# Release Notes for Draft Part 70 *Federal Register* Notice

The views expressed in the draft *Federal Register* notice do not necessarily represent the views of the U.S. Nuclear Regulatory Commission (NRC). The information in this document is the staff's proposal and has not yet been reviewed by the Commission. In accordance with specific Commission direction, NRC staff is making this information publicly available simultaneous with forwarding it to the Commission for its consideration. The Commission plans to meet at NRC Headquarters in Rockville, Maryland, to discuss the proposed Part 70 rulemaking on June 14, 1999 at 2:00.

**Contents of *Federal Register* Notice**:

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[7590-01-P]

**NUCLEAR REGULATORY COMMISSION**

**10 CFR Part 70**

RIN 3150 - AF22

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# Domestic Licensing of Special Nuclear Material; Possession of a Critical Mass of Special Nuclear Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations governing the domestic licensing of special nuclear material (SNM) for licensees authorized to possess a critical mass of SNM, that are engaged in one of the following activities: 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 of special nuclear material; or any other

activity involving a critical mass of SNM that the Commission determines could significantly affect public health and safety or the environment. The proposed amendments would identify appropriate consequence criteria and the level of protection needed to prevent or mitigate accidents that exceed these criteria; require affected licensees to perform an integrated safety analysis (ISA) to identify potential accidents at the facility and the items relied on for safety necessary to prevent these potential accidents and/or mitigate their consequences; require the implementation of measures to ensure that the items relied on for safety are available and reliable to perform their function when needed; require the inclusion of the safety bases, including a summary of the ISA, with the license application; and allow for licensees to make certain changes to their safety program and facilities without prior NRC approval.

DATES: The comment period expires (insert 75 days after publication in the *Federal Register*). Comments received after this date will be considered if it is practical to do so, but, the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Submit comments to: Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC, 20555-0001, Attention: Rulemakings and Adjudications Staff.

Deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m. on Federal workdays.

You may also provide comments via NRC's interactive rulemaking website through the NRC home page (http://www.nrc.gov). From the home page, select "Rulemaking" from the tool bar at the bottom of the page. The interactive rulemaking website can then be accessed by selecting "Rulemaking Forum." This site provides the ability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher by telephone at (301) 415-5905 or e-mail cag@nrc.gov.

FOR FURTHER INFORMATION, CONTACT: Theodore S. Sherr, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC, 20555-0001, telephone (301) 415-7260; e-mail tss@nrc.gov.

SUPPLEMENTARY INFORMATION:



## I. Background

A near-criticality incident at a low enriched fuel fabrication facility in May 1991 prompted NRC to review its safety regulations for licensees that possess and process large quantities of SNM. [See NUREG-1324, "Proposed Method for Regulating Major Materials Licensees" (U.S. Nuclear Regulatory Commission, 1992) for additional details on the review.] As a result of this review, the Commission and the staff recognized the need for revision of the regulatory base for these

licensees, especially for those possessing a critical mass of SNM. Further, the NRC staff concluded that to increase confidence in the margin of safety at a facility possessing this type and amount of material, a licensee should perform an ISA. An ISA is a systematic analysis that identifies:

1. Plant and external hazards and their potential for initiating accident sequences;
2. The potential accident sequences, their likelihood, and consequences; and
3. The structures, systems, equipment, components, and activities of personnel relied on to prevent or mitigate potential accidents at a facility.

NRC held public meetings with the nuclear industry on this issue during May and November 1995. The Nuclear Energy Institute (NEI) explained, to the Commission, industry's position on the need for revision of NRC regulations, in 10 CFR Part 70, at a July 2, 1996, meeting, and in a subsequent filing of a Petition for Rulemaking (PRM-70-7) in September 1996. NRC published in the *Federal Register* a notice of receipt of the PRM and requested public comments on August 21, 1996 (61 FR 60057). The PRM requested that NRC amend Part 70 to:

1. Add a definition for a uranium processing and fuel fabrication plant;
2. Require the performance of an ISA, or acceptable alternative, at uranium processing, fuel fabrication, and enrichment plants; and
3. Include a requirement for backfit analysis, under certain circumstances, within Part 70.

In SECY-97-137, dated June 30, 1997, the staff proposed a resolution to the NEI PRM and recommended that the Commission direct the staff to proceed with rulemaking. The staff's recommended approach to rulemaking included the basic elements of the PRM, with some modification. In brief, staff's proposed resolution was to revise Part 70 to include the following major elements:

1. Performance of a formal ISA, that would form the basis for a licensee's safety program. This requirement would apply to all licensed facilities or activities, subject to NRC regulation, that are authorized to possess SNM in quantities sufficient to constitute a potential for nuclear criticality (except power reactors and the gaseous diffusion plants regulated under 10 CFR Part 76);
2. Establishment of criteria to identify the adverse consequences that licensees must protect against;
3. Inclusion of the safety bases in a license application (i.e., the identification of the potential accidents, the items relied on for safety to prevent these accidents and/or mitigate their consequences, and the measures needed to ensure the availability and reliability of these items);
4. Ability of licensees, based on the results of an ISA, to make certain changes without NRC prior approval; and
5. Consideration by the Commission, after licensees' initial conduct and implementation of the ISA, of a qualitative backfitting mechanism to enhance regulatory stability.

In an SRM dated August 22, 1997, the Commission "... approved the staff's proposal to revise Part 70" and directed the NRC staff to "... submit a draft proposed rule...by July 31, 1998."

A draft proposed rule was provided to the Commission in SECY-98-185, "Proposed Rulemaking

- Revised Requirements for the Domestic Licensing of Special Nuclear Material," dated July 30, 1998. The draft proposed rule reflected the approach recommended in SECY-97-137. In particular, the safety basis for a facility, including the ISA results, would be submitted as part of an application to NRC, for review, and incorporated in the license. Also in SECY 98-185, the staff recommended that a qualitative backfit mechanism should be considered for implementation only after the safety basis, including the results of the ISA, is established and incorporated in the license, and after licensees and staff have gained experience with the implementation of the ISA requirement.

In response to SECY-98-185, the Commission issued an SRM dated December 1, 1998, which directed the staff not to publish the draft proposed rule for public comment. Instead, the Commission directed the staff to obtain stakeholder input and revise the draft proposed rule. In that SRM, the Commission also directed the staff to:

1. Decide what is fundamental for NRC's regulatory purposes for inclusion as part of the license or docket and what can be justified from a public health and safety and cost-benefit basis, and assure that Part 70 captures for submittal those few significant changes that currently would require license amendments;
2. Require licensees/applicants to address baseline design criteria and develop a preliminary ISA for new processes and new facilities;
3. Justify, on a health and safety or cost-benefit basis, any requirement to conduct a decommissioning ISA;
4. Require that any new backfit pass a cost-benefit test, without the "substantial" increase in safety test;
5. Require the reporting of certain significant events because of their potential to impact worker or public health and safety;
6. Clarify the basis for use of chemical safety and chemical consequence criteria, particularly within the context of the Memoranda of Understanding with the Occupational Safety and Health Administration (OSHA) and other government agencies;
7. Critically review the Standard Review Plan (SRP) to ensure that by providing specific acceptance criteria, it does not inadvertently prevent licensees or applicants from suggesting alternate means of demonstrating compliance with the rule; and
8. Request input on how applicable ISA methodologies should be employed in the licensing of new technologies for use within new or existing facilities.

As directed in the SRM, stakeholder input was solicited and obtained at public meetings held in December 1998 and January and March 1999. A website was established to facilitate communication with stakeholders and to solicit further input. The nuclear industry submitted comments by letters and postings on the website. This revised proposed rule incorporates much of the December 1, 1998 SRM direction and reflects language responsive to many of the comments received. It appears that most of the major concerns with the earlier draft proposed rule have been resolved.

## II. Description of Proposed Action

The proposed rule grants the NEI September 1996 PRM in part and modifies the petitioner's proposal as indicated in the following discussion.

The Commission is proposing to modify Part 70 to provide increased confidence in the margin of safety at certain facilities authorized to process a critical mass of SNM. The Commission believes that this objective can be best accomplished through a risk-informed and performance-based regulatory approach that includes:

1. The identification of appropriate risk levels, considering consequence criteria and the level of protection needed to prevent accidents that could exceed such criteria;
2. The performance of an ISA to identify potential accidents at the facility and the items relied on for safety;
3. The implementation of measures to ensure that the items relied on for safety are available and reliable to perform their function when needed;
4. The inclusion of the safety bases, including the ISA summary, in the license application; and
5. The allowance for licensees to make certain changes to their safety program and facilities without prior NRC approval.

The Commission's approach agrees in principle with the NEI petition. However, in contrast to the petition's suggestion that the ISA requirement be limited to "... uranium processing, fuel fabrication, and uranium enrichment plant licensees," the Commission would require the performance of an ISA for a broader range of Part 70 licensees that are authorized to possess a critical mass of SNM. The Part 70 licensees that would be affected include licensees engaged in one of the following activities: 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 of special nuclear material; or any other activity involving a critical mass of SNM that the Commission determines could significantly affect public health and safety. The proposed rule would not apply to licensees authorized to possess SNM under 10 CFR Parts 50, 60, 72, and 76.

