July 30, 1998 SECY-98-185

FOR: The Commissioners

FROM: L. Joseph Callan /s/
Executive Director for Operations

SUBJECT: PROPOSED RULEMAKING - REVISED REQUIREMENTS FOR THE DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

PURPOSE:

To obtain Commission approval to publish a proposed rule amending 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

SUMMARY:

A near-criticality incident at a low enriched fuel fabrication facility in May of 1991 prompted the U.S. Nuclear Regulatory Commission (NRC) to evaluate its safety regulations for licensees that possess and process large quantities of special nuclear material (SNM)[1]. As a result of this review, the Commission (SRM dated January 15, 1993) 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 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 integrated safety analysis (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 and their likelihood and consequences; and 3) the structures, systems, equipment, components, and activities of personnel relied on for safety to prevent or mitigate potential accidents at a facility.

CONTACT: Richard I. Milstein, NMSS/FCSS
(301) 415-8149

[1]The results of this review were documented in NUREG 1324, "Proposed Method for Regulating Major Materials Licensees."

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, in September 1996, of a Petition for Rulemaking (PRM 70-7) by NEI with NRC. The PRM requested that NRC amend Part 70 to: (1) add a definition for a uranium processing and fuel fabrication plant; (2) require the performance of an ISA, or acceptable alternative, at uranium processing, fuel fabrication, and enrichment plants; and (3) include a requirement for backfit analysis, under certain circumstances, within Part 70.

In SECY-97-137, dated June 30, 1997, the staff proposed a resolution to the NEI PRM and recommended that the Commission direct the staff to proceed with rulemaking. The staff's recommended approach to rulemaking included the basic elements of the petition, with some modification. In brief, the 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) 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 limits to identify the adverse consequences that licensees must protect against;
(3) Inclusion of the safety bases in the 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 petition'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 staff to "...submit a draft proposed rule...by July 31, 1998." In addition, the SRM requested that the supporting guidance documents and regulatory analysis be submitted with the proposed rule.

A public meeting on modifications to Part 70 was held on May 28, 1998, with a follow-up public meeting on July 15, 1998, to share information on NRC efforts to revise Part 70 and to provide an opportunity for the presentation of public and industry views on this matter. The presentation made by NRC provided information on the proposed modifications to Part 70 and the Standard Review Plan that has been developed to support the draft proposed rule. The industry presentation noted convergence of some of the past differences between industry and NRC, and concluded that the rulemaking can and should move forward, and industry can effectively implement the rule, if the rule is modified to clarify that:

(1) The ISA results will not be part of the license;
(2) Performance criteria are included to judge effectiveness of safety programs and grade structures, systems, and components (SSCs) important to safety; and
(3) The backfit provision is made immediately effective and uses quantitative methodologies

to the maximum extent possible.

Based on information provided by NRC staff, the industry representatives expressed the view that the differences concerning the second item are now less of a concern. The remaining two items are issues that the staff addressed in SECY-97-137. Regarding the first item, the industry view is that the ISA results should not be incorporated in the license, but become a part of the documented safety basis that would be available at the site for NRC review. The ISA results would not be provided, as part of an application, to NRC for review. With respect to the third item, backfit, the main industry concern appears to be that NRC staff may want to impose safety controls that the licensee would consider unnecessary to satisfy the performance criteria established in the rule. These remaining issues were previously reviewed in SECY-97-137 in which the staff recommended that these items be rejected and the Commission endorsed the staff's position.

The NRC staff remains in favor of the approach recommended in SECY-97-137. In particular, the staff continues to believe that the safety basis for a facility, including the ISA results, should be submitted, as part of an application, to NRC for review and incorporated in the license. Also, the staff believes that a qualitative backfit mechanism should be considered for implementation only after the safety basis, including the results of the ISA, is established and incorporated in the license, and after licensees and staff have gained experience with the implementation of the ISA requirement. However, given the views expressed by industry at the public meeting, the staff has included in the Federal Register notice a request for public comment on the intent to defer the implementation of a backfit provision in Part 70.

DISCUSSION:

The staff's proposed revisions to Part 70 are intended to provide a risk-informed, performance-based approach for increasing confidence in the margin of safety for licensees authorized to possess a critical mass of SNM. With two exceptions, the staff's approach is in accordance with the Commission's SRM of August 22, 1997. First, as the result of its experience in supporting the Department of Energy Regulatory Unit at Hanford with the Tank Waste Remediation System Privatization Project, the staff is recommending the inclusion of certain baseline design criteria in the proposed revisions to assure the safe design of new facilities and new processes at existing facilities. Second, the staff is recommending that the proposed revisions should not apply to all licensees authorized to possess a critical mass of SNM. Instead, the staff has identified a subset of these licensees that, based on their risk of operations, should be subject to the new requirements. A more detailed discussion of the major rule elements is presented in Attachment 1, "Discussion of the Proposed Rule's Major Elements." Most of the proposed modifications to Part 70 are found in a new Subpart H -- "Additional Requirements for Licensees Authorized to Possess a Critical Mass of Special Nuclear Material." Three draft guidance documents support the rulemaking - a Standard Review Plan, an ISA Guidance Document, and "Example Elements of an ISA Submittal -- Process Descriptions and Accident Analysis Summary."

COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. The Office of the Chief Information Officer has reviewed the proposed rule for information technology and information management implications and concurs in it. However, the rule amends information collection requirements that must be submitted to and received by the Office of Management and Budget no later than the date the rule is published in the Federal Register.

RESOURCES:

Resources to complete and implement the rule are included in the current budget.

RECOMMENDATIONS:

That the Commission:

1. Approve the notice of proposed rulemaking for publication (Attachment 2).

2. Certify that this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities, to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).3.

   Note:

   a. The proposed rule will be published in the Federal Register for a 75-day public comment period;

   b. A draft Regulatory Analysis will be available in the Public Document Room (Attachment 3);

   c. A draft Standard Review Plan will be available in the Public Document Room (Attachment 4);

   d. A draft ISA Guidance Document will be available in the Public Document Room (Attachment 5);

   e. A draft guidance document, “Example Elements of an ISA Submittal -- Process Descriptions and Accident Analysis Summary,” will be available in the Public Document Room (Attachment 6);

   e. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the reasons for it, as required by the Regulatory Flexibility Act;

   f. Copies of the Federal Register notice of proposed rulemaking will be distributed to all affected Commission licensees. The notice will be sent to other interested parties on request;

   g. A press release will be issued (Attachment 7);

   h. The appropriate Congressional committees will be informed (Attachment 8);

I A draft Environmental Assessment will be available in the Public Document Room (Attachment 9); and

j. This rule contains a new information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.).

L. Joseph Callan
Executive Director
for Operations

Attachments:
1. "Discussion of Proposed Rule's Major Elements"
2. Federal Register Notice - Proposed Rule
3. Regulatory Analysis (Draft)
4. Standard Review Plan (Draft)
5. ISA Guidance Document (Draft)
6. Example Elements of an ISA Submittal - Process Descriptions and Accident Analysis Summary (Draft)
7. Press Release (Draft)
8. Congressional Letters (Draft)
9. Environmental Assessment (Draft)

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* see previous concurrence

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NAME	RMilstein*		LRoché*		TSherr*		by fax EKraus		by memo EHalman		by telecom KWinsberg for STreby		by memo BShelton	
DATE	7/16/98		7/16/98		7/16/98		7/1/98		7/13/98		7/16/98		7/13/98	

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NAME	by e-mail CAbbott for JFunches		by e-mail TCombs for DRathbun		by telecom SGagner for WBeecher		ETen Eyck*		MKnapp		HLThompson		LJCallan	
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DISCUSSION OF PROPOSED RULE'S MAJOR ELEMENTS

Consequences of concern. An important element in the proposed rule is the identification of specific consequences against which licensees must provide adequate protection [10 CFR 70.60(b)]. These consequences, which are applicable to workers and members of the public, are categorized according to their level of severity (high and intermediate). Because accidents at fuel cycle facilities could result in human exposure to both radiological and chemical hazards, the proposed rule has adopted criteria that address both types of consequences. This approach satisfies the U.S. Nuclear Regulatory Commission's (NRC's) primary responsibility for radiation protection, in addition to its responsibility to protect workers and the public from the chemical hazards resulting from the processing of licensed nuclear material.

Graded Level of Protection. To ensure an acceptable level of risk at facilities that possess a critical mass of special nuclear material, the proposed rule [10 CFR 70.60(c)] calls for licensees to provide a graded level of protection against potential accidents. That level of protection must be sufficient to reduce the likelihood of such accidents to levels commensurate with their consequences. Thus, according to the proposed rule, the occurrence of any high-consequence event should be "highly unlikely," while the occurrence of any intermediate-consequence event should be "unlikely." Although the rule does not define the terms "highly unlikely" and "unlikely," the draft Standard Review Plan provides criteria for judging the likelihood of potential accidents. This guidance is based on a combination of qualitative and quantitative indicators, but does not require a probabilistic risk assessment.

Integrated Safety Analysis (ISA). According to the proposed rule [10 CFR 70.60(d)], licensees must demonstrate, based on the performance of an ISA, their ability to provide an adequate level of protection against potential accidents. An ISA is a systematic analysis to identify plant and external hazards and their potential for initiating accident sequences; the potential accident sequences and their likelihood and consequences; and the items (i.e., site, structures, systems, equipment, components, and activities of personnel) that are relied on for safety.

Measures to ensure continuous availability and reliability. 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, as required by the proposed rule [10 CFR 70.60(d)], an effective management system is needed to ensure that, when called upon, the items relied on for safety are 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 whose actions are 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 public health and safety. When operational 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.

Inclusion of safety bases in the application and changes to the safety bases. The performance of the ISA to identify the items relied on for safety and the measures established to ensure the continuous availability and reliability of such items are important elements in increasing confidence in the margin of safety. Nevertheless, without formal commitments to implement these items and measures, and to keep NRC informed of any changes in such commitments, the safety bases could become uncertain over time. Thus, the proposed rule calls for the incorporation of licensee commitments to these items and measures in the license application. In addition, all changes in such commitments shall be submitted to NRC as part of a revised license application, including any changes in the ISA results (10 CFR 70.72). The rule does, however, allow for certain changes to be made, based on the results of the ISA, without prior NRC approval, as long as such changes result in, at most, a minimal increase in the risk of accidents at the facility.

[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

II. Description of Proposed Action

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[2], 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

[2]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).

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;

(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.

<u>Chemical Consequences</u>. 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[3] 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 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

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[3]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 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[4]. 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.

[4]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).

TABLE 1 Radiological and Chemical Consequence Criteria

CONSEQUENCE	Worker		Public	
	Radiological	Chemical	Radiological	Chemical
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[5] 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.

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-

[5]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.

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[6] 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

[6]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.

terms. The "Standard Review 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[7]; chemical protection;

[7] 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.

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 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 ______,

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It could also include dynamic changes in surrounding conditions caused by an accident (e.g., the bursting of a high-pressure pipe).

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.

REFERENCES

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National Council on Radiation Protection and Measurements (NCRP), “Basic Radiation Protection Criteria,” NCRP Report No. 39, Washington, DC, 1971.

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U.S. Nuclear Regulatory Commission/ Occupational Safety and Health Administration (OSHA), “Memorandum of Understanding Between NRC and OSHA; Worker Protection at NRC-Licensed Facilities” (53 FR 43950; October 31, 1988).

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

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

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

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

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

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

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

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

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

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

Copies of the following draft regulatory guidance documents 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.

* * * * *

<u>Acute exposure</u> 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.

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

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

70.65 Additional content of applications.

70.66 Records.

§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.

<u>§70.64 Baseline design criteria for new facilities or new processes at existing facilities.</u>

(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) <u>Quality standards and records</u>. 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
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
Chlorotrifluoroethylene	20		100		300	
Crotonaldehyde	2		10		50	

CHEMICAL	MAXIMUM AIRBORNE CONCENTRATIONS					
	ERPG-1		ERPG-2		ERPG-3	
	ppm	mg/m^3	ppm	mg/m^3	ppm	mg/m^3
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	
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

CHEMICAL	MAXIMUM AIRBORNE CONCENTRATIONS					
	ERPG-1		ERPG-2		ERPG-3	
	ppm	mg/m^3	ppm	mg/m^3	ppm	mg/m^3
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	
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	

CHEMICAL	MAXIMUM AIRBORNE CONCENTRATIONS					
	ERPG-1		**ERPG-2**		**ERPG-3**	
	ppm	mg/m^3	ppm	mg/m^3	ppm	mg/m^3
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 within 24 hours 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, within 30 days 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.

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John C. Hoyle,

Secretary of the Commission.

PART 70 AMENDMENT

DRAFT REGULATORY ANALYSIS

July 24, 1998

ATTACHMENT 3

Table of Contents

PART 70 AMENDMENT

DRAFT REGULATORY ANALYSIS

1.0 Introduction

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend 10 CFR Part 70, "Domestic Licensing of Special Nuclear Materials," to obtain increased confidence in the margin of safety at major special nuclear material (SNM) facilities. The Commission believes that this objective can be best accomplished through a risk-informed, performance-based regulatory structure 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 a comprehensive, structured, integrated safety analysis (ISA), to identify potential accidents at the facility and the items relied on for safety; and (3) the implementation of measures to ensure that the items relied on for safety are continuously available and reliable. In addition, to ensure confidence in the margin of safety, the Commission believes that the safety basis for the facility should be incorporated in the license application.

The proposed rule is, in part, NRC's response in resolution of a Petition for Rulemaking (PRM-70-7) submitted by the Nuclear Energy Institute (NEI). The scope of the proposed rule is limited to licensees (and applicants for a license), authorized to possess a critical mass of SNM, that are engaged in the following activities: enriched uranium fuel fabrication; uranium enrichment; enriched uranium hexafluoride conversion; plutonium processing; mixed-oxide fuel fabrication; scrap recovery; and any other activity that the Commission determines poses a significant potential threat to public health and safety.

The purpose of this Regulatory Analysis is to help ensure that:

- NRC's decision to issue the proposed rule is based on adequate information concerning the need for and consequences of the proposal.
- Appropriate alternatives to regulatory objectives are identified and analyzed.
- No clearly preferable alternative is available to the proposed action.
- The direct and any indirect costs of implementation are justified by its effect on overall protection of the public health and safety.

2.0. Statement of the Problem

Investigation of a potential criticality incident in May of 1991 determined that 10 CFR Part 70 does not address facility changes nor does it address changes of procedures and methods that could affect the safe operation of the facility. Change reviews were found to be handled on a case-by-case basis during the development of license conditions, with some license conditions stated in a manner that promoted the exercise of discretion on the part of the licensee in establishing the need for change reviews.[8] The investigation found that the licensee's system of criticality safety controls was originally extensive and afforded true defense-in-depth. However, this system of controls deteriorated as operations proceeded and changes accumulated.[9]

This incident prompted the NRC staff to evaluate its safety regulations for licensees that possess and process large quantities of SNM. This evaluation concluded that NRC's existing safety regulations for materials licensees "... focus almost exclusively on radiological safety concerns, practically to the exclusion of process safety and managerial controls."[10] Furthermore, the review found that "... each licensee needs a strong managerial program of controls and hazard assessments to ensure and maintain the level of safety that existed when it received its initial license."[11] The evaluation also found that "... hazards analyses or engineering safety analyses of plant systems and components are not routinely performed"[12] by licensees.

There are a number of weaknesses with the current 10 CFR Part 70:

- It provides neither general design criteria nor performance objectives. Unlike

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[8] Discussed on page 12-4; NUREG-1450, *Potential Criticality Accident ..., May 29, 1991;* published August, 1991.

[9] Ibid., page 7-16.

[10] NUREG-1324, *Proposed Method for Regulating Major Materials Licensees*; published February, 1992; page 17.

[11] Ibid., page 18.

[12] Ibid., page 27.

10 CFR Parts 50 and 72, 10 CFR Part 70 contains no "general design criteria."[13] This would not be a problem if it contained detailed performance requirements in the manner of 10 CFR Part 61 or of 10 CFR 74.51. Unfortunately, the only safety performance objective mentioned in the current 10 CFR Part 70 is the overly general "protect health and minimize danger to life and property."

- It does not address clearly which facility changes require a license amendment;[14] does not require management review or audits of changes of procedures and methods; and does not mention managerial controls, including quality assurance. Repeatedly, serious events at licensees' facilities can be traced to: lack of procedures or to failure to follow procedures; poor or no training of staff to conduct assigned duties; insufficient retraining of staff; the staff's conduct of activities without management's knowledge or approval; poor sampling and measurement of health-related, safety-related or environmentally-related media; in some cases, poor sampling and measurement of process streams where the information was not required for material control and accounting purposes, i.e., was not subject to the requirements of 10 CFR 70.57; poor maintenance; a failure by management to follow up on safety-related commitments due to a lack of a safety culture within management, to poor tracking systems and to poor commitment reporting systems; a failure by management to control changes; and a failure to properly audit for management effectiveness and to implement corrective actions when audits did occur.

- 10 CFR Part 70 contains no explicit requirements for chemical safety, fire safety, and prevention of criticality accidents.

- 10 CFR Part 70 allows a licensee to continue operating indefinitely past its license expiration date if a renewal application has been received in time. This is referred to as being in "timely-renewal." A licensee in timely-renewal may have little incentive to come to closure on contentious safety issues holding up the license renewal.

- 10 CFR Part 70 does not emphasize commitments to a safety basis. Section 70.22(a)(7) and (8) require the application to contain *descriptions* of equipment. facilities

[13] Ibid., pages 17 and 30.

[14] NUREG-1450, page 7-17.

and procedures that will be used to protect health and safety. It does not specify that applications contain *enforceable commitments.* In practice, licensees and applicants for a license or for a license renewal do propose license conditions in Part 1 of their applications. Regulatory Guide 3.52, the Standard Format and Content Guide, specifies a two-part application, with only the first part containing proposed license conditions and the second part containing descriptive material. Licensees frequently have placed important safety information into the non-binding Part 2 of the application. This problem is compounded by the timely-renewal problem.

- 10 CFR Part 70 does not explicitly address licensee safety assessment. In 70.22(f), it does require plutonium processing and fuel fabrication applicants to include a "description and safety assessment of the design bases of the principal structures, systems and components of the plant," but no similar requirements apply to other SNM applicants. In practice, applicants do include safety analyses, as called for in Regulatory Guide 3.52; however, these do not comprehensively and systematically examine all hazards that could result in accidents of concern to the NRC. NUREG-1324 recommended that the regulation be revised to "require that a hazards analysis be performed for each system and component within each process that contains radioactive material or that serves as a barrier to the release of radioactive materials to an unauthorized location."

3.0. Objectives

The primary objective is to regulate major SNM licensees in an efficient, fair, and effective way, and in a manner that provides NRC with appropriate confidence in the margin of safety at these facilities. A secondary objective is to implement the resolution of a petition for rulemaking (Docket No. PRM-70-7) from NEI, as proposed in SECY-97-137.[15]

4.0. Background

On January 4, 1986, a worker lost his life during an accidental release of uranium hexafluoride

[15] Staff Requirements Memorandum, *SECY-97-137 - Proposed Resolution to Petition for Rulemaking Filed by the Nuclear Energy Institute*, August 22, 1997.

(UF_6) at a facility regulated under 10 CFR Part 40. A Congressional inquiry[16] into this accident criticized NRC's oversight of chemical hazards at NRC-regulated facilities. As a result of this accident, NRC also established an independent group, the Materials Safety Regulation Study Group (MSRSG), to evaluate regulatory practices at all fuel cycle facilities, including those regulated under Parts 40 and 70. The MSRSG concluded that there was a regulatory implementation gap over hazardous chemicals at NRC-regulated facilities.

As a result of the UF_6 release and the Study Group conclusions, an interagency Memorandum of Understanding (MOU) between NRC and the Occupational Safety and Health Administration was issued on October 31, 1988 (53 FR 433950). This MOU clarified NRC responsibility for chemical hazards resulting from processing of licensed radioactive materials. Although a branch technical position on chemical safety was published in 1989 (54 FR 11590), regulation of chemical hazards associated with processing licensed material has not been incorporated specifically into the licensing requirements of Part 70. The same is true of branch technical positions on fire safety,[17] management controls,[18] and requirements for operation.[19]

After a near-criticality incident on May 29, 1991, the NRC formed a Materials Regulatory Review Task Force to identify and clarify regulatory issues that need correction. The Task Force published NUREG-1324, which identified a number of weaknesses in the regulation of fuel cycle facility licensees in such areas as: quality assurance; maintenance; training and qualification; management controls and oversight; configuration management; chemical and criticality safety; and fire protection.

To determine whether the above weaknesses are still a problem today, the NRC reviewed the causes of a number of what it considers serious incidents and precursor events at fuel cycle

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[16]*NRC's Regulation of Fuel Cycle Facilities: A Paper Tiger*, Eighth Report by the Committee on Government Operations, June 18, 1987.

[17]*Branch Technical Position on Fire Protection for Fuel Cycle Facilities*, published in the Federal Register (54 FR 11595-98) dated March 21, 1989. See also NRC Information Notice 92-014, *U Oxide Fires at Fuel Cycle Facilities*, and draft Regulatory Guide DG-3006, *Standard Format & Content For Fire Protection Sections of License Applications for Fuel Cycle Facilities*, issued for comment April 30, 1993.

[18]*Branch Technical Position on Management Controls/Quality Assurance for Fuel Cycle Facilities*, published in the Federal Register (54 FR 11591-92) March 21, 1989.

