

Note: The [release notes](#) for the following draft rule text are posted as a separate file on this World Wide Web site.

Part 70 -- DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

1. The authority citation for Part 70 continues to read as follows:

AUTHORITY: Secs. 51, 53, 161, 182, 183, 68 Stat. 929, 930, 948, 953, 954, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2282, 2297f); secs. 201, as amended, 202, 204, 206, 88 Stat. 1242, as amended, 1244, 1245, 1246 (42 U.S.C. 5841, 5842, 5845, 5846). Sec. 193, 104 Stat. 2835, as amended by Pub. L. 104-134, 110 Stat. 1321, 1321-349 (42 U.S.C. 2243).

Sections 70.1(c) and 70.20a(b) also issued under secs. 135, 141, Pub. L. 97-425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 70.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 70.21(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 70.31 also issued under sec. 57d, Pub. L. 93-377, 88 Stat. 475 (42 U.S.C. 2077). Sections 70.36 and 70.44 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 70.61 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237). Section 70.62 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

2. The undesignated center heading "GENERAL PROVISIONS" is redesignated as "Subpart A -- General Provisions."

3. In 10 CFR 70.4, the definitions of Acute, Available and reliable to perform their function when needed, Configuration Management, Controlled site boundary, Critical mass of special nuclear material (SNM), Deviation from safe operating conditions, Double contingency, Hazardous chemicals produced from licensed material, Integrated safety analysis (ISA), Integrated safety analysis summary, Items relied on for safety, Management measures, New processes at existing facilities, Preliminary process hazards analysis (PHA), Unacceptable performance deficiencies, and Worker are added, in alphabetical order, as follows:

70.4 Definitions.

Acute as used in section 70.61θ of this Part means a single radiation dose or chemical exposure event or multiple radiation dose or chemical exposure events occurring within a short time (24 hours or less).

[Annotation: slightly modified]

Available and reliable to perform their function when needed as used in Subpart H of this Part means that, based upon the analyzed, credible conditions in the integrated safety analysis, items relied on for safety will perform their intended safety function and management measures will be implemented that ensure continuous compliance with the performance requirements of §70.61 of this Part, considering factors such as necessary maintenance, operating limits, common cause failures, and the likelihood and consequences of failure or degradation of the items and measures.

[Annotation: new definition]

Configuration management (CM) means ensuring, as part of the safety program, oversight and control of all design information, safety information, and modifications (both temporary and permanent) to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel.

[Annotation: new definition]

Controlled site boundary means the physical barrier surrounding the facility that is used by the licensee to control access. It may or may not coincide with the property boundary.

Critical mass of special nuclear material (SNM) means special nuclear material in a quantity exceeding 700 grams of contained uranium-235; 520 grams of uranium-233; 450 grams of plutonium; 1500 grams of contained uranium-235, if no uranium enriched to more than 4 percent by weight of uranium-235 is present; 450 grams of any combination thereof; or one-half such quantities if massive moderators or reflectors made of graphite, heavy water, or beryllium may be present.

Deviation from safe operating conditions means that a parameter that is controlled to ensure adequate protection is outside its established safety limits, or that an item relied on for safety has been lost or has been degraded so that it cannot perform its intended function.

Double contingency means a process design that incorporates sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.

Hazardous chemicals produced from licensed materials means substances having licensed material as precursor compound(s) or substances that physically or chemically interact with licensed materials; that are toxic, explosive, flammable, corrosive, or reactive to the extent that they can endanger life or health if not adequately controlled. These include substances commingled with licensed material, and include substances such as hydrogen fluoride that is produced by the reaction of uranium hexafluoride and water, but do not include substances prior to process addition to licensed material or after process separation from licensed material.

[Annotation: modified version of the NEI-proposed definition. The terms, process addition and process separation are used to indicate an intentional activity (as opposed to an accidental separation)]

Integrated safety analysis (ISA) means a systematic analysis to identify plant and external hazards and their potential for initiating accident sequences, the potential accident sequences, their likelihood and consequences, and the site, structures, systems, equipment, components, and activities of personnel that are relied on for safety. As used here, *integrated* means joint consideration of, and protection from, all relevant hazards, including radiological, nuclear criticality, fire, and chemical. However, with respect to compliance with the regulations of this Part, the focus of the integrated safety analysis is limited to the effects of all relevant hazards on radiological safety, prevention of nuclear criticality accidents, or chemical hazards directly associated with NRC licensed radioactive material.

