

(3) For all changes that affect the integrated safety analysis summary, the licensee shall submit to NRC annually, within 30 days after the end of the calendar year during which the changes occurred, revised integrated safety analysis summary pages.

(e) If a change covered by § 70.72 is made, the affected on-site documentation must be updated promptly.

(f) The licensee shall maintain records of changes to its facility carried out under this section. These records must include a written evaluation that provides the bases for the determination that the changes do not require prior Commission approval under paragraph (c) or (d) of this section. These records must be maintained until termination of the license.

#### § 70.73 Renewal of licenses.

Applications for renewal of a license must be filed in accordance with §§ 2.109, 70.21, 70.22, 70.33, 70.38, and 70.65 of this chapter. Information contained in previous applications, statements, or reports filed with the Commission under the license may be incorporated by reference, provided that these references are clear and specific.

#### § 70.74 Additional reporting requirements.

(a) Reports to NRC Operations Center. (1) Each licensee shall report to the NRC Operations Center the events described in Appendix A to Part 70.

(2) Reports must be made by a knowledgeable licensee representative and by any method that will ensure compliance with the required time period for reporting.

(3) The information provided must include a description of the event and other related information as described in § 70.50(c)(1).

(4) Follow-up information to the reports must be provided until all information required to be reported in § 70.50(c)(1) of this subpart is complete.

(5) Each licensee shall provide reasonable assurance that reliable communication with the NRC Operations Center is available during each event.

(b) Written reports. Each licensee that makes a report required by paragraph (a)(1) of this section shall submit a written follow-up report within 30

days of the initial report. The written report must contain the information as described in § 70.50(c)(2).

#### § 70.76 Backfitting.

(a) For each licensee, this provision shall apply to Subpart H requirements as soon as the NRC approves that licensee's ISA Summary pursuant to § 70.66. For requirements other than Subpart H, this provision applies regardless of the status of the approval of a licensee's ISA Summary.

(1) Backfitting is defined as the modification of, or addition to, systems, structures, or components of a facility; or to the procedures or organization required to operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position.

(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.

(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.

(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 finds and declares, with appropriately documented evaluation for its finding, any of the following:

(i) That a modification is necessary to bring a facility into compliance with Subpart H of this part;

(ii) 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;

(iii) 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

(iv) That the regulatory action involves defining or redefining what 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 the 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 must include a statement of the objectives of and reasons for the modification and the basis for invoking the exception. If immediate 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 license commitments, or there are two or more ways to reach an adequate level of protection, then ordinarily the licensee is free to choose the way that 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 in order to complete the backfit;

(3) Potential change in the risk to the public from the accidental release of radioactive material and hazardous chemicals produced from licensed material;

(4) Potential impact on radiological exposure or exposure to hazardous chemicals produced from licensed material of facility employees;

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

(6) The potential safety impact of changes in facility or operational complexity, including the relationship to proposed and existing regulatory requirements;

(7) The estimated resource burden on the NRC associated with the proposed backfit and the availability of such resources;

(8) The potential impact of differences in facility type, design, or age on the relevancy and practicality of the proposed backfit; and

(9) Whether the proposed backfit is interim or final and, if interim, the justification for imposing the proposed backfit on an interim basis.

(c) No license will be withheld during the pendency of backfit analyses required by the Commission's rules.

(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 or her designee.

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### Subpart I—Modification and Revocation of Licenses

#### § 70.81 Modification and revocation of licenses.

(a) The terms and conditions of all licenses shall be subject to amendment, revision, or modification by reason of amendments to the Atomic Energy Act of 1954, or by reason of rules, regulations or orders issued in accordance with the Act or any amendments thereto;