[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 70

RIN 3150 - AF22

Revised Requirements for the Domestic Licensing of Special Nuclear Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its safety regulations in the provisions 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; uranium fuel fabrication; uranium enrichment; enriched uranium hexafluoride conversion; plutonium processing; mixed-oxide fuel fabrication; scrap recovery; or any other activity involving a critical mass of SNM that the Commission determines could significantly affect public health and safety. 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; require the implementation of measures to ensure that the items relied on for safety are continuously available and reliable; require the inclusion of the safety bases, including the results of the ISA, in the license application; and allow for licensees to make certain changes to their 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: The 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. The interactive rulemaking website can then be accessed by selecting "New Rulemaking Website." 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, (301) 415-5905; e-mail cag@nrc.gov.

FOR FURTHER INFORMATION, CONTACT: Richard I. Milstein, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC, 20555-0001, telephone (301) 415-8149; e-mail rim@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A near-criticality incident at a low enriched fuel fabrication facility in May of 1991 prompted NRC to review its safety regulations for licensees that possess and process large quantities of SNM. [See "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 its regulatory base for

these licensees and, specifically, 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 of 1995. Industry's position on the need for revision of NRC regulations in Part 70 was articulated to the Commission by the Nuclear Energy Institute (NEI) at a July 2, 1996, meeting, and in the subsequent filing of a Petition for Rulemaking (PRM-70-7) by NEI with NRC 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 NRC staff proposed a resolution to the NEI PRM and recommended that the Commission direct the staff to proceed with rulemaking. The NRC staff's recommended approach to rulemaking included the basic elements of the PRM, with some modification. In brief, NRC staff proposed to revise Part 70 to include the following major elements:

(1) Performance of a formal ISA, which would form the basis for a licensee's safety program. This requirement would apply to all licensed facilities (except reactors and the gaseous diffusion plants regulated under 10 CFR Part 76) or activities, subject to NRC regulation, that are authorized to possess SNM in quantities sufficient to constitute a potential for nuclear criticality;

(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 or mitigate these accidents, and the measures needed to ensure the continuous availability and reliability of these items). (This is in contrast to the PRM's approach, where the ISA results would not be included in the license application);

(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 initial conduct and implementation of the ISA by the licensees, of a qualitative backfitting mechanism to enhance regulatory stability.

In a Staff Requirements Memorandum (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."

II. Description of Proposed Action

The Commission has decided to grant, in part, the NEI PRM by initiating this rulemaking. Further, the proposed rule adopts the petitioner's proposal 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 consequence criteria and the level of protection needed to prevent or mitigate accidents that 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 continuously available and reliable;

(4) The inclusion of the safety bases, including the ISA results, in the license application; and

(5) The allowance for licensees to make certain changes to their 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 broad 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; uranium fuel fabrication; uranium enrichment; enriched uranium hexafluoride conversion; plutonium processing; mixed-oxide fuel fabrication; scrap recovery; 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 regulatees 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 a public meeting held on May 28, 1998, the purpose of the 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 bases, including the results of the ISA, are 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 believes 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.

The majority of the proposed modifications to Part 70 are found in a new subpart, "Additional Requirements for Certain Applicants Authorized to Possess a Critical Mass of Special Nuclear Material," that consists of §§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 August 22, 1997, SRM. However, the Commission has decided that the new requirements should not apply to all licensees authorized to possess a critical mass of SNM. Instead, the Commission has identified a subset of these licensees that, based on the relatively high level of 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. This issue is further addressed in the discussion of §70.62.

Section 70.4, "Definitions."

The following fourteen definitions would be added to this section to provide a clear understanding of the meaning of the new subpart H, "Additional Requirements for Certain

Applicants Authorized to Possess a Critical Mass of Special Nuclear Material:" Acute exposure, Acute exposure guideline levels, Controlled site boundary, Critical mass of SNM, Deviation from safe operating conditions, Double contingency, Emergency response planning guidelines, Hazardous chemicals, Integrated safety analysis, Items relied on for safety, New process, Results of the ISA, Unacceptable vulnerabilities, and Worker.

Section 70.15, "Nuclear reactors."

A new section would be added to subpart B, "Exemptions," that exempts nuclear reactors licensed under Part 50 from the new subpart H, "Additional Requirements for Certain Applicants Authorized to Possess a Critical Mass of Special Nuclear Material."

Section 70.22, "Contents of applications."

Paragraph (f) would be removed. Paragraph (f) currently requires that, for plutonium processing and fuel fabrication facilities, certain additional safety-related information be submitted with an application. The new subpart H, "Additional Requirements for Certain Applicants Authorized to Possess a Critical Mass of Special Nuclear Material," would contain requirements for the submittal of information called for in paragraph (f) and is sufficient to allow the Commission to make a determination of adequacy.

Section 70.23, "Requirements for the approval of applications."

Paragraphs (a)(8), and (b) would be removed. These paragraphs currently require that the Commission, to approve an application, determine that the construction of a plutonium processing and fabrication facility meet certain conditions. These conditions would be covered in the new subpart H, "Additional Requirements for Certain Applicants Authorized to Possess a Critical Mass of Special Nuclear Material."

Section 70.60, "Safety performance requirements."

These requirements would establish the purpose of the new requirements, identify the potential adverse consequences that need to be protected against, establish the level of protection that is needed to ensure that the consequences of concern do not occur, and identify the safety program elements that allow licensees to demonstrate their ability to provide an adequate level of protection.

Section 70.60(a), "Purpose."

This paragraph would address the following questions: *Why* are the new requirements needed? *What* hazards need to be considered? *Who* are the intended beneficiaries? In general, the new requirements are intended to ensure that workers[1], the general public, and the environment are protected from radiological and certain chemical hazards associated with plant operations. All hazards, including fire, chemical, electrical, industrial, etc., that can potentially affect radiological safety, must be considered and addressed by licensees. In addition, chemical hazards that result from the processing of licensed nuclear material must also be considered.

The question 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 killed a worker. 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). As a result of that incident, NRC and the Occupational Safety and Health Administration (OSHA) established a memorandum of understanding (MOU) (1988) that identified the respective responsibilities of both agencies for the regulation of chemical hazards at nuclear facilities. The MOU identified the following four areas of responsibility. The NRC has responsibility for the first three areas, whereas OSHA has responsibility for the fourth area:

(1) Radiation risk produced by radioactive materials;

(2) Chemical risk produced by radioactive materials;

[1]A worker, in the context of this rulemaking, is defined as 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 10 CFR 20.1003).

(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.

The purpose of the "Safety Performance Requirements," as defined in §70.60(a), is consistent with the NRC/OSHA MOU.

Section 70.60(b), "Consequences of concern."

The NRC is responsible for ensuring that workers and the general public are protected from the hazards involved in the handling, processing, and storage of SNM. All hazards (including fire and chemical) that could result in radiological consequences are a subject of NRC concern. In addition, all chemical hazards resulting from the processing of licensed SNM that could directly affect a worker or member of the public are also a matter of NRC concern. Thus, NRC regulations need to address both radiological and chemical consequences. The following discussion provides information, on the consequences of human exposure to radiation and hazardous chemicals, that is relevant to the choice of appropriate consequence criteria. The actual choice of these criteria is discussed in §§70.60(b)(1)(ii)(A) and (B); 70.60(b)(1)(iii)(A) and (C); and 70.60(b)(2)(i)(A) and (B).

Radiological Consequences. In the past, the regulation of licensees authorized to possess SNM, under 10 CFR Parts 70 and 20, has concentrated on radiation protection for persons involved in nuclear activities conducted under normal operations. The proposed amendments to Part 70 would explicitly address the potential exposure of workers or members of the public to radiation as a result of accidents. Because accidents are unanticipated events that usually occur over a relatively short period of time, a regulation that seeks to assure adequate protection of workers and members of the public must limit the *risk* of such accidents. This can be accomplished by identifying appropriate consequence criteria and by limiting the likelihood of occurrence of the identified consequences. In selecting the radiological consequence criteria for use in the proposed rule, the Commission has examined the radiological criteria and design basis

accident scenarios used in existing NRC regulations to ensure that the proposed consequence criteria are consistent with criteria used in other Commission rules.

Chemical Consequences. The processing of SNM may involve the use or production of hazardous chemicals. For example, low enriched uranium fuel fabrication facilities convert uranium hexafluoride to uranium oxide by reaction with water (hydrolysis) to form uranyl fluoride and hydrogen fluoride. Uranyl fluoride, in addition to being radioactive, is a toxic uranium compound that can cause damage to the kidney. Hydrogen fluoride is highly toxic and poses a hazard to both workers and the general public. Other hazardous chemicals, including ammonia, nitric acid, and sulphuric acid, are also used at uranium fuel fabrication facilities. The effort to limit exposure of workers and the general public to hazardous chemicals is based on two concerns: acute exposures that could result from accidental releases, and chronic exposures (i.e., multiple and repeated exposures occurring over a long period of time -- days, months, or years), resulting from releases during normal operations.

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 U.S. Environmental Protection Agency (EPA) and the National Academy of Sciences (NAS), 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 (AIHA) 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 chemical 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.