Integrated safety analysis summary means the document submitted in conjunction with the license application, license amendment application, or license renewal application that provides a synopsis of the results of the integrated safety analysis and informs the Commission of the nature of the site, facility, and processes; the qualifications of individuals that performed the integrated safety analysis; the methodologies used; the accident sequences that, unless prevented or mitigated, could exceed the performance requirements in section §70.61 of this Part; the items relied on for safety that protect against those accidents, the measures that are implemented to

ensure the items are available and reliable to perform their function when needed; and the evaluations for compliance with the performance requirements of §70.61.

[Annotation: new definition. Also, see §70.65, which now specifies that ISA summary is submitted “on the docket” but not “in the license”].

Items relied on for safety means structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility or to mitigate their potential consequences.

Management measures mean the functions performed by the licensee, generally on a continuing basis, that are applied to items relied upon for safety, identified in the integrated safety analysis, to ensure they are available and reliable to perform their functions when needed. Management measures include configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance systems.

[Annotation: new definition]

New processes at existing facilities means systems-level or facility-level design changes to process equipment, process technology, facility layout, or types of licensed material possessed or used. This definition does not, generally, include component-level design changes or equipment replacement.

[Annotation: new definition]

Preliminary process hazards analysis (PHA) means an analysis undertaken during the early design or development phases of a process to identify the principal hazards and to enable them to be eliminated, minimized or controlled with minimal cost or disruption. The analysis also assists in identification and optimization of potential corrective, mitigative or preventive safety controls and management measures.

[Annotation: new definition]

Unacceptable performance deficiencies means deficiencies in the items relied on for safety or the measures used to assure the items are available and reliable to perform their function when needed, that need to be corrected to ensure an adequate level of protection as defined in 10 CFR 70.61(b), (c), or (d).

Worker means an individual whose assigned duties in the course of employment involve exposure to radiation and/or radioactive material from licensed and unlicensed sources of radiation (i.e., an individual who is subject to an occupational dose as in 20 CFR 20.1003).

4. The undesignated center heading “EXEMPTIONS” is redesignated as “Subpart B -- Exemptions.”

§§ 70.13a and 70.14 [Redesignated]

5. Sections 70.13a and 70.14 are redesignated as §§ 70.14 and 70.17, respectively.

6. Section 70.15 is added to read as follows:

70.15 Nuclear reactors.

The regulations in Subpart H do not apply to nuclear reactors licensed under 10 CFR Part 50.

7. The undesignated center heading “GENERAL LICENSES” is redesignated as “Subpart C -- General Licenses.”

8. The undesignated center heading “LICENSE APPLICATIONS” is redesignated as “Subpart D -- License Applications.”

§ 70.22 [amended]

9. In 10 CFR 70.22, paragraph (f) is removed and paragraphs (g) through (n) are redesignated as (f) through (m).

§ 70.23 [amended]

10. In 10 CFR 70.23, paragraph (a)(8) is removed, paragraph (b) is removed and reserved, and paragraphs (a)(9) through (a)(12) are redesignated as (a)(8) through (a)(11), respectively.

11. The undesignated center heading “LICENSES” is redesignated as “Subpart E -- Licenses.”

12. The undesignated center heading “ACQUISITION, USE AND TRANSFER OF SPECIAL NUCLEAR MATERIAL, CREDITORS’ RIGHTS,” is redesignated as “Subpart F -- Acquisition, Use, And Transfer Of Special Nuclear Material, Creditors’ Rights.”

13. The undesignated center heading “SPECIAL NUCLEAR MATERIAL CONTROL RECORDS, REPORTS AND INSPECTIONS” is redesignated as “Subpart G -- Special Nuclear Material Control Records, Reports, And Inspections.”

14. The undesignated center heading “MODIFICATION AND REVOCATION OF LICENSES” is redesignated as “Subpart I -- Modification and Revocation of Licenses.”

