures must be submitted and processed in accordance with §§ 53.1311, 15.1312, and 53.1313. In those cases</p>	<p>From Subpart F of Part 52. This section provides the requirements for the holder of an operating license or combined license issued under Part 53 that references a manufacturing license (ML) to propose a departure from the specified characteristics of the manufactured reactor. Other requirements related to the manufacturing license and changes to the ML by parties other than the holder of an operating license or combined license is</p>

<p>where a manufacturing license references a design certification rule, the amendment application must also request an exemption from the design certification rule in accordance with § 53.1315 if one or more elements of the certification information are adversely affected by the proposed change. Licenses must evaluate changes to the facility as described in the final safety analysis report but outside of the scope of the referenced manufacturing license using the criteria in § 53.1322.</p>	<p>included in Subpart H.</p>
<p>§ 53.1317 Amendments during construction</p> <p>(a) The holder of a construction permit under this part may request an amendment to the construction permit in order to gain Commission approval of the safety of selected design features or specifications, including proposed departures from a design certification rule or manufacturing license. Amendments to construction permits under this part must be requested and processed in accordance with §§ 53.1311, 53.1312, and 53.1313.</p> <p>(b) The holder of a combined license under this part for which the NRC has not yet made a finding in accordance with § 53.xxxx (52.103(g)) must request amendments required by §§ 53.1315 or 53.1322 no later than 45 days from the date the licensee begins the construction of the SSCs to implement the change or departure requiring NRC approval. The licensee proceeds with such changes at its own risk recognizing that there is a possibility that the amendment request will not be granted.</p>	<p>This section provides the requirements for amending the permit or license the holder of a construction permit or combined license issued under Part 53. Paragraph (a) reflects the same requirements as those in § 50.35(b). Paragraph (b) is similar to the process for Part 52 changes during construction and may change as the issue is discussed and resolved during the ongoing Parts 50/52 rulemaking.</p>
<p>§ 53.1320 Evaluating changes and updating licensing basis information without NRC prior approval.</p> <p>Sections 53.1321 through 53.1333 define the process for a licensee to evaluate changes to their facilities, procedures, programs, and organizations and to modify licensing basis information without NRC prior approval.</p>	<p>This section introduces the requirements for licensees to pursue changes to the licensing basis information in licensee controlled documents such as FSARs and program documents.</p>
<p>§ 53.1321 Updating final safety analysis reports.</p> <p>(a) Each holder of an operating license or combined license under this part for which the Commission has made the finding under § 53.xxxx (52.103(g)) must update the final safety analysis report (FSAR) originally submitted as part of the application for the license biennially or more frequently to assure that the information included in</p>	<p>This section provides the equivalent of § 50.71 for the updating of FSARs. Assuming a risk-informed approach in Subpart C results in PRA information being in the FSAR and therefore a separate PRA update requirement (§ 50.71(h)) is not included in this iteration of Subpart I. This section assumes that</p>

<p>the report contains the latest information developed. The submittal shall include the effects on the content of the FSAR of:</p> <ul style="list-style-type: none"> (1) changes made in the facility or procedures; (2) safety analyses and evaluations performed by the applicant or licensee either in support of approved license amendments or in support of conclusions that changes did not require a license amendment in accordance with § 53.1322; (3) updates related to the probabilistic risk assessments required under § 53.450; (4) the cumulative effects of the changes to the facility or procedures since the last update on the margins to the safety criteria in §§ 53.210, 53.220, 53.450(e), and 53.470. (5) analyses of new safety issues performed by or on behalf of the licensee at Commission request. <p>(b)(1) The licensee shall submit revisions containing updated information to the Commission, as specified in § 53.040, identifying the location of revised or new information.</p> <p>(2) The submittal shall include:</p> <ul style="list-style-type: none"> (i) a certification by a duly authorized officer of the licensee that either the information accurately presents changes made since the previous submittal, necessary to reflect information and analyses submitted to the Commission or prepared pursuant to Commission requirement, or that no such changes were made; and (ii) an identification of changes made under the provisions of § 53.1322 but not previously submitted to the Commission. <p>(c) During the period from the docketing of an application for a combined license under subpart H until the Commission makes the finding under § 53.xxxx (52.103(g)), the update to the FSAR providing the information required in (a)(1) through (a)(5) of this section and meeting the requirements of paragraph (b) of this section must be submitted annually.</p> <p>(d) The updated FSAR shall be retained by the licensee until the Commission terminates their license.</p>	<p>the PRA results and the related margins to safety criteria will be discussed in the FSAR and thus would be updated under (a)(4) in this section. The routine reporting of these margins also support the criteria for allowing changes without NRC approval in the following section (§ 53.1322).</p>
<p>§ 53.1322 Evaluating changes to facility as described in final safety analysis reports.</p> <p>(a) A licensee may make changes in the facility as described in</p>	<p>This section provides the equivalent of § 50.59 for evaluating changes to UFSAR and determining if a license amendment is required. The requirements</p>

the UFSAR and make changes in the procedures as described in the UFSAR without obtaining a license amendment pursuant to § 53.1311 only if:

