For the website, December 17, 1998

The views expressed in this document do not necessarily represent the views of the U.S. Nuclear Regulatory Commission (NRC). The information in this document represents NRC staff-developed draft language for possible inclusion in a package to be provided for Commission approval for publication as a proposed rule. In accordance with Commission direction, NRC staff is providing this information at this time for preliminary public comment and discussion. The public will have an opportunity also for formal comment once the Commission approves a rule for publication as a proposed rule.

Contents:

1. Release notes

A. We have attempted to provide annotations [in redlined-brackets] that identify parallels to the SECY 98-185 version of the rule or call attention to certain clarifying information or other changes. These annotations will be put on the website but removed in the proposed rule package language. (Appropriate parts of this information would reappear in the rule package's statement of considerations.) The following redrafts are revisions-in-total of sections §70.60 and §70.62 of the SECY 98-185 version of the rule. The SECY 98-185 version of the rule may be viewed or downloaded from this page by clicking on the highlighted link or by setting your browser to
http://techconf.llnl.gov/cgi-bin/library?source=*&library=dom_lic_lib&file=042-0035.wp
and clicking on either the WordPerfect (wp) or html version of 042-0002.

B. The purpose of the following redrafts of §70.60, §70.62, and related definitions was to clarify the apparent confusion regarding the rule being "consequence-driven" as opposed to "risk-informed." This confusion was a major topic of discussion at the December 3-4, 1998, public meeting on the draft rule. Another purpose was to clarify the responsibilities under NRC's 1988 memorandum of understanding (MOU) with the Occupational Health and Safety Administration (OSHA) [see note D, below], and to incorporate, in part, the comments provided by the Nuclear Energy Institute (NEI), in a letter dated November 4, 1998, on NRC regulation of chemical hazards. To accomplish these purposes, we combined the consequence and likelihood sections, to reflect risk, and separated the performance requirements from the descriptive requirements for integrated safety analyses (ISAs) and safety programs.

C. The fact that a topic does not appear in the following draft rule language does not indicate that the topic will not be reinserted into the draft language that the staff will submit for Commission approval for publication as a proposed rule. For example, in the draft rule language below, the annotation after section §70.62(c)(5) mentions that the staff is currently evaluating the appropriate contents and location for the requirements for preliminary integrated safety analysis. Thus, preliminary integrated safety analysis language was not included in this web posting even though it was in the parallel section in SECY 98-185. However, language regarding this subject will be included in the draft rule language. As another example, the draft

rule below (see 70.60(b)(5) and (c)(4)) does not reference the quantitative ERPG and AEGL chemical consequence standards, but adopts equivalent, qualitative language. We are still considering the merits of this approach.

D. As mentioned above, we believe the redrafts of these two rule sections provide clearer treatment of the 1988 NRC-OSHA MOU on responsibilities for hazards at NRC licensed facilities. Specifically, item (c) of the NRC-OSHA MOU states that NRC has the general purview for regulating "plant conditions which affect the safety of radioactive materials and thus present an increased radiation risk to workers." As an example, NRC's regulatory purview would include the impacts of chemical system failures or fires that cause failure of a nuclear safety system, and NRC's purview would include impacts of plant conditions on the ability of operators to perform an activity (administrative control) that is relied on for nuclear safety. The draft rule addresses these responsibilities in two ways/cases, the performance requirements (70.60) and the ISA requirements (70.62(c)(1)(iii)). Language very similar to item (c) of the NRC-OSHA MOU now appears in the ISA requirements in §70.62(c)(1)(iii). Also, through §70.60, if the failure of a "non-nuclear" system could disable a nuclear system and cause an unacceptable risk [such as the frequency of a worker dose exceeding 25 rem being greater than "unlikely"-- per 70.60(c)(1)]; then 70.60(d) would require that the non-nuclear system be designated as an "item relied on for safety" and controlled by the safety program (viz., it would be under NRC's regulatory purview). In addition, 70.60(b) and (c) specify risk-based standards for "hazardous chemicals produced from licensed material," such as HF gas accidentally released from a reaction of UF_6 with water. Sections 70.62(c)(1)(i) and (ii) also contain statements that correspond to MOU items (a) and (b). Inclusion of this language assures that each MOU item for which NRC has general regulatory purview will be explicitly addressed by licensees in the ISA.

E. We have added two paragraphs, §70.62(c)(2) and §70.62(c)(3), that deal with integrated safety analysis (ISA) team qualifications and ISA revalidation, respectively. These sections are very similar to requirements of the OSHA process safety management rule (specifically, 29 CFR 1910.119(e)(4) and (e)(6)). We believe that inclusion of these sections may be appropriate, not only for consistency with OSHA, but also in consideration of the further development of requirements on the submittal and contents of the ISA summary, what is "on the docket" and/or "in the license," and the process (e.g., NRC pre-approval or not) for making changes to the plant and items relied on for safety. Revalidating the ISA will also permit an opportunity for consideration and incorporation of recent industry and facility accidents into the ISA, and possibly an opportunity to incorporate different experiences (e.g., if staff changed) into the updated ISA.