§§ 70.61 and 70.62 [redesignated]

15. Sections 70.61 and 70.62 are redesignated as §§70.81 and 70.82, respectively.

16. The undesignated center heading “ENFORCEMENT” is redesignated as “Subpart J -- Enforcement.”

§§ 70.71 and 70.72 [redesignated]

17. Sections 70.71 and 70.72 are redesignated as §§70.91 and 70.92, respectively.

18. In Part 70, a new “SUBPART H” (§§ 70.60 - 70.74) is added to read as follows:

Subpart H - Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material.

Sec.

[70.60](#) [Applicability](#) [*Annotation: moved from 70.60(a) of SECY 98-185*]

[70.61](#) [Performance Requirements](#).

[70.62](#) [Safety Program and Integrated Safety Analysis](#)

[70.64](#) [Requirements for new facilities or new processes at existing facilities](#).

[70.65](#) [Additional content of applications](#).

[70.66](#) [Additional requirements for approval of license application](#).

[70.72 Facility changes and change process.](#) *[Annotation: There are two options in this posting]*

[70.73 Renewal of licenses.](#)

[70.74 Additional reporting requirements.](#) *[Annotation: not included in this posting]*

70.60 Applicability

The regulations in §70.61 through §70.74 shall apply, in addition to other applicable Commission regulations, to each applicant or licensee that is or plans to be engaged in enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, fabrication of mixed-oxide fuel or fuel assemblies, scrap recovery, decommissioning of facilities used for these activities, or any other activity that the Commission determines could significantly affect public health and safety.

70.61 Performance Requirements

(a) Each applicant or licensee shall demonstrate, in the integrated safety analysis performed in accordance with §70.62, compliance with the performance requirements in paragraphs (b), (c), and (d) of this section.

[annotation: requirements of §70.60(a) in SECY 98-185 are moved to §70.60; requirements of §70.60(d) of SECY 98-185 dealing with the safety program and ISA contents have been moved into §70.62 (below) for clarity]

(b) The risk of each credible high-consequence event must be limited, unless the event is highly unlikely, through the application of engineered controls, administrative controls, or both, that reduce the likelihood of occurrence of the event or its consequence. Application of additional controls is not required for those high-consequence events demonstrated to be highly unlikely. High-consequence events are those internally or externally initiated events that result in:

- (1) an acute worker dose of 1 Sv (100 rem) or greater total effective dose equivalent;
- (2) an acute dose outside the controlled site boundary of 0.25 Sv (25 rem) or greater total effective dose equivalent;
- (3) an intake outside the controlled site boundary of 30 mg or greater of uranium in soluble form; or

(4) an acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that: (i) could endanger the life of a worker, or (ii) outside the controlled site boundary, could lead to irreversible or other serious, long-lasting health effects. If an applicant possesses or plans to possess quantities of material capable of such chemical exposures, then the applicant shall propose appropriate quantitative standards for these health effects, as Part of the application information submitted pursuant to Section 70.65 of this Part.

[annotation: The ERPG and AEGL would be identified as acceptable standards in the SRP. Items (b)(5) and (c)(4) cover, for example, "HF;" and rely on §70.4 definitions, hazardous chemicals produced from licensed material and acute]

(c) The risk of each credible intermediate-consequence event must be limited, unless the event is unlikely, through the application of engineered controls, administrative controls, or both, that reduce the likelihood of occurrence of the event or its consequence. Application of additional controls is not required for those intermediate-consequence events demonstrated to be unlikely. Intermediate-consequence events are those internally or externally initiated events, that are not high-consequence events, that result in:

- (1) an acute worker dose of 0.25 Sv (25 rem) or greater total effective dose equivalent;
 - (2) an acute dose outside the controlled site boundary of 0.05 Sv (5 rem) or greater total effective dose equivalent;
 - (3) a 24-hour averaged release of radioactive material outside the restricted area in concentrations exceeding 5000 times the values in Table 2 of Appendix B to 10 CFR Part 20;
- or
- (4) an acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that: (i) could lead to irreversible or other serious, long-lasting health effects to a worker, or (ii) outside the controlled site boundary, could cause mild transient health effects. If an applicant possesses or plans to possess quantities of material capable of such chemical exposures, then the applicant shall propose appropriate quantitative standards for these health effects, as part of the application information submitted pursuant to Section 70.65 of this Part.

