June 2, 1999 SECY-99-147

FOR: The Commissioners

FROM: William D. Travers /s/
Executive Director for Operations

SUBJECT: PROPOSED RULEMAKING - 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."

BACKGROUND:

A near-criticality incident at a low enriched fuel fabrication facility in May 1991 prompted the Nuclear Regulatory Commission (NRC) to evaluate its safety regulations for licensees that possess and process large quantities of special nuclear material (SNM). As a result of this review, the Commission [Staff Requirements Memorandum (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.

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The Nuclear Energy Institute (NEI) explained to the Commission industry's position on the need for revision of NRC regulations in Part 70 at a meeting on July 2, 1996, and in a subsequent filing, in September 1996, of a Petition for Rulemaking (PRM 70-7). 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 Commission, in an SRM dated August 22, 1997, approved the staff's proposal to revise Part 70 and directed the staff to submit a draft proposed rule by July 31, 1998.

The staff forwarded a draft proposed rule to the Commission in SECY-98-185, "Proposed Rulemaking - Revised Requirements for the Domestic Licensing of Special Nuclear Material," dated July 30, 1998. SECY-98-185 also discusses the history of this rulemaking. The staff briefed the Commission about the draft proposed rule at a Commission meeting held on August 25, 1998. NEI expressed its concerns with the proposed rule at the same meeting. After the Commission meeting, the rule was discussed at a public meeting that was held on September 29, 1998.

The Commission issued an SRM dated December 1, 1998, that directed the staff not to publish the proposed rule contained in SECY-98-185 for public comment. Instead, the Commission directed the staff to obtain stakeholder input and revise the draft proposed rule. In that SRM, the Commission also directed the staff to: (1) decide what is fundamental for NRC's regulatory purposes for inclusion as part of the license or docket and what can be justified from a public health and safety and cost-benefit basis, and assure that Part 70 captures, for submittal, those few significant changes that currently would require license amendments; (2) require licensees/applicants to address baseline design criteria and develop preliminary ISAs for new processes and new facilities; (3) justify, on a health and safety or cost-benefit basis, any requirement to conduct a decommissioning ISA; (4) require that any new backfit pass a cost-benefit test, without the "substantial" increase-in-safety test; (5) require the reporting of certain significant events because of their potential to impact worker or public health and safety; (6) clarify the basis for use of chemical safety and chemical consequence criteria, particularly within the context of the Memoranda of Understanding with the Occupational Safety and Health Administration and other Government agencies; (7) critically review the Standard Review Plan (SRP) to ensure that by providing specific acceptance criteria, it does not inadvertently prevent licensees or applicants from suggesting alternate means of demonstrating compliance with the rule; and (8) request input on how applicable ISA methodologies should be employed in the licensing of new technologies for use within new or existing facilities.

DISCUSSION:

As directed in the SRM for SECY-98-185, stakeholder input was solicited and obtained at public meetings held in December 1998, and January and March 1999. A website was established to facilitate communication with stakeholders and to further solicit input. The nuclear industry submitted comments by letters and postings on the website. The draft proposed rule in the Federal Register Notice (Attachment 1) takes into consideration all public comments received through April 16, 1999. Attachment 2 discusses how the staff addressed the issues contained in the SRM, namely: (1) whether the ISA should be in the license; (2) the change process; (3) baseline design criteria; (4) preliminary ISA; (5) decommissioning; (6) backfit; (7) reporting of events; (8) chemical hazards; (9) SRP modifications; and (10) ISA methodologies used in the

licensing of new technologies. Attachment 3 discusses how the staff addressed the public comments.

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, and address many of the weaknesses identified in NUREG-1324. The draft proposed rule: (1) requires that each licensee or applicant establish a safety program; (2) identifies performance requirements, consisting of consequences and associated likelihoods, that limit the risk of accidents at the facility; and (3) contains a change process that allows licensees to make certain changes to the safety programs or the facilities without NRC preapproval, only post-notification, and describes those changes that require NRC preapproval. The safety program consists of process safety information; an ISA that analyzes facility hazards and potential accident sequences, and identifies items relied on for safety; and management measures to ensure that items relied on for safety are available and reliable to perform their function when needed. The draft proposed rule requires that an ISA summary be submitted with the application and be included on the docket but not in the license. Facility changes, including changes reflected in the ISA summary, are discussed in 10 CFR 70.72 of the rule. The change process in that section of the rule reflects the staff's recommended approach, which is also strongly supported by the industry. The staff recommends this approach because it focuses on high-risk changes, contains straightforward, objective criteria, and is consistent with the direction in the SRM. This approach differs significantly from the 10 CFR 50.59 approach which was designed for reactors and considered by the staff. The §50.59-like approach that was considered by the staff is included as Attachment 4, for the Commission's consideration.

With one exception, the staff's approach is in accordance with the Commission's SRM of December 1, 1998. The exception is that a preliminary ISA (or preliminary hazard analysis) is not required. The industry opposed submitting such an analysis, and, after consideration of industry's view, the staff decided that its pre-licensing needs could be addressed through existing requirements in 10 CFR 70.21(f).

As in SECY 98-185, the staff continues to believe that a qualitative backfit mechanism should be considered for implementation only after the safety basis is established and incorporated in the license, and after licensees and staff have gained experience with the implementation of the ISA requirements of the rule. However, given the views expressed by industry, the Federal Register Notice requests public comment on the intent to defer implementation of a backfit provision in Part 70. A more detailed discussion of backfit is contained in Attachment 2.

The Federal Register Notice also specifically requests public comment on how applicable ISA methodologies should be employed in the licensing of new technologies for use within new or existing facilities and on the NRC-OSHA interface with respect to regulation of chemical hazards.

Two draft guidance documents support the rulemaking, an SRP (Attachment 5), and an ISA guidance document (Attachment 6). The draft SRP provided as Attachment 5 to this Commission Paper reflects the results of extensive stakeholder interaction as it pertains to the SRP, including some of the more recent comments received. The staff continues to analyze the recent comments and will make further revisions to the SRP text, as considered appropriate. When the proposed rule is

published for comment, staff proposes to make available at that time the latest version of the draft SRP, i.e., reflecting additional revisions in response to the recent comments received.

The rulemaking package does not contain an enforcement and inspection plan. NMSS staff is developing a revised inspection program for fuel cycle facilities. As part of this activity, NMSS staff will address the inspection activities under the proposed rule, and will develop, with the Office of Enforcement, an enforcement approach. As part of the final rulemaking, these issues will be addressed.

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 approved 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 1).

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:

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

   2. A draft SRP will be available in the Public Document Room (Attachment 5);

   3. A draft ISA Guidance Document will be available in the Public Document Room (Attachment 6);

   d) A draft “Regulatory Analysis” will be available in the Public Document Room (Attachment 7);

   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 licensees. The notice will be sent to other interested parties on request;

7. A press release will be issued (Attachment 8);

8. The appropriate Congressional committees will be informed (Attachment 9);

i) A draft Environmental Assessment will be available in the Public Document Room (Attachment 10);

j) An Office of Management and Budget (OMB) clearance package must be submitted to OMB no later than the date the proposed rule is submitted to the Federal Register.

William D. Travers
Executive Director
for Operations

Attachments:
1. Federal Register Notice - Proposed Rule
2. Disposition of SRM Issues
3. Disposition of Public Comments
4. Section 70.72 Change Process Option 2
5. Standard Review Plan (Draft)
6. ISA Guidance Document (Draft)
7. Regulatory Analysis (Draft)
8. Press Release (Draft)
9. Congressional Letters (Draft)
10. Environmental Assessment (Draft)

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 70

RIN 3150 - AF22

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

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations governing the domestic licensing of special nuclear material (SNM) for licensees authorized to possess a critical mass of SNM, that are engaged in one of the following activities: enriched uranium processing; fabrication of uranium fuel or fuel assemblies; uranium enrichment; enriched uranium hexafluoride conversion; plutonium processing; fabrication of mixed-oxide fuel or fuel assemblies; scrap recovery of special nuclear material; or any other activity involving a critical mass of SNM that the Commission determines could significantly affect public health and safety or the environment. The proposed amendments would identify appropriate consequence criteria and the level of protection needed to prevent or mitigate accidents that exceed these criteria; require affected licensees to perform an integrated safety analysis (ISA) to identify potential accidents at the facility and the items relied on for safety necessary to prevent these potential accidents and/or mitigate their consequences; require the implementation of measures to ensure that the items relied on for safety are available and reliable to perform their function when needed; require the inclusion of the safety bases, including a summary of the ISA, with the license application; and allow for licensees to make certain changes to their safety program and facilities without prior NRC approval.