[19]*Branch Technical Position on Requirements for Operation for Fuel Cycle Facilities*, published in the Federal Register (54 FR 11591-92) March 21, 1989.

facilities reported after 1991.[20] Serious incidents are those involving harm or serious risk of harm to persons, while precursors are events which place a facility at increased risk of a serious incident. Serious incidents examined included:

a) Sept., 1992: Fire and explosion of 1700 grams of highly enriched uranium (HEU) contained in dissolver tray.

b) November, 1992: Toxic nitrogen oxides released onsite and offsite due to improper addition of process chemicals to licensed material.

c) Uranium contamination at facility due to a chemical explosion and fire in 1992.

d) October, 1992: Improper uranium solution sent to unsafe-geometry vaporization chest.

e) February, 1993: Large (124 Kg) spill of uranium dioxide (UO_2) powder due to unauthorized disabling of automatic limit switches that had not been adequately identified as safety related component.

f) May, 1993: Poor process control and quality assurance leading to obtaining a nonrepresentative sample of uranium dioxide for process measurement step.

g) Oct., 1993: Alert declared due to rooftop fire on plutonium building because of inadequate process controls.

h) January, 1994: Alert declared due to ten-minute release of UF_6 gas.

i) Sept. 1994: Spill of 188 Kg of enriched UO_2 powder.

j) Several times over the period 1994-95: Accumulation of uranium dust in ventilation ducts exceeding the criticality safety limits.

k) Nov., 1995: Inadequate maintenance program leading to UO_2 powder accumulation inside furnace due to crack in furnace muffle.

l) April, 1996: Site area emergency declared due to fire in process ventilation exhaust duct system.

m) August, 1996: Exothermic chemical reaction involving enriched uranium leading to fire caused by mixing of chemicals in a uranium recovery operation without appropriate attention to chemical hazards.

n) August, 1996: Operations in one process suspended due to flame in high level dissolver tray while dissolving poorly characterized uranium-beryllium material.

o) September, 1996: Second instance of a fire at the same facility in local ventilation duct

[20] Updated from Attachment 3 (Regulatory Concerns from Precursor Events at Fuel Cycle Facilities) to *Improving the regulation of Fuel Cycle Facilities: Overview,* distributed at the NRC Public Workshop on Improving NRC's Regulation of Fuel Cycle Facilities, November, 30, 1995.

system because of apparent improper change control.

p) October, 1996: Large spill of material in a licensee's uranium recovery area.

q) Dec., 1996: Calciner tube failure with subsequent accumulation of powder in annulus with loss of two criticality safety controls.

r) March, 1997: Alert declared after low enriched uranium spill from downblending equipment due to inadequate pre-operational testing.

s) April, 1997: Flashback fire in sintering furnace because of loss of process controls.

t) June, 1997: Loss of control on powder granulation hopper results in unacceptable accumulation of UO_2 powder.

u) July, 1997: Quantity of enriched uranium on transfer cart in excess of criticality mass limits.

v) Sept., 1997: Release of radioactive material from stack at levels higher than internal plant action limits, due to inadequate valving arrangement and procedure for kiln startup.

w) Jan., 1998: Moderation control in dry conversion process degraded when wrong additive used during a powder blend.

There continues to be a set of systemic program deficiencies at fuel cycle licensees that are determined to be consistent causes of serious incidents and precursors. These deficiencies are neither rare nor isolated in the industry.

An action plan for remedying deficiencies identified by NUREG-1324, approved by the Commission,[21] in addition to calling for improvements in the regulatory base, fostered an approach to license renewals that encouraged inclusion of a commitment to perform an ISA as a condition of the license.

On September 30, 1996, the NRC docketed a petition for rulemaking (Docket No. PRM-70-7) from NEI. The petitioner wrote:

> Over the past decade, while the formal requirements of Part 70 have not changed significantly, its application has. Licensees' documentation requirements have evolved significantly and additional requirements on the

[21] Staff Requirements Memorandum (SRM) on action plan for fuel cycle facilities (SECY-93-128), dated June 7, 1993.

> facilities have been imposed through the inspection and licensing processes. Regulatory predictability and stability associated with licensing and oversight of Part 70 facilities [have] suffered as a result. The industry believes that the ISA[22] requirement to evaluate risks (consequences and frequency) and the graded approach to safety (implementation and assurance), coupled with a backfit provision, would help to promote a stable and effective regulatory environment.

Staff submitted a proposed resolution to PRM-70-7 to the Commission (SECY-97-137) on June 30, 1997. That proposed resolution was endorsed by the Commission in an SRM dated August 26, 1997. Staff's recommended approach to rulemaking included the basic elements of the PRM-70-7, with some modifications. In brief, staff proposed to revise Part 70 to include the following major elements:

a) Performance of a formal ISA, which would form the basis for a facility's safety program. This requirement would apply to a subset of licensees authorized to possess a critical mass of SNM based on their risk of operations. According to the proposed rule, the performance of an ISA will be required of all licensees authorized to possess a critical mass of special nuclear material (SNM) that are engaged in one of the following activities: uranium processing, uranium fuel fabrication, uranium enrichment, 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.

b) Establishment of limits to identify the adverse consequences against which licensees must protect.

c) Inclusion of the safety bases in the license application (i.e., the identification of the potential accidents, the safety items relied on to prevent or mitigate these accidents, and the measures needed to ensure the continuous availability and reliability of these items).

d) Ability of licensees, based on the results of an ISA, to make certain changes without advance NRC review and permission.

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[22] The Petition uses ISA to stand for integrated safety assessment. NRC prefers the term integrated safety analysis.

The objective of the proposed rulemaking is to establish a risk-informed framework, for regulating major[23] SNM licensees, that provides NRC with increased confidence in the margin of safety. The intent is to establish requirements that strengthen regulatory oversight while minimizing the accompanying regulatory burden.

5.0 Alternatives

The alternatives considered are:

- Option 1 -- no action;
- Option 2 -- the proposed rule and standard review plan (SRP), which are consistent with SECY-97-137 and the SRM of August 22, 1997; and
- Option 3 -- a probabilistic risk analyses (PRA) version of the proposed rule.

These alternatives are described more fully in the following paragraphs.

5.1 Option 1 Description

Two alternatives, resulting in the establishment of two different baselines, are discussed under this option. The first baseline (1a) represents the Part 70 program as required by regulation and prior to imposition of license conditions resulting from the 1993 action plan (no ISAs). The second baseline (1b) reflects the required program under Part 70 with license conditions resulting from the action plan included in most license renewals. Thus, while both alternatives are considered to be "no action," the frame of reference for each is different. This is necessary to accurately reflect the incremental cost/benefit impact of the proposed rule.

5.1.1 Option 1a

Option 1a is a so-called "no-action" alternative that corresponds to the *status quo* that existed before initial implementation of the 1993 action plan for fuel cycle facilities. This alternative, which ignores the fact that most licensees are now required by license condition to prepare an

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[23] Major SNM licensee, in the context of this rulemaking, means, in general, a licensee whose approved activity involves mechanical or chemical processing of critical quantities of SNM. See the scope of the proposed rule for more detail.

ISA, is needed because the existing regulations in Part 70 do not explicitly require performance of an ISA. In the timeframe of Option 1a, NRC was criticized in House Report 100 -167 for concentrating on radiological hazards and largely ignoring other hazards. An ISA addresses all hazards, not just radiological hazards.

There are several requirements in the current Part 70 that specifically address public health and safety. Section 70.23, *Requirements for the approval of applications*, requires, among other things, a determination that the applicant's proposed equipment, facilities, and procedures be adequate to protect health and minimize danger to life or property. Similarly, 10 CFR 70.22 requires the applicant to provide a description of equipment, facilities, and procedures to protect health and minimize danger to life or property. Section 70.22 includes such examples of equipment and facilities as "... handling devices, working areas, shields, measuring and monitoring instruments, devices for the disposal of radioactive effluents and wastes, storage facilities, criticality accident alarm systems, etc." It includes "... procedures to avoid accidental criticality, procedures for personnel monitoring and waste disposal, post-criticality accident emergency procedures, etc." as examples of procedures. However, the descriptions were not necessarily comprehensive nor enforceable license commitments because they were not proposed as, nor incorporated into, the conditions of the licenses. In addition, the existing Part 70 does not explicitly require fire safety or chemical safety, except that fires and "... any associated chemical hazards directly incident"[24] to an accidental release of SNM are required to be considered in emergency planning for responding to accidents. Although "... procedures to avoid accidental criticality" are included as examples of proposed procedures to be contained in the license application, engineered means of preventing accidental criticality, which generally are more reliable than procedural means, and are preferred for criticality safety, are not addressed in the regulation.

For plants involved with plutonium, in addition to the above requirements, 10 CFR 70.22(f) specifically requires:

> Each application for a license to possess and use special nuclear material in a plutonium processing and fuel fabrication plant shall contain, in addition to the other information required by this section, a description of the [plant site], a description and safety assessment of the design bases of the principal structure,

[24] 10 Section CFR 70.22(I)(1)(ii).

> systems, and components of the plant, including provisions for protection against natural phenomena, and a description of the quality assurance program to be applied to the design, fabrication, construction, testing and operation of the structures, systems, and components of the plant.

A footnote to 10 CFR 70.23(b) notes that for plutonium facilities, "The criteria in appendix B of part 50 of this chapter will be used by the Commission in determining the adequacy of the quality assurance program."

Regulatory Guide 3.52, *Standard Format and Content for the Health and Safety Sections of License Renewal Applications for Uranium Processing and Fuel Fabrication*, provides the staff position on information that should be included in the application. Because this is a guidance document rather than a regulation, compliance with it is not mandatory. Regulatory Guide 3.52 identifies a two-part license renewal application, i.e., proposed license conditions in Part I and descriptive information (demonstration and performance record) in Part II. The information in Part I is noted to be of major importance to the NRC inspection and enforcement staff and, the Regulatory Guide states that Part I should be written to be inspectable and verifiable. The information in Part II, on the other hand, is stated to be of major importance to the NRC licensing staff, during the review of the license renewal application, and should be written to provide the basis for licensing decisions.[25]

According to Regulatory Guide 3.52:

> In the renewal application, the applicant should analyze the plant in terms of potential hazards and the means, including appropriate margins of safety, employed to protect against these hazards. Sufficient information should be included in Part II to allow the NRC licensing staff to perform independent analyses to confirm conclusions reached by the applicant. These analyses should include but are not limited to (1) the site and its relationship to accidents from natural phenomena, (2) operations involving radiation exposures, releases to the environment, and the application of the principle of as low as is reasonably achievable (ALARA), (3) nuclear criticality safety, (4) operations involving

[25] Regulatory Guide 3.52, Revision 1, November, 1986, page vii.

> hazardous chemicals, (5) confinement and control of radioactive materials, (6) projected effluent quantities and concentrations and effluent treatment, (7) reliability of the systems essential to safety, (8) prevention and control of fire and explosion, (9) radiological contingency planning, and (10) environmental impact associated with normal operations, abnormal conditions, and accidents.[26]

> The application should contain a safety analysis, including radiation safety and nuclear criticality safety, for each step of the process. The analysis should show how the commitments specified in Part I [of the application] will be met.[27]

> The types of accidents considered and their potential impact on occupational safety and the environment should be summarized.[28]

However, these analyses did not typically include identification of all the items relied on for safety nor did they comprehensively and systematically address all the hazards, such as chemical and fire hazards, that could cause a release of licensed material.

There is nothing in the current Part 70 that explicitly requires a licensee to notify NRC of changes it makes to its facility and procedures that could make the description in Part II of the application in need of update. As noted by an NRC Incident Investigation Team:

> The regulations in 10 CFR [Part] 70 do not address facility changes and changes of procedures and methods; i.e., there is no regulation comparable to that specified in 10 CFR 50.59, 'Changes, tests, and experiments.' Although the regulations in Part 70 do not explicitly address change reviews, they are handled on a case-by-case basis during the development of license conditions.[29]

5.1.2 Option 1b

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[26]Ibid., page viii.

[27]Ibid., page 29 (Section 15.2).

[28]Ibid., page 30 (Chapter 16).

[29]NUREG-1450

Under Option 1b, the actual *status quo* no-action alternative, NRC would retain the current Part 70 as it is. Licensees required by license condition to perform an ISA would continue to do so. An SRP would be developed, under this alternative, to promote licensing consistency and uniformity and provide standards for the quality and completeness of the ISA. NRC uses SRPs to provide guidance, to the staff, for review and evaluation of license applications. In addition to promoting uniformity and consistency in licensing reviews, SRPs help make information about regulatory reviews widely available and improve communication and understanding of the staff review process. An SRP provides guidance and compliance is not mandatory. The SRP acceptance criteria are not considered the only acceptable positions or approaches. Other positions or approaches that are consistent with the regulations may be proposed by an applicant. Under Option 1b, however, the current regulations are very broad and general (see the discussion in Option 1a, above). This allows licensees and applicants to challenge the need for performing a comprehensive and systematic ISA, for committing to use the ISA to evaluate changes, and for committing to ensure the continuous availability and reliability of the items relied on for safety, as identified in the ISA. The guidance provided in the SRP could be challenged by the absence of explicit regulatory requirements for protection against criticality, and chemical and fire hazards, as well as the absence of explicit requirements for an ISA. Furthermore, there would be no explicit regulatory requirement for configuration management and other management controls necessary to ensure that the licensee makes no changes, deliberate or inadvertent, that would decrease the continuous availability and reliability of items relied on for safety. (The regulatory basis could be said to exist currently in 10 CFR 70.32(b), which states that the Commission may incorporate in any license additional conditions and requirements necessary to protect the public health and safety. However, invoking that provision of the regulation for a generic requirement applicable to all of a class of applicants and licensees should be done through rulemaking.)

Option 1b also includes continuation of reporting criticality events under NRC Bulletin 91-01, *Reporting Loss of Criticality Safety Controls*, without making this reporting a regulatory requirement or expanding it to include reporting the loss of safety controls other than criticality safety controls.

5.2 Option 2 Description

Option 2 is the NRC's proposal to modify 10 CFR Part 70 by adding a new subpart that addresses the features described in SECY-97-137. This new subpart includes requirements aimed at increasing NRC's confidence in the margin of safety at certain licensed facilities authorized to possess a critical mass of special nuclear material. Option 2 is a risk-informed, 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; and (3) the implementation of measures to ensure that the items relied on for safety are continuously available and reliable. In addition, in order to ensure confidence in the margin of safety, the safety bases for the facility, including the results of the ISA, would be incorporated in the license application, and revisions to the safety bases (including revisions to the ISA results) would be required to be provided to NRC.

Also included in Option 2 are new reporting requirements, which are based on consideration of the consequences and likelihood of the risk involved, and are intended to replace and expand on the approach licensees have currently been using for reporting criticality events under Bulletin 91-01. The new approach is generic, i.e., it covers all types of potential incidents (not just criticality incidents) and items relied on for safety identified and described in the ISA, and establishes a time frame for reporting that is scaled according to the risk. The new reporting requirements would supplement the reporting requirements currently in the existing 10 CFR Part 70.

An SRP, which has been developed for the proposed rule and is being made available in conjunction with this rulemaking, would be issued to provide guidance to the staff for the review and evaluation of license applications, renewals, and amendments. The SRP acceptance criteria describe ways of complying, with the new requirements, that are acceptable to NRC. The SRP also serves as regulatory guidance for applicants who need to determine what information should be presented in an application.

To assist license reviewers in determining that the applicant's proposed protection is sufficient to reduce the likelihood of potential accidents to levels commensurate with their consequences, the draft SRP includes a risk matrix of consequence categories and likelihood categories. This matrix shows which combinations the staff would find acceptable.

5.3 Option 3 Description

Option 3 is similar to Option 2, except that licensees would be required to perform the ISA using quantitative risk analyses methodology (e.g. PRAs).

Component or "basic-element" reliability data, however, do not appear to be currently available to perform quantitative ISAs on fuel cycle facilities. These facilities may employ unique equipment for which failure data may not have been kept. In addition to mechanical failures, many activities at fuel cycle facilities have considerable human interaction, the failure of which, considering both acts of commission and acts of omission, is difficult to model. Also, because of the competitive nature of the fuel cycle industry, there is no shared reliability database as there is for the nuclear power industry. Accordingly, the reliability data needed to perform a PRA, one of the methods that may be used when conducting the ISA, would at best be difficult to assemble.

6.0. Value-Impact Analysis

This section of the Regulatory Analysis discusses the benefits and costs of each alternative. Ideally, the benefits would be converted into monetary values, as would any non-cost impacts, such as radiation exposure that could be involved in a rule that required entries into a radiation area for its implementation. The total of benefits and costs would then be algebraically summed to determine for which alternative the difference between the values and impacts was greatest.

However, for this rulemaking, the assignment of monetary values to benefits is not possible because:

- No model exists for assigning a monetary value to the benefit of increased NRC confidence in the margins of safety at the affected facilities.
- Available guidance for Regulatory Analyses provides a monetary conversion for stochastic exposure to radioactivity, but not for injuries and fatalities due to exposure to hazardous chemicals, which are a primary concern at these essentially chemical processing facilities.
- There also are no monetary criteria to use for injuries or fatalities due to high radiation

doses from criticality accidents, because the Regulatory Analysis guidelines of $2000 per person-rem "...is not applicable to deterministic health effects, including early fatalities."[30]

- Furthermore, available estimates of the likelihood and consequences of an accident at any of these facilities are subject to large uncertainties.

While better estimates may be available after the completion of the ISAs being performed by most fuel fabrication facilities as a condition of their last license renewal, non-quantifiable attributes will remain the primary benefits. Subjective judgement still would be required as to which of the alternatives best solves the problems identified in section 2 of this report. Thus in section 6.1 we discuss the benefits of each alternative in a qualitative manner only. In section 6.2 we present estimates of the cost to an average licensee and to the NRC for implementing each alternative. The costs in section 6.2 do not include potential savings in terms of averted worker lives lost, averted injuries, averted offsite contamination and cleanup, and averted incident investigation.

6.1 Benefits

6.1.1 Increased Confidence in the Margin of Safety

The performance, by fuel fabrication and enrichment applicants and licensees, of a comprehensive and systematic hazards analysis, as part of an ISA, together with implementation of any corrective actions identified by the ISA, and associated licensee commitments to maintain the items relied on for safety, are key elements for increasing NRC's confidence in the margin of safety at these facilities. Safety analyses that consider chemical, fire, criticality, and radiation safety separately, as opposed to in an integrated manner, can result in measures that enhance safety in one area but degrade it in another. As an obvious example, water may not be an acceptable fire-suppression medium in a moderator-controlled area. But other examples may not be so obvious. For instance, installation of a drip pan under a valve, to confine radioactive contamination, could constitute a criticality safety concern if its shape was not a safe geometry. The performance of ISAs will significantly improve licensee

[30] NUREG-1530, *Reassessment of NRC's Dollar per Person-Rem Conversion Factor Policy,* December, 1995. NUREG-1530 explains that applying cost to non-stochastic fatalities is inconsistent with the Commission's *Safety Goal Policy* wherein the Commission made clear that no death will ever be "acceptable" in the sense that the Commission would regard it as a routine or permissible event.

and NRC knowledge, regarding potential accidents and the items relied on for safety, to prevent or mitigate the consequences of these accidents. Only Options 2 and 3 ensure that: (a) ISAs will be performed by all affected licensees in an acceptable manner; (b) items relied on for safety will be identified and reviewed; (c) continuous reliability and availability of those items will be maintained; and, (d) future changes will not decrease safety at the facilities without NRC review.

Options 2 and 3 would correct the weaknesses identified with the current 10 CFR Part 70 (see section 2 of this Regulatory Analysis). The new section 70.60 would provide explicit safety performance requirements as well as baseline design criteria for new facilities. The risk-informed regulation specifies the consequences of concern and the graded levels of protection that must be provided. Proposed section 70.72 clarifies what changes the facility may make without submitting an amendment application, and ensures that all changes, whether or not an amendment is required, are subjected by the licensee to an appropriate safety review. In section 70.60(d)(3) the rule would require a safety program that includes configuration management controls and quality assurance. It also requires personnel to be trained and tested to ensure they understand the safety features that are relied on to prevent accidents. The required ISA would have to address chemical, fire, and criticality hazards, as well as radiological hazards.

In addition, Options 2 and 3 would mitigate the timely-renewal issue, because the safety features of the license would be kept up to date making it a living license. In addition, the issue of what commitments of the license application are binding in the license will be resolved because the items identified by the ISA as relied on for safety as well as the measures to ensure the continuous reliability and availability of those items will be enforceable license commitments.

The PRA approach (Option 3) would provide additional numerical values associated with the likelihood of accident sequences and would provide a basis for more refined grading of protection, if the data were available to allow the quantitative approach without excessive uncertainty bounds. In addition, with the availability of PRAs, it may be possible, for NRC to quantify the benefits of proposed changes to requirements on these facilities. Thus, any backfit analysis, which the Commission may wish to impose on itself in the future before new staff positions or regulatory requirements could be adopted, could be based on the results of a PRA.

Otherwise, backfit analyses would have to be primarily qualitative in nature, which makes implementation difficult. However, on balance, NRC believes that Option 3 would provide only a relatively small benefit compared with Option 2, and Option 3 is beset with problems associated with the unavailability of data and relatively little experience in the chemical industry with quantitative models.

6.1.2 Reduction in Frequency and Severity of Accidents

The processing of SNM at facilities licensed to possess a critical mass of SNM could result in a number of potential accidents with varying consequences. These accidents could include an inadvertent criticality; public or worker intake of uranium or plutonium; public or worker exposure to radiation; and public or worker exposure to hazardous chemicals that are used or generated during the processing of SNM.

6.1.2.1 Onsite Consequences

Deaths of two workers are directly attributable to accidents involving licensed nuclear material.[31] (In contrast, there have been no deaths, because of licensed radioactive material usages, from accidents at U.S.-licensed reactors.) Additional worker injuries and health concerns have resulted from radiation and chemical exposures resulting from NRC-licensed SNM processing operations.

Options 1b, 2 and 3 have the potential to prevent and mitigate the consequences and reduce the likelihood of accidents, compared with Option 1a, through the correction of any vulnerabilities discovered by licensees in their performance of ISAs. To the extent that they enhance plant personnel awareness of their plant's safety features and measures relied on to ensure the continuous reliability and availability of those features, these options have additional potential to reduce the likelihood of accidents.

Options 2 and 3 would be expected to be more effective than Option 1b in reducing the consequences and likelihood of accidents because they would apply uniformly to all major SNM

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[31] One death from a criticality at a licensed SNM scrap recovery plant, July 24, 1964, and one from the hydrogen fluoride vapor cloud resulting from release of UF_6 at Sequoyah Fuels Gore, Oklahoma, conversion plant, January 4, 1986.

licensees. Under Option 1b not all licensees have license conditions that require performance of ISAs and there is considerable variability in the license conditions regarding maintenance of the safety features. Furthermore, Option 1b is considerably more limited than Options 2 or 3 in maintaining ISAs as a tool for evaluating facility changes.

6.1.2.2 Offsite Consequences

Accidents at licensed fuel fabrication facilities have resulted in offsite releases of uranium compounds and contamination of offsite property. At least one has involved significant government and licensee effort to track, measure, and account for the material released. The types of accidents that would be of most concern to offsite population are a release of UF_6 to the atmosphere, a major fire resulting in loss of confinement of SNM, or accidents sending SNM or toxic chemicals through the ventilation stacks. As in the case of onsite accidents, Options 2 and 3 offer the greatest potential for reducing opportunities for accidents with significant offsite consequences. Only Options 2 and 3 provide the offsite consequence criteria against which to judge the adequacy of protection.