(d) In addition to complying with paragraphs (b) and (c) of this section, the risk of nuclear criticality accidents must be limited by assuring that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety. Preventive controls and measures shall be the primary means of protection against nuclear criticality accidents.

[annotation: prevention of criticality is stressed over mitigation. This paragraph is consistent with ANSI/ANS 8.1 - see §§4.1.2 and 4.2.3 of that standard].

(e) Each engineered or administrative control or control system necessary to comply with subsection (b), (c), or (d) of this section shall be designated as an item relied on for safety. The safety program, established and maintained pursuant to §70.62 of this Part, shall ensure that each item relied on for safety will be available and reliable to perform its intended function when needed and in the context of the performance requirements of this section.

70.62 Safety Program and Integrated Safety Analysis

(a) *safety program.* (1) Each licensee shall establish and maintain a safety program that ensures that actions taken will provide adequate protection from licensed materials, for worker and public health and safety and of the environment. The safety program may be graded such that management measures applied are commensurate with the reduction of the risk attributable to that item. Requirements for the safety program, including process safety information, integrated safety analysis, and management measures, are described in subsections (b) through (d) of this section.

[Annotation: in general (except 70.62(c)(3)), this section identifies the information that is maintained on-site, while 70.65 identifies the information that is submitted, on the docket, to NRC during licensing].

[Annotation: note "may be..." meaning the grading of safety program is permitted but not required].

[Annotation: "integrated safety analysis" and "management measures" are defined in §70.4]

(2) Each licensee shall establish and maintain records that demonstrate compliance with the requirements of this section.

[Annotation: (a)(1) and (a)(2) parallel §70.60(a) and §70.60(d)(6), respectively, in SECY 98-185]

(b) *process safety information*. Each licensee or applicant shall compile and maintain a set of process safety information to enable the performance of an integrated safety analysis. This process safety information must include information pertaining to the hazards of the materials used or produced in the process, information pertaining to the technology of the process, and information pertaining to the equipment in the process.

[Annotation: parallels §70.60(d)(1) in SECY 98-185]

(c) *integrated safety analysis*. (1) Each licensee or applicant shall conduct an integrated safety analysis, that is of appropriate detail for the complexity of the process, that identifies:

- (i) radiological hazards related to possessing or processing licensed material at its facility;
- (ii) chemical hazards of licensed material or hazardous chemicals produced from licensed material;
- (iii) facility hazards (e.g., chemical, fire, electrical and mechanical) which could affect the safety of licensed materials and thus present an increased radiological risk;

[Annotation: (i)-(iii) modified slightly from draft rule to explicitly address OSHA MOU]

- (iv) potential accident sequences caused by process deviations or other events internal to the plant and credible external events, including natural phenomena;
- (v) the consequence and the likelihood of occurrence of each potential accident sequence identified pursuant to paragraph (c)(1)(iv) of this section, and the methods used to determine the consequences and likelihoods; and
- (vi) each item relied on for safety identified pursuant to section 70.61(e) of this Part, the characteristics of its preventive, mitigative, or other safety function, and the assumptions and conditions under which the item is relied upon to support compliance with the performance requirements of §70.61 .

(2) *integrated safety analysis team qualifications*. In order to assure the adequacy of the integrated safety analysis, the analysis shall be performed by a team with expertise in engineering and process operations. The team shall include at least one person who has experience and knowledge specific to each process being evaluated, and persons who have experience in nuclear criticality safety, radiation safety, fire safety, and chemical process safety. One member of the team must be knowledgeable in the specific integrated safety analysis methodology being used.

[Annotation: paragraph (c)(2) added to match 29 CFR 1910.119(e)(4)]

(3) *Requirements for existing licensees.* Individuals holding an NRC license on <the effective date of this rule> shall, with regard to existing licensed activities:

(i) within 6 months of <the effective date of this rule>, submit, for NRC approval, a plan that describes the integrated safety analysis approach that will be used, the processes that will be analyzed, and the schedule for completing the analysis of each process. Pending the correction of unacceptable performance deficiencies identified by the integrated safety analysis, the licensee shall implement appropriate compensatory measures to ensure adequate protection.