Furthermore, the Commission is not currently proposing, as suggested in the NEI petition, to include a backfit provision in Part 70. Based on the discussions at public meetings held on May 28, 1998, and March 23, 1999, the purpose of the NEI-proposed backfit provision is to ensure that NRC staff does not impose safety controls that are not necessary to satisfy the performance requirements of Part 70, unless a quantitative cost-benefit analysis justifies this action. The Commission believes that once the safety basis, including the ISA summary, is incorporated in the license application, and the NRC staff has gained sufficient experience with implementation of the ISA requirements, a qualitative backfit mechanism could be considered. Without a baseline determination of risk, as provided by the initial ISA process, it is not clear how a determination of incremental risk, as needed for a backfit analysis, would be accomplished. Furthermore, although NEI previously stated that a quantitative backfit approach is currently feasible, it would appear that a quantitative determination of incremental risk would require a Probabilistic Risk Assessment, to which the industry has been strongly opposed. Given the differences of opinion on this subject, the Commission requests public comment on its intent to defer consideration of a qualitative backfit provision in Part 70, and any specific suggestions for backfit provisions that would specifically address fuel cycle backfit needs, and the information

that would be available to conduct the associated analysis.

The majority of the proposed modifications to Part 70 are found in a new Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material," that consists of 10 CFR 70.60 through 70.74. These proposed modifications to Part 70, discussed in detail below, are required to increase confidence in the margin of safety and are in general accordance with the approach approved by the Commission in its SRMs of August 22, 1997, and December 1, 1998.

## Section 70.4 Definitions.

Definitions of the following 12 terms would be added to this section to provide a clear understanding of the meaning of the new Subpart H: "Acute" , "Available and reliable to perform their function when needed", "Configuration management", "Critical mass of SNM", "Double contingency", "Hazardous materials produced from licensed materials", "Integrated safety analysis", "Integrated safety analysis summary", "Items relied on for safety", "Management measures", "Unacceptable performance deficiencies", and "Worker."

## Section 70.14 Foreign military aircraft.

This paragraph reflects an administrative change to renumber the paragraph from 70.13a.

## Section 70.17 Specific exemptions.

This paragraph reflects an administrative change to renumber the paragraph from 70.14.

## Section 70.50 Reporting requirements.

Paragraph (c) would be reworded to include information to be transmitted when making verbal or written reports to NRC. The new information derives from the specifics of the new Subpart H, such as sequence of events and whether the event was evaluated in the ISA. To the extent the new information is also applicable to licensees not subject to Subpart H, the information was added with no differentiation noted. The new information that would only apply to Subpart H licensees is noted.

## Section 70.60 Applicability.

This section lists the types of NRC licensees or applicants who would be subject to the new Part 70, Subpart H. The Commission has decided that the new requirements should not apply to all licensees authorized to possess critical masses of SNM. Instead, the Commission has identified a subset of these licensees that, based on the risk associated with operations at these facilities, should be subject to the new requirements. This change would exclude certain facilities (e.g., those authorized only to store SNM or use SNM in sealed form for research and educational

purposes) from the new requirements, because of the relatively low level of risk at these facilities. In general, the new Subpart is intended to ensure that the significant accidents that are possible at fuel fabrication facilities (and the other listed facility types) have been analyzed in advance, and that appropriate controls or measures are established to ensure adequate protection of workers,[(1)] public, and the environment. The requirements and provisions in Subpart H are in addition to, and not a substitute for, other applicable requirements, including those of the U.S. Environmental Protection Agency (EPA) and the U.S. Department of Labor, OSHA. The requirements being added by NRC only apply to NRC's areas of responsibility (radiological safety and chemical safety directly related to licensed radioactive material). In this regard, the requirements for hazards and accident analyses that NRC is adding are intended to complement and be consistent with the parallel OSHA and EPA regulations.

The regulation states that Subpart H does not apply to decommissioning activities. NRC notes that the existing regulation [§70.38(g)(4)(iii)] requires an approved decommissioning plan (DP) that includes " a description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning." Because the DP is submitted for NRC approval before initiation of "...procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area," the DP will continue to be the vehicle for regulatory approval of the licensee's practices for protection of health and safety during decommissioning. The ISA should provide valuable information with respect to developing the DP and the use of the ISA in this manner is encouraged.

## Section 70.61 Performance Requirements.

In the past, the regulation of licensees authorized to possess SNM, under 10 CFR Parts 20 and 70, has concentrated on radiation protection for persons involved in nuclear activities conducted under normal operations. The proposed amendments to Part 70 would explicitly address potential exposures to workers or members of the public and environmental releases as a result of accidents. Part 20 continues to be NRC's standard for protection of workers and public from radiation during normal operations, anticipated upsets (e.g., minor process upsets that are likely to occur one or more times during the life of the facility), and accidents. Although it is the Commission's intent that the regulations in Part 20 also be observed to the extent practicable during an emergency, it is not the Commission's intent that the Part 20 requirements apply as the design standard for all possible accidents at the facility, irrespective of the likelihood of those accidents. Because accidents are unanticipated events that usually occur over a relatively short period of time, the Part 70 changes seek to assure adequate protection of workers, members of the public, and the environment by limiting the risk (combined likelihood and consequence) of such accidents.

There are three risk-informed performance requirements for the rule, each of which is set out in 10 CFR 70.61: (1) section 70.61(b) states that high-consequence events must meet a likelihood standard of highly unlikely; (2) section 70.61(c) requires that intermediate-consequence events must meet a likelihood standard of unlikely; and (3) section 70.61(d) requires that risk of nuclear criticality be limited by assuring that all processes must remain subcritical under any normal or

credible abnormal conditions. The term "performance requirements" thus considers together consequences and likelihood. For regulatory purposes, each performance requirement is considered an equivalent level of risk. For example, the acceptable likelihood of intermediate-consequence events is allowed to be greater than the acceptable likelihood for high-consequence events.

A risk-informed approach must consider not only the consequences of potential accidents, but also their likelihood of occurrence. As mentioned above, the performance requirements rely on the terms "unlikely" and "highly unlikely" to focus on the risk of accidents. However, the Commission has decided not to include quantitative definitions "unlikely" and "highly unlikely" in the proposed rule, because a single definition for each term, that would apply to all the facilities regulated by Part 70, may not be appropriate. Depending on the type of facility and its complexity, the number of potential accidents and their consequences could differ markedly. Therefore, to ensure that the overall facility risk from accidents is acceptable for different types of facilities, the rule requires applicants to develop, for NRC approval (see §70.65), the meaning of "unlikely" and "highly unlikely" specific to their processes and facility. To accommodate this development, the Commission believes that the SRP is the appropriate document to include guidelines for licensees to use. A draft "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility" has been developed. The draft SRP provides one acceptable approach for the meaning of "unlikely" and "highly unlikely" that can be applied to existing fuel cycle facilities.

The general approach for complying with the performance requirements is that, at the time of licensing, each hazard (e.g., fire, chemical, electrical, industrial) that can potentially affect radiological safety is identified and evaluated, in an ISA, by the licensee. The impact of accidents, both internal and external, associated with these hazards is compared with the three performance requirements. Any (and all) structures, systems, components, or human actions, for which credit is taken in the ISA for mitigating (reducing the consequence of) or preventing (reducing the likelihood of) the accident such that all three performance requirements are satisfied, must be identified as an "item relied on for safety." "Items relied on for safety" is a term that is defined in 10 CFR 70.4, and in this approach, the applicant has a great deal of flexibility in selecting and identifying the actual "items." For example, they can be defined at the systems-level, component-level, or sub-component-level. "Management measures" [see discussion in 10 CFR 70.62(d)] are applied to each item in a graded fashion to ensure that it will perform its safety function when needed. The combination of the set of "items relied on for safety" and the "management measures" applied to each item will determine the extent of the licensee's programmatic and design requirements, consistent with the facility risk, and will ensure that at any given time, the facility risk is maintained safe and protected from accidents (viz., satisfies the performance requirements).

The proposed performance requirements also address certain chemical hazards that result from the processing of licensed nuclear material. The question of the extent of NRC's authority to regulate chemical hazards at its fuel cycle facilities was raised after an accident in 1986 at a Part 40 licensed facility, in which a cylinder of uranium hexafluoride ruptured and resulted in a worker fatality. The cause of the worker's death was the inhalation of hydrogen fluoride gas,

which was produced from the chemical reaction of uranium hexafluoride and water (humidity in air). Partly as a result of the coordinated Federal response and resulting Congressional investigation into that accident, NRC and the OSHA entered into an MOU, in 1988, that clarified the agencies' interpretations of their respective responsibilities for the regulation of chemical hazards at nuclear facilities. The MOU identified the following four areas of responsibility. Generally, NRC covers the first three areas, whereas OSHA covers the fourth area:

(1) Radiation risk produced by radioactive materials;

(2) Chemical risk produced by radioactive materials;

(3) Plant conditions that affect the safety of radioactive materials; and

(4) Plant conditions that result in an occupational risk, but do not affect the safety of licensed radioactive materials.

One goal of the performance requirements in §70.61 is to be consistent with the NRC-OSHA MOU. Therefore, the performance requirements in §70.61 include explicit standards for the MOU's first two areas of responsibility. In addition, the third MOU area of responsibility is specifically evaluated by licensees under the ISA requirements of §70.62(c)(1)(iii). As an example of the third MOU area, if the failure of a chemical system adjacent to a nuclear system could affect the safety of the nuclear system such that the radiation dose (and associated likelihood of that accident) exceeded a performance requirement, the chemical system failure would be within the scope of the ISA and the means to prevent the chemical system failure from impacting the nuclear system would be within NRC's regulatory purview.