- (1) A change to the technical specifications incorporated in the license is not required and
- (2) The change meets all of the following criteria:
 - (i) Does not result in a change to the frequency or consequences of an event sequence such that an event sequence previously deemed not risk significant becomes risk significant by the analyses performed in accordance with § 53.450(e).
 - (ii) Does not result in a change to the frequency or consequences of an event sequence such that an event sequence deemed risk significant in accordance with § 53.450(e) has a decrease of 10 percent or more in the calculated margins to the LBE evaluation criteria required to be established in accordance with § 53.450(e).
 - (iii) Does not result in a change to the frequency or consequences of one or more event sequences such that the margin between the calculated cumulative risks posed by the commercial nuclear plant and the safety criteria of § 53.220 decreases by 10 percent or more.
 - (iv) Does not involve a departure from a method of evaluation described in the UFSAR used in assessing margins in accordance with § 53.450(e) unless the results of the analysis are conservative or essentially the same, the revised method of evaluation has been previously approved by the NRC for the intended application, or the revised method of evaluation can be used in accordance with an NRC endorsed consensus code or standard.
 - (v) For commercial nuclear plants licensed under this part for which alternative evaluation criteria are applicable in accordance with § 53.470, does not result in a change to the frequency or consequences of event sequences such that the calculated margins between the results for event sequences evaluated in accordance with § 53.450(e) and the alternative evaluation criteria decreases by 25 percent or more.
- (3) In implementing this paragraph, the UFSAR is considered to include FSAR changes since submittal of the last update of the UFSAR pursuant to § 53.1320.

include a risk-informed approach for assessing the results of changes on LBEs and using criteria related to the impact on margins to acceptance criteria. The specific criteria include:

Paragraph (2)(i) which is based on the identification of risk-significant event sequences required by § 53.450 and an evaluation to determine if a proposed change to the facility or procedures would introduce a new risk-significant LBE

Paragraph (2)(ii) which addresses changes potentially affecting existing risk significant event sequences and assessing any reduction in margin to the LBE evaluation criteria

Paragraph (2)(iii) which addresses potential impacts on the cumulative risks and any potential decreases in margin to the safety criteria § 53.220. The use of a reduction of 10 percent in available margins is generally consistent with current practices for evaluating changes in 10 CFR 50.59 (see SOCs at 64 FR 53382 and related guidance in [NEI 96-07, Revision 1](#)).

Paragraph (2)(iv) which is similar to § 50.59(c)(2)(viii) and departures from previously approved methods of evaluating LBEs

Paragraph (2)(v) which addresses facilities applying alternative evaluation criteria by establishing a criterion related to the margins between LBEs and the alternative evaluation criteria.

(4) The provisions in this section do not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(b)(1) A licensee who references a design certification rule may make departures from the standard design, without prior Commission approval, unless the proposed departure involves a change to the design as described in the rule certifying the design, in which case the requirements of § 53.1315 are applicable.

(2) The licensee shall maintain records of all departures from the certified design of the facility and these records must be maintained and available for audit until the date of termination of the license. The licensee will identify the location and nature of departures from licensing basis information within supporting documents for a certified design within the updates to the safety analysis report required by § 53.1321.

(3) Licensees for which the NRC has docketed the certifications required under Subpart G of this part are not required to retain records of departures from the design of the facility associated with structures, systems, and components that have been permanently removed from service *using an NRC-approved change process*.

(c)(1) The licensee shall maintain records of changes in the facility and procedures made pursuant to paragraph (a) of this section. These records must include a written evaluation which provides the bases for the determination that the change does not require a license amendment pursuant to paragraph (a)(2) of this section.

(2) The licensee shall submit, as specified in § 53.040 of this part, a report containing a brief description of any changes, including a summary of the evaluation of each. A report must be submitted at intervals not to exceed 24 months. For combined licenses, the report must be submitted at intervals not to exceed 6 months during the period from the date of application for a combined license to the date the Commission makes its findings under 10 CFR 53.yyy (52.103(g)).