ATTACHMENT 1

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

this date.

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

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

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

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

SUPPLEMENTARY INFORMATION:

I. Background

II. Description of Proposed Action

I. Background

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

amount of material, a licensee should perform an ISA. An ISA is a systematic analysis that identifies:

(1) Plant and external hazards and their potential for initiating accident sequences;

(2) The potential accident sequences, their likelihood, and consequences; and

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

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

(1) Add a definition for a uranium processing and fuel fabrication plant;

(2) Require the performance of an ISA, or acceptable alternative, at uranium processing, fuel fabrication, and enrichment plants; and

(3) Include a requirement for backfit analysis, under certain circumstances, within Part 70.

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

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

(2) Establishment of criteria to identify the adverse consequences that licensees must protect against;

(3) Inclusion of the safety bases in a license application (i.e., the identification of the potential accidents, the items relied on for safety to prevent these accidents and/or mitigate their consequences, and the measures needed to ensure the availability and reliability of these items);

(4) Ability of licensees, based on the results of an ISA, to make certain changes without NRC prior approval; and

(5) Consideration by the Commission, after licensees' initial conduct and implementation of the ISA, of a qualitative backfitting mechanism to enhance regulatory stability.

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

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

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

(1) Decide what is fundamental for NRC's regulatory purposes for inclusion as part of the license or docket and what can be justified from a public health and safety and cost-benefit basis, and assure that Part 70 captures for submittal those few significant changes that currently would require license amendments;

(2) Require licensees/applicants to address baseline design criteria and develop a preliminary ISA for new processes and new facilities;

(3) Justify, on a health and safety or cost-benefit basis, any requirement to conduct a decommissioning ISA;

(4) Require that any new backfit pass a cost-benefit test, without the “substantial” increase in safety test;

(5) Require the reporting of certain significant events because of their potential to impact worker or public health and safety;

(6) Clarify the basis for use of chemical safety and chemical consequence criteria, particularly within the context of the Memoranda of Understanding with the Occupational Safety and Health Administration (OSHA) and other government agencies;

(7) Critically review the Standard Review Plan (SRP) to ensure that by providing specific acceptance criteria, it does not inadvertently prevent licensees or applicants from suggesting alternate means of demonstrating compliance with the rule; and

(8) Request input on how applicable ISA methodologies should be employed in the licensing of new technologies for use within new or existing facilities.

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

II. Description of Proposed Action

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

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

(1) The identification of appropriate risk levels, considering consequence criteria and the level of protection needed to prevent accidents that could exceed such criteria;

(2) The performance of an ISA to identify potential accidents at the facility and the items relied on for safety;

(3) The implementation of measures to ensure that the items relied on for safety are available and reliable to perform their function when needed;

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

(5) The allowance for licensees to make certain changes to their safety program and facilities without prior NRC approval.

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

Furthermore, the Commission is not currently proposing, as suggested in the NEI petition, to include a backfit provision in Part 70. Based on the discussions at public meetings held on May 28, 1998, and March 23, 1999, the purpose of the NEI-proposed backfit provision is to ensure that NRC staff does not impose safety controls that are not necessary to satisfy the performance

requirements of Part 70, unless a quantitative cost-benefit analysis justifies this action. The Commission believes that once the safety basis, including the ISA summary, is incorporated in the license application, and the NRC staff has gained sufficient experience with implementation of the ISA requirements, a qualitative backfit mechanism could be considered. Without a baseline determination of risk, as provided by the initial ISA process, it is not clear how a determination of incremental risk, as needed for a backfit analysis, would be accomplished. Furthermore, although NEI previously stated that a quantitative backfit approach is currently feasible, it would appear that a quantitative determination of incremental risk would require a Probabilistic Risk Assessment, to which the industry has been strongly opposed. Given the differences of opinion on this subject, the Commission requests public comment on its intent to defer consideration of a qualitative backfit provision in Part 70, and any specific suggestions for backfit provisions that would specifically address fuel cycle backfit needs, and the information that would be available to conduct the associated analysis.

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

Section 70.4 Definitions.

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

Section 70.14 Foreign military aircraft.

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

Section 70.17 Specific exemptions.

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

Section 70.50 Reporting requirements.

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

Section 70.60 Applicability.

This section lists the types of NRC licensees or applicants who would be subject to the new Part 70, Subpart H. The Commission has decided that the new requirements should not apply to all licensees authorized to possess critical masses of SNM. Instead, the Commission has identified a subset of these licensees that, based on the risk associated with operations at these facilities, should be subject to the new requirements. This change would exclude certain facilities (e.g., those authorized only to store SNM or use SNM in sealed form for research and educational purposes) from the new requirements, because of the relatively low level of risk at these facilities. In general, the new Subpart is intended to ensure that the significant accidents that are possible at fuel fabrication facilities (and the other listed facility types) have been analyzed in advance, and that appropriate controls or measures are established to ensure adequate protection of workers,[1] public, and the environment. The requirements and provisions in Subpart H are in addition to, and not a substitute for, other applicable requirements, including those of the U.S. Environmental Protection Agency (EPA) and the U.S. Department of Labor, OSHA. The

[1]A worker, in the context of this rulemaking, is defined as an individual whose assigned duties in the course of employment involve exposure to radiation and/or radioactive material from licensed and unlicensed sources of radiation (i.e., an individual who is subject to an occupational dose as in 10 CFR 20.1003).

requirements being added by NRC only apply to NRC's areas of responsibility (radiological safety and chemical safety directly related to licensed radioactive material). In this regard, the requirements for hazards and accident analyses that NRC is adding are intended to complement and be consistent with the parallel OSHA and EPA regulations.

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

Section 70.61 Performance Requirements.

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

There are three risk-informed performance requirements for the rule, each of which is set out in 10 CFR 70.61: (1) section 70.61(b) states that high-consequence events must meet a likelihood standard of highly unlikely; (2) section 70.61(c) requires that intermediate-consequence

events must meet a likelihood standard of unlikely; and (3) section 70.61(d) requires that risk of nuclear criticality be limited by assuring that all processes must remain subcritical under any normal or credible abnormal conditions. The term "performance requirements" thus considers together consequences and likelihood. For regulatory purposes, each performance requirement is considered an equivalent level of risk. For example, the acceptable likelihood of intermediate-consequence events is allowed to be greater than the acceptable likelihood for high-consequence events.

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

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

needed. The combination of the set of "items relied on for safety" and the "management measures" applied to each item will determine the extent of the licensee's programmatic and design requirements, consistent with the facility risk, and will ensure that at any given time, the facility risk is maintained safe and protected from accidents (viz., satisfies the performance requirements).

The proposed performance requirements also address certain chemical hazards that result from the processing of licensed nuclear material. The question of the extent of NRC's authority to regulate chemical hazards at its fuel cycle facilities was raised after an accident in 1986 at a Part 40 licensed facility, in which a cylinder of uranium hexafluoride ruptured and resulted in a worker fatality. The cause of the worker's death was the inhalation of hydrogen fluoride gas, which was produced from the chemical reaction of uranium hexafluoride and water (humidity in air). Partly as a result of the coordinated Federal response and resulting Congressional investigation into that accident, NRC and the OSHA entered into an MOU, in 1988, that clarified the agencies' interpretations of their respective responsibilities for the regulation of chemical hazards at nuclear facilities. The MOU identified the following four areas of responsibility. Generally, NRC covers the first three areas, whereas OSHA covers the fourth area:

(1) Radiation risk produced by radioactive materials;

(2) Chemical risk produced by radioactive materials;

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

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

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

OSHA provided comments, by a letter dated February 1, 1999, on a draft of the rule that had been revised to be consistent with the MOU. In that letter, OSHA expressed concerns that the rule language would preempt OSHA from enforcing any of its standards, rules or other

requirements with respect to chemical hazards at the facilities covered by the NRC draft rule. This concern is based on case law under the OSH Act. The pertinent provision in the OSH Act states:

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

NRC staff subsequently met with OSHA officials on February 25, 1999, and some clarifications and further information were provided at that meeting. As a result of the meeting discussions, some changes were made to the rule language to more clearly specify the scope of NRC involvement. However, these changes do not fully resolve the basic preemption issue. The problems identified with the rule are not unique, i.e., the preemption issue is generic and may already exist for any NRC-licensed facilities where there are requirements to analyze hazards. At the February 25 meeting, OSHA confirmed that the rule language is consistent with the October 21, 1988 MOU; indicated that they have no suggested changes to the MOU; and indicated that they are not opposed to the proposed rule. The Commission's view is that the proposed rule is consistent with NRC responsibilities and authority under the Atomic Energy Act, and consistent with the OSHA MOU. The only resolution of the preemption issue appears to be a legislative modification of the OSH Act. Public comments would be appreciated on any options that may have been overlooked.