OSHA provided comments, by a letter dated February 1, 1999, on a draft of the rule that had been revised to be consistent with the MOU. In that letter, OSHA expressed concerns that the rule language would preempt OSHA from enforcing any of its standards, rules or other requirements with respect to chemical hazards at the facilities covered by the NRC draft rule. This concern is based on case law under the OSH Act. The pertinent provision in the OSH Act states:

> "(b)(1) Nothing in this chapter shall apply to working conditions of employees with respect to which other Federal agencies, and State agencies acting under section 2021 of title 42, exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health." [29 U.S.C. §653(b)(1)]

NRC staff subsequently met with OSHA officials on February 25, 1999, and some clarifications and further information were provided at that meeting. As a result of the meeting discussions, some changes were made to the rule language to more clearly specify the scope of NRC involvement. However, these changes do not fully resolve the basic preemption issue. The problems identified with the rule are not unique, i.e., the preemption issue is generic and may already exist for any NRC-licensed facilities where there are requirements to analyze hazards. At

the February 25 meeting, OSHA confirmed that the rule language is consistent with the October 21, 1988 MOU; indicated that they have no suggested changes to the MOU; and indicated that they are not opposed to the proposed rule. The Commission's view is that the proposed rule is consistent with NRC responsibilities and authority under the Atomic Energy Act, and consistent with the OSHA MOU. The only resolution of the preemption issue appears to be a legislative modification of the OSH Act. Public comments would be appreciated on any options that may have been overlooked.

Within each performance requirement, NRC recognizes that the proposed radiological standards are more restrictive, in terms of acute health effects to workers or the public, than the chemical standards for a given consequence (high or intermediate) and that this is consistent with current regulatory practice. The choice of each criterion is discussed below in a paragraph-by-paragraph discussion of §70.61.

The use of any of the performance requirements is not intended to imply that the specified worker or public radiation dose or chemical exposure constitutes an acceptable criterion for an emergency dose to a worker or the public. Rather, these values have been proposed in this section as a reference value, to be used by licensees in the ISA (a forward-looking analysis) to establish controls (i.e., items relied on for safety and associated management measures) necessary to protect workers from potential accidents with low or exceedingly low probabilities of occurrence that are not expected to occur during the operating life of the facility.

Section 70.61(b) This section addresses performance requirements for high-consequence events.

The consequences identified in §70.61(b) of the proposed rule are referred to as "high-consequence events" and include accidental exposure of a worker or an individual located outside of the controlled area to high levels of radiation or hazardous chemicals. These accidents, if they occurred, would represent radiation doses to a worker or an individual located outside of the controlled area at levels with clinically observable biological damage or concentrations of hazardous chemicals produced from licensed material at which death or life-threatening injury could occur. The goal is to ensure an acceptable level of risk by limiting the combination of the likelihood of occurrence and the identified consequences. Thus, high-consequence events must be sufficiently mitigated to a lower consequence or prevented such that the event is highly unlikely (or lower). The application of "items relied on for safety" provides this prevention or mitigation function.

Section 70.61(b)(1). An acute exposure of a worker to a radiation dose of 1 Sv (100 rem) or greater total effective dose equivalent (TEDE) is considered to be a high-consequence event. According to the National Council on Radiation Protection and Measurements (NCRP, 1971), life-saving actions -- including the "...search for and removal of injured persons, or entry to prevent conditions that would probably injure numbers of people" -- should be undertaken only when the "...planned dose to the whole body shall not exceed 100 rems." This is consistent with a later NCRP position (NCRP, 1987) on emergency occupational exposures, that states "...when the exposure may approach or exceed 1 Gy (100 rad) of low-LET [linear energy transfer] radiation (or an equivalent high-LET exposure) to a large portion of the body, in a short time, the

worker needs to understand not only the potential for acute effects but he or she should also have an appreciation of the substantial increase in his or her lifetime risk of cancer."

Section 70.61(b)(2). The exposure of an individual located outside of the controlled area to a radiation dose of 0.25 Sv (25 rem) or greater TEDE is considered a high-consequence event. This is generally consistent with the criterion established in 10 CFR 100.11, "Determination of exclusion area, low population zone, and population center distance," and 10 CFR 50.34, "Contents of applications; technical information," where a whole-body dose of 0.25 Sv (25 rem) is used to determine the dimensions of the exclusion area and low-population zone required for siting nuclear power reactors.

Section 70.61(b)(3). The intake of 30 mg of soluble uranium by an individual located outside of the controlled area is considered a high- consequence event. This choice, which is based on a review of the available literature [Pacific Northwest Laboratories (PNL), 1994], is consistent with the selection of 30 mg of uranium as a criterion that was discussed during the Part 76 rulemaking, "Certification of Gaseous Diffusion Plants." In particular, the final rule that established Part 76 (59 FR 48944; September 23, 1994) stated that "The NRC will consider whether the potential consequences of a reasonable spectrum of postulated accident scenarios exceed...uranium intakes of 30 milligrams...." The final rule also stated that "The Commission's intended use of chemical toxicity considerations in Part 76 is consistent with its practice elsewhere [e.g., 10 CFR 20.1201(e)], and prevents any potential regulatory gap in public protection against toxic effects of soluble uranium."

Section 70.61(b)(4). An acute chemical exposure to hazardous chemicals produced from licensed material at concentrations that either (1) could cause death or life-threatening injuries to a worker; or (2) could cause irreversible health effects to an individual located outside of the controlled area, is considered a high-consequence event. Chemical consequence criteria corresponding to anticipated adverse health effects to humans from acute exposures (i.e., a single exposure or multiple exposures occurring within a short time -- 24 hours or less) have been developed, or are under development, by a number of organizations. Of particular interest, the National Advisory Committee for Acute Guideline Levels for Hazardous Substances is developing Acute Exposure Guideline Limits (AEGLs) that will eventually cover approximately 400 industrial chemicals and pesticides. The committee, which works under the auspices of the EPA and the National Academy of Sciences, has identified a priority list of approximately 85 chemicals. Consequence criteria for 12 of these have currently been developed and criteria for approximately 30 additional chemicals per year are expected. Another set of chemical consequence criteria, the Emergency Response Planning Guidelines (ERPGs), has been developed by the American Industrial Hygiene Association to provide estimates of concentration ranges where defined adverse health effects might be observed because of short exposures to hazardous chemicals. ERPG criteria are widely used by those involved in assessing or responding to the release of hazardous chemicals including "...community emergency planners and response specialists, air dispersion modelers, industrial process safety engineers, implementers of environmental regulations such as the Superfund Amendment and Reauthorization Act, industrial hygienists, and toxicologists, transportation safety engineers, fire protection specialists, and government agencies...." (DOE Risk Management Quarterly, 1997). Despite their general

acceptance, there are currently only approximately 80 ERPG criteria available, and some chemicals of importance (e.g., nitric acid) are not covered.

The qualitative language in the performance requirement allows the applicant/licensee to propose and adopt an appropriate standard, which may be an AEGL or ERPG standard, or where there is no AEGL or ERPG value available, the applicant may develop or adopt a criterion that is comparable in severity to those that have been established for other chemicals. For example, for the worker performance requirement, existing criteria that can be used by licensees to define appropriate concentration levels to satisfy the performance requirement are the AEGL-3 and ERPG-3. AEGL-3 is defined as "The airborne concentration (expressed in ppm or $mg/m^3$) of a substance at or above which it is predicted that the general population, including susceptible, but excluding hypersusceptible, individuals, could experience life-threatening effects or death." ERPG-3 is defined as "The maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing or developing life-threatening health effects." Similarly, for the public, AEGL-2 is defined as "The airborne concentration (expressed in ppm or $mg/m^3$) of a substance at or above which it is predicted that the general population, including susceptible, but excluding hypersusceptible, individuals, could experience irreversible or other serious, long-lasting effects or impaired ability to escape," and ERPG-2 is defined as "The maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing or developing irreversible or other health effects or symptoms that could impair an individual's ability to take protective action."

Section 70.61(c). This section addresses performance requirements for intermediate-consequence events.

The consequences identified in §70.61(c) of the proposed rule are referred to as "intermediate-consequence events" and include accidental exposure of a worker or an individual outside of the controlled area to levels of radiation or hazardous chemicals that generally correspond to permanent injury to a worker, transient injury to a non-worker, or significant releases of radioactive material to the environment. The goal is to ensure an acceptable level of risk by limiting the combination of the likelihood of occurrence and the identified consequences. Thus, "intermediate-consequence events" must be sufficiently mitigated to a lower consequence or prevented such that the event is unlikely (or lower). The application of "items relied on for safety" provides this prevention or mitigation function.

Section 70.61(c)(1). A worker radiation dose between 0.25 Sv (25 rem) and 1 Sv (100 rem) TEDE is considered an intermediate-consequence event [over 1 Sv (100 rem) is a high-consequence event]. This value was chosen because of the use of 0.25 Sv (25 rem) as a criterion in existing NRC regulations. For example, in 10 CFR 20.2202, "Notification of incidents," immediate notification is required of a licensee if an individual receives "... a total effective dose equivalent of 0.25 Sv (25 rem) or more." Also, in 10 CFR 20.1206, "Planned special exposures," a licensee may authorize an adult worker to receive a dose in excess of normal occupational exposure limits if a dose of this magnitude does not exceed 5 times the annual dose limits [i.e., 0.25 Sv (25 rem)] during an individual's lifetime. In addition, EPA's

Protective Action Guides (U.S. Environmental Protection Agency, 1992) and NRC's regulatory guidance (Regulatory Guide 8.29, 1996) identify 0.25 Sv (25 rem) as the whole-body dose limit to workers for life-saving actions and protection of large populations. NCRP has also stated that a TEDE of 0.25 Sv (25 rem) corresponds to the once-in-a-lifetime accidental or emergency dose for workers.