Federal regulations and internal U.S. Department of Energy (DOE) guidance require the use of ERPGs for emergency planning. Recognizing that ERPGs exist for a limited number of chemicals, DOE's Subcommittee on Consequence Assessment and Protective Actions developed Temporary Emergency Exposure Limits (TEELs) so that DOE facilities could perform complete hazard analysis and consequence assessments, even for chemicals lacking ERPGs. TEELs are not equivalent to ERPGs, but are approximations to ERPGs. They exist only until an ERPG is developed for a chemical. As of July 1997, 400 TEELs had been developed according to a methodology published in the American Industrial Hygiene Journal (1995). That methodology is not based directly on toxicological studies of the chemicals involved, but on a derived relationship between alternative exposure-limit parameters and the existing ERPG criteria. The use of the methodology results in a significant underestimation of the TEEL-2[2] level (0.6 mg/m^3) for soluble uranium and would be inconsistent with the criterion on soluble uranium intake (i.e., 30 mg) proposed in this rule.

A fourth set of chemical consequence criteria that was considered potentially applicable for acute exposure to hazardous chemicals is the Immediately Dangerous to Life and Health (IDLH) criteria established by the National Institute for Occupational Safety and Health (NIOSH). However, according to NIOSH, the IDLH criteria are defined "... only for the purpose

[2]TEEL-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 which could impair an individual's ability to take protective action.

of respirator selection." In addition, unlike the previously mentioned sets of criteria, there is only one IDLH level that has been defined. This would not facilitate the definition of multiple consequence levels for workers and the public, as intended in the proposed rule.

For chronic exposures of workers to hazardous chemicals during normal and off-normal operations, the permissible exposure limits (PELs) established by OSHA in 29 CFR 1910 are applicable. However, these limits are not relevant for acute exposures to hazardous chemicals.

Given the status of these various sets of consequence criteria, the Commission has chosen AEGLs and ERPGs, in that order, as criteria to be used for acute short-term exposure to hazardous chemicals. If a given chemical has an AEGL associated with it, that criterion should be used. If not, the ERPG criterion, if available, should be used. Appendix A contains the available AEGL values, and Appendix B contains the available ERPG values. If both AEGLs and ERPGs are available for a particular chemical, only the AEGL values will be presented. Although the TEELs cover a wide range of additional hazardous chemicals, the Commission has decided not to require their use at this time, because the methodology used to derive these values is not based on the toxicology of the chemicals involved and may, at least in certain cases, underestimate the limits. However, the use of the TEELs may be justified on a case-by-case basis in the absence of other applicable standards.

As a result of further study, new AEGL or ERPG values are expected to be established by the issuing organizations (EPA for AEGLs; AIHA for ERPGs). The Commission does not propose to engage in full, formal rulemaking with respect to these future changes, but will incorporate them in the codified appendices in final form by issuing an immediately effective final rule. The Commission believes that these purely technical changes or additions do not require comment and are, in addition, subject to the categorical exclusion in 10 CFR 51.22(c)(2).

General Approach

The consequences of concern, identified in §§70.60(b)(1) and (b)(2), describe those consequences that licensees must protect against[3]. The level of protection to be provided is discussed in §70.60(c) and depends on the severity of the consequences. The goal is to ensure an acceptable level of risk by limiting the likelihood of occurrence of the identified consequences. The consequences identified in §70.60(b)(1) of the proposed rule are considered to be *high consequences* and include the occurrence of a criticality, and accidental exposure of a worker or member of the public to high levels of radiation or hazardous chemicals. The consequences identified in §70.60(b)(2) are considered to be *intermediate consequences* and include accidental exposure of a worker or member of the public to moderate levels of radiation or hazardous chemicals, and significant releases of radioactive material to the environment. The proposed consequence criteria that are applicable to a member of the public are more restrictive than those that are applicable to a worker. Also, within each category (worker and public), NRC recognizes that the proposed radiological criteria are more restrictive (in terms of acute health effects) than the chemical criteria for a given level of severity (high or intermediate) and that this is consistent with current regulatory practice.

In some cases, a qualitative description of the consequence is used (e.g., a nuclear criticality); in other cases, a numerical criterion is used. For cases where numerical criteria have been used, NRC has based the criteria on values that have been developed previously by NRC or other government agencies or professional societies. Table 1 illustrates the radiological and chemical consequence criteria used in the proposed rule.

TABLE 1 Radiological and Chemical Consequence Criteria

	Worker		Public	
CONSEQUENCE	Radiological	Chemical	Radiological	Chemical

[3]The proposed rule does not address chemical and radiological consequences to workers and members of the public resulting from routine operations. These consequences are covered in other regulations (i.e., 10 CFR Part 20 and 29 CFR Part 1910).

High	> 1 Sv (100 rem)	> AEGL-3 (ERPG-3)	> 0.25 Sv (25 rem)	> AEGL-2 (ERPG-2)
Intermediate	< 1 Sv (100 rem) > 0.25 Sv (25 rem)	< AEGL-3 (ERPG-3) > AEGL-2 (ERPG-2)	< 0.25 Sv (25 rem) > 0.05 Sv (5 rem)	< AEGL-2 (ERPG-2) > AEGL-1 (ERPG-1)

Section 70.60(b)(1). This paragraph defines "high consequences."

Certain events that could occur at licensees' facilities are considered high-consequence events. They include the occurrence of an inadvertent criticality, the exposure of a worker or member of the public to levels of radiation at which clinically observable biological damage could occur, or concentrations of hazardous chemicals at which death or life threatening injury could occur.

Section 70.60(b)(1)(i). This paragraph deals with a nuclear criticality.

The occurrence of an inadvertent nuclear criticality is considered to be a high-consequence event. Although detecting and mitigating the consequences of a nuclear criticality are important objectives (see 10 CFR 70.63*)*, the prevention of a criticality is a primary NRC objective.

Section 70.60(b)(1)(ii)(A). This paragraph deals with an acute exposure of a worker to a radiation dose of 1 Sv (100 rem) or greater total effective dose equivalent (TEDE).

An acute exposure of a worker to a radiation dose of 1 Sv (100 rem) or greater 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." The use of the 1-Sv (100-rem) criterion is not intended to imply that 1 Sv (100 rem) constitutes an acceptable criterion for an emergency dose to a worker. Rather, this dose value has been proposed in this section as a reference value, which should be used by licensees to determine the level of protection (i.e., items relied on for safety, and measures to assure their continuous availability and reliability) needed to ensure an acceptably low level of risk to workers.

Section 70.60(b)(1)(ii)(B). This paragraph deals with an acute exposure of a worker to hazardous chemicals in concentrations exceeding AEGL-3 or ERPG-3 limits.

An acute exposure of a worker to hazardous chemicals at concentrations that could cause death or life-threatening injuries is considered a high-consequence event. Two existing criteria, AEGL-3[4] and ERPG-3, can be used to define such concentration levels. 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." If, for a particular chemical, the AEGL-3 value is available, it should be used. Otherwise, the ERPG-3 value should be used. If there is no AEGL or ERPG value available, then the applicant should adopt a criterion that is comparable in severity to those that have been established for other chemicals.

[4]Three levels of consequences are defined for each chemical (AEGL-1, AEGL-2, and AEGL-3) for four different exposure times: 30 minutes; 1 hour; 4 hours; and 8 hours. The AEGL value for a 1-hour exposure is chosen for consistency with the definition of ERPG.

Section 70.60(b)(1)(iii)(A). This paragraph deals with an acute exposure of a member of the public to a radiation dose of 0.25 Sv (25 rem) or greater TEDE.

The exposure of a member of the public to a radiation dose of 0.25 Sv (25 rem) TEDE is considered a high-consequence event. This is based on 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 70.60(b)(1)(iii)(B). This paragraph deals with an intake of 30 mg or greater of uranium in a soluble form by a member of the public.

The intake of 30 mg of soluble uranium by a member of the public 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 70.60(b)(1)(iii)(C). This paragraph deals with an acute exposure of a member of the public to hazardous chemicals in concentrations exceeding AEGL-2 or ERPG-2 criteria.

An acute exposure of a member of the public to hazardous chemicals at concentrations that could cause irreversible health effects is considered a high-consequence event. Two existing criteria, AEGL-2 and ERPG-2, can be used to define such concentration levels.

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." 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." If, for a particular chemical, the AEGL-2 value is available, it should be used. Otherwise the ERPG-2 value should be used. If there is no AEGL or ERPG value available, then the applicant should adopt a criterion that is comparable in severity to those that have been established for other chemicals.

Section 70.60(b)(2)(i)(A). This paragraph deals with an acute exposure of a worker to a radiation dose of between 0.25 Sv (25 rem) and 1 Sv (100 rem) TEDE.

The exposure of a worker to a radiation dose between 0.25 Sv (25 rem) and 1 Sv (100 rem) TEDE is considered an intermediate-consequence event. The basis for this choice is the use of 0.25 Sv (25 rem) as an exposure 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, the 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. However, its use is not intended to imply that 0.25 Sv (25 rem) constitutes an acceptable criterion for an emergency dose to a worker. Rather, this dose value has been proposed in this section as a reference value, which should be used by licensees to

determine the level of protection (i.e., items relied on for safety, and measures to assure their continuous availability and reliability) needed to ensure an acceptably low level of risk to workers.