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

The use of any of the performance requirements is not intended to imply that the specified worker or public radiation dose or chemical exposure constitutes an acceptable criterion for an emergency dose to a worker or the public. Rather, these values have been proposed in this section as a reference value, to be used by licensees in the ISA (a forward-looking analysis) to establish controls (i.e., items relied on for safety and associated management measures)

necessary to protect workers from potential accidents with low or exceedingly low probabilities of occurrence that are not expected to occur during the operating life of the facility.

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

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

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

Section 70.61(b)(2). The exposure of an individual located outside of the controlled area to a radiation dose of 0.25 Sv (25 rem) or greater TEDE is considered a high-consequence event. This is generally consistent with the criterion established in 10 CFR 100.11, "Determination of exclusion area, low population zone, and population center distance," and 10 CFR 50.34,

"Contents of applications; technical information," where a whole-body dose of 0.25 Sv (25 rem) is used to determine the dimensions of the exclusion area and low-population zone required for siting nuclear power reactors.

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

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

hazardous chemicals including "...community emergency planners and response specialists, air dispersion modelers, industrial process safety engineers, implementers of environmental regulations such as the Superfund Amendment and Reauthorization Act, industrial hygienists, and toxicologists, transportation safety engineers, fire protection specialists, and government agencies...." (DOE Risk Management Quarterly, 1997). Despite their general acceptance, there are currently only approximately 80 ERPG criteria available, and some chemicals of importance (e.g., nitric acid) are not covered.

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

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

The consequences identified in §70.61(c) of the proposed rule are referred to as "intermediate-consequence events" and include accidental exposure of a worker or an individual outside of the controlled area to levels of radiation or hazardous chemicals that generally correspond to permanent injury to a worker, transient injury to a non-worker, or significant releases of radioactive material to the environment. The goal is to ensure an acceptable level of

risk by limiting the combination of the likelihood of occurrence and the identified consequences. Thus, “intermediate-consequence events” must be sufficiently mitigated to a lower consequence or prevented such that the event is unlikely (or lower). The application of “items relied on for safety” provides this prevention or mitigation function.

Section 70.61(c)(1). A worker radiation dose between 0.25 Sv (25 rem) and 1 Sv (100 rem) TEDE is considered an intermediate-consequence event [over 1 Sv (100 rem) is a high-consequence event]. This value was chosen because of the use of 0.25 Sv (25 rem) as a criterion in existing NRC regulations. For example, in 10 CFR 20.2202, “Notification of incidents,” immediate notification is required of a licensee if an individual receives “... a total effective dose equivalent of 0.25 Sv (25 rem) or more.” Also, in 10 CFR 20.1206, “Planned special exposures,” a licensee may authorize an adult worker to receive a dose in excess of normal occupational exposure limits if a dose of this magnitude does not exceed 5 times the annual dose limits [i.e., 0.25 Sv (25 rem)] during an individual’s lifetime. In addition, EPA’s Protective Action Guides (U.S. Environmental Protection Agency, 1992) and NRC’s regulatory guidance (Regulatory Guide 8.29, 1996) identify 0.25 Sv (25 rem) as the whole-body dose limit to workers for life-saving actions and protection of large populations. NCRP has also stated that a TEDE of 0.25 Sv (25 rem) corresponds to the once-in-a-lifetime accidental or emergency dose for workers.

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

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

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

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

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

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

The third performance requirement states that the risk of nuclear criticality accidents must be limited by assuring that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety. It also requires that preventive controls and measures shall be the primary means of protection against nuclear criticality accidents. Although detecting and mitigating the consequences of a nuclear criticality are important objectives (e.g., for establishing alarm systems), the prevention of a criticality is a primary NRC objective.

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

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

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

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

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

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

Individuals who do not receive an occupational dose (as that term is used in Part 20) in the controlled area will be subject to the dose limits for members of the public in 10 CFR 20.1301. However, the Commission recognizes that certain licensees may have ongoing activities at their site (i.e., within the controlled area) that are not related to the licensed activities. For example, a non-nuclear facility may be adjacent to the nuclear facility but both are within the controlled area (which may be defined similar to the site boundary). This raises a question regarding the appropriate accident standard for these individuals. Protection of the individuals at the non-nuclear facility must consider that the nature of many potential accidents at a fuel cycle facility is such that there may not be sufficient time during which to take action to exclude individuals from the controlled area. Therefore, for purposes of the ISA accident evaluation, the rule explicitly contains two options for these individuals (as well as an implicit third option). In the first option, the licensee evaluates, in the ISA, the risk at its location (as opposed to that at any point at or beyond the controlled area boundary) and determines that it meets the performance requirements for members of the public. In the second option, performance requirements for workers may be applied to individuals in the controlled area if the provisions of Section 70.61(f)(2) are satisfied. These conditions ensure that the individuals are aware of the risks to them from the potential accidents at the nuclear facility and have received appropriate training and access to information. This parallels and is consistent with the use of the term, “Exclusion area”, by 10 CFR Parts 50 and 100, which states, “Activities unrelated to operation of the reactor may be permitted in an exclusion area under appropriate limitations, provided that no significant hazards to the public health and safety will result.” The implied third option is to define (or redefine) a controlled area such that within it only activities associated with the licensed nuclear facility are permitted.

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

Section 70.62 Safety Program and Integrated Safety Analysis.

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

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

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

Finally, each licensee would also be required to establish and maintain a log documenting each discovery that an item relied on for safety has failed to perform its function either in the context of the performance requirements of §70.61 or on demand. The phrase "...in the context of the performance requirements of §70.61" means that items relied on for safety that fail would

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

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

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

(1) Identify all hazards at the facility, including both radiological and non-radiological hazards. Hazardous materials, their location, and quantities, should be identified, as well as all hazardous conditions, such as high temperature and high pressure. In addition, any interactions that could result in the generation of hazardous materials or conditions should be identified.

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

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

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

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

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

Applicants for licenses to operate new facilities or new processes at existing facilities would be expected to design their facilities or processes to protect against the occurrence of the adverse consequences identified in 10 CFR 70.61, using the baseline design criteria 10 CFR 70.64(a). Before operation, applicants would be expected to update their ISAs, based on as-built conditions and submit the results to NRC as ISA summaries, along with the applications, following the requirements in 10 CFR 70.65(b).

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

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

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

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

The phrase “when needed” is used to acknowledge that a particular safety control need not be continuously functioning. For example, it may not be operational during maintenance or

calibration testing, or may not be required when the process is not operational or when special nuclear material is not present. However, the phrase, when needed, does not relieve a licensee from compliance with the performance requirements. For example, if a particular component is out for maintenance, the licensee must consider credible event sequences in developing the ISA and identifying items relied on for safety - a high-consequence event sequence still has to be highly unlikely. Compliance with the performance requirements in these cases can be established by various means including identification of additional items relied on for safety (and application of safety program management measures to them), or by limiting operations or placing the plant in a different operating mode during the maintenance of the item relied on for safety.