Section 70.61(c)(2). A dose to any individual located outside of the controlled area between 0.05 Sv (5 rem) and 0.25 Sv (25 rem) is considered an intermediate-consequence event. NRC has used a 0.05-Sv (5-rem) exposure criterion in a number of its existing regulations. For example, 10 CFR 72.106, "Controlled area of an ISFSI or MRS," states that "Any individual located on or beyond the nearest boundary of the controlled area shall not receive a dose greater than 5 rem to the whole body or any organ from any design basis accident." In addition, in the regulation of the above-ground portion of the geologic repository, 10 CFR 60.136, states that "...for [accidents], no individual located on or beyond any point on the boundary of the preclosure controlled area will receive...a total effective dose equivalent of 5 rem...." A TEDE of 0.05 Sv (5 rem) is also the upper limit of EPA's Protective Action Guides of between 0.01 to 0.05 Sv (1 to 5 rem) for emergency evacuation of members of the public in the event of an accidental release that could result in inhalation, ingestion, or absorption of radioactive materials.

Section 70.61(c)(3). The release of radioactive material to the environment outside the restricted area in concentrations that, if averaged over a period of 24 hours, exceed 5000 times the values specified in Table 2 of Appendix B to Part 20, is considered an intermediate-consequence event. In contrast to the other consequences criteria that directly protect workers and members of the public, the intent of this criterion is to ensure protection of the environment from the occurrence of accidents at certain facilities authorized to process greater than critical mass quantities of SNM. This implements NRC's responsibility for protecting the environment, in accordance with the Atomic Energy Act of 1954, et seq., and the National Environmental Policy Act of 1969, et seq.

The value established for the environmental consequence criterion is identical to the NRC Abnormal Occurrence (AO) criterion that addresses the discharge or dispersal of radioactive material from its intended place of confinement (Section 208 of the Energy Reorganization Act of 1974, as amended, requires that AOs be reported to Congress annually). In particular, AO reporting criterion 1.B.1 requires the reporting of an event that involves "...the release of radioactive material to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceed 5000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20, unless the licensee has demonstrated compliance with 10 CFR 20.1301 using 10 CFR 20.1302(b)(1) or 10 CFR 20.1302(b)(2)(ii)" [December 19, 1996; 61 FR 67072]. The concentrations listed in Table 2 of Appendix B to Part 20 apply to radioactive materials in air and water effluents to unrestricted areas. NRC established these concentrations based on an implicit effective dose equivalent limit of 0.5 mSv/yr (50 mrem/yr) for each medium, assuming an individual were continuously exposed to the listed concentrations present in an unrestricted area for a year.

If an individual were continuously exposed for 1 day to concentrations of radioactive material

5000 times greater than the values listed in Appendix B to Part 20, the projected dose would be about 6.8 mSv (680 mrem), or 5000 x 0.5 mSv/yr x 1 day x 1 yr/365 days. In addition, a release of radioactive material, from a facility, resulting in these concentrations, would be expected to cause some environmental contamination in the area affected by the release. This contamination would pose a longer-term hazard to the environment and members of the public until it was properly remediated. Depending on the extent of environmental contamination caused by such a release, the contamination could require considerable licensee resources to remediate. For these reasons, NRC considered the existing AO reporting criterion for discharge or dispersal of radioactive material as an appropriate consequence criterion in this rulemaking.

Section 70.61(c)(4). An acute chemical exposure to hazardous chemicals produced from licensed material at concentrations that either; a) to a worker, could cause irreversible health effects (but at concentrations below those which could cause death or life-threatening effects); or b) to an individual located outside of the controlled area, could cause notable discomfort (but at concentrations below those which could cause irreversible effects), is considered an intermediate-consequence event. Chemical consequence criteria corresponding to anticipated adverse health effects to humans from acute exposures (i.e., a single exposure or multiple exposures occurring within a short time -- 24 hours or less) have been developed, or are under development, by a number of organizations. Of particular interest, two existing standards, AEGL-2 and ERPG-2, can be used to define the concentration level for irreversible health effects, and two existing standards, AEGL-1 and ERPG-1, can be used to define the concentration level for notable discomfort. The qualitative language in the performance requirement allows the applicant/licensee to adopt and propose an appropriate standard, which may be an AEGL or ERPG standard, or where there is no AEGL or ERPG value available, the applicant may develop or adopt a criterion that is comparable in severity to those that have been established for other chemicals.

Section 70.61(d). This section addresses performance requirements for an accidental nuclear criticality.

The third performance requirement states that 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. It also requires that preventive controls and measures shall be the primary means of protection against nuclear criticality accidents. Although detecting and mitigating the consequences of a nuclear criticality are important objectives (e.g., for establishing alarm systems), the prevention of a criticality is a primary NRC objective.

The basis for this provision is the NRC strategic plan (NUREG-1614, Vol. 1), which, for nuclear materials safety, states NRC's performance goal of "...no accidental criticality involving licensed material." The language chosen for this performance requirement closely follows the language of the applicable industry standard, ANSI/ANS Standard 8.1-1983, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors."

Section 70.61(e). This section addresses items relied on for safety and management measures.

Paragraph 70.61(e) would require that each engineered or administrative control or control system that is needed to meet the performance requirements be designated as an item relied on for safety. This means that any control or control system that is necessary to maintain the acceptable combination of consequence and likelihood for an accident is designated an item relied on for safety. The importance of this section is that, once a control is designated as an item relied on for safety, it falls into the envelope of the safety program required by section 70.62. For example, records will be kept regarding the item, and management measures such as the configuration control program are applied to the item and to changes that affect the item, to ensure that the item will be available and reliable to perform its function when needed.

The failure of an item relied on for safety does not necessarily mean that an accident will occur which will cause one of the consequences listed in the performance requirements to be exceeded. Some control systems may have parallel (redundant or diverse) control systems that would continue to prevent the accident. The need for such defense-in-depth and single-failure resistance would ideally be based on the severity and likelihood of the potential accident. In other cases, the failure of an item may mean that the particular accident sequence is no longer "highly unlikely", or "unlikely." In these cases, the performance requirement is not met, and the expectation would be that a management measure would exist (possibly in the form of an operating procedure) that ensured that the facility would not operate in a condition that exceeds the performance requirement. For example, a facility that relies on emergency power could not operate for an extended time in the absence of an emergency power source even if grid power is available. In this manner, the items relied on for safety and the management measures complement each other to ensure adequate protection from accidents at any given time.

Section 70.61(f). This section addresses the term "controlled area" used in the performance requirements.

Section 70.61(f) requires licensees to identify a controlled area consistent with the use of that term in Part 20, and provides clarification regarding the activities that may occur inside the controlled area. The function of this term is to delimit an area over which the licensee exercises control of activities. Control includes the power to exclude individuals, if necessary. The size of the controlled area is not specified in the regulation because it will be dependent upon the particular activities that are conducted at the site and their relationship to the licensed activities. [Within the controlled area will be a restricted area (as defined in §20.1003), access to which is controlled by the licensee for purposes of radiation safety.]

Individuals who do not receive an occupational dose (as that term is used in Part 20) in the controlled area will be subject to the dose limits for members of the public in 10 CFR 20.1301. However, the Commission recognizes that certain licensees may have ongoing activities at their site (i.e., within the controlled area) that are not related to the licensed activities. For example, a non-nuclear facility may be adjacent to the nuclear facility but both are within the controlled area (which may be defined similar to the site boundary). This raises a question regarding the appropriate accident standard for these individuals. Protection of the individuals at the non-nuclear facility must consider that the nature of many potential accidents at a fuel cycle facility is such that there may not be sufficient time during which to take action to exclude

individuals from the controlled area. Therefore, for purposes of the ISA accident evaluation, the rule explicitly contains two options for these individuals (as well as an implicit third option). In the first option, the licensee evaluates, in the ISA, the risk at its location (as opposed to that at any point at or beyond the controlled area boundary) and determines that it meets the performance requirements for members of the public. In the second option, performance requirements for workers may be applied to individuals in the controlled area if the provisions of Section 70.61(f)(2) are satisfied. These conditions ensure that the individuals are aware of the risks to them from the potential accidents at the nuclear facility and have received appropriate training and access to information. This parallels and is consistent with the use of the term, "Exclusion area", by 10 CFR Parts 50 and 100, which states, "Activities unrelated to operation of the reactor may be permitted in an exclusion area under appropriate limitations, provided that no significant hazards to the public health and safety will result." The implied third option is to define (or redefine) a controlled area such that within it only activities associated with the licensed nuclear facility are permitted.

The Commission's intent is that the ISA does not evaluate compliance with the accident standards for individuals who make infrequent visits to the controlled area and restricted area (e.g., visitors). Use of the ISA to determine the risks to these individuals would need to consider second-order effects such as the probability of the individual being present at the time that the unlikely (or highly unlikely) accident occurred. This level of detail is unnecessary to accomplish the purpose of this rule (viz., to document and maintain the safety basis of the facility design and operations). Application of the Part 20 regulations provides adequate protection for these individuals. In addition, the provisions (i.e., performance requirements) to protect workers and non-workers during accidents should, implicitly, provide a degree of protection to the infrequently present individuals.