(ii) within 4 years of <the effective date of this rule>, unless otherwise specified by the conditions of a license held on <the effective date of this rule>, complete an integrated safety analysis, correct all unacceptable performance deficiencies, and submit an integrated safety analysis summary in accordance with §70.65 or the approved plan submitted under paragraph (c)(3)(i) of this section.

[Annotation: (c)(3) parallels §70.62(a)(1)-(3) from SECY 98-185.

[Annotation: the term unacceptable performance deficiencies is defined in §70.4]

[Annotation: section 70.62(d) revised in-total from §70.60(d)(3) in SECY 98-185.]

(d) *management measures.* Each applicant or licensee shall establish safety program management measures to provide continuing assurance of compliance with the performance requirements of section 70.61. The measures applied to a particular engineered or administrative control may be commensurate with the reduction of the risk attributable to that control. The safety program management measures shall ensure that engineered and administrative controls that are identified as relied on for safety pursuant to §70.61(e) of this Part are designed, implemented, and maintained, as necessary, to ensure they are available and reliable to perform their function when needed, in the context of compliance with the performance requirements of section 70.61 of this Part.

70.64 Requirements for new facilities or new processes at existing facilities

(a) *Baseline design criteria.* Each prospective applicant or licensee of the types listed in §70.60 of this Part shall address the following baseline design criteria in the design of new facilities or design of new processes at existing facilities. Applicants shall address these baseline design

criteria in establishing minimum requirements for their process design and description. Licensees shall maintain the application of these criteria unless the evaluation performed pursuant to paragraph (c) of this section demonstrates that a given item is not relied on for safety or does not require adherence to the specified criteria.

(1) Quality standards and records. The design must be established and implemented in accordance with a quality assurance program, to provide adequate assurance that items relied on for safety will be available and reliable to perform their function when needed. Appropriate records of these items must be maintained by or under the control of the licensee throughout the life of the facility.

(2) Natural phenomena hazards. The design must provide for adequate protection against natural phenomena with consideration of the most severe documented historical events for the site.

(3) Fire protection. The design must provide for adequate protection against fires and explosions.

(4) Environmental and dynamic effects. The design must provide for adequate protection from environmental conditions and dynamic effects associated with normal operations, maintenance, testing, and postulated accidents that could lead to loss of safety functions.

(5) Chemical protection. The design must provide for adequate protection against chemical hazards that may impact the storage, handling, and processing of licensed material, and against chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material.

(6) Emergency capability. The design must provide for emergency capability to maintain control of:

- (i) Licensed material;
- (ii) Evacuation of personnel; and
- (iii) Onsite emergency facilities and services that facilitate the use of available offsite services.

[Annotation: the statements of consideration should clarify that (6)(i) does not mean "material control and accountability." One example of (6)(i) would be to provide in the design for dikes around liquid bearing equipment].

(7) Utility services. The design must provide for continued operation of essential utility services, including reliable and timely emergency power to items relied on for safety.

(8) Inspection, testing, and maintenance. The design of items relied on for safety must provide for periodic inspection, testing, and maintenance, to ensure their continued function and readiness.

(9) Criticality control. The design must provide for criticality control including adherence to the double-contingency principle.

(10) Instrumentation and controls. The design must provide for inclusion of instrumentation and control systems to monitor and control the behavior of items relied on for safety.

(b) Facility and system design and plant layout must be based on defense-in-depth practices. The design process shall assure that, to the extent practicable, passive systems are selected over active systems, to increase overall system reliability; and features are incorporated that enhance safety by reducing challenges to items relied on for safety. For new processes at existing facilities, the design of the new process shall, to the extent practicable, correct unacceptable performance deficiencies that are identified through the performance of the integrated safety analysis for the existing processes.