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

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

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

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

A major feature of the proposed amendments to Part 70 is the requirement that licensees and applicants for a license perform an ISA and use the ISA process to develop risk-informed decisions regarding facility safety. The ISA process is applied to existing designs to identify risk insights on those areas that warrant additional preventive or mitigative measures. For new facilities, the proposed rule would require the performance of the ISA before construction [see the existing §70.21(f) and §70.23(a)(7)], and the updating of the ISA before beginning operations. For new processes and facilities, the Commission recognizes that good engineering practice dictates that certain minimum requirements be applied as design and safety considerations for any new nuclear process or facility. In addition, a fundamental element of NRC's safety philosophy is that designs and operations should provide for defense-in-depth protection against accidents. Therefore, the Commission has specified baseline design criteria in §70.64 that are similar in use to the general design criteria in Part 50 Appendix A; Part 72, Subpart F; and 10 CFR 60.131. The baseline design criteria identify 10 initial safety design considerations, including: a) quality standards and records; b) natural phenomena hazards; c) fire protection; d) environmental and dynamic effects[2]; f) chemical protection; g) emergency capability; h) utility services; i) inspection, testing, and maintenance; j) criticality control; and k) instrumentation and controls. The baseline design criteria do not provide relief from compliance with the safety performance requirements of §70.61. The baseline design criteria are generally an acceptable set of initial design safety considerations, which may not be sufficient to ensure adequate safety for all new processes and facilities. The ISA process is intended to identify additional safety features that may be needed. On the other hand, the Commission recognizes that there may be processes or facilities for which some of the baseline design criteria may not be necessary or appropriate, based on the results of the ISA. For these processes and facilities, any design features that are inconsistent with the baseline design criteria should be identified and justified.

Using the baseline design criteria and considering defense-in-depth practices in the design should result in a new facility design that is based on providing successive levels of protection

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

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

Section 70.65 Additional content of applications.

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

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

The plant and process descriptions, ISA team qualifications and methods, and definitions of terms used in the ISA, are all needed to fully understand the facility and the ISA and how it was developed. Although some of the facility information is also requested in §70.22, there may be information about the facility which would be too detailed for inclusion in the general site description, but would be needed to be included here to understand the ISA and ISA results. The demonstration of how the licensee meets §§70.24, 70.61, and 70.64 is a critical element in determining whether the applicant understands and complies with the regulations and can operate the facility safely. Another critical element is the applicant's identification of the items relied on for safety. Through the ISA process, the applicant should have identified potential accidents that can occur in individual processes and in the facility as a whole. As discussed earlier, these accidents are prevented or their consequences mitigated using controls that are identified in the ISA summary as items relied on for safety. It is important for NRC staff to review the items relied on

for safety, that were identified as such by the applicant or licensee, to determine whether potential accidents are adequately prevented or mitigated. Since items relied on for safety play a key role in assuring that the performance requirements are met, and because the applicant has great flexibility in selecting and identifying what the actual "items" are (as discussed in relation to §70.61), the items relied on for safety would be clearly and unambiguously identified on a list. This list of items is then managed and controlled by the applicant through the management measures in §70.61 to ensure that they continue to perform the safety function required. By evaluating the ISA methodology, and the ISA summary, supplemented by reviewing the ISA and other information, as needed, at the licensee's facility, the staff can better understand the potential hazards at the facility, how the applicant plans to address these hazards, and thereby have confidence in the safety basis on which the license will be issued.

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

Section 70.66 Additional requirements for the approval of license applications.

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

Section 70.72 Facility changes and change process.

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

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

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

The advantages of Option 1 are that it focuses on the most significant changes to the facility and is equivalent to looking at the highest risk changes. It contains very little subjective criteria and is therefore easier to implement and inspect. It also would likely only result in a few license amendments a year which is generally consistent with the past practice at these facilities. Since Option 1 would permit more changes without NRC pre-approval, a relatively short timeframe (90 days) for submitting updated ISA summary pages is required in order for NRC to have information that reflects the current status of the facility and to be confident that adequate protection is still provided with the changes, as reflected in the ISA summary. The advantages of

Option 2 are that NRC would have more control over the changes at the facilities, i.e., staff expects that more changes would be reviewed by the staff before being implemented; thus, it would be less likely that NRC would have a concern with a change after the fact; and it is consistent with the change control process at power reactors, where changes are reported only after 12 months.

The proposed rule language reflects Option 1.

Section 70.73 Renewal of licenses.

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

Section 70.74 Additional reporting requirements.

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

Appendix A Reportable Events.

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

Licensee reporting of events would consist of two reporting classes based on the hazard -- reports that must be made in 1 hour and those to be reported within 24 hours. According to this approach, licensees would report events based on two criteria: 1) whether actual consequences have occurred or whether a potential for such consequences exists; and 2) the seriousness of the consequences. The events that must be reported within the shortest timeframe (1 hour) are high-consequence events. These events encompass unintended criticalities and loss of criticality controls, and loss of chemical controls or the occurrence of chemical exposures that exceed the performance requirements in §70.61(b).

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

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

that is not identified in the ISA. This condition could be caused by a deviation from established safe operating conditions, by an unanticipated and unanalyzed set of circumstances, or by an improper analysis. This type of event would be reported within 24 hours.

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

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

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

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

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

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

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

Copies of the following draft regulatory guidance documents may be requested by writing to U.S. Nuclear Regulatory Commission, Reproduction and Distribution Services, Washington, DC 20555-0001: “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility” (Draft NUREG-1520); and “Integrated Safety Analysis Guidance Document” (Draft NUREG-1513).

Finding of No Significant Environmental Impact: Availability

The Commission has determined, under the National Environmental Policy Act of 1969, as amended, and the Commission’s regulations in Subpart A of 10 CFR Part 51, that this rule, if

adopted, would not be a major Federal action significantly affecting the quality of the human environment, and therefore an environmental impact statement is not required.

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

The determination of this Environmental Assessment is that there will be no significant offsite impact on the public from this action. However, the general public should note that NRC welcomes public participation. NRC has also committed to complying with Executive Order (EO) 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," dated February 11, 1994, in all its actions. Therefore, NRC has also determined that there are no disproportionate, high, and adverse impacts on minority and low-income populations. In the letter and spirit of EO 12898, NRC is requesting public comment on any environmental justice considerations or questions that the public thinks may be related to this proposed rule, but somehow were not addressed. Comments on any aspect of the Environmental

Assessment, including environmental justice, may be submitted to NRC, as indicated under the ADDRESSES heading.

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

Paperwork Reduction Act Statement

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

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

1. Is the proposed information collection necessary for the proper performance of NRC's function? Will the information have practical utility?
2. Is the burden estimate accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

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

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

Public Protection Notification

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

Regulatory Analysis

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

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

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act, as amended, 5 U.S.C. 605(b), the Commission certifies that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. This proposed rule would affect facilities that are authorized to possess a critical mass of SNM and who are engaged in one of the following activities: a) enriched uranium processing; b) fabrication of uranium fuel or fuel assemblies; c) uranium enrichment; d) enriched uranium hexafluoride conversion; e) plutonium processing; f) fabrication of mixed-oxide fuel or fuel assemblies; g) scrap recovery of special nuclear material; or h) any other activity involving a critical mass of SNM that the Commission determines could

significantly affect public health and safety or the environment. These licensees do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act, nor the size standards published by NRC (10 CFR 2.810).

Voluntary Consensus Standards

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

Backfit Analysis

NRC has determined that the backfit rule does not apply to this proposed rule; therefore, a backfit analysis is not required for this proposed rule because these amendments do not involve any provisions that would impose backfits as defined in 10 CFR Chapter I.

List of Subjects in 10 CFR Part 70

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

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

Part 70 -- DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

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

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

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

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

3. In §70.4, the definitions of Acute, Available and reliable to perform their function when needed, Configuration Management, Critical mass of special nuclear material, Double contingency, Hazardous chemicals produced from licensed material, Integrated safety analysis (ISA), Integrated safety analysis summary, Items relied on for safety, Management measures, Unacceptable performance deficiencies, and Worker are added, in alphabetical order, as follows:

§70.4 Definitions.

* * * * *

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

* * * * *

Available and reliable to perform their function when needed as used in Subpart H of this Part means that, based upon the analyzed, credible conditions in the integrated safety analysis, items

relied on for safety will perform their intended safety function when needed and management measures will be implemented that ensure continuous compliance with the performance requirements of §70.61 of this Part, considering factors such as necessary maintenance, operating limits, common cause failures, and the likelihood and consequences of failure or degradation of the items and measures.

* * * * *

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

* * * * *

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

* * * * *

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

* * * * *

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

Integrated safety analysis (ISA) means a systematic analysis to identify plant and external hazards and their potential for initiating accident sequences, the potential accident sequences, their likelihood and consequences, and the items relied on for safety. As used here, *integrated* means joint consideration of, and protection from, all relevant hazards, including radiological, nuclear criticality, fire, and chemical. However, with respect to compliance with the regulations of this Part, the NRC

requirement is limited to consideration of the effects of all relevant hazards on radiological safety, prevention of nuclear criticality accidents, or chemical hazards directly associated with NRC licensed radioactive material.