## Section 70.62 Safety Program and Integrated Safety Analysis.

This paragraph addresses the safety program, that includes process safety information, ISA, and management measures. The performance of an ISA, and the establishment of measures to ensure the availability and reliability of items relied on for safety when needed, are the means by which licensees demonstrate an adequate level of protection at their facilities. The ISA is a systematic analysis to identify plant and external hazards and their potential for initiating accident sequences; the potential accident sequences and their consequences; and the site, structures, systems, equipment, components, and activities of personnel relied on for safety. As used here, "integrated" means joint consideration of, and protection from, all relevant hazards, including radiological, criticality, fire, and chemical. The structure of the safety program recognizes the critical role that the ISA plays in identifying potential accidents and the items relied on for safety. However, it also recognizes that the performance of the ISA, by itself, will not ensure adequate protection. Instead, an effective management system is needed to ensure that the items relied on for safety are available and reliable to perform their function when needed. Detailed requirements for each part of the safety program are included in this section.

Section 70.62(a). Each licensee would be required to establish and maintain a safety program that demonstrates compliance with the performance requirements of §70.61. Although the ISA would be the primary tool in identifying the potential accidents requiring consequence mitigation and accident prevention, process safety information would be used to develop the ISA, and management measures would be used to ensure the availability and reliability of items relied on for safety identified through the ISA. The management measures may be graded according to the risk importance associated with an item relied on for safety.

The licensee is also required to establish and maintain records demonstrating that it has, and continues to meet, the requirement of this section. These records serve two major purposes. First, they can supplement information that has been submitted as part of the license application. Second, records are often needed to demonstrate licensee compliance with applicable regulations and license commitments. It is important, therefore, that an appropriate system of recordkeeping be implemented to allow easy retrieval of required information.

Finally, each licensee would also be required to establish and maintain a log documenting each discovery that an item relied on for safety has failed to perform its function either in the context of the performance requirements of §70.61 or on demand. The phrase "...in the context of the performance requirements of §70.61" means that items relied on for safety that fail would require logging even if their failures did not result in process upsets or accidents but could have resulted in the accident conditions they are protecting against, had all conditions been optimum for the accident. This would not include failures during times, such as routine maintenance on an item, when the item or measure was clearly documented to not be available. The log must contain: (a) the identity of the item that failed and the safety function affected; (b) date of discovery of the failure; (c) duration of time that the item was unable to perform its function; (d) any other affected items relied on for safety and their safety function; (e) affected processes; (f) the cause of the failure; (g) whether the failure was in the context of performance requirements, or on demand, or both; and (h) any corrective or compensatory actions taken. The log should be initiated at the time of discovery and updated promptly at the completion of each investigation of a failure of an item relied on for safety. The purpose of the log is to assist NRC in determining whether items relied on for safety are, in fact, available and reliable and in detecting system problems that may impact ISA evaluations.

Section 70.62(b). This paragraph would require the licensee to maintain process-safety information pertaining to the hazards of the materials used or produced in the process, the technology of the process, and the equipment in the process. NRC confidence in the margin of safety at its licensed facilities depends, in part, on the ability of licensees to maintain a set of current, accurate, and complete records available for NRC inspection. The process-safety information should be used in support of development of an ISA.

Section 70.62(c). This paragraph proposes requirements for conducting an ISA. There are four major steps in performing an ISA:

(1) Identify all hazards at the facility, including both radiological and non-radiological hazards. Hazardous materials, their location, and quantities, should be identified, as well as all hazardous

conditions, such as high temperature and high pressure. In addition, any interactions that could result in the generation of hazardous materials or conditions should be identified.

(2) Analyze the hazards to identify how they might result in potential accidents. These accidents could be caused by process deviations or other events internal to the plant, or by credible external events, including natural phenomena such as floods, earthquakes, etc. To accomplish the task of identifying potential accidents, the licensee needs to ensure that detailed and accurate information about plant processes is maintained and made available to the personnel performing the ISA.

(3) Determine the consequences of each accident that has been identified. For an accident with consequences at a "high" or "intermediate level," as defined in 10 CFR 70.61, the likelihood of such an accident must be shown to be commensurate with the consequences, as required in 10 CFR 70.61.

(4) Identify the items relied on for safety (i.e., those items that are relied on to prevent accidents or to mitigate their consequences, identified in the ISA). These items are needed to reduce the consequences or likelihood of the accidents to acceptable levels. The identification of items relied on for safety is required only for accidents with consequences at a high or intermediate level, as defined in 10 CFR 70.61.

It is expected that the licensee or applicant would perform the ISA using a "team" of individuals with expertise in engineering and process operations related to the system being evaluated; the team should include persons with experience in nuclear criticality safety, radiation safety, fire safety, and chemical process safety, as warranted by the materials and potential hazards associated with the process being evaluated. At least one member of the ISA team should be an individual who has experience and knowledge that is specific to the process being evaluated. Finally, at least one individual in the team must be knowledgeable in the specific ISA methodology being used.

Current Part 70 licensees, for whom the rule applies, would be required to develop plans and submit them to NRC within 6 months of the effective date of the rule. Each plan would identify the processes that would be subject to an ISA, the ISA approach that would be implemented for each process, and the schedule for completing the analysis of each process. Licensees would be expected to complete their ISA within 4 years of the effective date of the rule; correct any unacceptable vulnerabilities identified; and submit the results to NRC for approval in the form of an ISA summary that contains the information required by 10 CFR 70.65(b). Pending the correction of any unacceptable vulnerabilities, licensees would be expected to implement appropriate compensatory measures to ensure adequate protection until the vulnerability can be more appropriately corrected.

Applicants for licenses to operate new facilities or new processes at existing facilities would be expected to design their facilities or processes to protect against the occurrence of the adverse consequences identified in 10 CFR 70.61, using the baseline design criteria 10 CFR 70.64(a). Before operation, applicants would be expected to update their ISAs, based on as-built conditions

and submit the results to NRC as ISA summaries, along with the applications, following the requirements in 10 CFR 70.65(b).

The Commission believes that sufficient flexibility is permitted in the ISA methodology chosen to be able to accommodate a wide range of technologies. However, to assure that sufficient flexibility exists, the Commission is requesting comments on this matter.

Section 70.62(d). Although the ISA would play a critical role in identifying potential accidents and the items relied on for safety, the performance of an ISA would not, by itself, ensure adequate protection. In addition, as would be provided for in 10 CFR 70.62(d), an effective management system would be needed to ensure that the items relied on for safety are available and reliable to perform their function when needed. As stated before, management measures may be graded to better implement the results of the ISA.

Management measures are functions performed by the licensee, in general on a continuing basis, that are applied to items relied on for safety. Management measures include: a) configuration management; b) maintenance; c) training and qualifications; d) procedures; e) audits and assessments; f) incident investigations; g) records management; and h) other quality assurance elements. Changes in the configuration of the facility need to be carefully controlled to ensure consistency among the facility design and operational requirements, the physical configuration, and the facility documentation. Maintenance measures must be in place to ensure the availability and reliability of all hardware, identified as items relied on for safety, to perform their function when needed. Training measures must be established to ensure that all personnel relied on for safety are appropriately trained to perform their safety functions. Periodic audits and assessments of licensee safety programs must be performed to ensure that facility operations are conducted in compliance with NRC regulations and protect the worker and the public health and safety and the environment. When abnormal events occur, investigations of those events must be carried out to determine the root cause and identify corrective actions to prevent their recurrence and to ensure that they do not lead to more serious consequences. Finally, to demonstrate compliance with NRC regulations, records that document safety program activities must be maintained for the life of the facility.

This section also would require that the safety program ensure that each item relied on for safety would perform its intended function when needed and in the context of the performance requirements of this section. The utility of the two modifying requirements, "when needed," and "in the context of the performance requirements of this section," is clarified as follows:

The phrase "when needed" is used to acknowledge that a particular safety control need not be continuously functioning. For example, it may not be operational during maintenance or calibration testing, or may not be required when the process is not operational or when special nuclear material is not present. However, the phrase, when needed, does not relieve a licensee from compliance with the performance requirements. For example, if a particular component is out for maintenance, the licensee must consider credible event sequences in developing the ISA and identifying items relied on for safety - a high-consequence event sequence still has to be highly unlikely. Compliance with the performance requirements in these cases can be established

by various means including identification of additional items relied on for safety (and application of safety program management measures to them), or by limiting operations or placing the plant in a different operating mode during the maintenance of the item relied on for safety.

To illustrate, a loss of offsite power during a one-week maintenance outage of the emergency diesel generator that is relied on for safety would still be a credible event sequence. If the loss of power, combined with the generator's inoperable status, could result in a combination of dose and likelihood that exceeds a performance requirement, then the licensee would not be in compliance with the performance requirements of §70.61. A licensee cannot claim, after the maintenance, that since the power was not lost, the generator was available when needed. The concept is that the ISA is used as a risk-informed, forward-look at the credible facility hazards and their effects on plant systems and modes of operation. The rule would require that each item necessary to comply with the performance requirements be identified as important to safety and placed under the safety program management controls. In identifying each item, the ISA must consider various modes of operation and the likelihood that a given safety control will be inoperable (e.g., because of being off-line for maintenance) during credible event sequences.

The section would also require that the safety control perform its function "...in the context of the performance requirements of this section." This phrase indicates that the function of interest is the one credited in the ISA to meet certain consequence criteria with a certain frequency. Second, this phrase would require that additional safety controls be defined in cases where one control does not result in compliance with the performance requirement or has periods when it is inoperable. Using the loss of offsite power example again, a licensee would still be required to meet the risk-informed performance requirements of the rule when an emergency diesel generator used as an item relied on for safety is not operable or out of service for maintenance.

## Section 70.64 Requirements for new facilities or new processes at existing facilities.

This section deals with baseline design criteria for new facilities or new processes at existing facilities.