2. Clarifying modifications to 70.60

70.60 Performance Requirements for Certain Licensees Authorized to Possess Special Nuclear Material in Quantities Sufficient to Form a Critical Mass.

(a) Each applicant or licensee required to establish and maintain a safety program pursuant to §70.62 of this part shall demonstrate, in the integrated safety analysis, compliance with the performance requirements in paragraphs (b) and (c) of this section. [annotation: most requirements of previous 70.60(a) and 70.60(d), 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 (except for nuclear criticality) its consequence. Application of further 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) a nuclear criticality;
(2) an acute worker dose of 1 Sv (100 rem) or greater total effective dose equivalent;
(3) an acute dose outside the controlled site boundary of 0.25 Sv (25 rem) or greater total effective dose equivalent;
(4) an intake outside the controlled site boundary of 30 mg or greater of uranium in soluble form; or
(5) 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 a new §70.4 definition, *hazardous chemicals produced from licensed material*]

[annotation: "acute" is defined in section 70.4 (see below)]

(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 further 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) Each engineered or administrative control necessary to comply with subsection (b) or (c) 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 perform its intended function when needed and in the context of the performance

requirements of this section.

3. Clarifying modifications to 70.62

70.62 Safety Program, Integrated Safety Analysis, and Filing of Integrated Safety Analysis Summary

(a) *safety program.* (1) Each licensee engaged in enriched uranium processing, uranium fuel fabrication, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, mixed-oxide fuel fabrication, scrap recovery, or any other activity that the Commission determines could significantly affect public health and safety, 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 that item's reduction of the risk. 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: note "may be..." - grading of safety program is permitted but not required].

[annotation: by "management measures" we mean measures that assure that items used for safety will be available and perform their functions reliably when needed.]

(2) Each licensee shall establish records that demonstrate that the requirements of this section have been met. Each licensee shall maintain these records until license termination. [annotation: (a)(1) and (a)(2) parallels 70.60(a) and 70.60(d)(6), respectively, in SECY 98-185; note change to "license termination" instead of "lifetime of the plant"]

(3) If the decommissioning of a facility involves potentially hazardous activities such as chemical treatment of wastes, each licensee shall perform an ISA of the decommissioning process, demonstrate compliance with the performance requirements of section §70.60 of this part, and submit the results to NRC for approval before beginning such decommissioning activities. [annotation: parallels 70.62(b) 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:

(i) identifies radiological hazards resulting from possessing or processing licensed material at its facility;

(ii) identifies chemical hazards of licensed material or hazardous chemicals produced from licensed material resulting from possessing or processing licensed material at its facility;

(iii) identifies 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) identifies and provides the basis for potential accident sequences caused by process deviations or other events internal to the plant and credible external events, including natural phenomena;

(v) identifies and provides the basis for the consequence and the likelihood of occurrence of each potential accident sequence identified pursuant to paragraph (b)(1)(iv) of this section; and

(vi) identifies and provides the basis for each item relied on for safety identified pursuant to section §70.60(d) of this Part, and the characteristics of its preventive, mitigative, or other safety function.

(2) *integrated safety analysis team qualifications.* [annotation: this paragraph added to match 29 CFR 1910.119(e)(4)] In order to assure the adequacy of the integrated safety analysis, the integrated safety analysis shall be performed by a team with expertise in engineering and process operations, and the team shall include at least one employee who has experience and knowledge specific to each process being evaluated, and employees who have experience in nuclear criticality safety, radiation safety, fire safety, and chemical process safety. Also, one member of the team must be knowledgeable in the specific integrated safety analysis methodology being used.

(3) *integrated safety analysis revalidation.* The integrated safety analysis shall be periodically revalidated by a team meeting the requirements of paragraph (c)(2) of this section, to ensure that the integrated safety analysis is consistent with the current facility. The minimum period for such revalidation shall be at each filing of an application for renewal of a license pursuant to section §70.33 of this part [annotation: this paragraph added to match 29 CFR 1910.119(e)(6). The wording permits a more frequent period between revalidations, e.g., every 5 years as specified in 29 CFR 1910.119(e)(6) for the process hazards analysis].