6.1.3 Reduction in Frequency of Incidents

There have been and continue to be several incidents annually of safety significance. Reporting of these incidents to NRC causes both licensee and NRC resource expenditures to investigate and resolve such incidents. This reporting has value in that it provides the NRC with information needed for it to perform its oversight responsibility and requires a licensee to consider what went wrong and what steps might be needed to prevent a recurrence of this safety degradation, but the trend should be toward fewer incidents happening so that they do not require reporting. Under Option 1b, Bulletin 91-01 requests licensees to report loss of one or more criticality safety controls, but does not mandate those reports and does not address loss of other safety controls. Under Option 1b the NRC's confidence in the margin of safety would remain the same, and the annual number of incidents would also be unchanged.

Reversion to Option 1a, which does not include Bulletin 91-01, would cause a decrease in NRC confidence in the margin of safety. Option 1a would also not require any ISAs, and, therefore:

a) Plant and external hazards and their potential for initiating accident sequences would not be required to be identified;

b) The potential accident sequences, their likelihood, and consequences would not be required to be identified; and

c) The site structures, systems, equipment, components, and activities of personnel relied on to prevent or mitigate potential accidents at a facility would not be required to be identified.

As a result, more accident precursor incidents could be expected by a reversion to Option 1a.

Options 2 and 3 include a requirement that expands the reporting required by the current Part 70 to include reporting criticality incidents (Bulletin 91-01 incidents) as well as loss of other safety controls. The reporting requirements in these options have been written with consideration of risks associated with the full range of incidents of concern, to ensure that safety incidents in addition to criticality are included, but at the same time, to minimize the burden on licensees of reporting inconsequential or low-risk events. Options 2 and 3 would increase NRC confidence in the margin of safety. They should also lead to a reduction in accident precursor incidents due to the requirement that all major licensees perform ISAs, maintain them and use them to evaluate changes.

6.2 Cost Impacts

This section presents the incremental costs of transition from the baseline (Option 1b) to the proposed rule (Option 2) and from Option 2 to the PRA option (Option 3). It also discusses the sunk cost that was involved in the transition from the pre-1993 action plan (Option 1a) to Option 1b. Details on supporting cost assumptions are discussed in the Appendix.

Most existing licenses for facilities within the scope of the proposed rule (Option 2) contain license conditions that require the performance of an ISA, although not necessarily to the standards that would be established by the proposed rule and the guidance provided by the SRP. To a varying degree, some of the other provisions of the proposed rule and SRP are required by license condition in existing licenses. Following the usual practice for NRC Regulatory Analyses, no credit is given as sunk costs for licensee practices that can be discontinued by the licensee without a license amendment. On the other hand, licensee practices that are commitments included in a license application, provisions of a safety evaluation report (SER), provisions of a license condition, or provisions of a regulation, are considered to be part of the cost baseline (i.e., sunk costs).

The details of the costs are provided below and in the Appendix. A summary of the cost impacts is shown in Table 6.2-1. For licensees that have already implemented a set of license conditions that most nearly approaches the requirements of the proposed rule (Option 2), the range of estimated average incremental costs to implement the proposed rule are about $140,000 to $400,000 one-time costs and $20,000 to $40,000 per year. For those licensees with fewest changes in their license conditions under Option 1b, the per licensee range of estimated average incremental costs to implement Option 2 are about $700,000 to $2,200,000 one-time costs and $150,000 to $230,000 per year.

6.2.1 Option 1 Costs

6.2.1.1 Option 1 Licensee Cost Impacts

- Licensee Incremental Requirements of Option 1b vs Option 1a

Option 1a assumes a reversion to the licensing basis before the action plan was adopted. Incremental changes in requirements due to the action plan (i.e, Option 1b) varies by licensee, but for most licensees (5 of the current 7), included a license condition requiring the performance of an ISA. The standards for the ISA are not defined, and neither are the consequences of concern. Those licensees required by license condition to perform an ISA were all assumed to have to update their design basis documents to as built conditions before beginning the ISA. To varying degrees, Option 1b required establishing or upgrading existing configuration control, quality assurance, training and other measures for ensuring continuous reliability and availability of safety items identified by the ISA. There is considerable nonuniformity in these measures from one licensee to another under Option 1b. Option 1b also includes a license condition requiring 4 of the 7 current licensees to periodically update the demonstration part of their license applications. To account for these individual variations, weighted averages were used for the average costs of licensees already required to perform much of the proposed rule under Option 1b and those licensees currently required to perform little of the proposed rule.

- Implementation Costs of Option 1b Compared to Option 1a

Most of the cost involved in going from Option 1a to the Option 1b baseline has already been expended or is in the process of being expended, and is considered sunk cost. Costs that licensees have already expended or will spend in complying with license conditions on establishing configuration management programs, in updating piping and instrumentation drawings to match as-built and as-modified equipment, including the performance of ISAs, are

Table 6.2-1 Summary of Incremental Cost Impacts

	Costs for Current Licensees ($1,000)			
	Costs for average licensee preparing ISA under Option 1b		Costs for average licensee not preparing ISA under Option 1b	
	Low average	High average	Low average	High average
Incremental Sunk Cost of Option 1b Compared to 1a				
Average licensee one time cost ($[32]/licensee)	$700	$2,200	$80	$110
Average licensee recurring costs ($/licensee- year)	$170	$240	$40	$40
Average NRC one time cost ($/licensee)	$50	$110	$0	$110
Average NRC recurring costs ($/licensee- year)	($19)[33]	($18)	$0.5	$1.3
Incremental Cost of Option 2 Compared to Option 1b				
Average licensee one time cost ($/licensee)	$140	$400	$700	$2,200
Average licensee recurring costs ($/licensee- year)	$20	$40	$150	$230
Average NRC one time cost ($/licensee)	($6)	$10	$40	$90
Average NRC recurring costs ($/licensee- year)	($19)	($16)	($13)	($11)
Incremental Cost of Option 3 Compared to Option 1b[34]				
Average licensee one time cost ($/licensee)	$350	$1,400	$800	$3,200

[32] 1997 dollars.

[33] Savings are indicated as negative values, shown in parentheses.

[34] No difference in NRC cost was estimated for Option 3 versus Option 2.

	Costs for Current Licensees ($1,000)			
Average licensee recurring costs ($/licensee- year)	$60	$100	$200	$300

considered as the licensee sunk implementation costs for no-action baseline Option 1b. They are part of the baseline for this Regulatory Analysis. The licensees who are required to perform an ISA under Option 1b, implement measures to ensure the reliability and availability of items relied on for safety, are estimated to have license conditions costing on average[35] about $700,000 to $2,200,000 per licensee, with variations depending on several factors.

One factor is the number of complex systems the licensee has to analyze (i.e., the complexity of a licensee's facility and processes), and the labor hours required for each system. As discussed in the Appendix, this Regulatory Analysis presents cost averages based on information from a standard reference on hazards analysis published by the American Institute of Chemical Engineers (AIChE), and also presents cost averages based on communications from two major licensees regarding their cost experience.

Another factor affecting average costs is whether or not the license conditions for a licensee required to perform an ISA include associated requirements for implementation of new measures or upgrading of existing measures to assure the reliability and availability of items relied upon for safety. For example, only 2 of the 7 licensees are required to update their quality assurance of items relied on for safety, 3 have additional record keeping requirements, and 4 have new configuration management requirements. Furthermore, additional Option 1b requirements pertaining to staff training and to self-inspection and maintenance of items relied on for safety were imposed on 6 of the 7 licensees, not just the 5 required to perform an ISA.

Those licensees not performing an ISA under Option 1b are assumed to have incurred some incremental costs compared to Option 1a as a result of their last license renewal. These costs are associated with required enhancements or improvements to staff training, configuration management, quality assurance, and similar measures intended to better ensure safe operations. Average implementation costs for such actions for these licensees are estimated to be in the range of $80,000 to $110,000 per licensee.

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[35] In addition to variation in the average cost per licensee, individual licensees can expect to have cost variations about an average.

- Licensee Operational/Recurring Costs of Option 1b Compared to Option 1a

For a licensee with appropriate conditions in its license, the annual operational (recurring) sunk costs of Option 1b include the costs associated with maintaining configuration control, quality assurance, training and other measures for ensuring reliability and availability of safety items identified by the ISA. There are also recurring costs associated with facility changes which will require updating the ISA. In total, these recurring costs are estimated to average about $170,000 to $240,000 per licensee per year for those licensees required by license conditions to perform periodic updates of their ISAs and the demonstration sections of their license applications. Other licensees, with minimal requirements for improving Option 1a measures, are also assumed to expend, on average, about $40,000 per licensee-year more under their existing Option 1b requirements than under Option 1a.

6.2.1.2 Option 1 NRC Cost Impacts

- NRC Option 1b Implementation Costs

Additional NRC implementation costs are assumed to be required to develop an SRP for Option 1b, because the SRP draft that has been developed assumes the proposal of Option 2 is adopted as a regulation. Not having to expend those funds would be a cost savings in Options 2 and 3 relative to the baseline. These savings for Options 2 and 3 compared to Option 1b are estimated to be approximately 1 FTE (full-time equivalent), or about $110,000[36].

Under Option 1b, the NRC would incur implementation costs in reviewing ISAs for the five licensees required to performing an ISA and in evaluating the actions taken to better assure the availability and reliability of items relied on for safety. These NRC reviews and evaluations are estimated to require, on average, about 900 to 2000 staff-hours per licensee, or incremental NRC expenditures on the order of $50,000 to $110,000 per licensee for the five licensees performing ISAs under Option 1b.

- NRC Option 1b Operational/Recurring Costs

As discussed below, it is estimated that the NRC will have recurring net savings averaging about $19,000 per year per licensee over the long term under Option 1b compared to Option 1a.

The NRC incurs operational costs with Option 1b compared to Option 1a in reviewing periodic updates to the demonstration sections of the license applications. Four fuel cycle facility licensees are required to provide these periodic updates to the NRC. The review costs are estimated to be about $6,000 per licensee per year.

The NRC also expends additional time reviewing the increased number of event reports submitted by licensees as a result of the Bulletin 91-01 requests (and which are assumed to be part of the overall changes from Option 1a to Option 1b). These additional event report reviews are estimated to cost the agency between $3,600 and $9,000 per year, or between $500 and

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[36] The NRC labor rates used in this Regulatory Analysis are discussed in the "Costs per Hour" portion of the Appendix to this Regulatory Analysis.

$1,300 per year per licensee.

On the other hand, the NRC's costs associated with performing license renewal reviews are expected to be reduced for those licensees submitting periodic updates to the demonstration sections of their license applications. With Option 1b, four licensees are required to provided these updates. The estimated savings to the agency from reduced license renewal review expenditures is estimated to be about $25,000 per year per each of the four licensees.

6.2.2 Option 2 Costs

6.2.2.1 Option 2 Licensee Cost Impacts

- Incremental Requirements of Option 2 vs Option 1b

If a licensee were not required to do so for the Option 1b baseline alternative (two of the seven current licensees are not presently required to perform ISAs), Option 2 would include developing and documenting the required ISAs, including the identification of items relied on for safety and measures to ensure their availability and reliability. Those licensees performing an ISA under Option 1b would likely have to upgrade their existing analyses to meet the standards required by Option 2.

The safety of all existing operating licensees is considered to be adequate, and the licensees are considered competent to safely perform operations with SNM. Accordingly, it is expected that the changes in the current safety basis will not be dramatic, but rather a matter of refinement. It is assumed that for some licensees Option 2 would involve merely a review of their existing measures that ensure the reliability and availability of their safety items, while other licensees may have to establish some new, or upgrade existing, measures. Required actions would include:

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- Establish or upgrade measures to ensure that items relied upon for safety meet quality standards commensurate with their importance, and establish corresponding policies and procedures.

- Establish and maintain configuration control to assure that changes to processes and systems are reviewed, documented, communicated and implemented in a manner which satisfies safety requirements.

- Establish or upgrade any additional measures needed to ensure that items relied upon for safety are designed, constructed, inspected, calibrated, tested and maintained as necessary.

- Establish or upgrade training programs to ensure that personnel are trained, tested, and retested to assure they recognize and understand safety concerns.

- Establish records that demonstrate adherence to the foregoing requirements.

- New reporting requirements. (Option 2 also includes strengthening the event reporting requirements for affected licensees.)

Table 6.2-2 indicates the number of current Part 70 licensees judged likely to incur cost impacts by the foregoing provisions of the proposed rule with Option 2. Also shown are estimates of the relative efforts needed to establish measures or bring existing measures into compliance with the Option 2 requirements. The "relative effort needed to achieve compliance" is indicated as a fraction. A low value indicates that licensees in that group already have measures which are expected to largely satisfy the proposed rule requirements, and that the remaining effort to achieve full compliance is relatively small. A high value (1.0 is the maximum) indicates that existing measures are expected to need substantial improvement to comply with the proposed rule. A value of 1.0 assumes that affected licensees would be given essentially no credit for existing measures, and that an entirely new program would have to be established. The judgments of the relative effort needed to achieve compliance are based on NRC fuel cycle licensing staff suggestions and on comparisons of existing license conditions with the requirements of the proposed rule and with acceptance criteria of the draft Standard Review Plan.

Table 6.2-2 Relative Impact of Proposed Rule Reliability
and Availability Requirements on Affected Part 70 Licensees

Measures Needed to Assure Reliability and Availability of Items Relied on for Safety	Number of Licensees in Affected Group	Relative Effort Needed to Achieve Compliance with Proposed Rule
Quality assurance	2	0
	5	1.0
Design[37], construction, inspection, calibration, testing and maintenance measures for items relied upon for safety	6	0.25
	1	1.0
Additional personnel training	6	0.3
	1	0.8
Configuration control	4	0.1
	3	0.75
Additional record keeping	3	0
	4	0.6
Additional event reporting	7	1.0

- Implementation Costs of Option 2 Compared to Option 1b

Each affected applicant or licensee would incur some implementation costs under Option

[37] Replacement components are required to be of the correct design and materials.

2, even if the licensee already had conducted an ISA under Option 1b. One time implementation costs that licensees already required to perform an ISA would expend to go from Option 1b to Option 2 could include upgrading of the ISA to Option 2 standards (e.g., to review the ISA and update it where necessary based on the consequences of concern and other rule and SRP provisions). Weighted average incremental costs for upgrading existing ISAs to Option 2 standards and for measures to ensure reliability and availability of items relied on for safety are estimated at $140,000 to $400,000 per licensee for licensees already required to perform ISAs under Option 1b.

The licensees who have not committed to perform an ISA under Option 1b would have to do so under Option 2. Weighted average costs to perform an ISA and for measures to ensure reliability and availability of items relied on for safety are estimated to range from $700,000 to $2,200,000 per licensee for licensees who had minimal license conditions imposed under Option 1b.

- Incremental Operational Cost Impacts Compared to Option 1b

Once these measures were implemented, the licensees would incur recurring operational costs for maintenance and for periodic updates associated with changes to systems and processes. These costs include updates to ISAs to reflect changes to systems and processes, and recurring costs associated with additional personnel training, maintenance of configuration management, enhanced maintenance, testing, inspection activities, enhanced quality assurance, maintaining design basis information, and similar ongoing activities. In addition, Option 2 includes strengthening the event reporting requirements for affected licensees.

The incremental annual recurring or operational costs per licensee are estimated at $20,000 to $40,000 for an average licensee already required by Option 1b to do much of Option 2 requirements. The average annual cost for other licensees is estimated at $150,000 to $230,000.

6.2.2.2 Option 2 NRC Cost Impacts

- NRC Option 2 Implementation Costs

The NRC's incremental implementation activities under Option 2 would consist of initial evaluations of ISA submittals for those licensees who did not commit to perform an ISA under Option 1b, as well as reviews of revised ISAs for the other licensees. The costs of ISA reviews will depend on the type of ISA results documentation submitted by licensees. Option 2 would require licensees to submit sufficiently detailed ISA summaries, in contrast to the very brief or no submittals that are expected under Option 1b. The sufficiently detailed summaries are expected to reduce NRC staff expenditures of time and effort associated with reviewing ISAs, and reduce the need to spend time at licensee sites reviewing ISAs. For each of the two licensees performing an ISA for the first time, the NRC review and onsite evaluation costs with the ISA summaries are estimated at from $10,000 to $30,000 less than the comparable costs would have been under Option 1b, or an average cost of $40,000 to $80,000 per licensee.[38] For the five licensees whose initial ISAs were reviewed under Option 1b, the NRC's review of the revised ISAs under Option 2 is estimated to average about 120 to 360 staff hours, or about $6,000 to $20,000 per licensee.

Associated with the ISA evaluations would be reviews to assess the adequacy of licensee measures to ensure the reliability and availability of items relied upon for safety. These incremental implementation costs are assumed to require about 80 to 120 staff hours, or about $4,000 to $6,500 per licensee for licensees required to perform an ISA under Option 1b and on the order of $20,000 to$30,000 per licensee for the two licensees who did not perform an ISA under Option 1b.

- NRC Option 2 Operational/Recurring Costs

Incremental recurring NRC activities with Option 2 include reviews of ISA updates and reviews of additional licensee event reports expected under Option 2. Costs associated with license renewals are expected to be different with Option 2 compared to Option 1b.

Licensees would be required to submit updates to their ISA results as their ISAs are modified to reflect changes to systems and processes. NRC review of ISA updates for the

[38] It is assumed that reviews of ISAs prepared under Option 1b are completed prior to implementation of Option 2. Otherwise, the NRC cost of reviews would show a savings of $4,000 to $10,000 for each of the licensees preparing ISAs under Option 1b.

three licensees not required to provide updates to the demonstration part of their license applications under Option 1b is estimated to cost the NRC about $3700 per licensee per year under Option 2. On the other hand, NRC review of the ISA updates provided by the other four licensees is expected to require less labor effort per review than the update reviews under Option 1b, because the licensee submittals under Option 2 are expected to be more comprehensive, and hence easier to review, than under Option 1b. This is estimated to be a savings of about $2,000 per licensee per year. With a savings of $8000 per year for four licensees and an additional cost of $11,200 per year for three licensees, the net cost to the NRC is $3,200 per year, or a weighted average of $490 per year per licensee.

The increased number of licensee event reports expected with Option 2 are estimated to increase NRC operational costs by $10,000 to $25,000 annually compared to the cost of reviews under Option 1b, or $1,400 to $3,600 per licensee,

NRC costs associated with Option 2 license renewal efforts are expected to be reduced compared to those experienced with Option 1b, because all licensees will be required to submit periodic ISA updates and updates to other licensing information. These updates will enable the NRC to better keep abreast of changes made to licensee processes, systems, and facilities on an ongoing basis, which will reduce the review burden for license renewal applications. These savings are estimated to amount to about $18,000 per licensee per year.

6.2.3 Option 3 Costs

6.2.3.1 Option 3 Licensee Cost Impacts

- Incremental Requirements of Option 3 vs Option 1b

Option 3 is identical to Option 2 except that it would require PRA methodology to be used for performance of ISAs. In Option 2, PRA methodology is an option that licensees *may elect* to use for the performance of ISAs, but are not required to use. In general, NRC would not expect any licensees to elect to use PRA methodology under Option 2.

- Implementation Costs of Option 3 Compared to Option 1b

Option 3 is estimated have many of the same implementation costs as Option 2, but to be considerably more costly than Option 2 because of the PRA requirement. According to the Center for Chemical Process Safety:

> Although elements of the CPQRA[39] are being practiced today in the [chemical process industry], only a few organizations have integrated this process into their risk management program. ...The reason that these methods are not in more widespread use is that detailed CPQRA techniques are complex and cost-intensive, and require special resources and trained personnel.[40]

Based on the assumptions discussed in section A5 of the Appendix, the cost increase for implementation of Option 3 compared to Option 1b ranges from $350,000 to $1,400,000 for the average licensee required to perform an ISA under Option 1b and from $500,000 to $3,200,000 for the average licensee not required to perform an ISA under Option 1b.

- Operational/Recurring Costs of Option 3 Compared to Option 1b

Option 3 would have similar incremental operational costs as Option 2, but also additional costs, both because of the requirement to use quantitative ISAs (PRAs) to evaluate changes and additions to facilities and processes and because of the continued need to collect and update reliability data.

6.2.3.2 NRC Cost Impacts

No additional NRC costs or savings are attributed to the incremental requirement from Option 2 to Option 3.

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[39] The Center for Chemical Process Safety states, "The term ‘Chemical Process Quantitative Risk Analysis’ (CPQRA) is used to emphasize the unique character of this methodology as applied to the [chemical process industry]." For the purposes of this Regulatory Analysis, the more familiar term PRA has been used for chemical process quantitative risk analysis.

[40] *Guidelines for Chemical Process Quantitative Risk Analysis*, Center for Chemical Process Safety of the American Institute of Chemical Engineers, 1989, page xvii.

6.2.4 Summary of Cost Impacts

Incremental implementation and operational costs for each alternative are shown in Table 6.2-1 for two "average" licensees, one that was required under Option 1b to perform an ISA and one that was not. The differences in high and low costs for each situation reflect, among other things, differences between AIChE estimates and licensee estimates of the cost of performing an ISA.

For licensees that have already implemented a set of license conditions that most nearly approaches the requirements of the proposed rule (Option 2), the range of estimated average incremental costs to implement the proposed rule are about $140,000 to $400,000 one-time costs and $20,000 to $40,000 per year. For those licensees with fewest changes in their license conditions under Option 1b, the per licensee range of estimated average incremental costs to implement Option 2 are about $700,000 to $2,200,000 one-time costs and $150,000 to $230,000 per year. Option 3 implementation costs are estimated to be considerably higher.