Section 70.60(b)(2)(i)(B). This paragraph deals with an acute exposure of a worker to hazardous chemicals in concentrations between AEGL-2 (ERPG-2) and AEGL-3 (ERPG-3) criteria.

An acute exposure of a worker to hazardous chemicals at concentrations that could cause irreversible health effects (but below concentrations that could cause death or life-threatening effects) is considered an intermediate-consequence event. Two existing standards, AEGL-2 and ERPG-2, can be used to define the concentration level for irreversible health effects [see definitions in §70.60(b)(1)(iii)(C), above]. Two additional standards, AEGL-3 and ERPG-3, can be used to define the concentration level for death or life-threatening effects [see definitions in §70.60(b)(1)(ii)(B), above] . If, for a particular chemical, the AEGL values are available, they should be used. Otherwise the ERPG values should be used. If there are no AEGL or ERPG values available, then the applicant should adopt criteria that are comparable in severity to those that have been established for other chemicals.

Section 70.60(b)(2)(ii)(A). This paragraph deals with an acute exposure of a member of the public to a radiation dose between 0.05 Sv (5 rem) and 0.25 Sv (25 rem) TEDE.

The exposure of a member of the public to a radiation dose 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 geologic repository operations, 10 CFR 60.136, states that “...for Category 2 design basis events, 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 70.60(b)(2)(ii)(B). This paragraph deals with an acute exposure of a member of the public to hazardous chemicals in concentrations between AEGL-1 (ERPG-1) and AEGL-2 (ERPG-2) criteria.

An acute exposure of a member of the public to hazardous chemicals at concentrations that could cause notable discomfort (but below concentrations that could cause irreversible effects) is considered an intermediate-consequence event. Two existing standards, AEGL-1 and ERPG-1, can be used to define the concentration level for notable discomfort. AEGL-1 is defined as "The airborne concentration (expressed in ppm or mg/m3) of a substance at or above which it is predicted that the general population, including susceptible, but excluding hypersusceptible, individuals, could experience notable discomfort." ERPG-1 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 other than mild transient adverse effects or perceiving a clearly defined, objectionable odor." Two additional standards, AEGL-2 and ERPG-2, can be used to define the concentration level for irreversible health effects [see definitions in §70.60(b)(1)(iii)(C), above]. If, for a particular chemical, the AEGL values are available, they should be used. Otherwise the ERPG values should be used. If there are no AEGL or ERPG values available, then the applicant should adopt criteria that are comparable in severity to those that have been established for other chemicals.

Section 70.60(b)(2)(iii). This paragraph deals with a release of radioactive material to the environment.

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 on an annual basis.) 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 day. 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.

Several existing fuel fabrication licensees have chosen to demonstrate compliance with the public dose limit in 10 CFR 20.1301, using 10 CFR 20.1302(b)(1). However, in these cases, routine operations at the facilities do not release effluents that come anywhere close to approaching the Table 2 values in Appendix B to Part 20. Indeed, routine discharge of heavy metals such as uranium in concentrations that substantially exceed the Table 2 values in water or air effluents would be expected to cause extensive environmental contamination that would be difficult and expensive to remediate. This has been demonstrated by the extensive and expensive decommissioning actions that have been required at former fuel fabrication facilities in the United States (see NRC's "Site Decommissioning Management Plan," NUREG-1444). In addition, SNM-processing licensees would not be expected to use the compliance method in 10 CFR 20.1302(b)(2)(ii) because this is primarily directed at external radiation hazards, whereas the materials released from SNM processing facilities primarily represent internal radiation and chemical hazards. Consequently, there is no need to retain the caveat regarding alternative means of demonstrating compliance with the public dose limit, as found in the AO reporting criterion.

Section 70.60(c). This paragraph deals with the graded level of protection.

This section addresses the level of protection a licensee must provide to ensure an acceptable degree of risk at its facility. That protection must be sufficient to reduce the likelihood of potential accidents to levels commensurate with their consequences. In determining the appropriate level of protection that the licensee must provide, consideration may be given to the inherent likelihood of the accident. By inherent, we mean the likelihood of the accident, assuming no controls are in place. Thus, an accident that is initiated by an unlikely external event may require less protection (provided by the licensee) than an accident, with identical consequence, that is initiated by a more frequent event. For example, suppose a serious fire, with

high consequences, could be started as the result of a process deviation that is estimated to occur once per year. The level of protection needed to prevent or mitigate this accident would be greater than that needed to protect against a similar fire resulting from an unlikely external event, such as an earthquake that might occur once in 500 years. Thus, licensees may take credit for inherent "unlikeliness" of an accident in determining the level of protection that needs to be applied.

The goal of applying a graded level of protection is to reduce the likelihood or consequences of accidents[5] to ensure an acceptable level of risk at the licensee's facility. For each of the high-consequence events identified in the proposed §70.60(b), the Commission believes that the occurrence of such an event should be *highly unlikely* to occur during any given year of plant operation. For each of the intermediate-consequence events identified in the proposed §70.60(b), the Commission believes that the occurrence of such an event should be *unlikely* to occur during any given year of plant operation.

The Commission has decided not to include a quantitative definition of "unlikely" and "highly unlikely" in the proposed rule, because a single definition for each term may not be appropriate. Depending on the type of facility and its complexity, the number of potential accidents and their consequences, which are identified in the ISA, could differ markedly. Thus, even if the permitted likelihood for each event were quantitatively defined, the integrated risk for a given facility would depend on the number of such events that could occur and the consequences of those events. For example, some facilities may have few potential accidents in the "high-consequence" range while others may have many potential accidents in this range. Therefore, to ensure that the overall facility risk is acceptable for different types of facilities, guidelines for interpreting "likely" and "highly unlikely" may need to be adjusted accordingly. To accommodate the potential variation in these guidelines, the Commission believes that the standard review plan is the appropriate document to address these terms. The "Standard Review

[5]For exposures of workers or members of the public to radioactive or hazardous chemical materials during normal operations, adherence to the existing requirements of 10 CFR 20 and 29 CFR 1910 should be sufficient to protect the public health and safety.

Plan for the Review of a License Application for a Fuel Cycle Facility," which is being made available with the proposed rule, provides guidelines that can be applied to existing fuel cycle facilities. These guidelines have been selected so as to be consistent with the safety performance goals in the NRC Strategic Plan (NUREG-1614, Vol. 1). The Commission intends to publish standard review plans for different types of facilities licensed by NRC, as the need arises. Appropriate guidelines for such facilities can be addressed in the standard review plans at that time.

Section 70.60(d). This paragraph deals with the safety program.

ISA. The performance of an ISA, and the establishment of measures to ensure the continuous availability and reliability of items relied on for safety, are the means by which licensees are able to demonstrate their ability to provide 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, when called on, the items relied on for safety are continuously in place and operating properly.

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 70.60(b), the likelihood of such an accident must be shown to be commensurate with the consequences, as required in the proposed 10 CFR 70.60(c). Protection against accidents with consequences below the intermediate level threshold is assumed to be provided by adherence to existing NRC, OSHA, and EPA regulations.

(4) Identify the items relied on for safety (i.e., those items that are relied on to prevent or to mitigate the accidents identified in the ISA). Such items are needed to reduce the likelihood or consequences 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 the proposed 10 CFR 70.60(b).

Management control. Although the ISA plays a critical role in identifying potential accidents and the items relied on for safety, the performance of an ISA will not, by itself, ensure adequate protection. Instead, according to the proposed 10 CFR 70.60(d), an effective management system is needed to ensure that, when called on, the items relied on for safety are continuously available and reliable (i.e., in place and operating properly). Maintenance measures must be in place to ensure the continuous availability and reliability of all hardware relied on for safety. Training measures must be established to ensure that all personnel relied on for safety are appropriately trained to perform their safety functions. Human-system interfaces and safety-related procedures must be developed and implemented to enable personnel relied on for safety to effectively carry out their duties. 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. In addition, quality assurance measures need to be established to ensure that the items relied on for safety and the measures used to ensure their continuous availability and reliability are of sufficient quality. 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. When abnormal events occur, investigations of those events must be carried out 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.

Section 70.62. This section deals with requirements for the performance of ISAs and the filing of ISA results and license applications. These requirements address the question of who should perform ISAs, when they should be performed, and what ISA information should be provided to NRC.

The performance of an ISA would be required of all licensees authorized to possess a critical mass of SNM, that are engaged in one of the following activities: enriched uranium processing; uranium fuel fabrication; uranium enrichment; enriched uranium hexafluoride conversion; plutonium processing; mixed-oxide fuel fabrication; scrap recovery; or any other activity that the Commission determines could significantly affect public health and safety. The Commission believes that possession and processing of SNM in amounts sufficient to constitute a potential for criticality is a reasonable criterion for requiring the performance of an ISA. Licensees meeting this criterion are already subject to criticality monitoring and alarm requirements that ensure an adequate *response* to a criticality event after it occurs. The performance of an ISA provides the means for licensees to ensure adequate measures are taken to *prevent* a criticality event (or other high-consequence event) before it occurs. By limiting the requirement for performance of an ISA to licensees engaged in specific activities that involve major chemical or mechanical processing of SNM, the Commission recognizes that these

activities involve a higher degree of risk than the activities of licensees who are authorized to possess critical quantities of SNM, but do not perform any mechanical or chemical processing of critical or near-critical quantities of the SNM.