Integrated safety analysis summary means the document submitted with the license application, license amendment application, or license renewal application that provides a synopsis of the results of the integrated safety analysis and contains the information specified in §70.65(b).

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

* * * * *

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

* * * * *

Unacceptable performance deficiencies mean deficiencies in the items relied on for safety or the management measures that need to be corrected to ensure an adequate level of protection as defined in 10 CFR 70.61(b), (c), or (d).

* * * * *

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

4. In §70.8 paragraph (b) is revised to read as follows.

§70.8 Information collection requirements: OMB approval.

* * * * *

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

* * * * *

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

§§ 70.13a and 70.14 [Redesignated]

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

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

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

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

10. The undesignated center heading "ACQUISITION, USE AND TRANSFER OF SPECIAL NUCLEAR MATERIAL, CREDITORS' RIGHTS," is redesignated as "Subpart F -- Acquisition, Use, and Transfer of Special Nuclear Material, Creditors' Rights."

11. The undesignated center heading "SPECIAL NUCLEAR MATERIAL CONTROL RECORDS, REPORTS AND INSPECTIONS" is redesignated as "Subpart G -- Special Nuclear Material Control Records, Reports, and Inspections."

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

§70.50 Reporting Requirements

* * * *

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

(1) Licensees shall make reports required by paragraphs (a) and (b) of this section, and by section 70.74 and Appendix A of this Part if applicable, by telephone to the NRC Operations Center[3]. To the extent that the information is available at the time of notification, the information provided in these reports must include:

(i) Caller's name, position title and call back telephone number;

(ii) Date, time, and exact location of the event;

(iii) Description of the event, including;

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

(B) 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 to radiation or radioactive materials or chemicals (e.g., level of radiation exposure, concentration of chemicals, and duration of exposure);

(C) The sequence of occurrences leading to the event, including degradation or failure of structures, systems, equipment, components, and activities of personnel relied on to prevent potential accidents or mitigate their consequences; and

(D) Whether the remaining structures, systems, equipment, components, and activities of personnel relied on to prevent potential accidents or mitigate their consequences are available and reliable to perform their function.

(iv) External conditions affecting the event;

(v) Additional actions taken by the licensee in response to the event;

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

(vii) Current and planned site status, including any declared emergency class;

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

(ix) Status of any press releases related to the event that were made or are planned.

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[3] The commercial telephone number for the NRC Operations Center is (301) 816-5100.

(2) Written report. Each licensee who makes a report required by paragraph (a) or (b) of this section, or by §70.74 and Appendix A of this Part if applicable, shall submit a written follow-up report within 30 days of the initial report. Written reports prepared pursuant to other regulations may be submitted to fulfill this requirement if the report contains all of the necessary information and the appropriate distribution is made. These written reports must be sent to the U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, DC 20555, with a copy to the appropriate NRC regional office listed in Appendix D of 10 CFR Part 20. The reports must include the following:

(i) Complete applicable information required by §70.50(c)(1);

(ii) The probable cause of the event, including all factors that contributed to the event and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

(iii) Corrective actions taken or planned to prevent occurrence of similar or identical events in the future and the results of any evaluations or assessments; and

(iv) For licensees subject to Subpart H of this Part, whether the event was identified and evaluated in the Integrated Safety Analysis.

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

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

§§ 70.61 and 70.62 [Redesignated]

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

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

§§ 70.71 and 70.72 [Redesignated]

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

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

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

Sec.

§70.60 Applicability.

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

§70.61Performance Requirements.

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

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

(1) An acute worker dose of 1 Sv (100 rem) or greater total effective dose equivalent;

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

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

(4) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that:

(i) Could endanger the life of a worker, or

(ii) Could lead to irreversible or other serious, long-lasting health effects to any individual located outside the controlled area identified pursuant to paragraph (f) of this section. If an applicant possesses or plans to possess quantities of material capable of such chemical exposures, then the applicant shall propose appropriate quantitative standards for these health effects, as part of the information submitted pursuant to §70.65 of this Part.

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

(1) An acute worker dose of 0.25 Sv (25 rem) or greater total effective dose equivalent;

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

(3) A 24-hour averaged release of radioactive material outside the restricted area in concentrations exceeding 5000 times the values in Table 2 of Appendix B to 10 CFR Part 20; or

(4) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that:

(i) Could lead to irreversible or other serious, long-lasting health effects to a worker, or

(ii) Could cause mild transient health effects to any individual located outside the controlled area as specified in paragraph (f) of this section. If an applicant possesses or plans to possess quantities of material capable of such chemical exposures, then the applicant shall propose appropriate quantitative standards for these health effects, as part of the information submitted pursuant to §70.65 of this Part.

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

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

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

(1) Demonstrates and documents, in the integrated safety analysis, that the risk for those individuals at the location of their activities does not exceed the performance requirements of paragraphs (b)(2), (b)(3), (b)(4)(ii), (c)(2), and (c)(4)(ii) of this section; or

(2) Provides: (i) Training in accordance with 10 CFR 19.12(a)(1)-(5) to these individuals to ensure that they are aware of the risks associated with accidents involving the licensed activities as determined by the integrated safety analysis, and (ii) Conspicuously posts and maintains notices stating where the information in 10 CFR 19.11(a) may be examined by these individuals. Under these conditions, the performance requirements for workers specified in paragraphs (b) and (c) of this section may be applied to these individuals.

§70.62 Safety Program and Integrated Safety Analysis

(a) *Safety program.* (1) Each licensee shall establish and maintain a safety program that demonstrates compliance with the performance requirements of §70.61. The safety program may be graded such that management measures applied are commensurate with the reduction of the risk attributable to that item. The three elements of the safety program, namely process safety information, integrated safety analysis, and management measures, are described in paragraphs (b) through (d) of this section.

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

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

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

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

(i) Radiological hazards related to possessing or processing licensed material at its facility;

(ii) Chemical hazards of licensed material and hazardous chemicals produced from licensed material;

(iii) Facility hazards which could affect the safety of licensed materials and thus present an increased radiological risk;

(iv) Potential accident sequences caused by process deviations or other events internal to the plant and credible external events, including natural phenomena;

(v) The consequence and the likelihood of occurrence of each potential accident sequence identified pursuant to paragraph (c)(1)(iv) of this section, and the methods used to determine the consequences and likelihoods; and

(vi) Each item relied on for safety identified pursuant to §70.61(e) of this Part, the characteristics of its preventive, mitigative, or other safety function, and the assumptions and conditions under which the item is relied upon to support compliance with the performance requirements of §70.61 .

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

(3) *Requirements for existing licensees.* Notwithstanding other provisions regarding the effective date for Part 70 Subpart H requirements, licensees shall comply with the provisions in paragraphs (c)(3)(i), (ii), and (iii) of this section beginning on <the date of publication of the final rule>. Individuals holding an NRC license on <the date of publication of the final rule> shall, with regard to existing licensed activities:

(i) Within 6 months of <the date of publication of the final rule>, submit for NRC approval, a plan that describes the integrated safety analysis approach that will be used, the processes that will be analyzed, and the schedule for completing the analysis of each process.

(ii) Within 4 years of <the date of publication of the final rule>, complete an integrated safety analysis, correct all unacceptable performance deficiencies, and submit an integrated safety analysis summary in accordance with §70.65 or the approved plan submitted under paragraph (c)(3)(i) of this section.

(iii) Pending the correction of unacceptable performance deficiencies identified during the conduct of the integrated safety analysis, the licensee shall implement appropriate compensatory measures to ensure adequate protection.

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

§70.64 Requirements for new facilities or new processes at existing facilities.

(a) *Baseline design criteria.* Each prospective applicant or licensee shall address the following baseline design criteria in the design of new facilities. Each existing licensee shall address the following baseline design criteria in the design of new processes at existing facilities that require a license amendment under §70.72. The baseline design criteria must be applied to the design of new facilities and new processes, but do not require retrofits to existing facilities or existing processes (e.g., those housing or adjacent to the new process); however, all facilities and processes must comply with the performance requirements in §70.61. Licensees shall maintain the application of these criteria unless the evaluation performed pursuant to paragraph (c) of this section demonstrates that a given item is not relied on for safety or does not require adherence to the specified criteria.