A major feature of the proposed amendments to Part 70 is the requirement that licensees and applicants for a license perform an ISA and use the ISA process to develop risk-informed decisions regarding facility safety. The ISA process is applied to existing designs to identify risk insights on those areas that warrant additional preventive or mitigative measures. For new facilities, the proposed rule would require the performance of the ISA before construction [see the existing §70.21(f) and §70.23(a)(7)], and the updating of the ISA before beginning operations. For new processes and facilities, the Commission recognizes that good engineering practice dictates that certain minimum requirements be applied as design and safety considerations for any new nuclear process or facility. In addition, a fundamental element of NRC's safety philosophy is that designs and operations should provide for defense-in-depth protection against accidents. Therefore, the Commission has specified baseline design criteria in §70.64 that are similar in use to the general design criteria in Part 50 Appendix A; Part 72,

Subpart F; and 10 CFR 60.131. The baseline design criteria identify 10 initial safety design considerations, including: a) quality standards and records; b) natural phenomena hazards; c) fire protection; d) environmental and dynamic effects(2); f) chemical protection; g) emergency capability; h) utility services; i) inspection, testing, and maintenance; j) criticality control; and k) instrumentation and controls. The baseline design criteria do not provide relief from compliance with the safety performance requirements of §70.61. The baseline design criteria are generally an acceptable set of initial design safety considerations, which may not be sufficient to ensure adequate safety for all new processes and facilities. The ISA process is intended to identify additional safety features that may be needed. On the other hand, the Commission recognizes that there may be processes or facilities for which some of the baseline design criteria may not be necessary or appropriate, based on the results of the ISA. For these processes and facilities, any design features that are inconsistent with the baseline design criteria should be identified and justified.

Using the baseline design criteria and considering defense-in-depth practices in the design should result in a new facility design that is based on providing successive levels of protection such that health and safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating defense-in-depth practices is a conservatively designed facility and system that will exhibit greater tolerance for failures and external challenges. The risk insights obtained through performance of the ISA can be then used to supplement the final design by focusing attention on the prevention and mitigation of the potential accidents having higher-risk.

## Section 70.65 Additional content of applications.

In addition to the information that currently must be submitted to NRC, under §70.22, for a license application, this section requires additional information to be submitted to demonstrate compliance with the proposed new subpart. In particular, this additional information would need to include a description of the applicant's safety program established under §70.62, a description of the management measures, and an ISA summary.

The ISA summary would contain: a) a description of the site and the facility; b) a description of the team qualifications and ISA methodology; c) the processes analyzed in the ISA and the maximum consequences of each; d) a demonstration of how the licensee meets the requirements for criticality monitoring and alarms in §70.24; e) a demonstration of how the licensee meets the performance requirements of §70.61 and, if applicable, §70.64; f) a list of items relied on for safety and a description of their safety function; g) a description of the proposed standards used to assess the consequences from acute chemical exposures; and h) the definitions of "likely", "unlikely", "highly unlikely", and "credible" as used in the ISA.

The plant and process descriptions, ISA team qualifications and methods, and definitions of terms used in the ISA, are all needed to fully understand the facility and the ISA and how it was developed. Although some of the facility information is also requested in §70.22, there may be information about the facility which would be too detailed for inclusion in the general site

description, but would be needed to be included here to understand the ISA and ISA results. The demonstration of how the licensee meets §§70.24, 70.61, and 70.64 is a critical element in determining whether the applicant understands and complies with the regulations and can operate the facility safely. Another critical element is the applicant's identification of the items relied on for safety. Through the ISA process, the applicant should have identified potential accidents that can occur in individual processes and in the facility as a whole. As discussed earlier, these accidents are prevented or their consequences mitigated using controls that are identified in the ISA summary as items relied on for safety. It is important for NRC staff to review the items relied on for safety, that were identified as such by the applicant or licensee, to determine whether potential accidents are adequately prevented or mitigated. Since items relied on for safety play a key role in assuring that the performance requirements are met, and because the applicant has great flexibility in selecting and identifying what the actual "items" are (as discussed in relation to §70.61), the items relied on for safety would be clearly and unambiguously identified on a list. This list of items is then managed and controlled by the applicant through the management measures in §70.61 to ensure that they continue to perform the safety function required. By evaluating the ISA methodology, and the ISA summary, supplemented by reviewing the ISA and other information, as needed, at the licensee's facility, the staff can better understand the potential hazards at the facility, how the applicant plans to address these hazards, and thereby have confidence in the safety basis on which the license will be issued.

The ISA summary would be required to be submitted on the docket in conjunction with the license application but would not be considered part of the license. The ISA, on which the ISA summary is based, would be maintained current at the licensee's facility and available for NRC review, but it would not be submitted and docketed. The information and commitments contained in the license application that are incorporated into the license conditions cannot be changed without prior review and approval of NRC staff, at which time a license amendment is issued. Although the ISA summary will be on the docket, since it is not part of the license it can be changed without a license amendment, unless it reflects a change that cannot be made without prior approval per §70.72(c). However, the information used to perform the ISA, and the ISA summary, both form integral parts of the safety basis for issuance of the license and therefore must be maintained to adequately represent the current status of the facility. So that NRC knows the current status of the facility, changes to these documents, on which NRC based its safety conclusion, are to be submitted to NRC, as discussed in §70.72.

## Section 70.66 Additional requirements for the approval of license applications.

In addition to the requirements found in the existing rule (i.e., 10 CFR 70.23), the Commission must determine that the requirements in the new subpart, 10 CFR 70.60 through 70.66, will be satisfied.

## Section 70.72 Facility changes and change process.

This section deals with changes to site, structures, systems, equipment, components, and activities of personnel after a license application has been approved.

Past incidents at fuel cycle facilities have often resulted from changes not fully analyzed, not authorized by licensee management, or not adequately understood by facility personnel. Therefore, effective control of changes to a facility's site, structures, systems, equipment, components, and activities of personnel is a key element in assuring safety at that facility. This section would require the licensee to establish and use a system to evaluate changes and the potential impacts of those changes before implementing them. By using this system to evaluate, implement and track changes to the facility, the licensee can make certain changes without NRC pre-approval. If the change affects information contained in the ISA summary, the licensee would be required to notify NRC within 90 days of the change by submitting updated ISA summary pages in that time. For changes that affect the on-site documentation, such as the ISA, management measures or process-safety information, the licensee would be required to notify NRC within 12 months of the change. This update frequency would allow NRC staff to review the changes being made to the facility in enough time to ensure that the licensee's evaluations of potential impacts to health and safety were accurate. It also allows NRC staff to maintain relatively current facility and safety information on the docket at all times. In addition, maintaining the license and ISA summary so that they reflect the current configuration of the facility would facilitate a relatively simple, cost-effective license renewal process.

Some changes, however, would require NRC pre-approval before they can be implemented. These are changes that are considered major and could have a significant impact on health and safety. The staff considered two options for the types of changes that would require NRC pre-approval. Option 1 is consistent with the types of changes that have required pre-approval at Part 70 licensees in the past, and which the staff believes would require NRC pre-approval for only a relatively few significant changes. Option 2 is consistent with the change control process required for Part 50 licensees (power reactors) and which the staff believes would require more requests for NRC pre-approval.

The advantages of Option 1 are that it focuses on the most significant changes to the facility and is equivalent to looking at the highest risk changes. It contains very little subjective criteria and is therefore easier to implement and inspect. It also would likely only result in a few license amendments a year which is generally consistent with the past practice at these facilities. Since Option 1 would permit more changes without NRC pre-approval, a relatively short timeframe (90 days) for submitting updated ISA summary pages is required in order for NRC to have information that reflects the current status of the facility and to be confident that adequate protection is still provided with the changes, as reflected in the ISA summary. The advantages of Option 2 are that NRC would have more control over the changes at the facilities, i.e., staff expects that more changes would be reviewed by the staff before being implemented; thus, it would be less likely that NRC would have a concern with a change after the fact; and it is consistent with the change control process at power reactors, where changes are reported only after 12 months.

The proposed rule language reflects Option 1.

## Section 70.73 Renewal of licenses.

Under the proposed amendments to Part 70, changes to site, structures, systems, equipment, components, and activities of personnel made by the licensee pursuant to §70.72 would be documented on a continuing basis on-site. A description of those changes would also be sent to NRC periodically. This process is intended to keep the documents, which support the license, current and thereby establish a "living" license. In the past, the license renewal process was burdensome to NRC and the licensee because all changes made to the facility since the last license renewal would be reviewed at one time. However, with the proposed "living license," changes to the facility will be reviewed by NRC either before changes are made, or relatively shortly thereafter. As a result, review of the license renewal application is expected to be performed with minimal additional review of the licensee's safety program. This approval would be contingent on the licensee satisfying any requirements associated with the National Environmental Policy Act of 1969 as implemented in 10 CFR Part 51.

## Section 70.74 Additional reporting requirements.

The new requirements that would be incorporated in the proposed amendments to Part 70 would revise the reporting of events to NRC. This new approach, based on consideration of the risk and consequences established in 10 CFR 70.61(b) is intended to replace and expand on the approach licensees have currently been using for reporting criticality events under Bulletin 91-01. The new approach would cover all types of events, not just criticality events, and establish a timeframe for reporting that is scaled according to risk. The new reporting requirements are intended to supplement the requirements in the existing Parts 20 and 70 and elsewhere in the regulations. A more detailed discussion of the new requirements is found in the following discussion of Appendix A to Part 70.