These types of facilities include sub-critical assemblies, where the critical mass of material is fixed in place in such a manner that an inadvertent criticality is not credible; research facilities that are authorized to possess a critical quantity of material, but do not process more than a small fraction of that material at any one laboratory; facilities that are authorized only to store the material; and facilities no longer operating, for which the material is dispersed throughout the facility as residue in walls, floors, or other fixed structures. However, potentially hazardous activities involving cleanup and decommissioning at non-operating facilities would be subject to the ISA requirement.

The proposed rule would require current Part 70 licensees, for whom the rule would be applicable to develop compliance plans and submit them to NRC within 6 months of the effective date of the rule. Each compliance 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 ISAs within 4 years of the effective date of the rule, correct any unacceptable vulnerabilities identified, and submit to NRC the results for evaluation, approval, and incorporation in the license. Pending the correction of any unacceptable vulnerabilities, licensees would be expected to implement appropriate compensatory measures to ensure adequate protection. The process description in the ISA submittal should contain information that demonstrates the licensee's compliance with the criticality monitoring and alarm requirements in 10 CFR 70.24.

Applicants operating existing facilities that could become newly subject to the Commission's authority, such as DOE facilities, would be expected to perform ISAs and submit the results as part of their applications for licenses. The ISA submittals should contain information that demonstrates the licensees' compliance with the criticality monitoring and alarm requirements in 10 CFR 70.24.

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 the proposed 10 CFR 70.60(b). In addition, the initial designs are expected to comply with the criticality monitoring and alarm requirements in 10 CFR 70.24 and the baseline design criteria in the proposed 10 CFR 70.64.

Based on these initial designs, the applicants are expected to perform preliminary ISAs before construction of facilities. If the ISA results show deficiencies in the design, the design should be modified to assure that the items and measures planned to protect against identified accidents are adequate. On the other hand, if the ISA results show that a given item at a given facility is not relied on for safety, or that it does not require full adherence to the baseline criteria, then the facility design may be modified accordingly. The applicant is expected to submit the results of the preliminary ISA, based on the modified design of the facility, to NRC before construction. However, NRC approval is not necessary for the applicant to proceed with construction. The submittal should include the identification of all cases where a deviation from the baseline criteria is proposed, along with a justification for that decision. The submittal of the preliminary ISA for review by NRC provides an opportunity for applicants to get early feedback on the design of their facilities or processes. It is much more cost-effective to correct problems identified at the design stage than after the facility has been constructed.

After construction, but before operation, applicants would be expected to update their ISAs, based on as-built conditions, taking into account the results of the preliminary ISAs, and submit the results to NRC for approval. Any inconsistencies between the results of the updated ISAs and the preliminary ISAs should be identified in the submittals.

Section 70.64. 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. The ISA process is applied to existing designs to identify high risks that could warrant additional preventive or mitigative measures. For new

facilities or new processes at existing facilities, the proposed rule calls for the performance of the ISA before construction, and the updating of the ISA before beginning operations. However, 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. Therefore, the Commission has specified baseline design criteria in §70.64 that are similar 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: quality standards and records; natural phenomena hazards; fire protection; environmental and dynamic effects[6]; chemical protection; emergency capability; utility services; inspection, testing, and maintenance; criticality control; and instrumentation and controls. The baseline design criteria do not provide relief from compliance with the safety performance requirements of §70.60. The baseline design criteria are generally an acceptable set of initial design safety considerations, which may not be sufficient to assure 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 updated ISA. For such processes and facilities, any design features that are inconsistent with the baseline design criteria should be identified and justified.

Section 70.65. This section deals with the additional content of applications.

There is additional information that would need to be submitted to NRC as part of a license application to demonstrate compliance with the additional requirements that would be established in the proposed new subpart. This information is necessary to determine whether the applicant has provided an adequate level of protection at the facility. In particular, additional

[6] Environmental and dynamic effects are effects that could be caused by ambient conditions. For example, an item relied on for safety will need to function within its expected environment (i.e., under normal operating conditions, expected accident conditions, etc.). These conditions could include high temperatures, or a corrosive environment. It could also include dynamic changes in surrounding conditions caused by an accident (e.g., the bursting of a high-pressure pipe).

information would be needed to demonstrate how the applicant's safety program complies with 10 CFR 70.60(d). This information would include a description of the plant site and structures; the processes analyzed in the ISA; an appropriate summary of the results of the ISA, including the accident sequences, the consequences and likelihoods of such sequences; and the items relied on for safety; and the measures established to ensure the continuous availability and reliability of such items. The plant and process descriptions are needed to fully understand the results of the ISA, including the rationale for choosing the items relied on for safety. The evaluation of the applicant's safety program is a critical element in determining whether the facility is safe and should be issued a license. Finally, the license application, for an operating facility, should include a description of operational events that have occurred during the past 10 years that had a significant impact on the safety of the facility. These events should be addressed in the applicant's ISA to ensure that the range of accident sequences considered in the ISA encompasses actual events that have occurred at the facility.

The license application demonstrates how the applicant intends to meet the requirements of Part 70. The application provides information about the applicant's facility and processes and commitments that ensure the health and safety of workers, the general public and the environment. To ensure confidence that these commitments will be adhered to, and will not be changed without NRC knowledge or approval, the following condition will be inserted in the license: "Authorized use: For use in accordance with the statements, representations, and conditions in the application dated _____, and supplements dated_____. The application may be revised in accordance with the provisions of 10 CFR 70.72." This condition is similar to the ones currently in use. However, it would apply to the entire license application (not just a portion of the application, as was done previously), and would allow changes to be made without prior NRC approval, in accordance with 10 CFR 70.72.

Section 70.66. This section deals with records.

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. These records serve two major purposes. First, they can supplement information that has been submitted as part of the license application. For example, applicants would be required to submit the results of their ISAs to NRC for review. However, there may be substantial amounts of supporting material, at the licensed facility, relevant to that submittal, that NRC may wish to review. 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.

Section 70.68. This section deals with 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 proposed new subpart, 10 CFR 70.60 through 70.66, will be satisfied.

Section 70.72. This section deals with changes to site, structures, systems, equipment, components, and activities of personnel.

Past incidents at fuel cycle facilities have often resulted from changes not fully analyzed, not authorized by 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 confidence in the margin of safety at that facility. Any such change needs to be considered and evaluated by the licensee before the change is made. If the licensee evaluates the change, based on its ISA, and finds that it, at most, increases the risk at the facility to a minimal extent, then the licensee may make the change and then notify NRC within 60 days. Otherwise, the licensee would need to request a license amendment and get NRC approval before making the change. In either case, the change should be controlled by the licensee's configuration management system, and appropriate modifications to the license application (including, if applicable, the results of the ISA) should be submitted to NRC. Aside from providing increased confidence in the margin of safety, maintaining the

license so that it reflects the current configuration of the facility would facilitate a relatively simple, cost-effective license renewal process. The ability of licensees to make certain changes to their facility without prior NRC approval, as allowed in this proposed requirement, is analogous to existing requirements in 10 CFR 70.32.

Section 70.73. This section deals with the renewal of licenses.

Under the proposed amendments to Part 70, changes to site, structures, systems, equipment, components, and activities of personnel, made by a licensee, would be reflected in the license application, which would be submitted to NRC and incorporated as a condition of the license. This process would establish a "living" license that would be maintained on a current basis. As a result, the license renewal process is expected to be a pro forma activity in which NRC, based on its current knowledge of licensee activities, as reflected in the "living license," would approve the renewal 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. This section deals with additional reporting requirements.

The new requirements that would be incorporated in the proposed changes to Part 70 suggest a revised approach for reporting of events to NRC. This new approach, based on consideration of the consequences of concern established in 10 CFR 70.60(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 Part 70. A more detailed discussion of the new requirements is found in the discussion of Appendix C to Part 70.

Appendix A. "Acute Exposure Guideline Levels (AEGLs)" This appendix contains the AEGL values, for 1-hour exposures, that have been established by EPA. These values are referenced in 10 CFR 70.60(b).

Appendix B. "ERPG" This appendix contains the ERPG values that have been established by AIHA. These values are referenced in 10 CFR 70.60(b).

Appendix C. "Reportable Events"

To effectively fulfill its responsibilities, NRC needs to be aware of conditions that could result in an imminent danger to the worker or to public health and safety. In the event of an accident, NRC must be able to respond accurately to requests for information by the public and the media. In addition, to the extent possible, NRC needs to be able to provide appropriate assistance to licensees in their efforts to address potential emergencies. 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. Finally, NRC must track 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.