(c) *Preliminary process hazards analysis*. Each prospective applicant for a license or license amendment to operate a new facility or a new process at an existing facility shall:

(1) Initially design the facility or process to satisfy, with incorporated margins for uncertainty, the performance requirements of §70.610, the criticality monitoring and alarm requirements of §70.24, and the baseline design criteria in paragraph (a) of this section;

(2) Perform a preliminary process hazards analysis on the initial design that evaluates the initial design against the requirements in paragraph (c)(1) of this section and identifies potential design and engineered features that are projected to be relied on for safety;

(3) Identify in the preliminary process hazards analysis:

(i) the defense-in-depth strategy and conceptual means for compliance with the requirements referenced in paragraph (c)(1) of this section, for the anticipated higher-risk (i.e., consideration of consequence and likelihood) facility accident sequences;

(ii) administrative controls that supplement the design and engineered controls, if the administrative controls are expected to be identified as relied on for safety; and

(iii) any proposed, facility-specific or process-specific relaxations or additions to the baseline design criteria specified in §70.64(a), and a justification for any relaxation.

(4) Provide the preliminary process hazards analysis to NRC, for information, before proceeding with construction of the facility or process (NRC approval of the preliminary process hazards analysis is not required). The level of detail for the preliminary process hazards analysis that is provided to NRC shall be consistent with the maturity of the evolving design and sufficient to provide reasonable assurance of consistency of the design and design process with the requirements in this section; and

(5) Identify in the integrated safety analysis summary submitted in accordance with section §70.62(c)(3) of this Part, any inconsistencies between the preliminary process hazards analysis and the integrated safety analysis summary.

(d) For a new process at an existing facility subject to this section, the licensee shall file an application for amendment to the license in accordance with sections 70.21, 70.22, 70.34, and 70.65 of this Part, as applicable. Nothing in this section shall be construed as providing relief from compliance with any of the requirements in sections 70.21(f) and 70.23(a)(7) of this Part, 10 CFR Part 51, or other regulations.

70.65 Additional content of applications.

(a) In addition to the contents required by §70.22, each application must include a description of the applicant's safety program established under §70.62, including a summary of the integrated safety analysis and the management measures established to ensure the availability and reliability of items relied on for safety when needed and in the context of the performance requirements of §70.61.

(b) The summary of the integrated safety analysis shall be submitted with the license, or renewal application (and amendment application as necessary), but shall not be incorporated in the license. However, changes to the integrated safety analysis summary shall meet the conditions of §70.72. The summary of the integrated safety analysis shall contain:

[Annotation: §70.65(b) indicates that changes to the ISA summary would NOT require a license amendment]

(1) a description of the site with emphasis on those factors that could affect safety (i.e., meteorology, seismology);

- (2) a description of the facility with emphasis on those areas that could affect safety;
- (3) a description of each process analyzed in the integrated safety analysis including the theory of operation and information that demonstrates the licensee's compliance with the design requirements for criticality monitoring and alarms in §70.24;
- (4) a description of the integrated safety analysis team, qualifications, and the methods used to perform the integrated safety analysis;
- (5) a list of the accident sequences mitigated or prevented by more than one item relied on for safety including an evaluation of how the licensee meets the performance requirements in §70.61;
- (6) a list briefly describing all items relied on for safety which are identified pursuant to §70.61(e) in sufficient detail to explain their safety function;

[Annotation: this should be a brief list with only enough detail to indicate what safety function the item is performing, but should be more detailed than simply an item's serial number]

- (7) a list of all processes (defined as a single reasonably simple integrated unit operation within an overall production line) that contain an accident sequence for which the consequences unless mitigated or prevented by more than one or more items relied on for safety, would exceed the threshold performance requirements of §70.61. This must include the maximum consequences for non-criticality radiological, chemical and criticality for each process;

[Annotation: this is not asking for any complete accident sequences, only a list of the processes which could produce intermediate and high consequences and the maximum consequences in each area]

- (8) a description of the proposed quantitative standards used to assess the consequences from acute chemical exposure to licensed material or chemicals produced from licensed material materials which are on-site, or expected to be on-site as described in §70.61(b)(4) and (c)(4);
- (9) a descriptive list of any item relied on for safety that is the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of §70.61; and
- (10) a description of the definitions of likely, unlikely, highly unlikely, and credible as used in the evaluations in the integrated safety analysis.

70.66 Additional requirements for approval of license application.

An application for a license to possess a critical mass of special nuclear material will be approved if the Commission determines that the applicant has complied with the requirements of §70.23 and §§70.60 through 70.65.