## Appendix A Reportable Events.

The reporting of events supports NRC need to be aware of conditions that could result in an imminent danger to the worker or to public health and safety or to the environment. In particular, NRC needs to be aware of licensee efforts to address potential emergencies. Further, once safe conditions have been restored after an event, NRC has an interest in disseminating information on the event to the nuclear industry and other interested parties, to reduce the likelihood that the event will occur in the future. Also, in the event of an accident, NRC must be able to respond accurately to requests for information by the public and the media. Finally, NRC must evaluate the performance of individual licensees and the industry as a whole to fulfill its statutory mandate to protect the health and safety of the worker and the public and the environment.

Licensee reporting of events would consist of two reporting classes based on the hazard -- reports that must be made in 1 hour and those to be reported within 24 hours. According to this approach, licensees would report events based on two criteria: 1) whether actual consequences have occurred or whether a potential for such consequences exists; and 2) the seriousness of the

consequences. The events that must be reported within the shortest timeframe (1 hour) are high-consequence events. These events encompass unintended criticalities and loss of criticality controls, and loss of chemical controls or the occurrence of chemical exposures that exceed the performance requirements in §70.61(b).

Less serious events or failure to meet the performance requirements for reasons not otherwise specifically stated, that have occurred shall be reported within 24 hours. These include chemical exposure to licensed material or hazardous chemicals that exceed the lower threshold limits in §70.61(c)(4), and events that were dismissed in the ISA based on likelihood.

Events that could potentially lead to exceeding the performance requirements in §70.61 should also be reported. External events, such as a hurricane, tornado, earthquake, flood, or fire, either internal or external to the plant, that affected or could have affected a facility, must be reported within 24 hours. This reporting requirement would capture, for example, a tornado that strikes a facility, an earthquake motion experienced by a facility, or any type of fire. Since these events could have affected a facility, NRC would want to know about such events to assess a licensee's conclusion of whether any detrimental effects did in fact occur, or could have occurred in the absence of controls that were present but not part of the safety basis. Another category of potential events that would be reported is one that involves the existence of an unsafe condition that is not identified in the ISA. This condition could be caused by a deviation from established safe operating conditions, by an unanticipated and unanalyzed set of circumstances, or by an improper analysis. This type of event would be reported within 24 hours.

The proposed rule also would require concurrent reporting of events when a news release is made or if other Government agencies are notified, as is done under 10 CFR Part 50.72, to support NRC's ability to be responsive to questions concerning the safety of NRC-licensed facilities.

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U.S. Nuclear Regulatory Commission, "Certification of Gaseous Diffusion Plants" (59 FR 48944; September 23, 1994).

U.S. Nuclear Regulatory Commission, "Abnormal Occurrence Reports: Implementation of Section 208 of Energy Reorganization Act of 1974" (61 FR 67072; December 19, 1996).

U.S. Nuclear Regulatory Commission, "Site Decommissioning Management Plan," NUREG-1444, Washington, DC, October 1993.

U.S. Nuclear Regulatory Commission, "Strategic Plan, Fiscal Year 1997 - Fiscal Year 2002," NUREG-1614, Washington, DC, September 1997.

U.S. Environmental Protection Agency, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents," EPA-400-R-92-001, May 1992.

U.S. Nuclear Regulatory Commission, "Instruction Concerning Risks from Occupational Radiation Exposure," Regulatory Guide 8.29, Rev. 1, February 1996.

Theide, L., "Emergency Information Where It's Needed," DOE Risk Management Quarterly, Vol 5, No 2, Richland, WA, May 1997.

These documents are available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street, N.W. (Lower Level), Washington DC 20555-0001.

Copies of NUREG-1324, NUREG-1614, and NUREG-1444 may also be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington DC 20402-9328. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield VA 22161.

Regulatory Guide 8.29 may be purchased from the Government Printing Office (GPO) at the current GPO price. Information on current GPO prices may be obtained by contacting the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington DC 20402-9328. Issued guides may also be purchased from the National Technical Information Service on a standing-order basis. Details on this service may be obtained by writing NTIS, 5285 Port Royal Road, Springfield, VA 22161.

Copies of the following draft regulatory guidance documents may be requested by writing to U.S. Nuclear Regulatory Commission, Reproduction and Distribution Services, Washington, DC 20555-0001: "Standard Review Plan for the Review of a License Application for a Fuel Cycle

Facility" (Draft NUREG-1520); and "Integrated Safety Analysis Guidance Document" (Draft NUREG-1513).

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# Finding of No Significant Environmental Impact: Availability

The Commission has determined, under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement is not required.

The proposed amendments to Part 70 are intended to provide increased confidence in the margin of safety at certain facilities that possess a critical mass of SNM. To accomplish this objective, the amendments: (1) identify appropriate consequence criteria and the level of protection needed to prevent or mitigate accidents that exceed such criteria; (2) require affected licensees to perform an integrated safety analysis (ISA) to identify potential accidents at the facility and the items relied on for safety; (3) require the implementation of measures to ensure that the items relied on for safety are available and reliable to perform their function when needed; and (4) require the inclusion of the safety bases, as reflected in the ISA summary, in the license application. The language, in the proposed rule, that defines an environmental consequence of concern, is relevant to the question of environmental impact. Licensees would be required to provide an adequate level of protection against a "...release of radioactive material to the environment outside the restricted area in concentrations that, if averaged over 24 hours, exceed 5000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20." Implementation of the new amendments, including the requirement to protect against events that could damage the environment, is expected to result in a significant improvement in licensees' (and NRC's) understanding of the risks at their facilities and their ability to ensure that those risks are acceptable. For existing licensees, any deficiencies identified in the ISA would need to be promptly addressed. For new licensees, operations would not begin unless licensees demonstrated an adequate level of protection against potential accidents identified in the ISA. As a result, the safety and environmental impact of the new amendments is positive. There will be less adverse impact on the environment from operations carried out in accordance with the proposed rule than if those operations were carried out in accordance with the existing Part 70 regulation.

The determination of this Environmental Assessment is that there will be no significant offsite impact on the public from this action. However, the general public should note that NRC welcomes public participation. NRC has also committed to complying with Executive Order (EO) 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," dated February 11, 1994, in all its actions. Therefore, NRC has also determined that there are no disproportionate, high, and adverse impacts on minority and low-income populations. In the letter and spirit of EO 12898, NRC is requesting public comment

on any environmental justice considerations or questions that the public thinks may be related to this proposed rule, but somehow were not addressed. Comments on any aspect of the Environmental Assessment, including environmental justice, may be submitted to NRC, as indicated under the ADDRESSES heading.

NRC has sent a copy of the Environmental Assessment and this proposed rule to all State Liaison Officers and requested their comments on the Environmental Assessment. The Environmental Assessment is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, D.C. and the Part 70 website. Single copies of the environmental assessment are available from Barry Mendelsohn, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC, 20555-0001, telephone (301) 415-7262; e-mail: btm1@nrc.gov.

# Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.). This rule has been submitted to the Office of Management and Budget (OMB) for review and approval of the paperwork requirements.

The public reporting burden for this information collection is estimated to average 70 hours per response, and the recordkeeping burden is estimated to average 500 hours per licensee, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. NRC is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of NRC's function? Will the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of this proposed information collection, including suggestions for reducing the burden, to the Records Management Branch (T-6-F33), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail at bjs1@nrc.gov; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0009), Office of Management and Budget, Washington, DC 20503.

Comments to OMB on the information collections or on the above issues should be submitted by (insert 30 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to

comments received after this date.

## Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct nor sponsor, and a person is not required to respond to, the information collection.

## Regulatory Analysis

The Commission has prepared a draft Regulatory Analysis on this proposed regulation. The analysis examines the benefits and costs of the alternatives considered by the Commission. The draft Regulatory Analysis is available for inspection in the NRC Public Document Room, 2120 L Street N.W. (Lower Level), Washington, D.C. and the Part 70 website. Single copies of the analysis may be obtained from Barry T. Mendelsohn, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC, telephone (301) 415- 7262, e-mail: btm1@nrc.gov.

The Commission requests public comment on the draft Regulatory Analysis. Comments on the draft analysis may be submitted to NRC as indicated under the ADDRESSES heading.

## Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act, as amended, 5 U.S.C. 605(b), the Commission certifies that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. This proposed rule would affect facilities that are authorized to possess a critical mass of SNM and who are engaged in one of the following activities: a) enriched uranium processing; b) fabrication of uranium fuel or fuel assemblies; c) uranium enrichment; d) enriched uranium hexafluoride conversion; e) plutonium processing; f) fabrication of mixed-oxide fuel or fuel assemblies; g) scrap recovery of special nuclear material; or h) any other activity involving a critical mass of SNM that the Commission determines could significantly affect public health and safety or the environment. These licensees do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act, nor the size standards published by NRC (10 CFR 2.810).

## Voluntary Consensus Standards

The National Technology Transfer Act of 1995, Pub. L. 104-113, requires that Federal Agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC proposes to use the following voluntary consensus standard, ANSI/ANS Standard 8.1-1983, "Nuclear Criticality Safety in Operations with Fissionable Material Outside Reactors," developed by the American Nuclear Society. Portions of the standard were used in the definition of double contingency and in §70.61(d). The NRC invites comment on the applicability and use of other standards.

## Backfit Analysis

NRC has determined that the backfit rule does not apply to this proposed rule; therefore, a backfit analysis is not required for this proposed rule because these amendments do not involve any provisions that would impose backfits as defined in

10 CFR Chapter I.**List of Subjects in 10 CFR Part 70**

Criminal penalties, Hazardous materials transportation, Material control and accounting, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553, NRC is proposing to adopt the following amendments to Part 70.