NRC intends to take a graded approach for reporting licensee events, as illustrated in Table 2. According to this approach, licensees would report events based on whether actual consequences have occurred or whether a potential for such consequences exists. The most serious events, and those that must be reported within the shortest timeframe (1 hour) are high-consequence events that have actually occurred. Intermediate-consequence events that have actually occurred should be reported within 4 hours.

Events that could potentially lead to a consequence of concern should also be reported. External conditions, such as a hurricane, tornado, or flood, that could pose a threat to safety at a facility, should be reported within 4 hours. Deviations from safe operating conditions should be reported within a time period that depends on the severity of the potential consequence and

whether or not the licensee is able to correct the deviation within the specified period. A deviation from safe operating conditions means that a parameter that is controlled to ensure adequate protection is outside its established safety limits, or that an item relied on for safety is no longer operational or has been degraded so that it cannot perform its intended function. The reporting requirements for deviations from safe operating conditions are intended to be generally consistent with the reporting scheme established under Bulletin 91-01. For example, if a criticality control identified in the ISA is no longer operational, or degraded so that it cannot perform its intended function, that situation should be reported to NRC. If the control cannot be reestablished within 4 hours of discovery, the report should be made before expiration of the 4-hour time period. If the control has been reestablished within 4 hours of discovery, the report should be made within 24 hours. The term "reestablish" is intended to mean that the control identified in the ISA is made operative. Therefore, if a control fails and an ad-hoc control, not identified in the ISA, is established within 4 hours of discovery, a report to NRC would still have to be made before expiration of the 4-hour time period.

Another category of potential events that should 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, or by an unanticipated and unanalyzed set of circumstances. The timeframe for reporting this type of event would depend on how long it takes the licensee to remove the unsafe condition, and restore normal operations. If the licensee were unable to restore normal operating conditions within 4 hours, the report would need to be made before expiration of the 4-hour period. If the licensee were able to remove the unsafe condition and restore normal operations within 4 hours, the report would need to be made within 24 hours.

TABLE 2 Graded Reporting Requirements

Consequence Level	**Actual Exposures**	**Potential exposures**				
		External conditions posing threat to safety	Deviations from safe operating conditions **not corrected** within a specified period of time	Deviations from safe operating conditions **corrected** within a specified period of time	Unsafe condition, not identified in the ISA, and **not corrected** within a specified period of time.	Unsafe condition, not identified in the ISA, and **corrected** within a specified period of time.
High[1]	1 hr (I)(a)[2]	4 hr (II)c)	4 hr (II)(b)	24 hr (III)(a)	4 hr (II)(d)	24 hr (III)(c)
Intermediate[3]	4 hr (II)(a)		24 hr (III)(b)	30 day (IV)(a)		

TABLE 2 -CONTINUED

[1] High:

(1) A nuclear criticality, or

(2) Acute exposure of a worker to:

(i) A radiation dose of 1 Sv (100 rem) or greater TEDE, or

(ii) Hazardous chemicals in concentrations exceeding AEGL-3 (Appendix A) or ERPG-3 (Appendix B) criteria; or

(3) Acute exposure of a member of the public outside the controlled site boundary to:

(i) A radiation dose of 0.25 Sv (25 rem) or greater TEDE, or

(ii) An intake of 30 mg or greater of uranium in a soluble form, or

(iii) Hazardous chemicals in concentrations exceeding AEGL-2 (Appendix A) or ERPG-2 (Appendix B) criteria.

[2]() Paragraph reference to the proposed rule [e.g., (I)(a)].

[3] Intermediate:

(1) Acute exposure of a worker to:

(i) A radiation dose between 0.25 Sv (25 rem) and 1 Sv (100 rem) TEDE, or

(ii) Hazardous chemicals in concentrations between AEGL-2 (Appendix A) or ERPG-2 (Appendix B) criteria and AEGL-3 (Appendix A) or ERPG-3 (Appendix B) criteria; or

(2) Acute exposure of a member of the public outside the controlled site boundary to

(i) A radiation dose between 0.05 Sv (5 rem) and 0.25 Sv (25 rem) TEDE, or

(ii) Hazardous chemicals in concentrations between AEGL-1 (Appendix A) or ERPG-1 (Appendix B) criteria and AEGL-2 (Appendix A) or ERPG-2 (Appendix B) criteria; or

(3) 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 10 CFR Part 20.

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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 are available by request from the NRC Public Document Room: “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility” (Draft NUREG-1520); “Integrated Safety Analysis Guidance Document” (Draft NUREG-1513); and “Example Elements of an ISA Submittal -- Process Descriptions and Accident Analysis Summary.”

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 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 continuously available and reliable; and (4) require the inclusion of the safety bases, including the results of the ISA, 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 to 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. Single copies of the environmental assessment are available from Richard I. Milstein, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC, 20555-0001, telephone (301) 415-8149; e-mail: rim@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. The U.S. Nuclear Regulatory Commission 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 an information collection does not display a currently valid OMB control number, 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 costs and benefits of the alternatives considered by the Commission. The draft analysis is available for inspection in the NRC Public Document Room, 2120 L Street N.W. (Lower Level), Washington, D.C. 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 major nuclear fuel fabrication facilities that are authorized to possess a critical mass of SNM. 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).

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

Part 70 -- DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

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

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

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

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

3. In 10 CFR 70.4, the definitions of Acute exposure, Acute exposure guideline levels (AEGLs), Controlled site boundary, Critical mass of SNM, Deviation from safe operating conditions, Double contingency, Emergency response planning guidelines (ERPGs), Hazardous chemicals, Integrated safety analysis (ISA), Items relied on for safety, New process, Results of the ISA, Unacceptable vulnerabilities, and Worker are added, in alphabetical order, as follows:

§ 70.4 Definitions.

* * * * *

Acute exposure means a single exposure or multiple exposures occurring within a short time (24 hours or less).

Acute exposure guideline levels (AEGLs) mean chemical concentration levels, established by the National Advisory Committee for Acute Guideline Levels for Hazardous Substances, that, for a defined exposure, would result in anticipated adverse health effects to humans. The following three levels have been established:

(1) AEGL-1 means 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 notable discomfort.

(2) AEGL-2 means 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.

(3) AEGL-3 means 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.

* * * * *

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

* * * * *

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

* * * * *

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

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

* * * * *

Emergency response planning guidelines (ERPGs) mean chemical concentration levels, established by the American Industrial Hygiene Association, that, for a defined exposure, would result in anticipated adverse health effects on humans. The following three levels have been established:

(1) ERPG-1 means the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hour without experiencing other than mild transient adverse effects or perceiving a clearly defined, objectionable odor.

(2) ERPG-2 means 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 which could impair an individual's ability to take protective action.

(3) ERPG-3 means 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.

* * * * *

Hazardous chemicals mean substances that are toxic, explosive, flammable, corrosive, or reactive to the extent that they can cause significant damage to property or endanger life if not adequately controlled.

Integrated safety analysis (ISA) means a systematic analysis to identify plant and external hazards and their potential for initiating accident sequences, the potential accident sequences, their likelihood and consequences, and the site, structures, systems, equipment, components, and

activities of personnel that are relied on for safety. As used here, *integrated* means joint consideration of, and protection from, all relevant hazards, including radiological, criticality, fire, and chemical.

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

* * * * *

New process means, for a particular licensee, a change in the basic method for processing special nuclear material, where the new method is not currently specifically authorized by the NRC license.

* * * * *

Results of the ISA means the information obtained as a result of performing an ISA. It includes the identification of: (1) the radiological and non-radiological hazards at the facility; (2) the accident sequences that could result from such hazards; (3) the consequence and likelihood of occurrence of each accident sequence; and (4) the items relied on for safety.

* * * * *

Unacceptable vulnerabilities mean deficiencies in the items relied on for safety or the measures used to assure the continuous availability and reliability of such items that need to be corrected to ensure an adequate level of protection as defined in 10 CFR 70.60(c).

* * * * *

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

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

§§ 70.13a and 70.14 [Redesignated]

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

6. Section 70.15 is added to read as follows:

§ 70.15 Nuclear reactors.

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

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

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

§ 70.22 [amended]

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

§ 70.23 [amended]

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

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

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

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

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

§§ 70.61 and 70.62 [redesignated]

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

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

§§ 70.71 and 70.72 [redesignated]

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

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

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

Sec.

§70.60 Safety performance requirements.

(a) Purpose. Each licensee engaged in enriched uranium processing, uranium fuel fabrication, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, mixed-oxide fuel fabrication, scrap recovery, or any other activity that the Commission determines could significantly affect public health and safety, shall provide protection to its workers, the general public, and the environment against radiological (including criticality), chemical, and fire hazards that could result in the adverse consequences identified in paragraph (b) of this section. Consideration must be given to radiological consequences from all causes (including those resulting from fires and hazardous chemicals), and those chemical and environmental consequences that could result from the processing of special nuclear material.

(b) Consequences of concern. Each licensee shall protect against the occurrence of the following high and intermediate adverse consequences that could result from accidents involving the handling, storage, or processing of licensed special nuclear material:

(1) High consequences.