(4) *integrated safety analysis summary.* Each applicant or licensee shall submit an integrated safety analysis summary to NRC for approval, as appropriate: (i) in accordance with the requirements and schedule in paragraph (c)(5) of this section, if applicable; or (ii) as part of the license application contents, amendment application contents, or renewal application contents identified in §§70.21, §70.22, §70.33, §70.34, and §70.65.
[annotation: this paragraph requires the submitted ISA-summary (which used to be called 'results of the ISA.' This paragraph (c)(4) parallels 70.62(a)(1)-(3) that were in SECY 98-185). The contents of applications section (70.65, under development) and the definitions (70.4) will identify the contents of the ISA summary and what is to be "in the license," "on the docket," etc. We plan to move the SECY 98-185 sentence "The process description in the integrated safety analysis summary must include information that demonstrates the licensee's compliance with the design requirements for criticality monitoring and alarms in §70.24." to §70.65 (contents of applications) since it addresses the contents of the ISA summary and license application. Note also that the correction of 'unacceptable vulnerabilities' identified by the ISA, that was in the parallel section of

SECY 98-185, is now handled by 70.60(a)]

(5) *filing by 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 compliance 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 vulnerabilities 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 vulnerabilities, and submit an integrated safety analysis summary in accordance with paragraph (c)(4) of this section or the approved compliance plan submitted under paragraph (c)(5)(i) of this section.

[annotation: (c)(4) and (5) parallel 70.62(a)(1)-(3) that were in SECY 98-185. We are currently reevaluating: (1) if preliminary ISA requirements should appear here (as they did in the SECY 98-185 version), or another section (e.g., §70.64); and (2) the nature and contents of the preliminary ISA requirements. After this reevaluation, we may reinsert language here that parallels the old 70.62(a)(3)]
[annotation: unacceptable vulnerabilities is defined in Section 70.4 (see below)]

(d) *management measures.* [annotation: except as noted, this section parallels 70.60(d)(3) in SECY 98-185] To ensure that each item relied on for safety will perform its intended function when needed, the integrated safety analysis shall be used by licensees to establish safety program management measures. The safety program management measures shall ensure that:

(1) Engineered controls that are identified as relied on for safety pursuant to section §70.60(d) of this part are designed, constructed, inspected, calibrated, tested, and maintained, as necessary, to ensure the ability to perform their intended functions when needed. Items subject to this requirement include but are not limited to: principal structures of the plant; passive barriers relied on for safety (e.g., piping, glove boxes, containers, tanks, columns, vessels); active systems, equipment, and components relied on for safety; sampling and measurement systems used to convey information about the safety of plant operations; instrumentation and control systems used to monitor and control the behavior of systems relied on for safety; and utility service systems relied on for safety.

(2) Personnel are trained, tested, and retested, as necessary, to ensure that they understand, recognize the importance of, and are qualified to perform their duties that are identified as relied on for safety pursuant to section §70.60(d) of this part;

(3) Procedures that are identified as relied on for safety pursuant to section §70.60(d) of this part are developed, reviewed, approved, and distributed to ensure that personnel are able to perform the duties relied on for safety.

(4) Human-system interfaces are designed and implemented to ensure that personnel

relied on for safety are able to perform their duties that are identified as relied on for safety pursuant to section §70.60(d) of this part;

(5) Configuration changes to site, structures, process, systems, equipment, components, computer programs, personnel, procedures, and documentation are managed so that such modifications are reviewed, documented, communicated, and implemented in a systematic, controlled manner.

(6) Quality assurance that is commensurate with the item's reduction of risk is applied to each item relied on for safety identified pursuant to section §70.60(d) of this part.

(7) Periodic audits and assessments of the safety program are performed to ensure that an adequate level of protection is maintained at the facility. [annotation: parallels 70.60(d)(4) in SECY 98-185]

(8) Abnormal events are investigated and corrective actions taken to minimize the recurrence of these events. [annotation: parallels 70.60(d)(5) in SECY 98-185]

4. Related Definitions from §70.4

Acute as used in section §70.60 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]

Acute exposure guideline levels (AEGL) [Annotation: this term is not used in the rule anymore]

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 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.

Emergency response planning guidelines (ERPG) [Annotation: this term is not used in the rule anymore]

Hazardous chemicals [Annotation: this term is not used in the rule anymore]

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.

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

Results of the ISA [Annotation: this term is not used anymore - it was replaced by integrated safety analysis summary].

Integrated safety analysis summary means the portion of the license application, license amendment application, or license renewal application that has the purpose of informing the Commission of the nature of the facility, the plans for its use, and the evaluations that have been performed to evaluate if the facility has been constructed and will be operated in accordance with NRC requirements and will provide adequate protection from licensed materials, for worker and public health and safety and of the environment. [Annotation: new definition].

Unacceptable vulnerabilities mean deficiencies in the items relied on for safety or the measures used to assure their availability and reliability of such items when needed, that need to be corrected to ensure an adequate level of protection as defined in 10 CFR 70.60(b) or (c). [annotation: this term is now only used in one place - §70.62(c)(5) dealing with filing of the ISA summary by existing licensees].

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).