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

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

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

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

(5) Chemical protection. The design must provide for adequate protection against chemical risks produced from licensed material, plant conditions which affect the safety of licensed material, and hazardous chemicals produced from licensed material.

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

(i) Licensed material;

(ii) Evacuation of personnel; and

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

(7) Utility services. The design must provide for continued operation of essential utility services.

(8) Inspection, testing, and maintenance. The design of items relied on for safety must provide for adequate inspection, testing, and maintenance, to ensure their availability and reliability to perform their function when needed.

(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[4]. The design process must incorporate, to the extent practicable:

(1) Preference for the selection of engineered controls over administrative controls to increase overall system reliability; and

(2) Features that enhance safety by reducing challenges to items relied on for safety.

§70.65 Additional content of applications.

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[4] As used in §70.64, defense-in-depth practices means a design philosophy, applied from the outset and through completion of the design, that is based on providing successive levels of protection such that health and safety will not be wholly dependent upon any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating defense-in-depth practices is a conservatively designed facility and system that will exhibit greater tolerance to failures and external challenges. The risk insights obtained through performance of the integrated safety analysis can be then used to supplement the final design by focusing attention on the prevention and mitigation of the higher-risk potential accidents.

(a) In addition to the contents required by §70.22, each application must include a description of the applicant's safety program established under §70.62, including the integrated safety analysis summary and a description of the management measures.

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

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

(2) A general description of the facility with emphasis on those areas that could affect safety, including an identification of the controlled area boundaries;

(3) A description of each process (defined as a single reasonably simple integrated unit operation within an overall production line) analyzed in the integrated safety analysis in sufficient detail to understand the theory of operation; and, for each process, the hazards that were identified in the integrated safety analysis pursuant to §70.62(c)(1)(i)-(iii) and a general description of the types of accident sequences;

(4) Information that demonstrates the licensee's compliance with the performance requirements of §70.61; the requirements for criticality monitoring and alarms in §70.24; and, if applicable, the requirements of §70.64;

(5) A description of the team, qualifications, and the methods used to perform the integrated safety analysis;

(6) A list briefly describing all items relied on for safety which are identified pursuant to §70.61(e) in sufficient detail to understand their functions in relation to the performance requirements of §70.61;

(7) A description of the proposed quantitative standards used to assess the consequences from acute chemical exposure to licensed material or chemicals produced from licensed materials which are on-site, or expected to be on-site as described in §70.61(b)(4) and (c)(4);

(8) A descriptive list that identifies all items relied on for safety that are the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of §70.61; and

(9) A description of the definitions of likely, unlikely, highly unlikely, and credible as used in the evaluations in the integrated safety analysis.

§70.66 Additional requirements for approval of license application.

An application for a license from an applicant subject to Subpart H will be approved if the Commission determines that the applicant has complied with the requirements of §70.21, §70.22, §70.23 and §70.60 through §70.65.

§ 70.72 Facility changes and change process.

(a) The licensee shall establish a configuration management system to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel. This system must be documented in written procedures and must assure that the following are addressed prior to implementing any change:

(1) The technical basis for the change;

(2) Impact of the change on safety and health or control of licensed material;

(3) Modifications to existing operating procedures including any necessary training or retraining before operation;

(4) Authorization requirements for the change;

(5) For temporary changes, the approved duration (e.g., expiration date) of the change; and

(6) The impacts or modifications to the integrated safety analysis, integrated safety analysis summary, or other safety program information, developed in accordance with §70.62.

(b) Any change to site, structures, processes, systems, equipment, components, computer programs, and activities of personnel must be evaluated by the licensee as specified in paragraph (a) of this section, before the change is implemented. The evaluation of the change must determine, before the change is implemented, if an amendment to the license is required to be submitted in accordance with §70.34.

(c) The licensee may make changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, without prior Commission approval, if the change:

(1) does not:

(i) Create new types[5] of accident sequences that, unless mitigated or prevented, would exceed the performance requirements of §70.61 and that have not previously been described in the integrated safety analysis summary; or

(ii) Use new processes, technologies, or control systems for which the licensee has no prior experience;

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

(3) Does not alter any item relied on for safety, listed in the integrated safety analysis summary, that is the sole item preventing or mitigating an accident sequence that exceeds the performance requirements of §70.61; and

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

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

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

(3) A brief summary of all changes to the records required by §70.62(a)(2) of this Part, that are made without prior Commission approval, must be submitted to NRC every 12 months.

(e) If a change covered by §70.72 is made, the affected on-site documentation must be updated promptly.

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

[5] Any change in the defining characteristics of the elements of an accident sequence may change the “type” of the accident sequence for a given process. For example, a new type of accident could involve a different initiator, significant changes in the consequence, or a change in the safety function of a control (e.g., temperature limiting device versus a flow limiting device).

§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 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 Appendix A 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 for reporting.

(3) The information provided must include a description of the event and other related information as described in §70.50(c)(1)

(4) Follow-up information to the reports must be provided until all information required to be reported in §70.50(c)(1) of this Part is complete.

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

(b) *Written Reports*. Each licensee who makes a report required by paragraph (a)(1) of this section shall submit a written follow-up report within 30 days of the initial report. The written report must contain the information as described in §70.50(c)(2).

Appendix A to Part 70 – Reportable Safety Events

As required by 10 CFR 70.74, licensees subject to the requirements in Subpart H of Part 70, shall report:

(a) *One hour reports.* Events to be reported to the NRC Operations Center within 1 hour of discovery, supplemented with the information in 10 CFR 70.50(c)(1) as it becomes available, followed by a written report within 30 days:

(1) An inadvertent nuclear criticality.

(2) An acute intake by an individual of 30 mg or greater of uranium in a soluble form.

(3) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that exceeds the quantitative standards established to satisfy the requirements in §70.61(b)(4).

(4) An event or condition such that no items relied on for safety, as documented in the Integrated Safety Analysis summary, remain available and reliable, in an accident sequence evaluated in the Integrated Safety Analysis, to perform their function:

(i) In the context of the performance requirements in §70.61(b) and §70.61(c), or

(ii) Prevent a nuclear criticality accident (i.e., loss of all controls in a particular sequence).

(5) Loss of controls such that only one item relied on for safety, as documented in the Integrated Safety Analysis summary, remains available and reliable to prevent a nuclear criticality accident, and has been in this state for greater than eight hours.

(b) *Twenty-four hour reports.* Events to be reported to the NRC Operations Center within 24 hours of discovery, supplemented with the information in 10 CFR 70.50(c)(1) as it becomes available, followed by a written report within 30 days:

(1) Any event or condition that results in the facility being in a state that was not analyzed, was improperly analyzed, or is different from that analyzed in the Integrated Safety Analysis, and which results in failure to meet the performance requirements of §70.61.

(2) Loss or degradation of items relied on for safety that results in failure to meet the performance requirement of §70.61.

(3) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed materials that exceeds the quantitative standards that satisfy the requirements of §70.61(c)(4).

(4) Any natural phenomenon or other external event, including fires internal and external to the facility, that has affected or may have affected the intended safety function or availability or reliability of one or more items relied on for safety.

(5) An occurrence of an event or process deviation that was considered in the Integrated Safety Analysis and:

(i) Was dismissed due to its likelihood; or

(ii) Was categorized as unlikely and whose associated unmitigated consequences would have exceeded those in §70.61(b) had the item(s) relied on for safety not performed their safety function(s).

(c) *Concurrent Reports.* Any event or situation, related to the health and safety of the public or onsite personnel, or protection of the environment, for which a news release is planned or notification to other government agencies has been or will be made, shall be reported to the NRC Operations Center concurrent to the news release or other notification.

Dated at Rockville, Maryland, this ___ day of _____, 1999.

For the Nuclear Regulatory Commission.

_____

Annette Vietti-Cook,

Secretary of the Commission.