(i) A nuclear criticality;

(ii) Acute exposure of a worker to --

(A) A radiation dose of 1 Sv (100 rem) or greater total effective dose equivalent; or

(B) Hazardous chemicals in concentrations exceeding AEGL-3 (Appendix A) or ERPG-3 (Appendix B) criteria; or

(iii) Acute exposure of a member of the public outside the controlled site boundary to:

(A) A radiation dose of 0.25 Sv (25 rem) or greater total effective dose equivalent;

(B) An intake of 30 mg or greater of uranium in a soluble form; or

(C) Hazardous chemicals in concentrations exceeding AEGL-2 (Appendix A) or ERPG-2 (Appendix B) criteria.

(2) Intermediate consequences.

(i) Acute exposure of a worker to --

(A) A radiation dose between 0.25 Sv (25 rem) and 1 Sv (100 rem) total effective dose equivalent; or

(B) Hazardous chemicals in concentrations between AEGL-2 (Appendix A) or ERPG-2 (Appendix B) criteria and AEGL-3 (Appendix A) or ERPG-3 (Appendix B) criteria; or

(ii) Acute exposure of a member of the public outside the controlled site boundary to --

(A) A radiation dose between 0.05 Sv (5 rem) and 0.25 Sv (25 rem) total effective dose equivalent; or

(B) Hazardous chemicals in concentrations between AEGL-1 (Appendix A) or ERPG-1 (Appendix B) criteria and AEGL-2 (Appendix A) or ERPG-2 (Appendix B) criteria; or

(iii) 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 10 CFR Part 20.

(c) Graded level of protection. Each licensee shall provide a level of protection that is commensurate with the severity of the consequences resulting from credible accidents and the likelihood of any external events (e.g., natural phenomena) assumed to initiate or propagate such accidents. This graded level must apply to the items relied on for safety, identified in paragraph (d)(2)(iv) of this section, and to the measures used to assure their continuous availability and reliability, identified in paragraph (d)(3) of this section. The application of a graded level of protection must assure that --

(1) The occurrence of any of the high consequences identified in paragraph (b)(1) of this section is highly unlikely; and

(2) The occurrence of any of the intermediate consequences identified in paragraph (b)(2) of this section, is unlikely.

(d) Safety program. Each licensee shall establish and maintain a safety program that provides reasonable assurance that the accident consequences identified in paragraph (b) of this section are adequately protected against in accordance with paragraph (c).

(1) Each licensee shall compile and maintain a set of process safety information to enable the performance of an integrated safety analysis (ISA). 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.

(2) Each licensee shall perform an ISA to identify --

(i) All radiological and non-radiological hazards (e.g., chemical, fire, electrical, and mechanical);

(ii) Potential accident sequences caused by process deviations or other events internal to the plant (e.g., fires, explosions, or chemical releases) and credible external events, including natural phenomena (e.g., hurricanes, floods, tornadoes, earthquakes, tsunami, and seiches), fires, explosions, or chemical releases occurring offsite;

(iii) The consequence and likelihood of occurrence of each accident sequence identified pursuant to paragraph (d)(2)(ii) of this section; and

(iv) Items relied on for safety (i.e., structures, systems, equipment, components, and activities of personnel), that are relied on to prevent or mitigate those accidents identified under paragraph (d)(2)(ii) of this section, that exceed the consequences of concern stated in paragraph (b) of this section.

(3) To ensure the continuous availability and reliability of items relied on for safety identified under paragraph (d)(2)(iv) of this section, each licensee shall demonstrate that --

(i) Structures, systems, equipment, and components relied on for safety are designed, constructed, inspected, calibrated, tested, and maintained, as necessary, to ensure the continuous ability to perform their safety functions to satisfy paragraph (c) of this section. Items subject to this requirement include but are not limited to: principal structures of the plant; passive barriers relied on for safety (e.g., piping, glove boxes, containers, tanks, columns, vessels); active systems, equipment, and components relied on for safety; sampling and measurement systems used to convey information about the safety of plant operations; instrumentation and control systems used to monitor and control the behavior of systems relied on for safety; and utility service systems relied on for safety.

(ii) Personnel are trained, tested, and retested, as necessary, to ensure that they understand, recognize the importance of, and are qualified to perform their safety duties to satisfy paragraph (c) of this section;

(iii) Procedures relied on for safety are developed, reviewed, approved, and distributed to ensure that personnel are able to perform their safety duties to satisfy paragraph (c) of this section.

(iv) Human-system interfaces are designed and implemented to ensure that personnel relied on for safety are able to perform their safety duties to satisfy paragraph (c) of this section.

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

(vi) All items relied on for safety identified under paragraph (d)(2)(iv) of this section and measures established under paragraphs (d)(3)(i) through (d)(3)(v) of this section must meet quality standards that are commensurate with the importance of the safety functions performed. Management shall establish appropriate quality assurance policies and procedures to ensure that all items relied on for safety perform their safety functions and are continuously available and reliable.

(4) Each licensee shall conduct audits and assessments of its safety program to ensure that an adequate level of protection is maintained at the facility.

(5) Each licensee shall investigate abnormal events and take corrective action to minimize the recurrence of these events.

(6) Each licensee shall establish records that will demonstrate that the requirements of paragraphs (d)(1), (d)(2), (d)(3), (d)(4), and (d)(5) of this section have been met. Each licensee shall maintain these records for the lifetime of the plant.

§70.62 Requirements for the performance of ISAs and the filing of ISA results and license applications.

(a) Each applicant for a license under this subpart and each current licensee subject to this subpart shall perform an ISA as described in §70.60(d)(2).

(1) Each current licensee shall --

(i) Within 6 months of the effective date of this rule, submit, for NRC approval, a compliance plan that describes the ISA approach that will be used, the processes that will be analyzed, and the schedule for completing the analysis of each process; and

(ii) Within 4 years of the effective date of this rule, perform an ISA in accordance with the compliance plan submitted under paragraph (a)(1)(i) of this section, correct any unacceptable vulnerabilities identified in the ISA, and submit the results of the ISA as part of the license application contents identified in §70.65 to NRC, for approval. Pending the correction of any

unacceptable vulnerabilities identified in the ISA, the licensee shall implement appropriate compensatory measures to ensure adequate protection. The process description in the ISA submittal must include information that demonstrates the licensee's compliance with the design requirements for criticality monitoring and alarms in §70.24.

(2) Each applicant operating a facility that is newly subject to the Commission's authority shall perform an ISA, correct any unacceptable vulnerabilities identified in the ISA, and submit the results of the ISA as part of the license application contents identified in §§70.22 and 70.65 to NRC, for approval. The process description in the ISA submittal must include information that demonstrates the applicant's compliance with the design requirements for criticality monitoring and alarms in §70.24.

(3) Each applicant for a license to operate a new facility or a new process at an existing facility shall --

(i) Initially design the facility or process to protect against the occurrence of the adverse consequences identified in §70.60(b), meet the criticality monitoring and alarm requirements of §70.24, and meet the baseline design criteria in §70.64;

(ii) Perform a preliminary ISA and submit the results to NRC before construction of the facility or process. The results of the preliminary ISA must demonstrate an adequate level of protection, as defined in §70.60(c), against occurrence of the adverse consequences in §70.60(b). The preliminary ISA submittal shall include facility and process description and design information that demonstrates the applicant's incorporation of the criticality monitoring and alarm requirements in §70.24, and the baseline design criteria in §70.64. Any proposed relaxation in the application of the baseline design criteria, pursuant to §70.64(a), must be identified and justified in the preliminary ISA submittal; and

(iii) Before beginning operations, update the preliminary ISA and correct any unacceptable vulnerabilities identified in the ISA. The updated ISA must be based on as-built conditions and must take into account the results of the preliminary ISA. Any inconsistencies between the results of the updated ISA and the preliminary ISA must be identified.

(A) For new facilities submit the results of the ISA, as part of the license application contents identified in §§70.22 and 70.65, to NRC for approval.

(B) For new processes submit the results of the ISA and any revisions of the approved license application as part of an application for amendment of the license under §70.34.

(b) If the decommissioning of a facility involves potentially hazardous activities such as chemical treatment of wastes, each licensee shall perform an ISA of the decommissioning process, correct any unacceptable vulnerabilities identified in the ISA, and submit the results to NRC for approval before beginning such decommissioning activities.

§70.64 Baseline design criteria for new facilities or new processes at existing facilities.

(a) Applicants shall address the following baseline design criteria in the design of new facilities or design of new processes at existing facilities, before performing the preliminary ISA, in accordance with §70.62(a)(3)(ii). Applicants shall address these baseline design criteria in establishing minimum requirements for all items in their process design and description, which is provided in the application for a license or license amendment. Licensees shall maintain the application of these criteria unless the preliminary ISA, submitted before construction, pursuant to §70.62(b)(3)(iii), demonstrates that a given item is not relied on for safety or does not require adherence to the specified criteria.

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

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

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

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

(5) Chemical protection. The design must provide for adequate protection against chemical hazards related to the storage, handling, and processing of licensed nuclear material.

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

(i) Licensed material;

(ii) Evacuation of personnel; and

(iii) Onsite emergency facilities and services that facilitate the use of available offsite services.