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# 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 §70.4, the definitions of Acute, Available and reliable to perform their function when needed, Configuration Management, Critical mass of special nuclear material, Double contingency, Hazardous chemicals produced from licensed material, Integrated safety analysis (ISA), Integrated safety analysis**

**summary, Items relied on for safety, Management measures, Unacceptable performance deficiencies, and Worker are added, in alphabetical order, as follows:**

§70.4 Definitions.

*  *  *  *  *

Acute as used in 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).

*  *  *  *  *

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 when needed 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.

*  *  *  *  *

Configuration management (CM) means ensuring, as part of the safety program, oversight and control of design information, safety information, and modifications (both temporary and permanent) that might impact the ability of items relied on for safety to perform their function when needed.

*  *  *  *  *

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.

*  *  *  *  *

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.

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 items 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 NRC requirement is limited to consideration of 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 with the license application, license amendment application, or license renewal application that provides a synopsis of the results of the integrated safety analysis and contains the information specified in §70.65(b).

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 that could exceed the performance requirements in §70.61 or to mitigate their potential consequences. This does not limit the licensee from identifying additional structures, systems, equipment, components, or activities of personnel (i.e., beyond those in the minimum set necessary for compliance with the performance requirements) as items relied on for safety.

*  *  *  *  *

Management measures mean the functions performed by the licensee, generally on a continuing basis, that are applied to items relied upon for safety, to ensure the itmes 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 elements.

*  *  *  *  *

Unacceptable performance deficiencies mean deficiencies in the items relied on for safety or the management measures 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. In §70.8 paragraph (b) is revised to read as follows.**

§ 70.8 Information collection requirements: OMB approval.

*  *  *  *  *

(b) The approved information collection requirements contained in this part appear in §§ 70.9, 70.14, 70.19, 70.20a, 70.20b, 70.21, 70.22, 70.24, 70.25, 70.32, 70.33, 70.34, 70.38, 70.39, 70.42, 70.50, 70.51, 70.52, 70.53, 70.57, 70.58, 70.59, 70.60, 70.61, 70.62, 70.64, 70.65, 70.66, 70.72, and Appendix A.

*  *  *  *  *

**5. The undesignated center heading "EXEMPTIONS" is redesignated as "Subpart B -- Exemptions."**

§§ 70.13a and 70.14 [Redesignated]

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

**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."**

**9. The undesignated center heading "LICENSES" is redesignated as "Subpart E -- Licenses."**

**10. 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."**

**11. 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."**

**12. In §70.50 paragraph (c) is revised to read as follows.**

§ 70.50 Reporting Requirements

* * * * *

(c) Preparation and submission of reports. Reports made by licensees in response to the requirements of this section must be made as follows:

1. Licensees shall make reports required by paragraphs (a) and (b) of this section, and by section 70.74 and Appendix A of this Part if applicable, by telephone to the NRC Operations Center[(3)]. To the extent that the information is available at the time of notification, the information provided in these reports must include:
    1. Caller's name, position title and call back telephone number;
    2. Date, time, and exact location of the event;
    3. Description of the event, including;
        1. Radiological or chemical hazards involved including isotopes, quantities, and chemical and physical form of any material released;
        2. Actual or potential health and safety consequences to the workers, the public, and the environment, including relevant chemicaland radiation data for actual personnel exposures to radiation or radioactive materials or chemicals (e.g., level of radiation exposure, concentration of chemicals, and duration of exposure);
        3. The sequence of occurrences leading to the event,including degradation or failure of structures, systems, equipment, components,and activities of personnel relied on to prevent potential accidents or mitigate their consequences; and
        4. Whether the remaining structures, systems, equipment, components, and activities of personnel relied on to prevent potential accidents or mitigate their consequences are available and reliable to perform their function.
    4. External conditions affecting the event;
    5. Additional actions taken by the licensee in response to the event;
    6. Status of the event (e.g., whether the event is on-going or was terminated);
    7. Current and planned site status, including any declared emergency class;
    8. Notifications related to the event that were made or are planned to any local, State, or other Federal agencies;
    9. Status of any press releases related to the event that were made or are planned.
2. Written report. Each licensee who makes a report required by paragraph (a) or (b) of this section, or by §70.74 and Appendix A of this Part if applicable, shall submit a

written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the report contains all of the necessary information and the appropriate distribution is made. These written reports must be sent to the U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, with a copy to the appropriate NRC regional office listed in Appendix D of 10 CFR Part 20. The reports must include the following:

1. Complete applicable information required by §70.50(c)(1);
2. The probable cause of the event, including all factors that contributed to the event and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;
3. Corrective actions taken or planned to prevent occurrence of similar or identical events in the future and the results of any evaluations or assessments; and
4. For licensees subject to Subpart H of this Part, whether the event was identified and evaluated in the Integrated Safety Analysis.

(d) The provisions of §70.50 do not apply to licensees subject to §50.72. They do apply to those Part 50 licensees possessing material licensed under Part 70 who are not subject to the notification requirements in §50.72.

**13. 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]

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

**15. The undesignated center heading "ENFORCEMENT" is redesignated as "Subpart J -- Enforcement."**

§§ 70.71 and 70.72 [Redesignated]

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

**17. 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.

The regulations in §70.61 through §70.74 apply, in addition to other applicable Commission regulations, to each applicant or licensee that is or plans to be: (1) authorized to possess greater than a critical mass of special nuclear material, and (2) 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 of special nuclear material, or any other activity that the Commission determines could significantly affect public health and safety. The regulations in §70.61 through §70.74 do not apply to decommissioning activities performed pursuant to other applicable Commission regulations including §70.25 and §70.38 of this Part. Also, the regulations in §70.61 through §70.74 do not apply to activities that are certified by the Commission pursuant to Part 76 of this chapter or licensed by the Commission pursuant to other parts of this chapter.

## §70.61Performance Requirements.

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

(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 of 0.25 Sv (25 rem) or greater total effective dose equivalent to any individual located outside the controlled area identified pursuant to paragraph (f) of this section;

3. An intake of 30 mg or greater of uranium in soluble form by any individual located outside the controlled area identified pursuant to paragraph (f) of this section; or

4. An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that:
    1. Could endanger the life of a worker, or
    2. Could lead to irreversible or other serious, long-lasting health effects to any individual located outside the controlled area identified pursuant to paragraph (f) of this section. 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 information submitted pursuant to §70.65 of this Part.

(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 of 0.05 Sv (5 rem) or greater total effective dose equivalent to any individual located outside the controlled area identified pursuant to paragraph (f) of this section;
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:

1. Could lead to irreversible or other serious, long-lasting health effects to a worker, or
2. Could cause mild transient health effects to any individual located outside the controlled area as specified in paragraph (f) of this section. 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 information submitted pursuant to §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 must be the primary means of protection against nuclear criticality accidents.

(e) Each engineered or administrative control or control system necessary to comply with paragraphs (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.

(f) Each licensee must establish a controlled area, as defined in §20.1003, in which the licensee retains the authority to determine all activities, including exclusion or removal of personnel and property from the area. For the purpose of complying with the performance requirements of this section, individuals who are not workers, as defined in §70.4, may be permitted to perform ongoing activities (e.g., at a facility not related to the licensed activities) in the controlled area, if the licensee:

1. Demonstrates and documents, in the integrated safety analysis, that the risk for those individuals at the location of their activities does not exceed the performance requirements of paragraphs (b)(2), (b)(3), (b)(4)(ii), (c)(2), and (c)(4)(ii) of this section; or
2. Provides: (i) Training in accordance with 10 CFR 19.12(a)(1)-(5) to these individuals to ensure that they are aware of the risks associated with accidents involving the licensed activities as determined by the integrated safety analysis, and (ii) Conspicuously posts and maintains notices stating where the information in 10 CFR 19.11(a) may be examined by these individuals. Under these conditions, the performance requirements for workers specified in paragraphs (b) and (c) of this section may be applied to these individuals.

## §70.62 Safety Program and Integrated Safety Analysis

(a) *Safety program.*

1. Each licensee shall establish and maintain a safety program that demonstrates compliance with the performance requirements of §70.61. The safety program may

be graded such that management measures applied are commensurate with the reduction of the risk attributable to that item. The three elements of the safety program, namely process safety information, integrated safety analysis, and management measures, are described in paragraphs (b) through (d) of this section.

2. Each licensee shall establish and maintain records that demonstrate compliance with the requirements of paragraphs (b) through (d) of this section.
3. Each licensee shall establish and maintain a log, available for NRC inspection, documenting each discovery that an item relied on for safety or management measure has failed to perform its function either in the context of the performance requirements of §70.61 or upon demand. This log must identify the item relied on for safety or management measure that has failed and the safety function affected, the date of discovery, date (or estimated date) of the failure, duration (or estimated duration) of the time that the item was unable to perform its function, any other affected items relied on for safety or management measures and their safety function, affected processes, cause of the failure, whether the failure was in the context of the performance requirements or upon demand or both, and any corrective or compensatory action that was taken. The log must be initiated at the time of discovery and updated promptly upon the conclusion of each investigation of a failure of an item relied on for safety or management measure.

(b) *Process safety information.* Each licensee or applicant shall maintain 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.

(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:
    1. Radiological hazards related to possessing or processing licensed material at its facility;
    2. Chemical hazards of licensed material and hazardous chemicals produced from licensed material;
    3. Facility hazards which could affect the safety of licensed materials and thus present an increased radiological risk;
    4. Potential accident sequences caused by process deviations or other events internal to the plant and credible external events, including natural phenomena;
    5. 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
    6. Each item relied on for safety identified pursuant to §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