7.0. Decision Rationale

a) Option 1b, the actual or *de facto* no-action alternative, provides some of the desired improvements in the confidence in the margin of safety, but in an uneven and incomplete manner. It lacks a satisfactory mechanism for ensuring that changes between license renewals do not result in decreased safety, and hence it prevents the Commission from having continued confidence in the margins of safety. In addition, this option does not satisfactorily address degradation of margins of safety in future renewals, if licensees resist imposition of ISA license conditions, as one licensee did in the last round of license renewals.

b) Option 1a would result in a reduction in NRC confidence in the margin of safety. Although the direct licensee costs of this option are considerably lower than for the other options, some of this savings is illusory because the licensees have already expended effort (i.e., Option 1b) that they do not recover by ceasing efforts at developing ISAs. Furthermore, this option would not ensure that licensees have adequate knowledge of the safety basis for their facilities, which likely would lead to more incidents and subsequent NRC investigations, with a greater likelihood of an accident. Hence, Option 1b is preferred to Option 1a.

c) The distinction between Option 2 and Option 3 is that Option 3 would require licensees to use a PRA methodology in performing the ISAs. It is clear however, that this alternative would entail significant additional licensee costs, in comparison to Option 2. NRC does not consider the benefits of Option 3 to be significantly greater than those of Option 2. Therefore, Option 2 is preferred to Option 3.

d) For the reasons stated in (a) through (c) above, Option 2 is superior to Options 1a and 1b (the no-action alternatives) and Option 3.

Based on the above analysis, NRC believes that the proposed rule, if adopted, would provide the needed increase in the confidence in the margin of safety, at affected facilities, in the least costly manner.

Cost Assumptions and Averaging Approach

A1 Estimating Cost of Performing an ISA

The cost of performing an ISA was estimated on the basis of three factors, namely, the labor hours to analyze a single complex system, the cost per hour of that labor loaded with overhead factors, and the equivalent number of complex systems to be analyzed. A simple system is estimated to require about one-fourth the effort of a complex system.

A1.1 Labor Hours

With regard to the factor of labor hours per system, the information obtained from licensees implies that most of their ISA efforts to date consisted of HAZOP[41] analyses, and What-If was used to a lesser extent. An evaluation of the total projected ISA effort of one licensee indicated that a split of 2/3 HAZOP, 1/3 What-If may be a reasonable assumption. The labor required to accomplish these analyses can vary widely, depending on the type of analysis performed, the complexity of the target systems, and the number of people making up the evaluation team.

Guidance in the AIChE document on qualitative hazards analysis[42] was used to estimate the range in the labor requirements for HAZOP and What-if analyses. The estimate is based on the following assumptions:

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- the minimum team size would be 5 people, and the maximum size would be 8 people.

41 A description of HAZOP and What-If analysis methodologies may be found in the draft NUREG-1513, *Integrated Safety Analysis Guidance Document*, which is included in this rulemaking package and is available at the NRC Public Document Room. A more detailed description is available in *Guidelines for Hazard Evaluation Procedures, Second Edition with Worked Examples*, Center for Chemical Process Safety of the American Institute of Chemical Engineers (AIChE), 1992. This is one of the chemical industry references cited by the Occupational Safety and Health Administration in its rulemaking on Process Safety Management rulemaking (10 FR 6356, February 24, 1991.)

42 Ibid.

- the documentation efforts would be performed by only two members of the team.

- the estimates apply to complex systems.

The results are shown in Table A.

Using the above HAZOP/What-if split with the foregoing "mean" efforts, and noting that not all team members are needed to perform certain of the activities, gives an estimate of 800 labor-hours for analysis of one complex system. This value was used as one basis for estimating
ISA efforts.

In addition to the labor effort included above for documenting the ISA, an additional effort by licensees was assumed to be needed for those options requiring the submittal of comprehensive summaries of ISA results to the NRC. The effort to prepare these ISA submittals was estimated to require about two person-weeks (80 hrs) per system to prepare.

A1.2 Costs per Hour

Average industry labor rates for skill categories assumed to be representative of the work required were estimated based partially on information obtained from fuel fabrication licensees. Licensee actions and activities involved in performing work that might be required by alternatives under consideration in this Regulatory Analysis were assumed to be accomplished by two types of work groups. Group 1 could be used to perform analytical efforts which were not overly complex, and could include activities such as creating or revising procedures.
Group 2 would be needed to perform more complex evaluations such as performing ISAs and determining measures needed to assure the reliability and availability of items relied on for safety. Each group was assumed to include management, engineers, and clerical

staff. Somewhat different mixes were assumed for each group. For example, Composite Group 1 was assumed to require 15% management, 70% engineering staff, and 15% clerical support, while Composite Group 2 had 15 % management, 75% senior engineering staff, and 10% clerical support. The resulting composite labor rate as generated accounted for basic wages, applicable overheads, fringe benefits, and profit. The resulting loaded labor rates for licensees were $50.50 for Composite Group 1 and $57.00 for Composite Group 2. (These labor rate estimates may be somewhat overestimated, because chemical industry experience applying HAZOP and What-if is that teams need someone trained in the hazards analysis methodology but usually need no management member, only a single engineer, and the balance are typically process operators and maintenance personnel.)

NRC labor rates were derived from NUREG/CR-4627[43]. These rates were escalated to 1997 dollars using trends established by the Gross National Product Price Deflator index. The resulting NRC labor rate was taken to be $53.40 per hour. Following standard practice for NRC Regulatory Analyses, this rate is not fully burdened, but represents base wages for staff plus an allowance for management efforts and for efforts by support staff.

A1.3 Number of Systems

The third factor in determining the cost of performing an ISA is the number of complex and simple systems at an average facility. A major fuel fabrication facility generally includes the process steps listed in Table B. Following AIChE guidelines, this type of facility can be considered to consist of four complex and six simple systems.

Of the current seven major fuel cycle licensees that would be subject to this rulemaking, four can be characterized as equivalent to the above plant description. One only loads pellets into fuel rods and assembles rods into fuel bundles, so has no complex process systems, and therefore its ISA should require much less effort. Another facility is also primarily involved in mechanical rather than chemical processes, except for wet scrap recovery operations. It is estimated to have about three complex and a dozen simple systems. The seventh current major licensee is estimated to have about 12 complex

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43 NUREG/CR-4627, Rev.2, *Generic Cost Estimates*; Science and Engineering Associates, February 1992.

systems.

The AIChE guidelines indicate that an ISA for a simple system, using HAZOP and What-If analysis, can be performed for about one-quarter of the effort required for a complex system. On average then, it could be assumed that a typical major fuel cycle licensee has the equivalent of about 6 complex systems.

However, information from one major fuel fabrication licensee is that it has 28 systems in its ISA (complexity not specified), which implies a different breakdown than indicated in Table B. Using 28 systems, 18 of which conservatively are assumed to be complex, for the four licensees whose operations may be roughly characterized by Table B, it was estimated that the seven major fuel cycle licensees averaged the equivalent of 15.5 complex systems per licensee. The same licensee provided an estimate of its cost to perform an ISA, from which it was estimated that they used about 1780 labor hours per system. Licensee opinion that the AIChE estimates may be too low was also stated by a second major licensee, who could not provide cost of performing an ISA but did claim that the AIChE labor estimates per system were a factor of three too low.

A1.4 Error Sources in Estimates of Performing an ISA

The AIChE estimates may be somewhat low because they neither include criticality as a hazard nor include any accident analyses that might be necessary. The possibility is also recognized that information provided by licensees could include costs that may not be solely attributable to the performance of an ISA, such as the cost of criticality analyses that would be done even if an ISA was not performed, and the cost of bringing plant diagrams up to date, which we are considering as a cost separate from the ISA. The true costs of performing an ISA probably lies somewhere between these two extremes.

A2 Estimating Costs of Related Measures

In addition to the costs of preparing for, performing, and documenting the ISA, there are several related activities that may have cost impacts. Licensees that expended resources in upgrading measures (e.g., training) under Option 1b requirements, but that were considered not to fully meet the standards to be imposed by Option 2, were assumed to expend the balance of the resources under Option 2 needed to achieve a complete program (i.e., to meet acceptance criteria in the SRP). For example, if a licensee expended 70% of the resources under Option 1b needed to establish a suitable employee training program, that licensee was assumed to expend 30% under Option 2 to achieve a fully compliant program (0.7 + 0.3 = 1.0). The only exception to this approach was that the five licensees performing an ISA under Option 1b were assumed on average to expend 15% of the full ISA development costs under Option 2 to bring their ISAs up to Option 2 standards.

Table C indicates the level of effort estimated for these upgrade or implementation actions. Estimated implementation costs for these activities are also shown.

Most of the activities listed in Table C had their implementation efforts estimated on a per-system basis. The exception is the staff training/retraining. The training efforts assumed that training manuals would be upgraded based on ISA results and that affected staff members would be required to take enhanced training. The number of affected staff members per facility was based on the number of individuals at fuel facilities with measurable doses (see NUREG-1272). Record keeping expenditures assumed that new storage space and new

storage equipment (I.e., new filing cabinets, new computer data storage systems) would have to be provided, and were assumed to be dependent on the number of systems characterizing
the facility.

The implementation costs to establish or upgrade the measures needed to assure the reliability and availability of items relied on for safety were assumed to affect all licensees to some degree under Option 2, depending on the quality and comprehensiveness of their existing measures. The relative impacts for various licensee groups were noted in Table 6.22. Table D indicates the associated cost ranges for upgrading these existing measures or establishing needed measures.

A3 Estimating Annual Cost of Operations

Operational costs for each alternative were estimated using incremental annual operational costs associated with the alternative. Costs that occur less frequently than annually were prorated to an annual basis, using the assumption of a 20 year remaining plant life. To convert to present value, a discount rate of 7% was used. The 7% discount rate is suggested in NUREG/BR-0058, Rev. 2.

Incremental licensee operational costs associated with alternatives may include maintaining system and process safety information current, retraining and testing personnel, maintaining configuration control records, and updating process safety information. Table E shows the estimated licensee efforts and costs associated with these activities.

In addition, past history indicates that changes are frequently made to systems and facilities licensed under Part 70, or new processes are added to existing facilities. The data accumulated by the NRC over the past several years indicated that, on average, fuel fabrication licensees had roughly five minor modifications per year, and also had the equivalent of two substantial modifications or additions every three years, or about two thirds of a major modification per year. Major modifications require license amendments. The cost of demonstrating the safety of a proposed amendment will possibly be less with an ISA available to help provide a basis for demonstrating safety, but no credit for such savings was taken in this Regulatory Analysis. Table E includes the annual estimated hours for updating ISAs for minor process modifications. The effort needed to update an ISA for these types of modifications was estimated to be about 20% of the effort needed to evaluate a complex system. Thus, the annual ISA updating effort was assumed to be the equivalent of each licensee performing an ISA of slightly more than one complex system.

The estimates provided in Table E do not give credit for existing measures that could partially or completely satisfy the specified requirements. Such existing measures and measures already required by current license conditions could reduce the actual cost impacts to licensees. Accordingly, the estimates in Table E were multiplied by indicated factors to arrive at the cost estimates reported in section 6.2.

The maintenance of ISAs and the requirement to keep licensing basis information current are expected to reduce considerably the effort expended by licensees in preparing license renewal submittals. The NRC currently expends in excess of three staff years in renewing the license of a typical fuel cycle facility. The assumption was made that licensees probably expend about three times this amount in preparing their renewal applications. The assumption was also made that licensee efforts associated with license renewals would be reduced by about a factor of three under the proposed rule conditions compared to the situation that exists today. The value of these savings over the remaining plant life (assumed to be 20 years) is estimated to average a present value of $580,000 to $860,000 per licensee, or about $55,000 to $80,000 (savings) per licensee per year.

Table F summarizes the estimated recurring cost impacts of Option 2 compared to Option 1b. The licensee groups with the lower costs are those that, under Option 1b, are already performing some or all of the required actions called for with Option 2; the converse is true for the licensee groups with the higher cost ranges.

A4 New Reporting Costs

The assumption was made that the issuance of new reporting requirements under Options 2 and 3 would result in event reporting trends analogous to what was experienced with the issuance of Bulletin 91-01. That trend showed a several-fold increase in the number of event reports per year for the first 3-4 years after issuance of the bulletin, and

then subsequently decreasing to a level about two and one-half times the number of event reports experienced prior to issuance of the bulletin. The current average number of these reports in recent years has been about 2.1 per licensee-year for major licensees. The estimate of incremental reporting costs assumed that this historical trend will be repeated, starting from the current level of event reports. The number of such events was assumed to be proportional to the number of equivalent complex systems characterizing fuel cycle facilities. To estimate costs, it was further assumed that licensees would expend about one person-week in preparing each event
report and responding to NRC inquiries. The resulting average incremental reporting cost is estimated to be in the range of $4,000 to $11,000 per licensee per year (averaged over remaining facility lifetime).[44]

A5 PRA Cost Analysis

It is estimated that implementation of a quantitative ISA based on PRA methodology would be at least 1.5 times more expensive than a qualitative ISA. In addition, the quantitative ISA is assumed to require a reliability data collection effort to support the analysis. The qualitative ISAs already committed to by licensees could be helpful for the PRAs, and credit was given for these commitments. This basis resulted in estimated incremental quantitative ISA costs of $185,000 to $1.1 million per licensee, on average, for licensees performing a qualitative ISA under Option 1b. Licensees not performing an ISA under Option 1b would incur costs, on average, of between $400,000 and $2.4 million per licensee to perform the quantitative analysis. (This is the incremental cost from Option 1b, rather than the incremental cost from Option 2.) In addition, the initial data collection efforts (e.g., failure rates) necessary for PRAs are estimated to cost an additional $60,000 to $160,000 per licensee. Other implementation costs for Option 3 would be the same as those noted for Option 2.

Operational costs would also be higher. The annual data collection efforts are estimated to cost between $2,000 and $6,000 per licensee. For licensees with ISA commitments

[44] Event reporting is assumed to increase by a factor of about 5 over baseline values for the first 3-4 years after the new requirements are issued, and then to about 2.5 times the pre-change level for the balance of the facility life. Thus, the reporting expenditures are not constant over the remaining life of a facility. Averaging over remaining facility life is a way of presenting the equivalent annual costs without getting into the complexity of the early year costs versus the later year costs.

under Option 1b, the efforts associated with performing quantitative ISA updates are in the range of $50,000 to $120,000 more per licensee annually than those for qualitative ISAs. Licensees without ISA commitments under Option 1b would be expected to expend about $75,000 to $160,000 annually per licensee to update quantitative ISAs.

A6 Cost Summaries

Table 6.2-1 itemizes estimated cost impacts to licensees in transitioning from one option to another. Costs are shown for the transitions from Option 1a to Option 1b (considered to be sunk costs), from Option 1b to Option 2, and from Option 1b to Option 3. Estimates are provided for both implementation and operational/recurring activities. All costs are on a per-licensee basis. Table 6.2-1 provides estimates for two categories of licensees: those which, in the context of the transition being considered, have already been required to implement a license condition that encompasses the proposed requirement to some significant degree, and those which have either not previously had such a license condition or whose implementation of the license condition is expected to need substantial improvement to satisfy the proposed alternative.

As shown in Table 6.2-1, there are large variations in the costs to each licensee, because of variations in licensees processes, variations in the current licensing basis for the licensees, and uncertainties in the cost estimates.

To summarize these cost estimates, the low and high average costs for each cost element were added. In addition, Table G shows total costs to the seven current licenses and "average costs." The values in Table G were rounded off in Table 6.2-1, so as not to imply a high degree of certainty in the estimates.

Table A. AIChE Labor Estimates for Performing a Complex System ISA

ISA Activity	HAZOP Analysis Complex System		What-If Analysis Complex System	
	Low	High	Low	High
Preparation	2d	4d	1d*	3d*
Modeling	-	-	-	-
Evaluation	1w	3w	3d	5d
Documentation	2w*	6w*	1w*	3w*
Labor with 5 member team, hrs	440	1,240	216	488
Labor with 8 member team, hrs	608	1,696	288	608
"Mean" Effort, labor-hrs/system	996		400	

d=day, w=week

*Activity typically performed by 2 team members

Table B. Systems Characterizing Typical Full Scope Fuel Fabrication Facilities

System	Segment	
Shipping/Receiving	1 - UF_6 receiving	S
	2 - UF_6 cylinder washing	
	3 - Shipping container refurbishment	
UF_6 conversion	4 - UF_6 vaporization	C
	5 - formation of UO_2F_2	
	6 - Calcination to produce UO_2	
	7 - Offgas system	
	8 - HF recovery	
	9 - waste handling	
UO_2 powder production	10 - blending	S
	11 - refining	
UO_2 pellet formation	12 - pressing	C
	13 - sintering	
	14 - grinding	
Fuel rod loading	15 - pellet loading and end plugs	S
Fuel bundle assembly	16 - mechanical process of joining fuel and poison rods together. with spacers and end plates	S
Scrap recovery	17 - Dissolution	C
	18 - Solvent extraction	
Waste treatment & handling	19 - liquid wastes	C
	20 - solid wastes	
	21 - gaseous wastes/effluents	
Laboratory operations	22 - product quality and accountability measurements	S
Ventilation systems	23 - ducts and filters	S
Estimated number of complex (C) systems		4

Estimated number of simple (S) systems	6

Table C. ISA-Related Implementation Activities

Implementation Activity	Burden per Licensee[45]		
	Hours	Cost (in 1997 dollars)	Hourly rate ($/hr)
Compile and update baseline process safety information (if existing baseline process safety information is out of date).	1,200-3,100 hrs	$60,000 - $160,000	$50.50
Establish or upgrade measures that ensure that items relied on for safety are designed, constructed, inspected, calibrated, tested and maintained as necessary	600-1,550 hrs	$35,000 - $90,000	$57.00
Establish or upgrade training programs to ensure that personnel are trained, tested, and retested to assure they recognize and understand safety concerns	24 hrs/ staff; ~350 affected staff/licensee	$295,00 - $320,000	$33.00 per student-hr
Establish and maintain configuration control to ensure that changes are reviewed, documented, and adequately communicated to affected staff and parties	350-540 hrs	$30,000 - $60,000	$57.00
Establish or upgrade measures to ensure that items relied on for safety meet quality standards commensurate with their importance, and establish corresponding policies and procedures	620-1,000 hrs	$90,000 - $140,000	$57.00
Establish and maintain records that demonstrate adherence to new regulatory requirements	-	$30,000 - $75,000	-

45 The estimated per licensee costs in this table account for cost differences due to differences in the number of systems assumed for affected facilities. The range does not account for uncertainties in the individual estimates. The labor efforts and costs shown do not give credit for existing measures to which licensees may already be committed. Adjustments for sunk costs for existing commitments are discussed in section 6.2.1.

Cost per Licensee (in 1997 dollars)	$540,000 - $840,000

Table D. Cost Impacts of Proposed Rule Reliability
and Availability Requirements on Affected Part 70 Licensees

Measures Needed to Assure Reliability and Availability of Items Relied on for Safety	Number of Licensees in Affected Group	Cost Impacts to Achieve Compliance with Proposed Rule
Quality assurance	2	0
	5	$18,000 - $30,000
Design[46], construction, inspection, calibration, testing and maintenance measures for items relied upon for safety	6	$10,000 - $22,000
	1	$35,000 - $90,000
Personnel training	6	$90,000 - $100,000
	1	$235,000 - $260,000
Configuration management	4	$3,000 - $6,000
	3	$22,000 - $42,000
Record keeping	3	0
	4	$18,000 - $45,000

46 Replacement components are required to be of the correct design and materials.

Table E Estimated Incremental Operational Activities Burden Per Licensee Per Year

Incremental Operational Activity	Average Annual Burden per Licensee		
	Hours	$	Rate, $/hr
Maintaining process safety information up to date	120-310 hrs	$6,000 - $15,000	$50.50
Personnel training/retraining	5,700 hrs	$185,000	$33/ student -hr
Configuration management	520-675 hrs	$26,000 - $34,000	$50.50
Updating ISA for process and system changes	750-1,660 hrs	$50,000 - $110,000	$57.00
Estimated Annual Costs for All Foregoing Activities, per licensee	$280,000-$345,000		

Table F. Licensee Recurring Cost Impacts of Option 2 Relative to Option 1b

Affected Area or Activity	Number of Licensees in Affected Group	Recurring Cost Impacts to Achieve Compliance with Proposed Rule, $/licensee-year
Update ISA	4	$10,000 - $20,000
	3	$50,000 - $110,000
Maintaining design basis documentation	6	$2,000 - $5,000
	1	$5,000 - $12,000
Personnel training	6	$55,000
	1	$150,000
Design, construction, inspection, calibration, testing and maintenance, quality assurance, recordkeeping	4	$3,000 - $4,000
	3	$20,000 - $25,000
Event reporting	7	$4,000 - $11,000
License renewals	4	($55,000)
	3	($80,000)

Table G - Incremental Cost Impacts

(In thousands of 1997 dollars)

G-1 Incremental Cost of Option 1.b Compared to 1a

Cost1'Item	Number of lic. already with req.	Cost to a licensee already with requirement		Number of lic. needing to add req.	Cost to a licensee to add requirement		Sum of costs to all licensees already with requireme		Sum of costs to all licensees previously without requirement	
		Low	High		Low	High	Low	High	Low	High
One time Cost										
Update design basis documents to as-built conditions	5	$60	$160	2	0	$0	$300	$800	$0	$0
Perform initial ISA	5	$275	$1,575	2	0	$0	$1,375	$7,875	$0	$0
Design, construction, inspection, calibration, testing and maintenance	6	$25	$65	1	0	$0	$150	$390	$0	$0
Enhanced staff training	6	$210	$225	1	$60	$65	$1,260	$1,350	$60	$65
Configuration control	4	$25	$50	3	$10	$15	$100	$200	$30	$45
Quality assurance	2	$35,	$60	5	0	$0	$70	$120	$0	$0
Record keeping	3	$30	$75	4	$10	$30	$90	$225	$40	$120
Total Cost of Elements		**$660**	**$2,210**		**$80**	**$110**				
Average number of licensees	4.4286			2.5714						
Total industry one time cost for Option 1b							$3,345	$10,960	$130	$230
Average licensee one time cost for Option 1b							**$755**	**$2,475**	**$51**	**$89**
Recurring Costs per Year										

Table G - Incremental Cost Impacts (cont.)

Update design basis documents to as-built conditions (re changes)	6	$4	11	1	0	$0	$24	$66	$0	$0
Update ISAs for modifications	4	$40	90	3	0	$0	$160	$360	$0	$0
Staff training	6	$130	130	1	$35	$35	$780	$780	$35	$35
Configuration control, quality assurance, inspection, test, maintenance	4	$25	30	3	$6.5	$8.5	$100	$120	$20	$26
License renewals	4	($25)	($25)	3	$0	$0	($100)	($100)	$0	$0
Total Cost of Elements		**$174**	**$236**		**$42**	**$44**				
Average number of licensees	4.8			2.2						
Total industry annual recurring cost for Option 1b							$964	$1,226	$55	$61
Average licensee annual recurring cost for Option 1b							**$201**	**$255**	**$25**	**$27**

Table G - Incremental Cost Impacts (cont.)