(3) The records of changes in the facility must be maintained until the termination of an operating license or combined license issued under this part, or the termination of a renewed license issued under [], whichever is later. Records of changes in procedures must be maintained for a period of 5 years.

Consistent with 10 CFR 52.63(b)(2)

<p>(d) [Reserved] (e) [Reserved]</p>	
<p>§ 53.1330 Control of licensing basis information in program descriptions. Program documents are included in licensing basis information to describe programmatic contributions to meeting the requirements in Subpart B and to describe measures taken to ensure compliance with specific NRC regulations. §§ 53.1332 through 53.1333 define the process for a licensee to evaluate changes to the program documents included in the licensing basis information submitted to the NRC and to modify such programs without NRC prior approval.</p>	
<p>§ 53.1332 Updating program documents included in licensing basis information. (a) Each holder of an operating license or combined license under this part must biennially or more frequently update the program documents submitted as part of the applications to obtain or maintain the license to assure that the information included in the documents contains the latest information developed. The submittals shall include the effects on the content of the program documents of: (1) changes made in the facility, procedures, licensee's organization, or site environs; (2) safety analyses and evaluations performed by the applicant or licensee either in support of approved license amendments or in support of conclusions that changes did not require a license amendment in accordance with § 53.1321; (3) analyses of new safety issues performed by or on behalf of the licensee at Commission request; and (4) changes to the programs as a result of operating experience, corrective actions, or other reasons deemed appropriate to ensure the programs serve their underlying purpose to support the requirements in Subpart B or other NRC regulations. (b)(1) The licensee shall submit revisions containing updated information to the Commission, as specified in § 53.040, identifying the location of revised or new information. (2) The submittal shall include (i) a certification by a duly authorized officer of the licensee that either the information accurately</p>	<p>This section provides the equivalent of UFSAR updates for key program documents. This iteration provides a uniform approach for program documents, which correspond to the programs required under Subpart F. The staff is interested in stakeholder views on the benefits of a common approach versus the current practice of establishing program-specific requirements for reporting and change control.</p>

<p>presents changes made since the previous submittals, necessary to reflect information and analyses submitted to the Commission or prepared pursuant to Commission requirement, or that no such changes were made; and (ii) an identification of changes made under the provisions of § 53.1321 but not previously submitted to the Commission.</p> <p>(c) The updated program documents shall be retained by the licensee until the Commission terminates their license.</p>	
<p>§ 53.1333 Evaluating changes to programs included in licensing basis information.</p> <p>(a) A licensee may make changes to the facility, procedures, or organizations or address changes to site environs as described in the program documents included in licensing basis information without obtaining prior NRC approval only if:</p> <p>(1) A change to the technical specifications incorporated in the license is not required,</p> <p>(2) An exemption from an NRC regulation is not required,</p> <p>(3) The change conforms to program-specific requirements included in regulations or technical specifications,</p> <p>(4) The change meets all of the following criteria:</p> <p>(i) Does not result in a change to the frequency or consequences of an event sequence such that an event sequence previously deemed not risk significant becomes risk significant by the analyses performed in accordance with § 53.450(e).</p> <p>(ii) Does not result in a change to the frequency or consequences of an event sequence such that an event sequence deemed risk significant in accordance with § 53.450(e) has a decrease of 10 percent or more in the calculated margins to the event category evaluation criteria required to be established in accordance with § 53.450(e).</p> <p>(iii) Does not result in a change to the frequency or consequences of one or more event sequences such that the margin between the calculated cumulative risks posed by the commercial nuclear plant and the safety criteria of § 53.220 decreases by 10 percent or more.</p> <p>(iv) Does not involve a departure from a method of evaluation described in the FSAR (as updated) used in assessing margins in</p>	<p>This iteration provides a uniform approach for program documents, which correspond to the programs required under Subpart F. The staff is interested in stakeholder views on the benefits of a possibly developing a common approach versus the current practice of establishing program-specific requirements for reporting and change control. Note that this current iteration includes pointers in (a)(2) and (a)(3) that would allow program-specific change control criteria to be defined in other regulations or administrative section of technical specifications. Where needed, the staff is seeking stakeholder views on the appropriate location and possible criteria for evaluating specific program documents.</p>

