material or chemicals produced from licensed materials which are on-site, or expected to be on-site as described in §70.61(b)(4) and (c)(4); (8) A descriptive list that identifies all items relied on for safety that are the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of §70.61; and (9) A description of the definitions of unlikely, highly unlikely, and credible as used in the evaluations in the integrated safety analysis.

§ 70.66 Additional requirements for approval of license application.

(a) An application for a license from an applicant subject to subpart H will be approved if the Commission determines that the applicant has complied with the requirements of §§70.21, 70.22, 70.23, and 70.60 through 70.65.

(b) Submittals by existing licensees in accordance with §70.62(c)(3)(i) will be approved if the Commission determines that:

(1) The integrated safety analysis approach is in accordance with the requirements of §§70.61, 70.62(c)(1), and 70.62(c)(2); and

(2) The schedule is in compliance with §70.62(c)(3)(ii).

(c) Submittals by existing licensees in accordance with §70.62(c)(3)(ii) will be approved if the Commission determines that:

(1) The requirements of §70.65(b) are satisfied; and

(2) The performance requirements in §70.61(b), (c) and (d) are satisfied, based on the information in the ISA Summary, together with other information submitted to NRC or available to NRC at the licensee’s site.

§ 70.72 Facility changes and change process.

(a) The licensee shall establish a configuration management system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel. This system must be documented in written procedures and must assure that the following are addressed prior to implementing any change:

1. The technical basis for the change;
2. Impact of the change on safety and health or control of licensed material;
3. Modifications to existing operating procedures including any necessary training or retraining before operation;
4. Authorization requirements for the change;
5. For temporary changes, the approved duration (e.g., expiration date) of the change; and
6. The impacts or modifications to the integrated safety analysis, integrated safety analysis summary, or other safety program information, developed in accordance with §70.62.

(b) Any change to site, structures, processes, systems, equipment, components, computer programs, and activities of personnel must be evaluated by the licensee as specified in paragraph (a) of this section, before the change is implemented. The evaluation of the change must determine, before the change is implemented, if an amendment to the license is required to be submitted in accordance with §70.34.

(c) The licensee may make changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, without prior Commission approval, if the change:

1. Does not:
   (i) Create new types of accident sequences that, unless mitigated or prevented, would exceed the performance requirements of §70.61 and that have not previously been described in the integrated safety analysis summary; or
   (ii) Use new processes, technologies, or control systems for which the licensee has no prior experience;

2. Does not remove, without at least an equivalent replacement of the safety function, an item relied on for safety that is listed in the integrated safety analysis summary and is necessary for compliance with the performance requirements of §70.61;

3. Does not alter any item relied on for safety, listed in the integrated safety analysis summary, that is the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of §70.61; and
§ 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

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