G-2 Incremental Cost of Option 2 Compared to Option 1b

Cost Item	Number of lic. already with req.	Cost to a licensee already with requirement		Number of lic. needing to add req.	Cost to a licensee to add requirement		Sum of costs to all licensees already with requireme		Sum of costs to all licensees previously without requirement	
		Low	High		Low	High	Low	High	Low	High
One time Cost										
Update design basis documents to as-built conditions	5	0	0	2	$60	$160	$0	$0	$120	$320
Cost of performing ISA or refining earlier ISA	5	$40	$240	2	$275	$1,575	$200	$1,200	$550	$3,150
Design, construction, inspection, calibration, testing and maintenance	6	$10	$22	1	$35	$90	$60	$132	$35	$90
Enhanced staff training	6	$90	$100	1	$235	$260	$540	$600	$235	$260
Configuration control	4	$3	$6	3	$22	$42	$12	$24	$66	$126
Quality assurance	2	0		5	$18	$30	$0	$0	$90	$150
Record keeping	3	0	0	4	$18	$45	$0	$0	$72	$180
Total Cost of Elements		**$143**	**$368**		**$663**	**$2,202**				
Average number of licensees	4.4286			2.5714						
Total industry one time cost for Option 2							$812	$1,956	$1,168	$4,276
Average licensee one time cost for Option 2							**$183**	**$442**	**$454**	**$1,663**

Table G - Incremental Cost Impacts (cont.)

Recurring Costs per Year										
Update design basis documents to as-built conditions	6	$2	$5	1	$5	$12	$12	$30	$5	$12
Updates to ISA	4	$10	$20	3	$50	$110	$40	$80	$150	$330
Recurring training	6	$55	$55	1	$150	$150	$330	$330	$150	$150
Configuration control, quality assurance, inspection, test, maintenance	4	$3	$4	3	$20	$25	$12	$16	$60	$75
Enhanced event reporting requirements	4	$4	$11	3	$4	$11	$16	$44	$12	$33
License renewals	4	**($55)**	**($55)**	3	**($80)**	**($80)**	**($220)**	**($220)**	**($240)**	**($240)**
Total Cost of Elements		**$19**	**$40**		**$149**	**$228**				
Average number of licensees	4.6667			2.3333						
Total industry annual recurring cost for Option 2							$190	$280	$137	$360
Average licensee annual recurring cost for Option 2							**$41**	**$60**	**$59**	**$154**

Table G - Incremental Cost Impacts (cont.)

G-3 Incremental Cost of Option 3 Compared to Option 1b

Cost Item	Number of lic. already with req.	Cost to a licensee already with requirement		Number of lic. needing to add req.	Cost to a licensee to add requirement		Sum of costs to all licensees already with requireme		Sum of costs to all licensees previously without requirement	
		Low	High		Low	High	Low	High	Low	High
<u>One time Cost</u>:										
Update design basis documents to as-built conditions	5	0	0	2	$60	$160	$0	$0	$120	$320
Establish reliability data base	5	$60	160	2	$60	$160	$300	$800	$120	$320
Cost of performing PRA or additional cost for converting qualitative ISA to PRA	5	$185	$1,100	2	$400	$2,400	$925	$5,500	$800	$4,800
Design, construction, inspection, calibration, testing and maintenance	6	$10	$22	1	$35	$90	$60	$132	$35	$90
Enhanced staff training	6	$90	$100	1	$235	$260	$540	$600	$235	$260
Configuration control	4	$3	$6	3	$22	$42	$12	$24	$66	$126
Quality assurance	2	0	0	5	$18	$30	$0	$0	$90	$150
Record keeping	3	0	0	4	$18	$45	$0	$0	$72	$180
Total Cost of Elements		**$348**	**$1,388**		**$848**	**$3,187**	$1,837	$7,056	$1,538	$6,246
Average number of licensees	4.5			2.5						
Total industry one time cost for Option 3							$1,837	$7,056	$920	$5,120
Average licensee one time cost for Option 3							**$408**	**$1,568**	**$368**	**$2,048**

Table G - Incremental Cost Impacts (cont.)

Recurring Costs per Year										
Maintaining reliability data	5	$2	$6	2	$2	$6	$10	$30	$4	$12
PRA updates for changes	5	$50	$120	2	$75	$160	$250	$600	$150	$320
Update design basis documents to as-built conditions	6	$2	$5	1	$5	$12	$12	$30	$5	$12
Recurring training	6	$55	$55	1	$150	$150	$330	$330	$150	$150
Configuration control, quality assurance, inspection, test, maintenance	4	$3	$4	3	$20	$25	$12	$16	$60	$75
Enhanced event reporting requirements	4	$4	$11	3	$4	$11	$16	$44	$12	$33
License renewals	4	($55)	($55)	3	($80)	($80)	($220)	($220)	($240)	($240)
Total Cost of Elements		**$61**	**$146**		**$176**	**$284**	**$410**	**$830**	**$141**	**$362**
Average number of licensees	**4.8571**			**2.1429**						
Total industry annual recurring cost for Option 3							**$410**	**$830**	**$141**	**$362**
Average licensee annual recurring cost for Option 3							**$84**	**$171**	**$66**	**$169**

DRAFT NUREG 1513 JUNE 12, 1998

Integrated Safety Analysis Guidance Document

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

R. Milstein

AVAILABILITY NOTICE

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R. Milstein

Division of Fuel Cycle Safety and Safeguards
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

ABSTRACT

In [TBD] the NRC proposed a revised rule, 10 CFR Part 70, for licensing the use of special nuclear material. In the proposed rule, NRC included a requirement that certain licensee/applicants subject to 10 CFR 70 conduct an integrated safety analysis (ISA). The purpose of this document is to provide guidance to NRC fuel cycle licensee/applicants on how to perform an integrated safety analysis (ISA) and document the results. In particular, the document defines an ISA, identifies its role in a facility's safety program, identifies and describes several generally accepted ISA methods, and provides guidance in choosing a method.

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1 INTRODUCTION

1.1 Historical Context

Integrated safety analysis (ISA) is a systematic examination of a facility's processes, equipment, structures, and personnel activities to ensure that all relevant hazards that could result in unacceptable consequences have been adequately evaluated and appropriate protective measures have been identified.

Although the application of formal ISA techniques (known in the chemical industry as process hazard analysis (PHA)) was established about 40 years ago, its growth in recent years was spurred by a number of serious chemical accidents that illustrated the need to ensure a higher level of safety. In analyzing the causes of these accidents and the response of management, it was recognized that the correction of problems after an accident occurs is not necessarily conducive to the prevention of future accidents. Although the immediate problem may be solved, a systematic analysis of the entire facility is needed to identify other, unrelated potential accidents, and the measures needed to prevent their occurrence or mitigate their consequences.

The recognition of ISA as a critical element in managing process safety is evidenced in the industry standards that have been developed (American Institute of Chemical Engineers (1992)[47], American Petroleum Institute (1990), and Chemical Manufacturing Association (1992)) as well as recent State (New Jersey (1986), California (1986), Delaware (1988), and Nevada

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[47] References are cited herein by author and date of publication.

(1991)) and Federal regulations (Occupational Safety and Health Administration (OSHA) (1992), U.S. Environmental Protection Agency (EPA) (1993), and U.S. Department of Energy (DOE) orders (1994)).

1.2 Regulatory Basis

In [TBD], the U.S. Nuclear Regulatory Commission published a revised rule, 10 CFR Part 70, for licensing the use of special nuclear material. In this rule, NRC included a requirement that certain licensee/applicants subject to 10 CFR Part 70 conduct an "integrated safety analysis." The ISA is expected to form the basis of a safety program that requires adequate controls and systems to be in place to ensure the safe operation of the facility. Recognizing that NRC fuel cycle facilities are, to a large extent, chemical processing plants, the ISA techniques that have been applied to plants in the chemical and petrochemical industries are generally applicable to the NRC facilities. In fact, their application at other (non-NRC) nuclear fuel cycle facilities is well established. Nuclear fuel reprocessing plants (e.g., Idaho Chemical Processing Plant (ICPP) and Barnwell) developed and applied ISA methods in the 1970s; other DOE fuel cycle facilities developed and applied ISAs in the 1980s. ISA techniques applied to nuclear fuel cycle facilities must address the special hazards that are present at such facilities and their potential for causing criticality incidents and radiological releases, as well as certain chemical releases.

1.3 Purpose of Document

The purpose of this document is to provide guidance to NRC fuel cycle licensees/applicants on how to perform an ISA and document the results. In particular, this document identifies and describes several generally accepted approaches that are used to *analyze the hazards found in chemical processing plants. Although there are other critical elements that make up a robust safety program, such as training, maintenance, incident investigation, emergency planning, etc., this document discusses these elements only as they are affected by the ISA process. It does not provide detailed guidance about these elements. Nor does it address acceptance criteria for the ISA. Instead, these topics are addressed in the "Standard Review Plan for the Review of License Applications for Nuclear Fuel Cycle Facilities under 10 CFR Part 70."*

In developing the ISA guidance for its licensees, NRC has relied on information from various sources, with particular emphasis on information in Guidelines for Hazard Evaluation Procedures Second Edition With Worked Examples, developed by the American Institute of Chemical Engineers (1992). This reference book contains descriptions of most ISA techniques currently in use. Examples of the application of ISA methods to nuclear fuel cycle facilities, which are found in Appendix B, were provided under contract to NRC by Savannah River Technology Center.

NRC is also cognizant of regulations on Process Safety Management of Highly Hazardous Chemicals, developed by OSHA (1992) and Risk Management Programs for Chemical Accidental Release Prevention, developed by EPA (1993). The ISA guidance provided in this document is intended to be consistent with the requirements of OSHA and EPA so as to minimize the regulatory burden on NRC licensees. It should be recognized, however, that the scope of NRC's concerns differs from those of OSHA and EPA. NRC is responsible for addressing radiological, nuclear criticality, and certain chemical hazards (i.e. UF_6 *release) not covered under other regulations. Therefore, while it is anticipated that analyses done to satisfy requirements of OSHA and EPA may be useful, it is also expected that such analyses will need to be extended to address NRC requirements.*

1.4 Outline of This Document

The document will discuss the following:

- ***Definition of an ISA***
- ***The role of ISA in a facility's safety program***
- ***ISA methods***
- ***Choosing an ISA method***
- ***Choosing an ISA team***
- ***Conducting the ISA***
- ***Documenting the results***

2 INTEGRATED SAFETY ANALYSIS

2.1 Definition

According to the revised Part 70, an integrated safety analysis 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."***

In essence, ISA is a systematic examination of a facility's processes, equipment, structures, and personnel activities to ensure that all relevant hazards that could result in unacceptable consequences have been adequately evaluated and appropriate protective measures have been identified. In general, the ISA should provide:

- ***a description of the structures, equipment, and process activities at the facility,***

- ***an identification and systematic analysis of hazards at the facility,***

- ***a comprehensive identification of potential accident/event sequences that would result in unacceptable consequences, and the expected likelihoods of those sequences,***

- ***an identification and description of controls (i.e., structures, systems, equipment, or components) that are relied on to limit or prevent potential accidents or mitigate their consequences, and***

- *an identification of measures taken to ensure the availability and reliability of identified safety systems.*

At NRC-licensed fuel cycle facilities, the unacceptable consequences of concern (within NRC's regulatory authority) include those that result in the exposure of workers or members of the public to excessive levels of radiation and hazardous concentrations of certain chemicals. The mechanism for such exposure could be a release of radioactive material, or an inadvertent nuclear chain reaction involving special nuclear material (criticality). The release of hazardous chemicals is also of regulatory concern to NRC but only to the extent that such hazardous releases result from the processing of licensed nuclear material or have the potential for adversely affecting radiological safety. OSHA and EPA are responsible for regulating all other aspects of chemical safety at the facility.

There are a number of ISA methods that may be used to analyze the process hazards at NRC-licensed facilities (see Section 2.3, "ISA Methods"). Although these techniques were established primarily as tools to analyze process hazards at chemical facilities (i.e., explosive and toxic materials), they can be logically extended to address radiological and nuclear criticality hazards.

In general, ISA techniques use either an inductive or a deductive analysis approach. The inductive (or bottom-up) approach attempts to identify possible accident sequences by examining, in detail, deviations from normal operating conditions. Except for the event tree method, most inductive methods are best suited for analyzing single-failure events (i.e., those events caused by the failure of a single control). (With some effort, some of the inductive methods may be extended to address multi-failure events.) The deductive (or "top-down") approach, on the other hand, is more suited for identifying combinations of equipment failures and human errors that can result in an accident (i.e., multi-failure events). Usually, the deductive approach identifies a top event (usually a severe consequence), and attempts to explain the various ways (including single- and multi-failure events) that the top *event can occur. Generally, the inductive approaches are useful in identifying a broad range of potential accidents. The deductive approaches, on the other hand, provide a deeper understanding of the mechanism by which a particular accident might occur. That is, they help identify the possible pathways (i.e., combinations of failures) and root causes that could lead to an accident. By identifying the root causes, the deductive approaches can provide assurance that common-mode failures are understood and are properly addressed.*

One potentially effective approach for implementing an ISA program is to combine the two types of techniques, using the inductive approach (e.g., HAZOP) to identify the broad range of potential accidents and the deductive approach (qualitative Fault-Tree) to analyze in detail the most significant of those accidents (or any others that are postulated). For example, suppose that a HAZOP analysis identified a potential explosion that could result in a significant radiological release and exposure of the public. A fault-tree analysis might then be used to identify the other combinations of failures which could cause the explosion and the controls used to prevent or mitigate the accident to acceptable levels of risk.

2.2 The Role of ISA In a Facility's Safety Program

One of the results of an ISA is the identification of controls, both engineered and administrative, that are needed to limit or prevent accidents or mitigate their effects. The identification of controls, however, is not sufficient to guarantee an adequate level of safety. In addition, an effective management system is needed to ensure that, when called on, these controls are in place and are operating properly. Elements to be addressed in the management system include:

1. *Procedures (development, review, approval, and implementation)*
2. *Training and Qualification*

3. Maintenance, Calibration, and Surveillance

4. Management of Change (Configuration Management)

5. Quality Assurance

6. Human-System Interfaces

7. Audits and Self-Assessments

8. Emergency Planning

9. Incident Investigation

10. Records Management

The importance of these management elements cannot be overstated. ISA may be capable of identifying potential accidents and the controls needed to prevent them, but it cannot ensure effective implementation of the controls and their proper operation. Without a strong management control system in place, the safety of a facility cannot be ensured.

2.3 ISA Methods

The American Institute of Chemical Engineers (AIChE) (1992) provides information on the most common hazard evaluation techniques used for analyzing process systems and identifying potential accidents.[48] Chapter 4 of that reference provides an overview of each technique including a short description, the purpose of using the technique, the types of results obtained, and the

[48] There are other references that describe ISA methodologies. However, the AIChE text is clear, comprehensive, and is well-suited to practitioners of hazard analysis.

resource requirements. Chapter 6 provides a more comprehensive discussion including information on the technical approach, analysis procedure, anticipated work product, and available computer aids. In addition, each method is illustrated with a brief example. Finally, Part II of AIChE (1992) "Worked Examples," provides practical, detailed examples of how some of the ISA methods are applied.

To demonstrate the application of the ISA methods to facilities that process nuclear materials, Appendix B of this guidance document provides several examples of the application of these methods to processes taken from the nuclear fuel cycle.

Twelve methods are discussed in AIChE (1992):

1. *Safety Review*
2. *Checklist Analysis*
3. *Relative Ranking*
4. *Preliminary Hazard Analysis*
5. *What-If Analysis*
6. *What-If/Checklist Analysis*
7. *Hazard and Operability Analysis (HAZOP)*
8. *Failure Modes and Effects Analysis (FMEA)*
9. *Fault Tree Analysis*
10. *Event Tree Analysis*
11. *Cause-Consequence Analysis*

12. Human Reliability Analysis

The first five methods (Safety Review, Checklist Analysis, Relative Ranking, Preliminary Hazard Analysis, and What-If Analysis) are considered to be particularly useful when a broad identification and overview of hazards is required (see Section 2.6.1, "Scope of Analysis"). The next three methods (What-If/Checklist, HAZOP, and FMEA) are more suitable for performing detailed analyses of a wide range of hazards, to identify potential accident sequences. The last four methods (Fault Tree, Event Tree, Cause-Consequence Analysis, Human Reliability Analysis) are best used to provide in-depth analysis of specific accidents that have been identified using other methods. In general, their use requires a higher degree of analyst expertise and increased time and effort.

The methods identified in this section are all considered "qualitative" methods in the sense that they can provide important insights useful for reducing risk without requiring a quantitative estimation of risk. Some of the qualitative methods (e.g., HAZOP, FMEA, Fault Tree, and Event Tree) may also be used to provide input to a full quantitative risk assessment (QRA). QRA, which is most often used when the consequences of an accident are very severe, is a technique that provides quantitative estimates of the risk of accidents. In addition to providing information useful for prioritizing measures for reducing risk, QRA can also be used to demonstrate that the frequency of occurrence of a severe accident is acceptably small. Guidance for licensees interested in conducting a QRA is provided in AIChE (1989).

In addition to the methods identified above, several other approaches have been developed in industries other than the chemical process industry. These include the Hazard Barrier Target technique, Digraph Analysis, Management Oversight Risk Tree (MORT) Analysis, Hazard Warning Structure, and Multiple Failure/Error Analysis. The MORT approach is particularly useful

in analyzing the role of management and management systems in preventing accidents and would be a useful supplement to other techniques (Johnson, 1973; Johnson, 1980; Knox and Eicher, 1983).

Both EPA's proposed Risk Management Program rule (40 CFR Part 68) and OSHA's Process Safety Management Rule (29 CFR 1910.119) require the use of one or more of the following ISA approaches:

What-If, Checklist, What-If/Checklist, HAZOP, FMEA, Fault Tree Analysis, or an appropriate equivalent method.

2.4 Choosing An ISA Method

The choice of a particular method or combination of methods will depend on a number of factors including the reason for conducting the analysis, the results needed from the analysis, the information available, the complexity of the process being analyzed, the personnel and experience available to conduct the analysis, and the perceived risk of the process. Based on these factors, Appendix A (AIChE, 1992) provides a detailed flow chart that guides the ISA practitioner in choosing a particular method. If an approach has been chosen to satisfy OSHA and EPA regulations, and if its use is appropriate for addressing NRC concerns, consideration may be given to using that method for conducting an ISA.

One of the most important factors in determining the choice of an ISA approach is the information that is needed from the analysis. To satisfy NRC requirements as defined in Part 70, the licensee/applicant should choose a method capable of identifying specific accident/event sequences in addition to the safety controls that prevent such accidents or mitigate their consequences. Each of the methods discussed below have this capability.

For identifying single-failure events (i.e., those accidents that result from the failure of a single control), What-If, Preliminary Hazard Analysis, What-If/Checklist, FMEA, or HAZOP are the recommended approaches. Appendix B.1 provides, as an example, partial results from a What-If analysis of criticality hazards present during the pelletizing, rod loading, and fuel bundle assembly operations at a fuel fabrication facility. Because criticality events are perceived to be high risk, redundant controls are normally provided to preclude their occurrence. Although the What-If technique is not the optimum choice for analyzing redundant systems, useful results were obtained, in this case, by considering separately the failures of the moderation and geometry control systems. To explicitly demonstrate adherence to the double contingency principle, however, the What-If analysis should be supplemented by the application of an approach more suited to redundant systems, such as the qualitative fault tree method.

According to AIChE (1992), the choices identified above (i.e., What-If, Preliminary Hazard Analysis, What-If/Checklist, FMEA, or HAZOP) should be narrowed to the latter three approaches if the perceived risk of the potential accident sequences is high. At a nuclear fuel fabrication facility, one of the most safety-significant operations is the vaporization of uranium hexafluoride$_6$ (UF_6). Because of the potential occurrence of an inadvertent criticality or the release of toxic UF_6 and hydrogen fluoride (HF), the vaporization process is a good candidate for analysis by the HAZOP method, a structured technique that is particularly suited for analysis of chemical operations. Appendix B.2 contains excerpts of results obtained from a HAZOP analysis of a UF_6 dry conversion process.

If the results of the ISA are expected to be used as input into a QRA study, then HAZOP, FMEA, Fault-Tree, Event-Tree, or Human Reliability Analysis are the approaches recommended by AIChE (1992). Even if a QRA study is not envisioned, these methods (as well as Cause-Consequence Analysis) are recommended if the accidents analyzed are likely to result in consequences *caused by multiple failures.*[49] *At a nuclear fuel fabrication plant, because of the potentially serious consequences resulting from a release of* UF_6 *during vaporization, a qualitative fault tree analysis of this event is justified, particularly to identify the redundant systems that are available to provide protection. Appendix B.3 contains the results of a fault tree analysis used to model the sequences of events that could lead to a release of* UF_6.

Some ISA methods are more systematic than others. For example, the HAZOP technique provides a detailed framework for studying each process, line by line, in an exhaustive manner. Each process variable (such as flow, temperature, pressure), a description of deviations from normal values, potential consequences of these deviations, and existing controls, are recorded. Another systematic approach, FMEA, considers the various failure modes of equipment items and evaluates the effects of these failures on the system or plant. On the other hand, the What-If technique relies on a relatively unstructured "brainstorming" approach to create a list of questions addressing hazards or specific accident events that could produce an undesirable consequence in a system or process. Whereas the structured nature of the HAZOP and FMEA approaches may partially compensate for weaknesses in the analysis team, the What-if technique, to a greater extent, relies on the experience and knowledge of the hazard analysis team for its thoroughness and success.

In addition to the ISA methods described above, there are additional methods or tools, also considered part of the ISA approach, that are used to identify hazards at the facility and to analyze the consequences of potential accidents. For identifying hazards at the facility and their potential interactions, the interaction matrix approach identified in Section 2.6.3 of this document should be considered. For analyzing the consequences of potential accidents, the methods identified in the "Nuclear Fuel Cycle Facility

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[49]*HAZOP and FMEA, although primarily used to address single-failure events, can be extended to address multiple failure situations.*

Accident Analysis Handbook," (U.S. Nuclear Regulatory Commission, 1998) should be considered.