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

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

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

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

(b) Facility and system design and plant layout must be based on defense-in-depth practices. Features must be incorporated that enhance safety by reducing challenges to items relied on for safety. Where practicable, passive systems and features must be selected over active systems and features, to increase overall system reliability.

§70.65 Additional content of applications.

In addition to the contents required by §70.22, each application for a license to possess a critical mass of special nuclear material for use in the activities described in §70.60(a), must contain --

(a) A description of the applicant's site, structures, and the processes analyzed in the ISA;

(b) A description of the applicant's safety program established under §70.60(d), including the results of the ISA and the measures established to ensure the continuous availability and reliability of items relied on for safety; and

(c) For currently operating facilities, a description of operational events, within the past 10 years, that had a significant impact on the safety of the facility.

§70.66 Records.

The applicant or licensee shall establish and maintain onsite, readily available for Commission inspection, a system of legible, current, accurate, complete, and easily retrievable records to document application-related and license-related information required by applicable parts of this chapter, Commission action, license condition, and commitments by the applicant or licensee. Records must be retained for the period specified by the applicable parts of this chapter, Commission action, license condition, and commitments made by applicant or licensee. If a retention period is not otherwise specified, these records must be retained until the Commission terminates the license or determines that they are no longer required.

§70.68 Additional requirements for approval of license application.

An application for a license to possess a critical mass of SNM will be approved if the Commission determines that the applicant has complied with the requirements of §70.23 and §§70.60 through 70.66.

§70.72 Changes to site, structures, systems, equipment, components, and activities of personnel.

(a) Except for a new process, subject to the requirements of §70.62(a)(3), any change to site, structures, systems, equipment, components, and activities of personnel must be evaluated by the licensee before the change, to determine whether the change increases the likelihood or consequences of an accident at the facility. The evaluation must be based on the licensee's ISA results, developed in accordance with §70.60(d)(2), and other safety program information, developed in accordance with §70.60(d)(3), which are part of the license application contents identified in §70.65.

(b) A licensee may make a change to site, structures, systems, equipment, components, and activities of personnel, without prior Commission approval, if the change --

(1) Results in, at most, a minimal increase in the likelihood or consequences of an accident previously evaluated in the ISA;

(2) Would not create the potential for an accident different from any previously evaluated in the ISA; and

(3) Is not inconsistent with NRC requirements and license conditions.

(c) For any change authorized under paragraph (b) of this section, the licensee shall submit revised pages to the license application, including any changes in the results of the ISA, to NRC within 60 days of initiation of the change.

(d) For any change that is not authorized under paragraph (b) of this section, the licensee shall file an application for an amendment of its license, as specified in §70.34, that authorizes the change. As part of the application for the amendment, the licensee shall perform an ISA of the change and submit any revisions of the ISA and the license application to NRC for approval. The licensee shall also provide, as required by Part 51 of this chapter, any necessary revisions to its environmental report.

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

§70.73 Renewal of licenses.

Applications for renewal of a license must be filed in accordance with §§ 2.109, 70.21, 70.22, 70.33, 70.38, and 70.65. Information provided in applications, including the results of the ISA, must be current, complete, and accurate in all material respects. Information contained in previous applications, statements, or reports filed with the Commission under the license may be incorporated by reference, provided that these references are clear and specific.

§70.74 Additional reporting requirements.

(a) Reports to NRC Operations Center.

(1) Each licensee shall report to the NRC Operations Center the events described in paragraphs I, II, and III of Appendix C to Part 70.

(2) Reports must be made by a knowledgeable licensee representative and by any method that will ensure compliance with the required time period (1, 4, or 24 hours) for reporting.

(3) The information provided must include a description of the event and other related information as described in paragraph V of Appendix C to Part 70.

(4) Followup information to the reports must be provided until all information required to be reported in paragraph (a)(3) of this section is complete.

(5) Duplicate reports to the Commission are not required for events when the reports are made in compliance with other parts of this chapter, provided that the reports comply with the requirements of this section concerning addressees, information content, and timeliness of filing.

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

(b) Written reports.

(1) Each licensee shall provide a written report to NRC, of the events described in paragraph IV of Appendix C to Part 70, within 30 days of discovery. The written report must contain the information described in paragraph VI of Appendix C to Part 70.

(2) Each licensee who makes a report required by paragraph (a) of this section shall submit a written followup report within 30 days of the initial report. The written report shall contain the information as described in paragraph VI of Appendix C to Part 70.

19. Appendix A to Part 70 is added to read as follows:

Appendix A to Part 70 - Acute Exposure Guideline Level Values* for 1-Hour Exposure Periods

CHEMICAL	BIOLOGICAL ENDPOINTS					
	AEGL-1		AEGL-2		AEGL-3	
	ppm	mg/m^3	ppm	mg/m^3	ppm	mg/m^3
1,2-Dichloroethene	13	53	40	160	141	564
1,1 & 1,2-Dimethylhydrazines	NA	NA	3	7.4	11	27
Aniline	8	30	12	46	20	76
Arsine	NA	NA	0.17	0.5	0.5	1.6
Chlorine	1	2.9	2	5.8	20	58

CHEMICAL	BIOLOGICAL ENDPOINTS					
Ethylene Oxide	No values derived	No values derived	110	198	200	360
Fluorine	2	3.1	5	7.8	13	20
Hydrazine	0.1	0.1	6	8	33	43
Methylhydrazine	NA	NA	1	1.9	3	5.6
Nitric Acid	0.5	1.3	4	10	13	34
Phosphine	Nondisabling	Nondisabling	0.25	0.35	1.5	2.1

*The values in this appendix are taken from EPA's proposed AEGL values for these chemicals (62 FR 58840; October 30, 1997).

20. Appendix B to Part 70 is added to read as follows:

Appendix B to Part 70 - Emergency Response Planning Guidelines Concentration Levels

CHEMICAL	MAXIMUM AIRBORNE CONCENTRATIONS					
	ERPG-1		ERPG-2		ERPG-3	
	ppm	mg/m^3	ppm	mg/m^3	ppm	mg/m^3
Acetaldehyde	10		200		1000	
Acrolein	0.1		0.5		3	
Acrylic Acid	2		50		750	
Acrylonitrile	10		35		75	
Allyl Chloride	3		40		300	
Ammonia	25		200		1000	
Benzene	50		150		1000	
Benzyl Chloride	1		10		25	
Beryllium		NA		0.025		0.1
Bromine	0.2		1		5	
1,3 Butadiene	10		200		5000	
n-Butyl Acrylate	0.05		25		250	
n-Butyl Isocyanate	0.01		0.05		1	
Carbon Disulfide	1		50		500	
Carbon Tetrachloride	20		100		750	
Chlorine	1		3		20	
Chlorine Trifluoride	0.1		1		10	
Chloroacetyl Chloride	0.1		1		10	
Chloropicrin	NA		0.2		3	
Chlorosulfonic Acid		2		10		30

CHEMICAL	MAXIMUM AIRBORNE CONCENTRATIONS						
	ERPG-1		ERPG-2		ERPG-3		
	ppm	mg/m^3	ppm	mg/m^3	ppm	mg/m^3	
Chlorotrifluoroethylene	20		100		300		
Crotonaldehyde	2		10		50		
Cyanogen Chloride	NA		0.4		4		
Diborane	NA		1		3		
Diketene	1		5		50		
Dimethylamine	1		100		500		
Dimethyldichlorosilane	0.8		5		25		
Dimethyl Disulfide	0.01		50		250		
Dimethylformamide	2		100		200		
Dimethyl Sulfide	0.5		500		2000		
Diphenylmethane Diisocyanate		0.2		2		25	
Epichlorohydrin	2		20		100		
Ethylene Oxide	NA		50		500		
Fluorine	0.5		5		20		
Formaldehyde	1		10		25		
Furfural	2		10		100		
Hexachlorobutadiene	3		10		30		
Hexafluoroacetone	NA		1		50		
Hexafluoropropylene	10		50		500		
Hydrogen Chloride	3		20		150		
Hydrogen Cyanide	NA		10		25		
Hydrogen Fluoride	2		20		50		
Hydrogen Peroxide	10		50		100		
Hydrogen Sulfide	0.1		30		100		

CHEMICAL	MAXIMUM AIRBORNE CONCENTRATIONS						
	ERPG-1		ERPG-2		ERPG-3		
	ppm	mg/m^3	ppm	mg/m^3	ppm	mg/m^3	
Iodine	0.1		0.5		5		
Isobutyronitrile	10		50		200		
2-Isocyanatoethyl methacrylate	NA		0.1		1		
Lithium Hydride		0.025		0.1		0.5	
Methanol	200		1000		5000		
Methyl Bromide	NA		50		200		
Methyl Chloride	NA		400		1000		
Methyl Iodide	25		50		125		
Methyl Isocyanate	0.025		0.5		5		
Methyl Mercaptan	0.005		25		100		
Methylene Chloride	200		750		4000		
Methyltrichlorosilane	0.5		3		15		
Monomethylamine	10		100		500		
Perchloroethylene	100		200		1000		
Perfluoroisobutylene	NA		0.1		0.3		
Phenol	10		50		200		
Phosgene	NA		0.2		1		
Phosphorus Pentoxide		5		25		100	
Propylene Oxide	50		250		750		
Styrene	50		250		1000		
Sulfur Dioxide	0.3		3		15		
Sulfuric Acid		2		10		30	
Tetrafluoroethylene	200		1000		10000		
Tetramethoxysilane	NA		10		20		