DISPOSITION OF STAFF REQUIREMENTS MEMORANDUM (SRM) ISSUES

In response to SECY-98-185, the Commission issued a Staff Requirements Memorandum (SRM), dated December 1, 1998, that directed the staff to obtain stakeholder input and revise the draft proposed 10 CFR Part 70 rule revisions while considering the input received, and according to Commission direction. In that SRM, the Commission directed the staff to: (1) decide what is fundamental, for NRC's regulatory purposes, for inclusion as part of the license or docket, and what can be justified from a public health and safety and cost-benefit basis, and assure that Part 70 captures, for submittal, those few significant changes that currently would require license amendments; (2) require licensees/applicants to address baseline design criteria and develop a preliminary integrated safety analysis (ISA) for new processes and new facilities; (3) justify, on a health and safety or cost-benefit basis, any requirement to conduct a decommissioning ISA; (4) require that any new backfit pass a cost-benefit test, without the "substantial" increase-in-safety test; (5) require the reporting of certain significant events because of their potential to impact worker or public health and safety; (6) clarify the basis for use of chemical safety and chemical consequence criteria, particularly within the context of the Memoranda of Understanding with the Occupational Safety and Health Administration and other Government agencies; (7) critically review the Standard Review Plan (SRP) to ensure that by providing specific acceptance criteria, it does not inadvertently prevent licensees or applicants from suggesting alternate means of demonstrating compliance with the rule; and (8) request input on how applicable ISA methodologies should be employed in the licensing of new technologies for use within new or existing facilities.

The following discussion describes how the staff incorporated the Commission direction.

Issue 1(a): ISA Summary in the License

A. Contents of SECY-98-185

In SECY-98-185 the staff proposed that the results or summary of the ISA be submitted along with the license application and that this information would be considered part of the license. This was stated in 10 CFR 70.65, which addressed the additional information that is required to be submitted with the license application, to comply with the new proposed subpart. One of the reasons for including the ISA summary as part of the license was to control, and to keep NRC informed of, future changes to the document.

B. Commission Direction in SRM to SECY-98-185

The Commission, in an SRM to SECY-98-185, directed the staff as follows:

"The Commission agrees that Part 70 should require licensees to perform, document, maintain, and update an Integrated Safety Analysis (ISA)." " The Commission was not persuaded that it is necessary for the results of the ISA to be included in the license and is concerned that such a requirement would bring with it the need for what appears to be an unworkable 10CFR 50.59-like change process.

C. Comments received during public interaction on draft rule language

During the December 3-4, 1998 public meeting, the Nuclear Energy Institute (NEI) stated its continued concern that placing the ISA summary in the license would create numerous and unnecessary license amendments. In a follow-up letter dated December 22, 1998, NEI stated that it concurred with the Commission that licensees should be required to perform, document, maintain, and update an ISA; however NEI does not believe the ISA summary should be in the license. It stated:

> "This requirement would create an unnecessary administrative burden in managing commercially sensitive documents, would drastically increase the number of requests for license amendments(via a 10 CFR 50.59-like change process), would require appreciable administrative support and would force both the NRC and licensee to allocate significant resources away from safety at the facilities."

D. Staff response to SRM and disposition of comments

In response to these concerns the staff has removed the requirement for the ISA summary to be included as part of the license. The summary is required to be submitted in conjunction with the license application but will be maintained on the docket. Since the document is not contained in the license, an amendment is not required before a change for those changes that are permitted by 10 CFR 70.72(c).

Issue 1(b): 10 CFR 70.72 Change Process

A. Contents of SECY-98-185

In SECY-98-185 the staff proposed a modified 10 CFR 50.59-type change process. Section 70.72 stated

> A licensee may make changes 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 a potential for an accident different from any previously evaluated in the ISA; and
> 3) Is not inconsistent with NRC requirements and license conditions.

B. Commission Direction in SRM to SECY-98-185

The Commission, in an SRM to SECY-98-185, directed the staff as follows:

"With regard to changes to the ISA or safety program, Part 70 does need to capture for submittal those few significant changes that currently would require license amendments. The staff should decide what is fundamental for NRC's regulatory purposes for inclusion as part of a license or docket and what can be justified from a public health and safety and cost-benefit basis."

C. Comments received during public interaction on draft rule language

NEI has commented that the proposed change process in SECY-98-185 would require too many amendments and would require NRC pre-approval for small changes that industry is currently allowed to make without pre-approval.

In a letter dated January 26, 1999, NEI stated that the change mechanism should be structured "...to limit the number of change (and license amendment) requests to the NRC to those that are risk-

significant..." and "...(it) should be risk-informed and be consistent with current practices in the regulation of fuel cycle facilities."

In addition, NEI also stated in that letter:

> "NEI is concerned, however, that the proposed 70.72 change mechanism may prove difficult to implement. The inherently qualitative nature of the ISA used to establish whether or not NRC pre-approval is needed for a change makes assessment of what constitutes '...a minimal increase...' a highly subjective call".

D. Staff response to SRM and disposition of comments

In response to these concerns the staff has revised the change process as reflected in Section 70.72. The staff reviewed all license amendment requests that NRC has received for Part 70 licensees over the past 3 years. In addition, the Task Force determined that only substantial changes to the facilities required license amendments in the past for fuel cycle licensees, such as the creation and use of a new process at a facility (i.e., downblending, or increased enrichment). This section was then revised to place the threshold for pre-approval of changes at a level consistent with past practice. In addition the subjective "more than minimal" words were removed and specific situations where pre-approval would be required were added. This section was also modified to tie-back to the information submitted as part of the ISA summary. This helps remove the subjective nature of the determination of pre-approval, and made it clear which information should be considered when making this determination.

Issue 2(a): Baseline Design Criteria (BDC)

A. Contents of SECY-98-185

In SECY-98-185, 10 CFR 70.64, the staff proposed that a set of 10 BDC be applied to new facilities and to new processes at existing facilities. These BDC represent design principles that were to be applied from the outset of the design activity (i.e., before obtaining risk information through the performance of the ISA or preliminary ISA). The draft statement of considerations for SECY-98-185 explained the purpose of the BDC requirements:

> . . . 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 10 CFR 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; chemical protection; emergency capability; utility services; inspection, testing, and maintenance; criticality control; and instrumentation and controls. The baseline design criteria do not provide relief from compliance with the safety performance requirements of [then] 10 CFR 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.

B. Commission Direction in SRM to SECY-98-185

The Commission, in the SRM to SECY-98-185, directed the staff as follows:

> "Part 70 should also require licensees/ applicants to address baseline design criteria . . . for new processes and new facilities."

C. Comments received during public interaction on draft rule language

NEI provided two separate written comments on this issue during the period of public interaction on the staff's draft requirements. NEI's second set of comments was a change in position from the first. In addition, one existing Part 70 licensee submitted comments in this area through the World Wide Web discussion forum. Each of the comments is described below.

In a January 26, 1999, letter, NEI commented on the BDC requirement in SECY-98-185:

> ". . . the December 1, 1998 Staff Requirements Memorandum (SRM) for SECY-98-185 supports the need for a license applicant to *address* baseline criteria in the design of a new facility or process. NEI recommends that this requirement remain in the proposed Part 70 revisions, but that it not apply to existing licensees."

The basis provided for this recommendation and the added emphasis on the word *address* was given by NEI as:

> . . . a properly executed ISA will have already addressed baseline design criteria and other factors to protect against undesirable consequences in a risk-informed manner. There is, therefore, no need for a current licensee to address or adhere to the baseline design criteria of §70.74 [sic; §70.64 intended]. The license commitment to perform, implement, update, and maintain an ISA is a broad licensing basis which encompasses, by reference, stringent baseline design criteria. NEI further believes that changes to an existing facility (e.g., process technology) should not be subject to the §70.64 baseline design criteria.

In a second set of written comments provided March 26, 1999, NEI commented on the staff's revised rule language that was posted on the World Wide Web on March 1, 1999. These NEI recommendations represented changes in position from the earlier NEI comments. NEI no longer objected to the application of BDC to existing licensees, subject to limitation and clarification:

> The baseline design criteria (BDC) should be clarified to state that BDC should not be backfitted onto existing facilities or processes, even if the new process is housed in an existing building or is adjacent to an existing process. Unless a licensee proposes a change that lies outside a facility's licensing basis, the licensee should not be subject to the provisions of §70.64. For new processes at existing facilities NEI has modified §70.64 to state that the BDC would only apply if implementation of the new process would require a license amendment under §70.72.

NEI provided suggested rewording for 10 CFR 70.64(a) and also for 10 CFR 70.64(b), regarding a design preference for the selection of engineered controls over administrative controls. NEI also: (1) recommended deletion of the definition "new process at existing facility"; (2) commented that the regulation should not mandate that licensees identify a "defense-in-depth" strategy or incorporate "defense-in-depth" design principles for new facilities and new processes at existing facilities; and (3) recommended that the BDC on instrumentation and controls should be incorporated into the BDC for inspection, testing, and maintenance (under a new name, "monitoring, inspection, testing, and maintenance"). NEI stated that "defense-in-depth" was appropriate for inclusion as guidance, but was not appropriate for rule language.