2.5 Choosing A Team

One of the most important factors in ensuring a successful ISA is the knowledge and experience of the team that is assembled to perform the analysis. Although each method may present a somewhat different rationale for choosing team members, there are some general principles that should be followed. First, the leader of the team should be knowledgeable in the chosen ISA method. This would imply that the leader have formal training in that particular method. The leader should have a thorough understanding of process operations and hazards, but, to avoid a conflict of interest, he should not be the designated expert (e.g., the process engineer) on the process being analyzed. Also, the leader should be able to interact effectively with a diverse group, to build a team consensus. Second, at least one member of the team should have specific and detailed experience in the process being analyzed. Third, the team should consist of members who have a variety of expertise and experience. In particular, engineering, maintenance, and process operations experience should be represented. The presence of process operators is especially important since they have a practical understanding of how the process operates and how problems are likely to occur. Specific safety disciplines such as radiological, criticality, and chemical should also be represented when these hazards are important. In addition, an individual needs to be assigned the responsibility of recording the proceedings in a systematic fashion.

The composition of the team is somewhat dependent on the method used. An approach that is highly systematic like the HAZOP and FMEA analyses may not require the same degree of expertise as a less systematic approach such as the "What-If," which relies to a greater extent on the experience of the team members.

2.6 Conducting The ISA

2.6.1 Scope of Analysis

2.6.1.1 Consequences of Concern

Before conducting the ISA, it is important to define the scope of the analysis including the consequences of concern. In general, NRC is interested in radiological, nuclear criticality, and certain chemical consequences that can affect worker or public safety. In particular, NRC's proposed revision to Part 70 identifies five high consequence events and five intermediate consequence events. The former include the occurrence of a criticality, accidental exposure of a worker to high levels of radiation or hazardous chemicals, and accidental exposure of a member of the public to high levels of radiation or hazardous chemicals. The latter include accidental exposure of a worker to intermediate levels of radiation or hazardous chemicals, accidental exposure of a member of the public to intermediate levels of radiation or hazardous chemicals, and a significant release of radioactive material to the environment. To ensure an acceptable level of risk at a facility, NRC's proposed revision to 10 CFR Part 70 requires that sufficient controls be in place so that the occurrence of any high consequence event is "highly unlikely," and the occurrence of any intermediate consequence event is "unlikely." Definitions for these terms are provided in the "Standard Review Plan for the Review of License Applications for Nuclear Fuel Cycle Facilities under 10 CFR Part 70," (U.S. Nuclear Regulatory Commission, TBD).

2.6.1.2 Physical Scope of Analysis

The ISA should take into account the following factors in conducting the analysis: site characteristics, the structures on the site,

the equipment and materials in use, the processes in operation, and the personnel operating the facility. Credible external events resulting from meteorological and seismological phenomena and their potential for causing accidents at the facility also need to be addressed. Meteorological phenomena would include tornados, hurricanes, precipitation, and flooding.

2.6.1.3 Analysis Assumptions

Any assumptions made in performing the ISA should be explicitly documented and examined for reasonableness. For example, any initiating events deemed to be "incredible," such as airplane crashes, meteorite impact, etc., should be justified and documented. By documenting the assumptions, the licensee will be better able to recognize any future changes that invalidate the assumptions and thus require modification to the ISA.

2.6.2 Process Safety Information

Detailed and accurate information about plant processes is essential for conducting a complete and thorough ISA. In fact, the absence of certain types of process safety information may prevent the use of a particular ISA method or may delay the performance of an ISA.

The type of information available to perform an ISA varies depending on the life cycle of the process or facility being analyzed. During the early stages of the life cycle (i.e., research and development, conceptual design), only basic chemical and physical data may be available. At the detailed design stage, additional information specific to the process may be compiled. Finally, during the operations stage, a wealth of new information, based on operating history, is expected to become available. Since the value of the ISA is directly related to the completeness and accuracy of the process safety information that is available for use, the analysis of

an operating facility may provide more meaningful results than a similar analysis of a new facility or process.

Tables 2.1 and 2.2 (AIChE, 1992) provide a comprehensive list of process safety information that may be needed to perform an ISA. In addition, OSHA (1991) has identified a minimum set of process safety information that it believes is necessary to conduct process hazard analyses for those areas/materials under OSHA purview. The information is categorized as pertaining to hazardous chemicals, to the technology of the process, and to the equipment in the process.

Table 2.1 Examples of Information Used to Perform a Hazard Evaluation Study

- *Chemical reaction equations and stoichiometry for primary and important secondary or side reactions*
- *Type and nature of catalysts used*
- *Reactive chemical data on all streams, including in-process chemicals*
- *Kinetic data for important process reactions, including the order, rate constants, approach to equilibrium, etc.*
- *Kinetic data for undesirable reactions, such as decompositions and autopolymerizations*
- *Process limits stated in terms of pressure, temperature, concentration, feed-to-catalyst ratio, etc., along with a description of the consequences of operating beyond these limits*
- *Process flow diagrams and a description of the process steps or unit operations involved, starting with raw material storage and feed preparation and ending with product recovery and storage*
- *Design energy and mass balances*
- *Major material inventories*
- *Description of general control philosophy (i.e., identifying the primary control variables and the reasons for their selection)*
- *Discussion of special design considerations that are required because of the unique hazards or properties of the chemicals involved*
- *Safety, health, and environmental data for raw materials, intermediates, products, by-products, and wastes*
- *Regulatory limits and/or permit limits*
- *Applicable codes and standards*
- *Variances*
- *Plot plans*

- ***Area electrical classification drawings***
- ***Building and equipment layouts***
- ***Electrical classifications of equipment***
- ***Piping and instrumentation drawings***
- ***Mechanical equipment data sheets***
- ***Equipment catalogs***
- ***Vendor drawings and operation and maintenance manuals***
- ***Valve and instrumentation data sheets***
- ***Piping specifications***
- ***Utility specifications***
- ***Test and inspection reports***
- ***Electrical one-line drawings***
- ***Instrument loop drawings and logic diagrams***
- ***Control system and alarm description***
- ***Computer control system hardware and software design***
- ***Operating procedures (with critical operating parameters)***
- ***Maintenance procedures***
- ***Emergency response plan and procedures***
- ***Relief system design basis***
- ***Ventilation system design basis***
- ***Safety system(s) design basis***
- ***Fire protection system(s) design basis***
- ***Incident reports***
- ***Meteorological data***
- ***Population distribution data***
- ***Site hydrology data***
- ***Previous safety studies***
- ***Internal standards and checklists***
- ***Corporate safety Policies***
- ***Relevant industry experience***

Source: Copyright 1992 by the American Institute of Chemical Engineers; reproduced by permission of Center for Chemical Process Safety of AIChE.

Table 2.2 Common Material Property Data for Hazard Identification

Acute toxicity

- *inhalation (e.g, LC_{LO})*
- *oral (e.g., LD_{50})*
- *dermal*

Chronic toxicity

- *inhalation*
- *oral*
- *dermal*

Carcinogenicity

Mutagenicity

Teratogenicity

Exposure limits

- *TLV*
- *PEL*
- *STEL*
- *IDLH*
- *ERPG*

Physical properties (cont'd)

- *vapor pressure*
- *density or specific volume*
- *corrosivity/erosivity*
- *heat capacity*
- *specific heats*

Reactivity

- *process materials*
- *desired reaction(s)*
- *side reaction(s)*
- *decomposition reaction(s)*
- *kinetics*
- *materials of construction*
- *raw material impurities*
- *contaminants (air, water, rust, lubricants, etc.)*
- *decomposition products*
- *incompatible chemicals*
- *pyrophoric materials*

Stability

- *shock*
- *temperature*
- *light*
- *polymerization*

Biodegradability

Aquatic toxicity

Persistence in the environment

Odor threshold

Physical properties
- *freezing point*
- *coefficient of expansion*
- *boiling point*
- *solubility*

Flammability/Explosivity
- *LEL/LFL*
- *UEL/UFL*
- *dust explosion parameters*
- *minimum ignition energy*
- *flash point*
- *autoignition temperature*
- *energy production*

Abbreviations:

ERPG	*Emergency Response Planning Guidelines*
IDLH	*Immediately Dangerous to Life and Health*
LEL	*Lower Explosive Limit*
LFL	*Lower Flammable Limit*
PEL	*Permissible Exposure Level*
STEL	*Short Term Exposure Limit*
TLV	*Threshold Limit Value*
UEL	*Upper Explosive Limit*
UFL	*Upper Flammable Limit*

Regarding hazardous chemicals, OSHA requires (29 CFR 1910.119) compilation of the following information: toxicity information, permissible exposure limits, physical data, reactivity data, corrosivity data, thermal and chemical stability data, and hazardous effects of inadvertent mixing of different chemicals. Information about specific materials can be obtained from the chemical suppliers and manufacturers who can provide material safety data sheets (MSDSs), product literature, and general chemical expertise. Information can also be obtained from industrial and professional organizations such as the AIChE, the American Petroleum Institute (API), or the Chemical Manufacturers Association (CMA).

For the technology of the process, OSHA requires assembling the following information: a block flow diagram or simplified process flow diagram, process chemistry, maximum intended inventory, safe upper and lower limits for such items as temperatures, pressures, flows, and compositions.

Regarding the equipment used in the process, OSHA requires collecting the following information: materials of construction, piping and instrumentation diagrams (P&IDs), electrical classification, relief system design and design basis, ventilation system design, design codes and standards employed, material and energy balances, and safety systems (e.g., interlocks, detection, and suppression systems).

A minimum set of process safety information considered acceptable for performing an ISA is addressed in the Standard Review Plan for the Review of License Applications for Nuclear Fuel Cycle Facilities under 10 CFR Part 70 (199_).

For the results of the ISA to be valid, the information required to perform the ISA must be accurate and current. If such information is not available, then the information must be developed to permit the performance of an ISA.

2.6.3 Hazard Identification

A hazard is defined as an inherent physical, radiological, or chemical characteristic that has the potential for causing harm to people, to the environment or to property. Before an analysis of hazards can begin, it is first necessary to identify those hazards. Although NRC's primary responsibility is to regulate radiological hazards, the Agency also addresses certain hazardous chemicals (i.e., those chemicals that are radioactive themselves, that result from the processing of licensed nuclear material, or that have the potential for adversely affecting radiological safety).

To identify hazards at a facility, certain types of information should be available regarding the materials used at the facility. For uranium and other materials that pose radiological hazards, the radiological properties of concern should be identified (e.g., radioactive half-life, biological half-life, decay mode, etc.). In addition, the conditions under which available fissionable material could support a self-sustaining nuclear reaction (i.e., pose a criticality hazard) should be identified. For addressing chemical hazards, typical material properties such as toxicity, flammability, reactivity, etc. should be considered by the licensee (see Table 2.2 of this document and OSHA (1991).

Other information useful in identifying hazards and hazardous materials include piping and instrumentation diagrams, process flow diagrams, plot plans, topographic maps, utility system drawings, and major types of process equipment, etc.

The nature and extent of hazards is affected by process conditions and the interactions that can occur between hazardous materials. Therefore, information about these interactions should also be taken into account in identifying hazards. A systematic approach for addressing these issues might make use of an "interaction matrix" [see Section 3.3, AIChE (1992)]. An example of this technique for the ammonium diuranate (ADU) process at a nuclear fuel fabrication facility is given in Appendix B.4. Such a matrix indicates incompatibilities among various materials used in the process that could result in potential accidents. Several of the ISA methods listed in Section 2.3, "ISA Methods," could also be used to facilitate the hazard identification process. These include Safety Review, Checklist Analysis, Relative Ranking, Preliminary Hazard Analysis, and What-If Analysis.

At a minimum, the results of the hazard identification process should document radioactive materials, fissile materials, flammable materials, toxic materials, hazardous reactions, and hazardous process conditions. The documentation should include maximum intended inventory amounts and the location of the hazardous materials on-site. In addition, the hazards (i.e, radiological, chemical, etc.) of each process in the facility should be identified.

2.6.4 Performing the Analysis

Each ISA method is performed in its own unique fashion. HAZOP, for example, concentrates on process upset conditions whereas FMEA examines the failures of equipment and components. The goal of all methods, however, is to identify possible accident sequences and the controls needed to prevent or limit their occurrence or mitigate the consequences.

2.6.4.1 Preparation

Despite differences in the various methods, certain aspects of the ISA process are generally applicable. First, the preparation for

the ISA should be thorough (i.e., the team should be selected, a schedule developed, information gathered and distributed, the process divided into sections, and a methodology for recording information developed). The team should be aware of the scope of the evaluation and the objectives of the analysis. The leader should give an overview of the ISA method to the team in order that they know what procedure will be used and how it is carried out. The leader should stress that the team's primary role is initially one of problem identification rather than problem solving.

2.6.4.2 Team meetings

The ability to perform a successful analysis is dependent on the effectiveness of team meetings and the capabilities of the team leader. It is important that an atmosphere conducive to free and open expression is maintained so that the team members can fully engage themselves in the ISA process. The meetings need to be kept on track so that the analysis is systematically performed, section by section.

If, during the team meetings, documentation is found to be out-of-date, or other information is needed to complete the analysis, then updated or more complete information should be provided or developed. The responsibility for these tasks needs to be assigned to appropriate team members. Once the new information has been compiled, additional meetings may be necessary to consider the implication of the new information.

For each of the ISA methods identified earlier (Section 2.3 of this document), Chapter 6 of AIChE (1992) provides information on how to perform an analysis using that approach, and the results that can be obtained. In addition, part II of AIChE (1992) provides a description of how each method is applied to a fictional but realistic process. The description includes a dramatization, of team meetings, that gives the reader a good understanding of how the meetings and the analyses are actually performed.

2.6.4.3 Integration

ISA, as the name implies, is intended to provide an "integrated" analysis of facility hazards. That is, the analysis should take into account interactions among different types of hazards. For example, the release and ignition of an explosive material (chemical/fire hazard) could affect the release of radioactive materials (radiological hazard). Indeed, the controls (sprinkler system) used to protect against one hazard (fire) may increase the likelihood of an accident involving a different hazard (criticality). The ISA should take into account the interactions of various hazards and controls, to ensure that the combination of controls proposed to address multiple hazards assures an acceptable level of overall risk.

The integration of ISA results is likely to be fostered by a process that encourages a simultaneous consideration of all types of process hazards. This approach would allow the multidisciplinary team to discuss the optimization of controls needed to prevent or mitigate all process accidents identified. An alternative approach would be to conduct separate analyses for each of the types of hazards (i.e., radiological, chemical, fire, and criticality) and assemble the entire ISA team for the purpose of optimizing and integrating the findings of these studies.

The effort at integration of analysis results also applies to the case where the overall system analysis has been arbitrarily divided into several smaller sub-system analyses, to reduce complexity. In this case, care must be taken to avoid the inadvertent omission of domino or cascading effects. For example, a fire in one subsystem may spread to a second subsystem causing a release of toxic material. Each subsystem analysis should take into account the input and output of materials and energy that can affect and be affected by the other subsystems. Appendix C illustrates a situation involving a system that has been divided into three subsystems, each with varying degrees of interaction among them.

2.6.5 Results of the Analysis

The results of an ISA consist of an identification of potential accidents, the consequences of the accidents and their likelihood of occurrence, and the controls (i.e., the structures, systems, equipment, components, and personnel) relied on to prevent the accidents from occurring or to reduce their consequences.

2.6.5.1 Accident Sequences

Although the formats for recording the results of an ISA differ depending on the method used (see Chapter 6 of AIChE (1992)), the essential information obtained is a description of potential accident sequences. (An accident sequence is "a specific unplanned sequence of events that results in an undesirable consequence.") Therefore, an important product of an ISA consists of a description of all accident sequences identified and recorded during the analysis process. The description of an accident sequence should include the initiating event, any factors that allow the accident to propagate (enablers), and any factors that reduce the risk (likelihood or consequence) of the accident (controls).

Table 1.3 from AIChE (1992) provides a list of possible initiating events, propagating events, risk reduction factors (controls), and incident outcomes. The initiating events can be categorized as process upsets, management system failures, human errors, and external events (e.g, high winds, floods). Propagating events include equipment failure, ignition sources, management system failure, human error, domino effects (other containment failures or material releases), and external conditions. Risk reduction factors include control/operator responses, safety system responses, mitigation system responses, and emergency plan responses, etc.

2.6.5.2 Consequences and Likelihoods

In addition to the description of the accident sequence, an estimate of the consequences resulting from the accident should be described in the ISA. If the sequence would result in a release of radioactive material, or if a criticality would occur, the dose to the nearest member of the public should be estimated[50]. If uranium is released in soluble form, the intake by the nearest member of the public should be estimated. If HF (produced by the reaction of UF_6 with moist air) is released, the intake of HF should be estimated. Similar estimates should be made for the exposure of workers. These estimates are needed to determine the level of control needed to protect against the occurrence of the accident. If the health effects exceed the consequences of concern (Section 2.6.1.1, "Consequences of Concern"), then the controls that are used must provide reasonable assurance that such unmitigated consequences will not take place. The degree of assurance should be commensurate with the potential consequences. In particular, the new amendments to Part 70 call for a graded level of protection to ensure that the occurrence of any high consequence event is "highly unlikely" and the occurrence of any intermediate consequence event is "unlikely." The ability to meet these conditions requires that licensees estimate the likelihood of occurrence of potential accidents identified in the ISA.

2.6.5.3 Safety Controls

One of the most important results obtained from the ISA is the identification of the controls (i.e., structures, systems, equipment, components, and personnel) needed to ensure the safe operation of the facility. Safety controls used at a facility can be characterized as either administrative or engineered. Administrative controls are generally not considered to be as reliable as engineered controls since human errors usually occur more frequently than equipment failures (AIChE, 1992). Engineered

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[50]Further guidance on the calculation of consequences will be provided in the chemical safety and radiological safety chapters of the Standard Review Plan (SRP) and in the "Nuclear Fuel Cycle Facility Accident Analysis Handbook (U.S Nuclear Regulatory Commission, 1998).

controls may be categorized as being "passive" or "active." Passive controls include pipes or vessels that provide containment. Active controls include equipment such as pumps or valves that perform a specific function related to safety. In general, passive controls are considered to be less prone to failure than active controls.

The ISA process by itself cannot ensure the effective design and implementation of the controls, and their proper operation. Instead, other elements of the licensee's safety program are relied on to provide this assurance. For example, as part of the measures used to ensure criticality, radiological, chemical, and fire safety, design criteria for relevant safety controls are established. (The controls identified in the ISA should adhere to these criteria.) Quality Assurance (QA) measures should ensure that the safety controls implemented at the plant satisfy the design criteria. Training measures should confirm that the personnel called on to operate or interact with the controls are properly trained. Maintenance and equipment inspection measures should ensure that the engineered controls are reliable and maintained in proper working order. Audits and inspections are conducted to determine whether standard operating procedures are being followed.

In choosing the controls needed to protect against the occurrence of a particular event sequence, both the number and the effectiveness of such controls should be taken into account. For engineered controls, in addition to their inherent effectiveness, maintenance, calibration, and surveillance measures provide assurance that the controls are in place and in working order. Depending on the degree to which a particular control is relied on (i.e., whether it is the only control or one of several redundant controls), maintenance measures should be appropriately graded to that specific control. Similarly, for administrative controls, training measures and audit/inspection measures should be tailored to ensure the specific reliability needed for each control. For example, if the facility is relying on a single individual on duty at a particular time to take action (i.e., close a valve or turn a switch) to avoid a major accident, that person should receive special training and the person's performance should be carefully

monitored. In addition, the man-machine interface for that individual should be carefully designed. All of this information is necessary to provide a clear understanding of the controls used in the process, and their effectiveness.

In summary, to provide reasonable assurance that a particular accident sequence will not occur, the licensee/applicant should not only identify the control(s) that have been implemented, but also reference the specific features of its safety program (i.e., training, quality assurance, maintenance, calibration, and surveillance, etc.) that ensure the reliability of those controls.

2.6.6 Documenting the ISA Results

NRC regulations (i.e., Part 70) require the licensee to document the performance and results of the ISA process to demonstrate that it was conducted using sound practices and that it comprehensively identifies the structures, systems, equipment, components, and personnel relied on for safe operations. Documentation of the ISA is also important in supporting good risk management decisions and in supporting other safety program activities such as maintaining accurate standard operating procedures, managing change (configuration management), investigating incidents, and conducting audits and inspections, etc. Finally, documentation is necessary to consolidate and maintain the results of the study for future use.

The ISA documentation should include not only the results of the analysis (i.e., the description of accident sequences), but other information related to the conduct of the ISA. The amount of information used and generated during the ISA process can be substantial. The process safety information alone can include many detailed drawings and diagrams as well as hundreds of pages of specifications, procedures, etc. In addition to the process safety information, the documentation of the ISA should include a description of the site, the facility, the processes that were analyzed, the method that was used, the people who performed the *analysis, the time frame during which the analysis was performed, the potential accident sequences that were identified, and the safety controls and associated management controls that have been identified and implemented to prevent or mitigate the consequences of the identified accidents. The important assumptions made in the analysis should also be documented. All documentation associated with the ISA process should be maintained by the licensee's Configuration Management System to assure that it is representative of the current status of the facility.*

The information submitted for NRC review as part of a license or license renewal application is expected to be a subset of the entire ISA documentation. This information is described in the "Standard Review Plan for License Applications for Nuclear Fuel Cycle Facilities under 10 CFR Part 70" [to be published]. The Standard Review Plan will also address the role of the Configuration Management System in maintaining contol of the ISA documentation.

2.6.6.1 Site Description

A brief description of the site should be provided including information on site meteorology, seismology, topography, demography, and any other factors that have safety significance.

2.6.6.2 Facility Description

The objective of this description is to define the boundaries of the analysis and identify those facility-specific factors that could have a bearing on potential accidents and their consequences.

The description should include the location of the facility, and the presence of nearby activities or structures, such as factories, railroads, airports, and dams, etc., that could pose a hazard to the facility. It should also include the number of workers in the

work force and the different skills needed for operation. In addition, it should include the location of all of the buildings at the facility and their relationship to the licensed operation.

2.6.6.3 Process Description

The documentation of the ISA should contain a description of each process analyzed. This should include:

- ***a discussion of the basic theory that the process is based on,***

- ***a discussion of the function of major components used in the process and a summary of normal process operations,***

- ***a summary of the dimensions, materials, and configuration of lines and vessels used in the process, and***

- ***a reference list of system documents (i.e., drawings, procedures, etc.) used to perform the ISA.***

2.6.6.4 ISA Method

The documentation should identify the method or methods chosen to perform the ISA and should explain the basis on which the choice was made.

2.6.6.5 ISA Team

The documentation should identify the members of the team used to perform the ISA and should explain the basis on which the choice was made. The experience and qualifications of team members should be included.