[Annotation: this is a renumbered section 70.68 from SECY 98-185. It's content is unchanged. Section 70.66 that was in SECY 98-185, on records, was deleted because it was redundant to the combination of the existing recordkeeping requirements, the draft requirements in §70.62, and the requirements to record changes planned for §70.72]

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 shall be documented in written procedures and shall 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;
- (4) necessary time period for the change;
- (5) authorization requirements for the change;
- (6) for temporary changes, the approved duration (e.g., expiration date) of the change; and
- (7) 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) Except for a new process subject to the requirements of §70.64, any change to site, structures, processes, systems, equipment, components, computer programs, and activities of personnel shall 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) Employees involved in operating a process, maintenance employees, and contract employees whose job tasks will be affected by a change shall be informed of, and trained in, the change prior to start-up of the process or portion of the process.

Paragraph (d) Option 1

(d) 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 create new unmitigated accident sequences that exceed the performance requirements of section 70.61; or

(2) does not remove, without an equivalent replacement, an item relied on for safety that is listed in the integrated safety analysis summary;

(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;

[Annotation: routine maintenance activities authorized under § 70.62 (i.e., painting, replacing worn parts, like for like replacements) are not considered changes]

(4) is not otherwise prohibited by this section, license condition, or order.

(e) *[Only applies to Option 1]* In addition to complying with the requirements of paragraph (d), any licensee for which the initial facility license was issued after [the effective date of this rule]; and those licensees that are specified by the Director of the Office of Nuclear Materials Safety and Safeguards, by license condition or order can make changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel without prior NRC approval, only if the change does not result in more than a minimal increase in the risk of an accident previously evaluated in the integrated safety analysis.

(f) *[Only applies to Option 1]* Upon license renewal, or as may be otherwise specified by order by the NRC Director of the Office of Nuclear Materials Safety and Safeguards, a licensee may be relieved from the requirements of (e) of this section provided that future changes will comply with the requirements of (d) of this section.

Paragraph (d) Option 2

(d)(1) A licensee may make changes in the facility described in the integrated safety analysis and integrated safety analysis summary, make changes in the procedures as described in the integrated safety analysis and integrated safety analysis summary, and conduct test or experiments not described in the integrated safety analysis or integrated safety analysis summary without obtaining a license amendment pursuant to §70.34 only if:

- i) a change to the license application or license condition is not required, and
- ii) The change, test or experiment does not meet any of the criteria in Paragraph (d)(2) of this section.

2) A licensee shall obtain a license amendment pursuant to §70.34 prior to implementing a change, test, or experiment if the change, test or experiment would:

- i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the integrated safety analysis;
- ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of an item relied on for safety previously evaluated in the integrated safety analysis;
- iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the integrated safety analysis;
- iv) Result in more than a minimal increase in the consequences of a malfunction of an item relied on for safety previously evaluated in the integrated safety analysis;
- v) Create the possibility for an accident of a different type than previously evaluated in the integrated safety analysis;
- vi) Create the possibility for a malfunction of an item relied on for safety with a different result than any previously evaluated in the integrated safety analysis; or
- vii) Result in more than a minimal change in a method of analysis described in the integrated safety analysis .

(g)(1) For any changes that affect the integrated safety analysis summary, as submitted in accordance with 70.65, but do not require NRC pre-approval, the licensee shall submit revised pages to the integrated safety analysis summary, to NRC, within 90 days of the change.

(2) For changes that require pre-approval under §70.72, the licensee must submit an amendment request to the NRC in accordance with §70.34 and §70.65.

(3) A summary of all changes to the process safety information, integrated safety analysis, or management measures required by section 70.62 of this Part, that are made without prior Commission approval, shall be submitted to NRC every 6 months.

[Annotation: this is simply a list containing a summary of the changes made and does not require the submission of change pages or all of the details involved in the determination to make the change.]

(h) If a change covered by §70.72 results in a change to the on-site process safety information, integrated safety analysis, or management measures required by section 70.62 of this Part, the affected documentation shall be updated promptly.

(i) 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 (d or e) 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](#). Information provided in applications, including the integrated safety analysis summary, must be current, complete, and accurate in all material respects. 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.

[Annotation: except for the change in terminology from 'results of the ISA' to 'ISA Summary,' this section is unchanged from SECY 98-185]

70.74 Additional reporting requirements.

[Annotation: This section is under development, it will be posted on this website at a later date]