<p>accordance with § 53.450(e) unless the revised method of evaluation has been previously approved by the NRC or can be used in accordance with an NRC endorsed consensus code or standard.</p> <p>(v) For commercial nuclear plants licensed under this part for which alternative evaluation criteria are applicable in accordance with § 53.470, the change does not result in a change to the frequency or consequences of event sequences such that the calculated margins between the results for event sequences evaluated in accordance with § 53.450(e) and the alternative threshold values decreases by 25 percent or more.</p> <p>(5) In implementing this paragraph, the program documents (as updated) are considered to include changes since submittal of the last updates of the program documents pursuant to § 53.1331.</p> <p>(6) The provisions in this section do not apply to changes to the program documents when the applicable regulations establish more specific criteria for accomplishing such changes.</p>	
<p>§ 53.1340 Transfer of licenses or permits.</p> <p>(a) No commercial nuclear plant license or permit issued under this part, or any right thereunder, shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of the license to any person, unless the Commission gives its consent in writing.</p> <p>(b)(1) An application for transfer of a license or permit shall include:</p> <p>(i) For a commercial nuclear plant license or permit issued under this part, as much of the information described in §§ 53.1130, 53.xxxx, and 53.yyyy of this part with respect to the identity and technical and financial qualifications of the proposed transferee as would be required by those sections if the application were for an initial license. The Commission may require additional information such as data respecting proposed safeguards against hazards from radioactive materials and the applicant's qualifications to protect against such hazards.</p> <p>(ii) A statement of the purposes for which the transfer of the license or permit is requested, the nature of the transaction necessitating or making desirable the transfer of the license or permit, and an agreement to limit access to Restricted Data pursuant to</p>	<p>This section provides the equivalent of § 50.80 for the possible transfer of an early site permit, construction permit, operating license, or combined license.</p>

<p>§ 53.1140. The Commission may require any person who submits an application for license or permit pursuant to the provisions of this section to file a written consent from the existing licensee or a certified copy of an order or judgment of a court of competent jurisdiction attesting to the person's right (subject to the licensing requirements of the Act and these regulations) to possession of the facility or site involved.</p> <p>(2) [Reserved]</p> <p>(c) After appropriate notice to interested persons, including the existing licensee, and observance of such procedures as may be required by the Act or regulations or orders of the Commission, the Commission will approve an application for the transfer of a license or permit, if the Commission determines:</p> <p>(1) That the proposed transferee is qualified to be the holder of the license or permit; and</p> <p>(2) That transfer of the license or permit is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission pursuant thereto.</p>	
<p>§ 53.1350 Termination of license.</p> <p>(a) When a licensee for a commercial nuclear plant licensed under this part has determined to permanently cease operations the licensee shall, within 30 days, submit a written certification to the NRC, consistent with the requirements of Subpart G.</p> <p>(b) Once fuel has been permanently removed from the reactor system, the licensee shall submit a written certification to the NRC that meets the requirements of Subpart G.</p> <p>(c)(1) Upon docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor system, or when a final legally effective order to permanently cease operations has come into effect, the 10 CFR part 53 license no longer authorizes operation of the reactor or emplacement or retention of fuel into the reactor system.</p> <p>(2) Activities associated with decommissioning will be carried out in accordance with the requirements and procedures in Subpart G.</p> <p>(3) The Commission shall terminate the license if it determines that—</p> <p>(i) The remaining dismantlement has been performed in</p>	<p>This section provides the equivalent of § 50.82 for the possible termination of an operating license or combined license.</p>

<p>accordance with the approved license termination plan required in Subpart G, and</p> <p>(ii) The final radiation survey and associated documentation, including an assessment of dose contributions associated with parts released for use before approval of the license termination plan, demonstrate that the facility and site have met the criteria for decommissioning in 10 CFR part 20, subpart E.</p>	
<p>§ 53.1360 Information requests.</p> <p>The holder of an early site permit, construction permit, operating license, or combined license shall at any time before expiration of the license, upon request of the Commission, submit, as specified in § 53.040 written statements, signed under oath or affirmation, to enable the Commission to determine whether or not the license should be modified, suspended, or revoked. Except for information sought to verify licensee compliance with the current licensing basis for that facility, the NRC must prepare the reason or reasons for each information request prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information. Each such justification provided for an evaluation performed by the NRC staff must be approved by the Executive Director for Operations or his or her designee prior to issuance of the request.</p>	<p>This section provides the equivalent of § 50.54(f) for a possible request for information that the NRC would issue to holders of an early site permit, construction permit, operating license, or combined license.</p>
<p>§ 53.1370 Revocation, suspension, modification of licenses, permits, and approvals for cause.</p> <p>A license, permit, or standard design approval issued under this part may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or in the supplemental or other statement of fact required of the applicant; or because of conditions revealed by the application or statement of fact of any report, record, inspection, or other means which would warrant the Commission to refuse to grant a license, permit, or approval on an original application; or for failure to manufacture a reactor, or construct or operate a facility in accordance with the terms of the permit or license, provided, however, that failure to make timely completion of the proposed construction or alteration of a facility under a construction permit a combined license under this part shall be governed by the</p>	<p>This section provides the equivalent of § 50.100 for the possible revocation, suspension, or modification of a license or permit.</p>