2.6.6.6 Accident Sequences

The documentation should include a description of accident sequences identified in the analysis and the consequences of those accidents. For those accidents that have consequences that exceed the levels identified in Section 2.6.1.1. ("Consequences of Concern"), the information provided should also specifically address the initiating event, any factors that allow the accident to propagate, and any factors that reduce the risk of the accident.

2.6.6.7 Controls

Because the implementation of controls and their effectiveness is crucial to the safety of the facility, documentation of the ISA process should include a list of safety controls (i.e, structures, systems, equipment, components, and personnel relied upon for safety) used in each process and, for each, the associated management controls (i.e., QA, maintenance, training, etc.) used to ensure its appropriate functioning.

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APPENDIX A

Flowchart for Selecting a Hazards Analysis Technique

Figure A-1

Example flowchart for selecting an HE technique.

Source: Copyright 1992 by the American Institute of Chemical Engineers; reproduced by permission of Center for Chemical Process Safety of AIChE.

Example flowchart for selecting an HE technique. (Cont.)

Example flowchart for selecting an HE technique. (Cont.)

Example flowchart for selecting an HE technique. (Cont.)

Example flowchart for selecting an HE technique. (Cont.)

Example flowchart for selecting an HE technique. (Cont.)

Example flowchart for selecting an HE technique. (Cont.)

Abbreviations:

HE = hazard evaluation

HAZOP = hazard and operability analysis

SR = safety review

FMEA = failure modes and effects analysis

CL = checklist analysis

ET = event tree analysis

RR = relative ranking

FT = fault tree analysis

PHA = preliminary hazard analysis

CCA = cause-consequence analysis

WI = what=if analysis

HRA = human reliability analysis

WI/CL = what=if/checklist analysis

Example flowchart for selecting an HE technique. (Cont.)

Figure A-2

Criteria for selecting HE techniques.

APPENDIX B

Application of ISA to Nuclear Fuel Cycle Processes

B.1 What-If Analysis of the Pelletizing, Rod-loading, and Fuel Bundle Assembly Steps

In this example, the what-if method is used to study criticality hazards in a uranium fuel fabrication operation. The process, shown in Figure B-1, begins with a roll-type compaction unit that takes uranium oxide (UO_2) powder and binder-lubricant and combines it before feeding to the pellet presses where pellets are formed. The pellets are transferred in boats to the sintering furnace, where the pellets are sintered in a hydrogen atmosphere to 95 percent theoretical density. The pellets are then ground to precise dimensions, and dried. Dried and inspected pellets are loaded into empty fuel tubes that are pressurized and sealed. Finished fuel rods are bundled into assemblies and stored.

In the following analysis, it is assumed that the prevention of an inadvertent criticality is accomplished by preventing the presence of excess moderating material and by maintaining appropriate geometric controls.

Figure B.1

Uranium Fuel Fabrication

What-If Analysis of Pelletizing Step

Subject: Criticality

What-If/Cause	Consequence/Hazard	Safeguards
Moderation Control Fails Because:	**Geometry Control Fails Because:**	
Hydraulic fluid leaks.	Cart tips over.	Moderator reaches powder/criticality.
Powder is not dry enough.	Powder builds up in pelletizing equipment.	Moderator reaches powder/criticality.
Room floods.	Small powder storage container breaks.	Moderator reaches powder/criticality.
Bulk powder storage container collects and holds liquid.	Sintering boats are stacked too high.	Moderator reaches powder/criticality.

		bottom of carts.
Safe geometry exceeded/criticality.	*All hydraulic fluid systems are shielded from powder.*	*Buildup prevention devises within equipment.*
Safe geometry exceeded/ criticality.	*Multiple quality control steps for analytical results.*	*Containers are of rugged construction, containers are administratively protected.*
Safe geometry exceeded/ criticality.	*No piped water systems in bulk powder handling areas.*	*Training, administrative controls*
Safe geometry exceeded/ criticality.	*Bulk containers are moved with sealed opening facing down.*	
	Passive stops welded to	

What-If Analysis of Fuel Rod Loading and Bundle Assembly Steps

Subject: Criticality

What-If/Cause	*Consequence/Hazard*	*Safeguards*
Moderation Control Fails		
Because:		
	Assemblies are stored too	
Assembly shroud collects	***close.***	***Moderator reaches***
moderator.		***rods/criticality.***
	Assemblies are spaced too	
Room floods.	***closely during cleaning.***	***Moderator reaches***
		rods/criticality.
	Rods dissolve during	
	cleaning step.	
Geometry Control Fails		
Because:	***Poison inserted to***	
	supplement geometry is	
Stored fuel rods are	***removed.***	***Safe geometry***
stacked.		***exceeded/criticality.***

		Wash tanks have spacers to control distance.
Safe geometry exceeded/ criticality.	*Shrouds are split to prevent accumulation.*	*Wash tank contents are strictly controlled.*
Safe geometry exceeded/ criticality.	*No piped water systems in bulk powder handling areas.*	*Boral shelves are fixed inside carts.*
Safe geometry exceeded/ criticality.		
Safe geometry exceeded/ criticality.	*Storage and transport containers have controlled thickness, only one channel of rods may be transported at a time, administrative controls and training.*	
	Storage racks control spacing.	

B.2 Hazard and Operability Analysis Analysis of the Vaporization Step of UF_6 Dry Conversion

In this example, the Hazard and Operability Analysis (HAZOP) Method is used to model the hazards in a uranium hexafuoride (UF_6) dry conversion process. The process is depicted in the following figure. In the process, UF_6 gas is converted to a dry powder. The UF_6 gas arrives in a large steel cylinder that is loaded into a horizontal vaporizer chest, heated by circulating hot water sprays. The vaporized UF_6 and superheated steam are then introduced to a slab-shaped disentrainment chamber at the feed end of a conversion kiln. Here they undergo dry hydrolysis to form uranyl fluoride ($U0_2F_2$) powder and hydrogen fluoride (HF) gas. The powder falls to the chamber bottom and is continuously removed to the discharge end of the kiln. Hydrogen (H_2) gas and superheated steam are fed to the kiln discharge en to strip the fluoride and reduce the powder to uranium dioxide (UO_2). H_2, HF, nitrogen (N_2), and steam are continuously removed from the kiln through process filters. Product powder is continuously removed into a UO_2 check-hopper, which is nitrogen-purged.

The first step in the HAZOP process is to apply guide words to process parameters, as illustrated below for "Pressure."

Process Section: *Vessel - Vaporizer Steam Chest*

Design Intention: *Vaporize UF_6*

Guide Word: *High*

Process Parameter: *Pressure*

Deviation: *High Pressure in UF_6 cylinder*

Consequences:	*1) Potential criticality concern*
	2) Release of UF_6 to vaporizer and atmosphere
Causes:	*1) Low/no flow in emergency cooling water*
	2) Overfilled cylinder
Safeguards:	*1) High pressure indicator and alarm*
	2) Administrative controls

The steps are then repeated for additional parameters and guide words, and the results tabulated in the HAZOP Study Table (Table B-1). Note that only the vaporization step in the dry conversion process has been included in the table.

Figure B.2

UF_6 Dry Conversion Process

Varporization Operation Waste Handling System

Figure B.3

UF_6 Dry Conversion Process

Hydrolysis Operation

Table B-1 HAZOP Study Table

Item Number	*Deviation*	*Causes*	*Consequences*	*Safeguards*
		5.0 VESSEL - VAPORIZER STEAM CHEST		
5.1	*High Level*	*Level probe failure* *Normal condensate drain overwhelmed or plugged and passive overflow line plugged* *High flow in the emergency cooling water line (Item 4.1)*	*Potential criticality concern - Loss of barrier* *Potential safety concern - Cylinder floating, breaking pigtail*	*Vaporizer gravity drain* *Passive overflow line with strainer to prevent line plugging* *Preventive maintenance on vaporizer.* *Administrative control to check for debris (foreign material) after maintenance and before each cylinder installation* ** (Note: During the Nuclear Criticality Safety Evaluation (NCSE), it was*

determined that this interlock cannot be regarded as a criticality safety significant interlock for slab thickness.)

Operability test of level float at each cylinder installation

High-level alarm

Table B-1 (Cont'd)

Item Number	*Deviation*	*Causes*	*Consequences*	*Safeguards*

5.0 VESSEL - VAPORIZER STEAM CHEST (Continued)

5.2	*Low level*		*6.2)*	
			Rapid cooling of the steam chest or steam condensation	
5.3	*High temperature*	*High flow in the 120-psig plant steam to vaporizer (raw steam) (Item 2.1)*		
5.6	*Low pressure in the vaporizer steam chest*	*Low/no flow in the emergency cooling water line when needed (Item 4.2)*		
		Low/no flow in the 120-psig plant steam line to the vaporizer (Item 2.2)		
5.4	*Low temperature*	*Valve in vent line closed*		
5.5	*High pressure in the vaporizer steam chest*	*High pressure in the steam supply (Item 2.7)*		
		Low/no flow in the vaporizer steam chest vent line to scrubbers S-675 (A&B) (Item		

No consequence of interest (NCI)		*(draws air in at 1-inch WC vacuum)*
Potential loss of containment if the temperature exceeds the temperature rating of the cylinder vessel (Item 5.11)	*High-temperature alarm* *Temperature indication*	
Potential loss of production form solid UF_6 plug in the pigtail; also unable to maintain the cylinder pressure	*Temperature indication*	
Release of steam with the potential for injury to personnel (e.g., burn hazard)	*Conservation vent valve on vaporizer vent line (relieves at 2 inches (WC) pressure)*	
Potential leak (Item 5.11)		
Potential rupture (Item 5.12)		
Potential process upset	*Conservation vent valve on vaporizer vent line*	

Table B-1 (Cont'd)

Item Number	Deviation	Causes	Consequences	Safeguards
		5.0 VESSEL - VAPORIZER STEAM CHEST (Continued)		
5.7	High pressure in the UF_6 cylinder	Low/no flow in the emergency cooling water (Item 4.2) Heat overfilled cylinder	UF_6 cylinder leak or rupture Reverse flow in the vaporizer steam chest vent line to scrubbers S-675 (A&B) (Item 6.3) Low temperature in the vaporizer steam chest, valve hot box, vaporizer safe sump and check hopper vents to S-675 and S-665 A&B (Item 6.6)	
5.10	High concentration of UF_6			
5.8	Low pressure in the UF_6 cylinder	Empty UF_6 cylinder		
5.9	High concentration of dirt, dust, rust, and debris	High concentration of rust in the emergency cooling water (Item 4.11) Accumulation of dirt, dust, and debris during maintenance		

Potential criticality concern (UO_2F_2-H_20 in the vaporizer)- Damage pigtail and release UF_6 to the vaporizer and the atmosphere *High flow in the UF_6 gas line to the kiln (Item 7.1)* *Potential criticality concern - Backflow of moderator into UF_6 cylinder (Item 7.3)* *Low pressure in the UF_6 gas line to the kiln (Item 7.8)* *NCI - Conductivity false alarm* *Potential for plugging drain lines* *Potential release or personnel exposure to UF_6 and/or HF acid*	*Potential criticality concern*	*High-pressure indication and alarm in UF_6 gas line to the kiln* *Administrative controls to verify net weight of cylinder is less than maximum safe fill limits before use* *Conductivity monitor* *Administrative control to check for debris (foreign material) after maintenance and before each cylinder installation* *Ventilation scrubber to*	*remove potential UF_6 or HF releases and prevent release to the atmosphere* *Detect breach of UF_6 containment in vaporizer* *Conductivity monitor*

Table B-1 (Cont'd)

Item Number	Deviation	Causes	Consequences	Safeguards
		5.0 VESSEL - VAPORIZER STEAM CHEST (Continued)		
5.11	*Leak of UF_6 cylinder in vaporizer steam chest*	*High temperature (Item 5.3)*	*Potential criticality concern*	*Administrative controls for checking for leaks*
		Faulty connections on the cylinder valve	*Potential release or personnel exposure to UF_6 and/or HF acid*	*Startup checklist*
		High pressure (Item 5.5)		
		Cylinder valve leaking		
		Corrosion		
		External impact		*Conductivity monitor*
		Valve or gasket failure		*Ventilation scrubber to remove potential UF_6 or HF releases and prevent release to the atmosphere*
		Improper maintenance		

5.12	*Rupture of UF_6 cylinder in vaporizer steam chest*	*Faulty connections on the cylinder* *Cylinder valve leaking* *Crane failure* *Pigtail failure* *Cylinder failure* *High pressure (Item 5.5)* *Corrosion* *External impact*	*Potential criticality concern* *Potential release or personnel exposure to UF_6 or HF acid*	*Cylinder recertification every 5 years* *Ventilation scrubber to remove potential UF_6 or HF releases and prevent release to the atmosphere* *Administrative controls to verify net weight of cylinder is less than maximum safe fill limits before use*

B.3 Qualitative Fault-tree Analysis of Major UF_6 Release

1. INTRODUCTION

In this example, Fault Tree Analysis is used to model the scenarios leading to a uranium hexafluoride (UF_6) release during vaporization.

Figure B.2 shows an example system for vaporization of UF_6. The system consists of a vaporizer chest with steam supply, emergency cooling water, receiving tank, safe sumps, and reservoir and scrubber system. The Fault Tree for Release of UF_6 during Vaporization (Figure B.4 and Table B-2) is a qualitative model of the vaporizer chest only. The UF_6 is transported in large steel cylinders. The vaporizer chest is designed to enclose this cylinder and all its connections, and the steam condensate line is supplied with a conductivity cell (with alarm, automatic steam shutoff, and isolation capability) for the detection of leaks.

2. ANALYSIS

The first step in the analysis is to define the problem by documenting the Top Event, Existing Conditions, and Physical Boundaries. The vaporization process is studied and a logic diagram is constructed that documents all the various mechanisms that can lead to a release of UF_6, which is the Top Event for this tree. The logic uses AND gates to represent events that must exist simultaneously to result in the Top Event. For example, under Gate 2 in the tree, for a liquid release to the building to occur, there must be two events; a release within the chest, and a failure to detect and stop it in time (Gates 6 AND 8). The logic uses OR gates for events where any single one event can result in the Top Event. For example, under Gate 8 in the tree, there are three separate ways (failures for the steam condensate to carry UF_6 out; instrument fails to detect, fails to shutoff, or fails to alarm; and operator does not catch this failure.

3. EVALUATION

The next step in the analysis is to determine the minimal cutsets, shown in Table B-3 labeled as such. Since no values were assigned to this example, the computer program assigned a probability of 1 to all basic events. Qualitatively, it can be seen that a release of UF_6 to the buildings can occur as a result of a single event, such as an impact to the piping or valve assuming that the HEPA filters fail to contain the release. It should be noted that some events described in this tree are a combination of events (i.e., cylinder rupture is a result of an overweight cylinder and failure to check weight on arrival). Quantification of the top event would require failure rates, human error probabilities, and historical operating data.

Figure B.4

Fault Tree for Release of UF_6 During Vaporization (Page 1)

Fault Tree for Release of UF_6 During Vaporization (Cont.) (Page 2)

Fault Tree for Release of UF_6 During Vaporization (Cont.) (Page 3)

Table B-2

Fault Tree Event Index

Gate/Event Name	Page	Zone
EVENT1	2	1
EVENT10	2	2
EVENT11	3	7
EVENT12	2	3
EVENT13	3	2
EVENT14	1	3
EVENT15	1	2
EVENT2	3	3
EVENT3	3	4
EVENT4	3	4
EVENT5	3	1
EVENT6	3	2
EVENT7	3	6
EVENT8	3	6
EVENT9	2	2
G1	1	1
G1	2	2
G10	1	2
G2	2	2

G3	*2*	*4*
G4	*2*	*3*
G4	*3*	*4*
G5	*2*	*4*
G5	*3*	*6*
G6	*2*	*1*
G6	*3*	*5*
G7	*3*	*6*
G8	*2*	*2*
G9	*2*	*3*
GT	*1*	*2*

TABLE B-3 CUTSETS FOR EXAMPLE UF6 RELEASE FAULT TREE

Set No.	Event Name	Description	C	B.E. Prob	Calc. Result	Cutset Prob
	GT					0.00E+00
1.	EVENT11	Leak Large Enough to Activate Relief Valve				1.00E+00
	EVENT13	Pigtail Leaks.				
	EVENT15	HEPA Filter Failure				
2.	EVENT11	Leak Large Enough to Activate Relief Valve				1.00E+00
	EVENT15	HEPA Filter Failure				
	EVENT6	Cylinder Leaks at Valve.				
3.	EVENT15	HEPA Filter Failure				
	EVENT2	Cylinder Valve Damaged by External Event				1.00E+00
4.	EVENT15	HEPA Filter Failure				
	EVENT4	Crane Mishandles and Damages Cylinder.				1.00E+00
5.	EVENT15	HEPA Filter Failure				
	EVENT3	Piping to Hydrolysis Step Leaks or Is Damaged by External Event				1.00E+00
6.	EVENT11	Leak Large Enough to Activate Relief Valve				1.00E+00
	EVENT15	HEPA Filter Failure				
	EVENT5	Cylinder Rupture				

Set No.	Event Name	Description	C	B.E. Prob	Calc. Result	Cutset Prob
7.	EVENT13	Pigtail Leaks.				1.00E+00
	EVENT15	HEPA Filter Failure				
	EVENT7	Chest Gasket Leaks.				
8.	EVENT15	HEPA Filter Failure				1.00E+00
	EVENT6	Cylinder Leaks at Valve.				
	EVENT7	Chest Gasket Leaks.				
9.	EVENT15	HEPA Filter Failure				1.00E+00
	EVENT5	Cylinder Rupture				
	EVENT8	Operator Fails to Seal Chest.				
10.	EVENT13	Pigtail Leaks.				1.00E+00
	EVENT15	HEPA Filter Failure				
	EVENT8	Operator Fails to Seal Chest.				
11.	EVENT15	HEPA Filter Failure				1.00E+00
	EVENT6	Cylinder Leaks at Valve.				
	EVENT8	Operator Fails to Seal Chest.				
12.	EVENT12	Operator Fails to Detect Conductivity Cell without Alarm.				1.00E+00
	EVENT15	HEPA Filter Failure				
	EVENT6	Cylinder Leaks at Valve.				
	EVENT9	Steam Condensate Line Conductivity Cell Fails to Alarm				

Set No.	Event Name	Description	C	B.E. Prob	Calc. Result	Cutset Prob
13.	*EVENT12*	*Operator Fails to Detect Conductivity Cell without Alarm.*				*1.00E+00*
	EVENT15	*HEPA Filter Failure*				
	EVENT5	*Cylinder Rupture*				
	EVENT9	*Steam Condensate Line Conductivity Cell Fails to Alarm*				
14.	*EVENT12*	*Operator Fails to Detect Conductivity Cell without Alarm.*				*1.00E+00*
	EVENT13	*Pigtail Leaks.*				
	EVENT15	*HEPA Filter Failure*				
	EVENT9	*Steam Condensate Line Conductivity Cell Fails to Alarm*				
15.	*EVENT14*	*HEPA Filter Not in Place*				*1.00E+00*
	EVENT6	*Cylinder Leaks at Valve.*				
	EVENT7	*Chest Gasket Leaks.*				
16.	*EVENT15*	*HEPA Filter Failure*				*1.00E+00*
	EVENT5	*Cylinder Rupture*				
	EVENT7	*Chest Gasket Leaks.*				
17.	*EVENT10*	*Automatic Steam Shutoff Fails.*				*1.00E+00*
	EVENT13	*Pigtail Leaks.*				
	EVENT15	*HEPA Filter Failure*				
18.	*EVENT1*	*Steam Condensate Line Conductivity Cell Fails to Detect.*				*1.00E+00*
	EVENT15	*HEPA Filter Failure*				
	EVENT6	*Cylinder Leaks at Valve.*				

Set No.	Event Name	Description	C	B.E. Prob	Calc. Result	Cutset Prob
19.	EVENT1	Steam Condensate Line Conductivity Cell Fails to Detect.				1.00E+00
	EVENT15	HEPA Filter Failure				
	EVENT5	Cylinder Rupture				
20.	EVENT1	Steam Condensate Line Conductivity Cell Fails to Detect.				1.00E+00
	EVENT13	Pigtail Leaks.				
	EVENT15	HEPA Filter Failure				
21.	EVENT10	Automatic Steam Shutoff Fails.				1.00E+00
	EVENT15	HEPA Filter Failure				
	EVENT6	Cylinder Leaks at Valve.				
22.	EVENT10	Automatic Steam Shutoff Fails.				1.00E+00
	EVENT15	HEPA Filter Failure				
	EVENT5	Cylinder Rupture				
23.	EVENT11	Leak Large Enough to Activate Relief Valve				1.00E+00
	EVENT13	Pigtail Leaks.				
	EVENT14	HEPA Filter Not in Place				
24.	EVENT11	Leak Large Enough to Activate Relief Valve				1.00E+00
	EVENT14	HEPA Filter Not in Place				
	EVENT6	Cylinder Leaks at Valve.				
25.	EVENT14	HEPA Filter Not in Place				1.00E+00
	EVENT2	Cylinder Valve Damaged by External Event				
26.	EVENT14	HEPA Filter Not in Place				1.00E+00
	EVENT4	Crane Mishandles and Damages Cylinder.				

Set No.	*Event Name*	*Description*	*C*	*B.E. Prob*	*Calc. Result*	*Cutset Prob*
27.	*EVENT14*	*HEPA Filter Not in Place*				*1.00E+00*
	EVENT3	*Piping to Hydrolysis Step Leaks or Is Damaged by External Event.*				
28.	*EVENT14*	*HEPA Filter Not in Place*				*1.00E+00*
	EVENT5	*Cylinder Rupture*				
	EVENT8	*Operator Fails to Seal Chest.*				
29.	*EVENT13*	*Pigtail Leaks.*				*1.00E+00*
	EVENT14	*HEPA Filter Not in Place*				
	EVENT7	*Chest Gasket Leaks.*				
30.	*EVENT14*	*HEPA Filter Not in Place*				*1.00E+00*
	EVENT6	*Cylinder Leaks at Valve.*				
	EVENT8	*Operator Fails to Seal Chest.*				

B.4 Interaction Matrix for ADU Process

Table B-4 Chemical Matrix for ADU Process

	UF_6	UNH	UO_2F_2	ADU	HF	HNO_3	NH_4OH	NH_3	H_2O	STEAM	N_2
UF_6		X				X			X	X	
UNH	X										
UO_2F_2											
ADU											
HF							X	X			
HNO_3	X						X	X			
NH_4OH					X	X					
NH_3					X	X					

H_2O	***X***										
STEAM	***X***										
N_2											

X - Indicates incompatability, potential worker hazard.