CHEMICAL	MAXIMUM AIRBORNE CONCENTRATIONS					
	ERPG-1		ERPG-2		ERPG-3	
	ppm	mg/m^3	ppm	mg/m^3	ppm	mg/m^3
Titanium Tetrachloride		5		20		100
Toluene	50		300		1000	
1,1,1,Trichloroethane	350		700		3500	
Trichloroethylene	100		500		5000	
Trichlorosilane	1		3		25	
Trimethoxysilane	0.5		2		5	
Trimethylamine	0.1		100		500	
Uranium Hexafluoride		5		15		30
Vinyl Acetate	5		75		500	

The values in this appendix are taken from *The AIHA Emergency Response Planning Guidelines and Workplace Environmental Exposure Level Guides Handbook,* copyright 1998 by the American Industrial Hygiene Association (AIHA). AIHA recommends use of these values with the full documentation provided in the Emergency Response Planning Guidelines (ERPGs) published annually by AIHA. For further information, contact AIHA at (703) 849-8888.

21. Appendix C to Part 70 is added to read as follows:

Appendix C to Part 70 -- Reportable Safety Events

As required by 10 CFR 70.74, licensees who are authorized to possess a critical mass of special nuclear material shall report the following safety events (see table A-1 of this appendix):

I. Events to be reported within 1 hour of discovery, followed by a written report within 30 days.

(a) An accident from the processing of licensed material that resulted in any of the following consequences:

(1) A nuclear criticality.

(2) Acute exposure of a worker to --

(i) A radiation dose of 1 Sv (100 rem) or greater total effective dose equivalent, or

(ii) Hazardous chemicals in concentrations exceeding AEGL-3 (Appendix A) or ERPG-3 (Appendix B) criteria.

(3) Acute exposure of a member of the public outside the controlled site boundary to --

(i) A radiation dose of 0.25 Sv (25 rem) or greater total effective dose equivalent,

(ii) An intake of 30 mg or greater of uranium in a soluble form, or

(iii) Hazardous chemicals in concentrations exceeding AEGL-2 (Appendix A) or ERPG-2 (Appendix B) criteria.

II. Events to be reported within 4 hours of discovery, followed by a written report within 30 days.

(a) An accident from the processing of licensed material that resulted in any of the following consequences:

(1) Acute exposure of a worker to --

(i) A radiation dose between 0.25 Sv (25 rem) and 1 Sv (100 rem) total effective dose equivalent, or

(ii) Hazardous chemicals in concentrations between AEGL-2 (Appendix A) or ERPG-2 (Appendix B) criteria and AEGL-3 (Appendix A) or ERPG-3 (Appendix B) criteria.

(2) Acute exposure of a member of the public outside the controlled site boundary to --

(i) A radiation dose between 0.05 Sv (5 rem) and 0.25 Sv (25 rem) total effective dose equivalent, or

(ii) Hazardous chemicals in concentrations between AEGL-1 (Appendix A) or ERPG-1 (Appendix B) criteria and AEGL-2 (Appendix A) or ERPG-2 (Appendix B) criteria.

(3) 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 10 CFR Part 20.

(b) A deviation from safe operating conditions that has not been corrected within 4 hours and has the potential, as identified in the ISA, for causing an accident with one or more of the consequences specified in paragraph I(a) of this appendix.

(c) An external condition that poses a threat to the performance of items that are relied on for safety (e.g., site, structures, systems, equipment, components, or activities of personnel). These conditions would include natural phenomena (e.g., hurricanes, floods, tornados, earthquakes), fires, or chemical releases.

(d) A potentially unsafe condition that has not been corrected within 4 hours and that has not been identified or analyzed in the integrated safety analysis (ISA).

III. Events to be reported <u>within 24 hours</u> of discovery, followed by a written report within 30 days.

(a) A deviation from safe operating conditions that was corrected within 4 hours and had the potential, as identified in the ISA, for causing an accident with one or more of the consequences specified in paragraph I(a) of this appendix.

(b) A deviation from safe operating conditions that has not been corrected within 24 hours and has the potential, as identified in the ISA, for causing an accident with one or more of the consequences specified in paragraph II(a) of this appendix.

(c) A potentially unsafe condition that was corrected within 4 hours and was not identified or analyzed in the ISA.

IV. Events to be reported in writing, to NRC, <u>within 30 days</u> of discovery.

(a) A deviation from safe operating conditions that was corrected within 24 hours and had the potential, as identified in the ISA, for causing an accident with one or more of the consequences specified in paragraph II(a) of this appendix.

V. Licensee reports to the NRC Operations Center, as required by 10 CFR 70.74(a), shall include, to the extent that the information is applicable and available at the time the report is made, the following:

(a) Caller's name and position title.

(b) Date, time, and location of the event.

(c) Description of the event, including --

(1) Sequence of occurrences leading to the event, including degradation or failure of items relied on for safety.

(2) Radiological or chemical hazards involved including isotopes, quantities, and chemical and physical form of any material released.

(3) Actual or potential health and safety consequences to the workers, the public, and the environment, including relevant chemical and radiation data for actual personnel exposures (e.g., level of radiation exposure, concentration of chemicals, and duration of exposure).

(4) Items that are relied on to prevent or to mitigate the health and safety consequences, and whether the ability of those items to function has been affected by the event.

(5) For events involving deviations from safe operating conditions, the process parameters that are deviant, the normal operating and safety limits on these parameters, and the current values of these parameters.

(d) External conditions affecting the event.

(e) Additional actions taken by the licensee in response to the event.

(f) Status of the event (e.g., whether the event is on-going or was terminated).

(g) Current and planned site status, including any declared emergency class.

(h) Notifications related to the event that were made or are planned to any local, State, or other Federal agencies.

(i) Issue of a press release by the licensee related to the event that was made or is planned.

VI. Licensee written reports required by 10 CFR 70.74(b) shall consist of a completed NRC Form 366 and shall be forwarded to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001. Each written report must include the following information:

(1) Complete applicable information required by paragraph V of this appendix.

(2) Whether the event was identified in the ISA.

(3) Cause of the event, including all factors that contributed to the event.

(4) Corrective actions taken to prevent occurrence of similar or identical events in the future.

TABLE A-1 GRADING OF REPORTING REQUIREMENTS

Consequence Level	**Actual Exposures**	**Potential exposures**				
		External conditions posing threat to safety	Deviations from safe operating conditions **not corrected** within a specified period of time	Deviations from safe operating conditions **corrected** within a specified period of time	Unsafe condition, not identified in the ISA, and **not corrected** within a specified period of time.	Unsafe condition, not identified in the ISA, and **corrected** within a specified period of time.
High[1]	1 hr (I)(a)[2]	4 hr (II)c)	4 hr (II)(b)	24 hr (III)(a)	4 hr (II)(d)	24 hr (III)(c)
Intermediate[3]	4 hr (II)(a)		24 hr (III)(b)	30 day (IV)(a)		

TABLE A-1 FOOTNOTES

[1] High:

(1) A nuclear criticality, or

(2) Acute exposure of a worker to:

(i) A radiation dose of 1 Sv (100 rem) or greater TEDE; or

(ii) Hazardous chemicals in concentrations exceeding AEGL-3 (Appendix A) or ERPG-3 (Appendix B) criteria; or

(3) Acute exposure of a member of the public outside the controlled site boundary to:

(i) A radiation dose of 0.25 Sv (25 rem) or greater TEDE; or

(ii) An intake of 30 mg or greater of uranium in a soluble form, or

(iii) Hazardous chemicals in concentrations exceeding AEGL-2 (Appendix A) or ERPG-2 (Appendix B) criteria.

[2] ( ): Paragraph reference to the proposed rule [e.g., (I)(a)].

[3] Intermediate:

(1) Acute exposure of a worker to:

(i) A radiation dose between 0.25 Sv (25 rem) and 1 Sv (100 rem) TEDE; or

(ii) Hazardous chemicals in concentrations between AEGL-2 (Appendix A) or ERPG-2 (Appendix B) criteria and AEGL-3 (Appendix A) or ERPG-3 (Appendix B) criteria; or

(2) Acute exposure of a member of the public outside the controlled site boundary to

(i) A radiation dose between 0.05 Sv (5 rem) and 0.25 Sv (25 rem) TEDE, or

(ii) Hazardous chemicals in concentrations between AEGL-1 (Appendix A) or ERPG-1 (Appendix B) criteria and AEGL-2 (Appendix A) or ERPG-2 (Appendix B) criteria; or

(3) 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 10 CFR Part 20.

Dated at Rockville, Maryland, this ___ day of _____, 1998.

For the Nuclear Regulatory Commission.

_____

John C. Hoyle,

Secretary of the Commission.