<p>provisions of § 53.12xx; or for violation of, or failure to observe, any of the terms and provisions of the act, regulations, license, permit, approval, or order of the Commission.</p>	
<p>§ 53.1380 Backfitting.</p> <p>(a)(1) Backfitting is defined as the modification of or addition to systems, structures, components, or design of a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position after the date of the nuclear plant license issued under this part.</p> <p>(2) Except as provided in paragraph (a)(4) of this section, the Commission shall require a systematic and documented analysis pursuant to paragraph (b) of this section for backfits which it seeks to impose.</p> <p>(3) Except as provided in paragraph (a)(4) of this section, the Commission shall require the backfitting of a facility only when it determines, based on the analysis described in paragraph (b) of this section, that there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection.</p> <p>(4) The provisions of paragraphs (a)(2) and (a)(3) of this section are inapplicable and, therefore, backfit analysis is not required and the standards in paragraph (a)(3) of this section do not apply where the Commission or staff, as appropriate, finds and declares, with appropriated documented evaluation for its finding, either:</p> <ul style="list-style-type: none"> (i) That a modification is necessary to bring a facility into compliance with a license or the rules or orders of the Commission, or into conformance with written commitments by the licensee; or (ii) That regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security; or (iii) That the regulatory action involves defining or redefining what 	<p>This section provides the equivalent of § 50.109 for the possible backfitting of requirements to holders of licenses or permits. This first iteration may require additional measures to fully capture all of the finality provisions within Subpart H and the staff expects to update and clarify as additional sections of Subpart H are developed.</p>

level of protection to the public health and safety or common defense and security should be regarded as adequate.

(5) The Commission shall always require the backfitting of a facility if it determines that such regulatory action is necessary to ensure that the facility provides adequate protection to the health and safety of the public and is in accord with the common defense and security.

(6) The documented evaluation required by paragraph (a)(4) of this section shall include a statement of the objectives of and reasons for the modification and the basis for invoking the exception. If immediately effective regulatory action is required, then the documented evaluation may follow rather than precede the regulatory action.

(7) If there are two or more ways to achieve compliance with a license or the rules or orders of the Commission, or with written licensee commitments, or there are two or more ways to reach a level of protection which is adequate, then ordinarily the applicant or licensee is free to choose the way which best suits its purposes. However, should it be necessary or appropriate for the Commission to prescribe a specific way to comply with its requirements or to achieve adequate protection, then cost may be a factor in selecting the way, provided that the objective of compliance or adequate protection is met.

(b) In reaching the determination required by paragraph (a)(3) of this section, the Commission will consider how the backfit should be scheduled in light of other ongoing regulatory activities at the facility and, in addition, will consider information available concerning any of the following factors as may be appropriate and any other information relevant and material to the proposed backfit:

(1) Statement of the specific objectives that the proposed backfit is designed to achieve;

(2) General description of the activity that would be required by the licensee or applicant in order to complete the backfit;

(3) Potential change in the risk to the public from the accidental off-site release of radioactive material;

(4) Potential impact on radiological exposure of facility employees;

(5) Installation and continuing costs associated with the backfit, including the cost of facility downtime or the cost of construction delay;

<p>(6) The potential safety impact of changes in plant or operational complexity, including the relationship to proposed and existing regulatory requirements;</p> <p>(7) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;</p> <p>(8) The potential impact of differences in facility type, design or age on the relevancy and practicality of the proposed backfit;</p> <p>(9) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.</p> <p>(c) No licensing action will be withheld during the pendency of backfit analyses required by the Commission's rules.</p> <p>(d) The Executive Director for Operations shall be responsible for implementation of this section, and all analyses required by this section shall be approved by the Executive Director for Operations or his designee.</p>	
<p>§ 53.1390 Renewal (TBD)</p>	<p>A section may be added to more fully describe or reference the processes related to requesting and processing applications to renew early site permits, construction permits, operating licenses, and combined licenses.</p>