Table B-5 Reactive Chemical Hazards for ADU Process

No	Chemical Name	Hazard Information	Bretherick 3rd e Reference page
1	Ammonia	Potentially violent or explosive reactor contact with nitric acid. A jet of ammonia will ignite in nitric acid vapor (ambient temperature). Incompatable with HF, HNO_3, and UF_6. Emits toxic fumes of NO_2 when heated.	1177
2	Ammonium Hydroxide	Incompatable with HF, HNO_3, and UF_6	1205
3	Hydrogen Fluoride	Violent reaction with NH_4OH Reacts with steam or water to produce toxic and corrosive fumes.	1044
4	Nitric Acid	The common chemical most frequently involved in reactive incidents; reactions do not generally require addition of heat. Ignition on contact with HF. Incompatible with NH_4OH Will react with steam or water to produce heat and toxic and corrosive fumes. The oxidizing power and hazard potential of HNO_3 increase with concentration.	1100
5	Uranium Hexafluoride	Violent reaction with water	1078
6	Uranyl Nitrate (UNH)	Decomposes at 100 ℃	1302
7	Steam		
8	Water		

Notes: 1. MP at 2 atmospheres. Volatile crystals sublime. Triple point - 64.0 °C.

Chemical reactions:

1. $UF_6 + UO_2(NO_3)_2.6H_2O$ + water --> $UO_2F_2 + 4HF + UO_2(NO_3)_2.6H_2O$ + heat

   or, in the absence of water, UF_6 *could strip some water from UNH, for example,* $3UF_6 + 2UO_2(NO_3)_2.6H_2O \rightarrow 3UO_2F_2 + 6HF + UO_2(NO_3)_2.3H_2O$
   (Other similar reactions are also possible.)

2. $UF_6 + HNO_3$ + water --> $UO_2F_2 + 4HF + HNO_3$ + heat

3. $UF_6 + 2H_2O \rightarrow UO_2F_2 + 4HF$

4. UF_6 + Steam --> $UO_2F_2 + 4HF$

5. $HF + NH_4OH \rightarrow NH_4F + H_2O$

6. $HF + NH_4OH \rightarrow NH_4F + H_2O$

7. $HNO_3 + NH_4OH \rightarrow NH_4NO_3 + H_2O$

8. $HNO_3 + NH_3 \rightarrow NH_4NO_3$

None of the above reactions requires elevated temperatures or pressures.

Ammonium fluoride (CAS No. 12125-01-8) has MW = 37.1 and decomposes on heating. It is corrosive to tissue. Ammonium nitrate (CAS No. 6484-52-2) has MW = 80.1 and MP = 169.6 °C and decomposes above 210 °C, evolving nitrogen oxides. A powerful oxidizer, it may explode under confinement and high temperatures. Uranium oxyfluoride (CAS No. 13536-84-0) has MW = 308.0 and emits toxic F-fumes when heated to decomposition. Its regulatory limits are measured as uranium.

APPENDIX C

Subsystem Analysis and Integration

Subsystem Analysis and Integration

A systematic approach to hazards analysis is essential to ensure that completeness is accomplished. Historically, errors that occur in safety analyses are non-conservative; that is, hazards and accidents are overlooked, interactions ignored, frequencies underestimated, and consequences estimated at levels less than what might be reasonably expected. Thus, the first consideration that should be handled is systematically establishing the boundaries or limits to be analyzed. Boundaries must be established, for individual analyses, comprising the total assessment. To establish these analytical limits, we must determine if material or energy can be transferred away from an accident in a manner that can adversely affect people, equipment, processes, or the environment. The distance outward is governed by the limits established by consequences judged to be significant.

Given the outer bounds of the overall analysis, the next step is to decide on whether a single, all-encompassing analysis should be made or whether to subdivide the analysis into smaller increments. Large, single analyses are typically complex and cumbersome but enable the analyst to include all interactions that can occur among systems. Dividing the overall analysis into small independent studies reduces the complexity; however, it increases the possibility of omitting system interactions and common-cause effects or failures. The pragmatic approach is to perform several separate analyses, but ensure that both output and input of materials and energies that can affect each analysis are properly considered. This is illustrated in Figure C.1.

In system A, the energy released by an accident does not have an impact beyond the system boundary. The materials released do not impact other systems, but do contribute to the impact on the overall analysis. System A is, therefore, a candidate for an analysis independent of the other systems to be considered.

In system B, the energy released by an accident adversely impacts system C. The materials released do not impact other systems, but do contribute to the impact on the overall analysis. The effects of the materials released from this system defines the envelope of the overall analysis. Because system B is unaffected by the other systems, it, too, may be analyzed independently. However, the energy impact from system B to system C must be considered in the analysis of system C.

In system C, the energy released by an accident adversely impacts system D, and the materials released from system D adversely impacts system C. Because of the interactions of the two systems, consideration should be given to analyzing both systems together to avoid omitting common-cause effects that the interactions might have.

Examples of accidents that might fall into the various categories could be an uncontrolled chemical reaction in system A, an explosion in system B that damages equipment in system C, and a fire in system C that releases flammable gases in system D that intensify the fire in system C and propagate to system D.

Each system must be analyzed separately for each accident.

Figure C.1

Selection of overall and individual analyses.

NRC CONSIDERS CHANGES TO REGULATIONS

FOR SPECIAL NUCLEAR MATERIAL LICENSEES

The Nuclear Regulatory Commission is considering amending its regulations to provide increased confidence in the safety margin for some licensed facilities that possess and process large quantities of certain types of uranium and plutonium.

The proposed amendments would require affected licensees to analyze their facilities carefully to identify potential accidents. The licensees would have to take actions to reduce the likelihood and effects of the postulated accidents if their consequences could exceed specified limits.

The proposed changes result from an NRC review of its regulations after a fuel fabrication facility nearly had an unintended criticality (i.e., a nuclear chain reaction) in May of 1991. As a result of this review, the NRC concluded that, in order to increase confidence in the safety margin, similar licensees should perform an integrated safety analysis. Such an analysis would identify:

(1) Plant and external hazards and their potential for causing accidents;

(2) Potential accident sequences and their likelihood and consequences;

(3) Structures, systems, equipment, components and activities of personnel relied on to prevent or mitigate potential accidents at the facility.

The regulations would apply to licensees that are authorized to possess a "critical mass" of "special nuclear material"

and 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 special nuclear material that the Commission determines could significantly affect public health and safety.

"Special nuclear material" refers to plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Commission determines to be special nuclear material, but does not include natural uranium. The term also refers to any material artificially enriched by any of these materials.

A "critical mass" of special nuclear material contains more than: 700 grams of uranium-235; 520 grams of uranium-233; 450 grams of plutonium; 1,500 grams of 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.

Currently the NRC's regulation of licensees authorized to possess special nuclear material concentrates on protecting public health and safety during nuclear activities conducted under normal operations. The proposed amendments would extend NRC's regulatory framework to address explicitly the potential exposure of workers or members of the public to radiation and hazardous chemicals as a result of accidents.

The NRC held public meetings on these issues in May and November of 1995 and again on May 28 and July 15 of this year.

The proposed rule amendments would partly grant and partly deny a petition filed in September 1996 by the Nuclear Energy Institute, which sought changes to Part 70, "Domestic Licensing of Special Nuclear Material," of the NRC's regulations.

The proposed new regulations would require licensees to perform an integrated safety analysis, as described above, which would include identification of the radiological and chemical consequences of credible potential accidents at their facilities. A plan for performing the analysis would have to be submitted within six months of the effective date of the amendments to the regulations, and the analysis would have to be conducted within four years. Results of the analysis would be incorporated into the license.

Licensees further would have to establish a safety program that provides reasonable assurance of protection against accidents that could result in releases of radioactive materials or hazardous chemicals in excess of NRC criteria.

Licensees also would have to ensure that structures, systems, equipment and components relied on for safety are designed, constructed and maintained so they will perform their safety function. Licensee personnel would have to be trained and tested to confirm their qualifications to perform their safety duties. Management would have to establish appropriate quality assurance procedures to ensure that items relied on for safety perform their safety functions and are continuously available and reliable.

Applicants for a license to operate a new facility would have to design that facility to provide an adequate level of protection against accidents. They would also have to perform a preliminary integrated safety analysis before

constructing the facility and update the analysis before beginning operations.

Other provisions of the proposed revisions to the regulation are discussed in a Federal Register notice to be issued shortly.

Interested persons are invited to submit comments, within 75 days of the Federal Register notice, to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff. Comments may also be submitted electronically through the NRC web site at http://ruleforum.llnl.gov/cgi-bin/rulemake.

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July 21, 1998

The Honorable Dan Schaefer, Chairman

Subcommittee on Energy and Power

Committee on Commerce

United States House of Representatives

Washington, DC 20515

Dear Mr. Chairman:

The U.S. Nuclear Regulatory Commission (NRC) has sent to the Office of the Federal Register for publication, the enclosed proposed rule to amend 10 CFR Part 70, concerning domestic licensing of special nuclear material.

The objective of the proposed rule is to increase confidence in the margin of safety at facilities authorized to possess special nuclear material in sufficient quantities to be of criticality concern. The proposed rule would: 1) identify appropriate consequence criteria and the level of protection needed to prevent or mitigate accidents that exceed these criteria; 2) require affected licensees to perform an integrated safety analysis (ISA) to identify potential accidents at the facility and the items relied on for safety; 3) require licensees to implement measures to ensure that the items relied on for safety are continuously available and reliable; 4) require the inclusion of the safety bases, including the results of the ISA, in a facility's license application; and 5) allow for licensees to make certain changes to their facilities without prior NRC approval.

The proposed amendments will be subject to a 75-day public comment period.

Sincerely.

Dennis K. Rathbun, Director

Office of Congressional Affairs

Enclosure:

As stated

cc: Representative Ralph Hall

Draft July 16, 1998

The Honorable James M. Inhofe, Chairman
Subcommittee on Clean Air, Wetlands, Private
Property, and Nuclear Safety
Committee on Environmental and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The U.S. Nuclear Regulatory Commission (NRC) has sent to the Office of the Federal Register for publication, the enclosed proposed rule to amend 10 CFR Part 70, concerning domestic licensing of special nuclear material.

The objective of the proposed rule is to increase confidence in the margin of safety at facilities authorized to possess special nuclear material in sufficient quantities to be of criticality concern. The proposed rule would: 1) identify appropriate consequence criteria and the level of protection needed to prevent or mitigate accidents that exceed these criteria; 2) require affected licensees to perform an integrated safety analysis (ISA) to identify potential accidents at the facility and the items relied on for safety; 3) require licensees to implement measures to ensure that the items relied on for safety are continuously available and reliable; 4) require the inclusion of the safety bases, including the results of the ISA, in a facility's license application; and 5) allow for licensees to make certain changes to their facilities without prior NRC approval.

The proposed amendments will be subject to a 75-day public comment period.

Sincerely.

Dennis K. Rathbun, Director

Office of Congressional Affairs

Enclosure:

As stated

cc: Senator Bob Graham

UNITED STATES NUCLEAR REGULATORY COMMISSION

Environmental Assessment and Finding of No Significant Impact

(PRE-DECISIONAL DRAFT)

For

Proposed Amendments to 10 CFR Part 70

July 21, 1998

ATTACHMENT 9

Division of Fuel Cycle Safety and Safeguards

Office of Nuclear Material Safety and Safeguards

Environmental Assessment and Finding of No Significant Impact

TABLE OF CONTENTS

Environmental Assessment and Finding of No Significant Impact

(PRE-DECISIONAL DRAFT)

For

Proposed Amendments to 10 CFR Part 70

Description of the Proposed Action

The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations in 10 CFR Part 70 (Part 70), "Domestic Licensing of Special Nuclear Material," to establish a risk-informed, performance-based framework for regulating special nuclear material (SNM) licensees engaged in uranium processing, uranium fuel fabrication, scrap recovery, or related activities. This action is being taken in response to a Petition for Rulemaking (PRM 70-7) filed by the Nuclear Energy Institute (NEI) in September 1996, as documented in SECY-97-137, "Proposed Resolution to Petition for Rulemaking Filed by the Nuclear Energy Institute." The amendments are intended to provide for increased confidence in the margin of safety at fuel cycle facilities by ensuring that licensees systematically identify items (i.e., structures, systems, equipment, components and personnel activities) necessary for protection of health and environmental safety and ensure that these items remain continuously available and reliable. The revised Part 70 would apply to certain facilities that are authorized to process SNM in quantities sufficient to constitute a critical mass (except reactors and gaseous diffusion plants).

NRC is proposing to add safety performance requirements with the following major elements:

1. Identification of appropriate consequence criteria and items relied on for safety to prevent or mitigate accidents that exceed the established criteria;

2. Performance of an Integrated Safety Analysis (ISA) to identify potential accidents at the facility and the items relied upon for safety;

3. Measures to ensure that items relied on for safety are continuously available and reliable;

4. Inclusion of the safety bases, including the results of the ISA, in the license application; and

5. Flexibility for licensees to make certain changes to their facilities, based on the results of the ISA, that do not increase risk without prior NRC approval.

The Commission's approach, outlined above, agrees in principle with the NEI's petition, with the modifications described in SECY-97-137. These new requirements would apply to licensees engaged in various activities , listed above, including seven currently operating commercial nuclear fuel cycle facilities in the United States. These facilities are already licensed by NRC and subject to the existing requirements in 10 CFR Part 70.

Need for the Proposed Action

The proposed amendments to Part 70 are necessary to provide for increased confidence in the margin of safety at SNM facilities that possess more than a critical mass of SNM. In general the new requirements are intended to ensure that workers, the general public, and the environment are protected from radiological and certain chemical hazards associated with plant operations. A near-criticality incident at a low enriched fuel fabrication facility in May of 1991 prompted NRC staff to evaluate its safety regulations for large materials licensees. (See NUREG-1324 and NUREG-1450 for additional details.) As a result of this review, the Commission and the staff recognized the need for revision of its regulatory basis for these facilities and, specifically, those possessing a critical mass of special nuclear material. Although licensee programs at existing SNM processing facilities are adequate to protect the public, more than three decades of experience with fuel fabrication and SNM processing in the U.S. has surfaced systemic deficiencies in licensee safety programs, especially in the areas of configuration management, maintenance, quality assurance, and safety analysis. The weaknesses identified with the current Part 70 regulatory framework parallel these deficiencies. That is, the current Part 70 does not require the identifications of items relied on for safety; does not require licensees to address fire and chemical process safety; does not require the prevention of an inadvertent criticality; does not require the reporting of all significant facility changes to NRC; and does not require implementation of most managerial controls, including maintenance and quality assurance. It is not a risk-informed regulation in that no specific performance objectives are established and no systematic safety analysis is required to demonstrate compliance with such objectives.

In summary, the existing regulations do not explicitly require a comprehensive, systematic and integrated analysis to identify hazards, such as criticality, fire, chemical releases, and their potential for causing accidents that could affect workers, the public and the environment. Nor do the existing regulations require the identification of items relied on for safety and the measures to assure their continuous availability and reliability. There is a need, therefore, to revise the existing regulations to include these features so as to provide increased confidence in the margin of safety and in the continuous availability and reliability of the items relied on for safety at licensed facilities. The Commission believes such revisions to Part 70 constitute a risk-informed, performance-based approach in which the items relied on for safety and the measures to assure their continuous availability and reliability are selected commensurate with the risk.

The two primary alternatives to be considered are: 1) Option 1-no-action, and 2) Option 2- the proposed rule revision and development of a standard review plan (SRP). Option 2 is consistent with SECY-97-137 which was approved by the Commission in SRM of August 22, 1997.

Option 1

Option 1 is the status-quo, no action alternative that reflects the current Part 70 requirements with added varying license conditions requiring ISAs in most, but not all, license renewals. In the time frame prior to Option 1, NRC was criticized in House Report 100-167 for concentrating on radiological hazards and largely for ignoring other hazards. Under Option 1, those licensees required to perform an ISA would continue to do so. An SRP could be developed to promote some consistency and uniformity and provide standards for the quality and completeness of the ISA. However, in addition to current inconsistencies among licensees under Option 1, there are other licensees that are not performing ISAs at all. Therefore, an SRP would not bridge this regulatory gap, since requirements are set in the regulations and the current Part 70 lacks such needed requirements.

Option 2

Option 2 is the Commission's proposal to modify 10 CFR Part 70 by adding a new subpart, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material," that consists of 10 CFR 70.60 to 70.74. This new subpart includes requirements aimed at increasing NRC's confidence in the margin of safety. It will also establish consistency in the manner that affected licensees are regulated. These new requirements, although briefly discussed above, are discussed in detail in the Statement of Consideration and Regulatory Analysis to the proposed Part 70.

Environmental Impacts of Proposed Alternatives

Option 2

The potential environmental impacts of Option 2, the proposed action, are those which arise from the additional effort licensees may require to perform an ISA and implement the safety-related performance requirements[51], and the benefits to the public health

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51 Administrative burdens associated with the proposed revisions to Part 70 are discussed in detail in the Regulatory Analysis of the rule.

and safety and the environment. Using a risk-informed regulatory framework, the proposed action establishes specific performance objectives and requires licensees to conduct an integrated safety analysis (ISA) to demonstrate compliance with these objectives. Adherence to the new performance objectives, which include the establishment of consequence criteria and corresponding likelihood goals, is expected to lessen potential impacts on workers, members of the public, and the environment from accidents at the SNM processing facilities.

Option 2, the proposed action, has positive effects on environmental protection, i.e., it would decrease the likelihood of worker, public, and environmental exposure to radioactive and hazardous materials as a result of an accident. Specifically, the proposed action would require that licensees do the following:

1. Provide protection against accidents with the following consequences so that their occurrence would be highly unlikely:
   (a) A nuclear criticality, or
   (b) 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 or ERPG-3 limits; or
   (c) 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; or
      (ii) An intake of 30 mg or greater of uranium in a soluble form, or
      (iii) Hazardous chemicals in concentrations exceeding AEGL-2 or ERPG-2 limits.

2. Provide protection against accidents with the following consequences so that their occurrence would be unlikely:
   (a) 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 or ERPG-2 limits and AEGL-3 or ERPG-3 limits; or

(b) 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 or ERPG-1 limits and AEGL-2 or ERPG-2 limits.

(c) Prompt 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.

4. For operating facilities and facilities involved in hazardous decommissioning activities, perform an ISA to identify potential accidents and the items relied on for safety.

5. For new facilities and new processes at existing facilities, design such facilities to meet baseline design criteria to protect against potential environmental and safety problems; perform a preliminary ISA to identify potential accidents and the items relied on for safety, and update the ISA prior to beginning operations.

6. Report events that affect public health and safety or the environment, or that relate to the loss or degradation of items relied on for safety.

The benefits of the proposed action in reducing the likelihood of potential accidents and mitigating environmental impacts are real although not readily quantifiable. As discussed in the Regulatory Analysis, the implementation of the proposed action is expected to reduce the frequency and severity of accidents at affected licensed facilities. The reduction should translate into fewer accident-related injuries, fewer exposures to workers, reduced cleanup, and less environmental contamination. Quantification of these benefits was not performed because of the lack of risk information, i.e., baseline data relating to the number, impact, severity, and consequence of accidents, that was available. Therefore, negative and positive impacts in this environmental assessment are assessed qualitatively.

Option 1

The first alternative, Option 1-no action or status quo, does not provide increased confidence in the margin of safety because it fails to provide a risk-informed performance-based regulatory framework. There are no specific performance objectives in the existing rule, and there is no requirement for licensees to perform a safety analysis to identify potential accidents and the items relied on for safety. Further, without such a risk-informed, performance-based regulatory framework and the consistency fostered by the proposed action, a large amount of licensee and NRC resources could be consumed by continuing to implement the existing requirements. The impact of the first alternative is a likelihood of more incidents of environmental significance which could have been anticipated and prevented had proper requirements been in place. Although it is possible that licensees would have already identified the possibility of such accidents and have effective controls in place, this outcome cannot be reliably expected because the regulatory framework is not in place to require such outcomes. Under this option, licensees would have considerable freedom in deciding which accidents are significant and should be protected against, the method of determining which items would be relied on for safety, and which measures would assure the continuous availability and reliability of these items.

Under this no action alternative, the result would be a potentially higher risk of accidents with significant consequences, with additional NRC staff and licensee resources expended for subsequent investigations and enforcement.

Summary

The potential environmental impacts of the proposed action are expected to be positive and are preferable to the no action, status-quo alternative because the proposed action accomplishes the greatest gain in protecting the environment for the administrative resources expended. This conclusion may be summarized from Table 1 below.

TABLE 1: ENVIRONMENTAL IMPACTS OF PROPOSED ALTERNATIVES

	Effect on Increase Confidence in Margin of Safety	Will Address Safety Deficiencies Previously Identified	Environmental Impact
Option 1-no action	less than Option 2	less than Option 2	less than Option 2
Option 2: Proposed Action	increase	yes	reduced likelihood of accident and increased mitigation of potential environmental consequences.

Environmental Justice

NRC is committed to complying with Executive Order 12898 -- Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (EO 12898), dated February 11, 1994, in all its actions. As no significant environmental impacts have been identified, NRC staff has determined that there can be no disproportionately high and adverse effects or impacts on minority or low-income populations. Consequently, further evaluation of environmental justice concerns, as outlined in Executive Order 12898, is not warranted.

Finding of No Significant Impact

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 these proposed amendments, 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 determination of this environmental assessment is that there will be no significant environmental impact from this action. 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 these proposed amendments but somehow were not addressed. NRC uses the following working definition of "environmental justice:" the fair treatment and meaningful involvement of all people, regardless of race, ethnicity, culture, income, or educational level with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.

List of Agencies and Persons Contacted

Nuclear Energy Institute
General Electric Company
Westinghouse Electric Company
U.S. Department of Energy

References

NUREG-1324, *Proposed Method for Regulating Major Material Licensees*, USNRC, February 1992.

NUREG-1450, *Potential Criticality Accident at the General Electric Nuclear Fuel and Component Manufacturing Facility, May 29, 1991,* USNRC, August 1991.

Draft Regulatory Analysis for Proposed Revisions to 10 CFR Part 70, USNRC, 1998

Draft Statement of Consideration for Proposed Revisions to 10 CFR Part 70, 1998

Principal Contributors:

FCSS staff