The only other comment related to BDC was submitted by a Part 70 licensee on the World Wide Web site discussion forum. The comment took issue with the draft definition posted by the staff -- New Processes at Existing Facilities -- stating that one reasonable interpretation of the definition would result in many more changes requiring application of BDC, and NRC preapproval of the new process, than the staff likely intended.

D. Staff response to SRM and disposition of comments

The new rule language continues to apply BDC to new facilities and new processes at existing facilities. The staff believes that the clarifications that have been made to the draft rule text related to BDC are consistent with the Commission's direction provided in the SRM and will partially address NEI's and industry's concerns in this area. An exception is that, contrary to the NEI comment, the rule continues to require that the design process incorporate defense-in-depth practices in the design of new facilities and processes.

The staff generally agrees with the approach recommended in NEI's comments submitted on March 26, 1999. In summary, NEI's suggested approach requires application of the BDC to new processes at existing facilities if the new processes would require a license amendment under the 10 CFR 70.72 (i.e, "§50.59-like") facility change process -- changes under 10 CFR 70.72 that are not new processes (e.g., component-level changes) would not be subject to the BDC. The staff agrees with an NEI comment that the definition of "new processes at existing facilities" is unnecessary in 10 CFR 70.4, because the term is adequately described in section 10 CFR 70.64. The staff did not agree with NEI's previous recommendation to, in effect, only apply BDC to new licensees.

The staff believes the BDC are consistent with risk-informed regulation, in that, for new processes or new facilities, NRC would recognize that, because of factors such as limited operating experience, good engineering practice dictates that certain minimum requirements be applied as design and safety principles, generally independent of the risk-informed information that will be ultimately obtained and incorporated through the ISA. Note that the draft rule would allow for later incorporation of risk information, obtained through the ISA, that suggests that some BDC do not apply, or that alternative or additional BDC are appropriate for the specific process being analyzed.

The staff has clarified the BDC rule language in response to NEI's concern that application of BDC to "new processes" should not result in the need for retrofits to existing facilities/processes, even if the new process is housed in an existing building or is adjacent to an existing process. The staff agrees that the BDC are intended to apply only to the new process or new facility, and should not be construed to require retrofitting of existing facilities. However, every process or facility would need to comply with the performance requirements of 10 CFR 70.61.

The staff does not agree with NEI's recommendation to delete the requirements that, for newly-designed facilities and processes, "facility and system design and plant layout must be based on

defense-in-depth practices." To clarify this issue, the staff added a footnote to section 10 CFR 70.64(b) that discusses the relevance and use of the term "defense-in-depth." The staff agrees with NEI's comments regarding preference of engineered controls over administrative controls (to increase reliability). Words similar to those proposed by NEI were incorporated, in lieu of the SECY-98-185 language, which expressed preference for "passive systems" over "active systems." This language also helps clarify the meaning of "defense-in-depth."

The staff also does not agree with NEI's recommendation to delete BDC number 10, "Instrumentation and Control Systems." NEI's comments of March 26 stated that this BDC should be incorporated into the BDC for "Inspection, Testing, and Maintenance" (under a new name, "Monitoring, Inspection, Testing, and Maintenance"). The staff prefers a separate BDC for instrumentation and control systems, to be consistent with other Commission regulations (e.g., 10 CFR 60.131), and because the term "monitoring" as used in the NEI-suggested changes connotes "instrumentation," but not necessarily "controls."

Issue 2b: Preliminary ISA

A. Contents of SECY-98-185

In SECY-98-185, 10 CFR 70.62(a)(3) of the staff's proposed language required each applicant for a new facility or new process at an existing facility to perform a preliminary ISA and submit the results to NRC before construction of the facility or process. The preliminary ISA was to be submitted, but NRC approval was not required. The preliminary ISA would include facility and process description and design information that demonstrates the applicant's incorporation of criticality monitoring and alarm requirements in 10 CFR 70.24, the BDCs in 10 CFR 70.64, and the performance requirements. The preliminary ISA would also describe any proposed relaxation in the application of the BDC. The statement of considerations explained the preliminary ISA requirements:

> Based on [the new process' or new facility's] 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.

B. Commission Direction in SRM to SECY-98-185

The Commission, in the SRM to SECY-98-185, directed the staff as follows:

> "Part 70 should also require licensees/ applicants to . . . develop preliminary ISA for new processes and new facilities."

C. Comments received during public interaction on draft rule language

NEI provided two separate written comments on preliminary ISA during the period of public interaction on the staff's draft requirements. NEI's second set of comments was a change in position from the first. In addition, one existing Part 70 licensee submitted comments in this area through the World Wide Web discussion forum. Each of the comments is described below.

At first, in a December 22, 1998, letter, NEI expressed support of performance and submittal (for NRC review, but not approval) of the preliminary ISA. NEI noted that the preliminary ISA is a concept that is consistent with industry's current practice and the concepts supported by the American Institute of Chemical Engineering (AIChE), under the name "Process Hazards Analysis (PHA)." Therefore, NEI recommended a change to the term, *preliminary process hazards analysis* (PHA) throughout the proposed Part 70 revisions and suggested a definition of preliminary PHA be included in Section 70.4 of the rule. NEI remarked:

> A license applicant would submit a preliminary PHA to the NRC at the conceptual engineering phase of the project. NRC could use the preliminary PHA for informational purposes, acknowledging that the process or facility design may undergo several refinements and redesigns prior to its eventual construction and commissioning. Based on the results of the submitted, preliminary PHA, the NRC would communicate to the applicant any concerns (e.g. over the proposed design or engineering methodology, inadequate compliance with current baseline design criteria, etc.) and recommendations for improvement.

In a second written comment provided March 26, 1999, NEI commented on the staff's revised rule language that was posted on the World Wide Web on March 1, 1999. This version of the draft rule clarified the function (which remained consistent with that in SECY-98-185) of the preliminary PHA and its relationship to the ISA. The new NEI recommendation was for deletion of the definition *preliminary process hazard analysis*, and a change in terminology from *preliminary process hazard*

analysis to *preliminary process hazard evaluation*. NEI further recommended that submittal of the *preliminary process hazard analysis* to NRC not be required:

> The requirement to prepare a preliminary process hazards evaluation (§70.64(c)) for new facilities or processes appears open-ended. The Rule specifies neither how the preliminary process hazards evaluation is to be used in the licensing process nor what response the NRC is to provide to the license applicant upon receipt and review of the submitted information. Applicants for Part 70 licenses have traditionally discussed proposed projects or facility changes with the NRC. The NRC has always supported this prudent and open exchange of information and industry will continue this approach in the future. NEI does not see a need to codify in Part 70 the requirement to submit a preliminary process hazards evaluation, especially when no approval of this analysis is required or formal feedback from the NRC is mandated. NEI recommends, therefore, that paragraphs (4) and (5) of draft §70.74 [sic; §70.64 is the intended reference] be deleted. *[note: 10 CFR 70.64(c)(4)-(5) in SECY-98-185 concerned submittal of the preliminary ISA to NRC and noted that its NRC approval was not required].*

The only other comment related to preliminary ISA was submitted by a Part 70 licensee on the World Wide Web site discussion forum. The comment was that although performance of a preliminary process hazards analysis appears to be a reasonable requirement, providing it to NRC before construction is an exercise that appears to have no function in the licensing process, and forcing early and sufficient pre-licensing communication through regulation is inappropriate.

D. Staff response to SRM and disposition of comments

In the staff's proposed rule language, any requirements regarding the preliminary PHA (or preliminary ISA) have been removed. The staff reviewed the existing provisions in Part 70 to see how they relate to the new revisions that will be added to Part 70 Subpart H. Relevant existing provisions are in 10 CFR 70.21(f) and 70.23(c)(2). Section 70.21(f) requires:

> An application for a license to possess and use special nuclear material for processing and fuel fabrication, scrap recovery, or conversion of uranium hexafluoride, or for the conduct of any other activity which the Commission has determined pursuant to subpart A of part 51 of this chapter will significantly affect the quality of the environment shall be filed at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted, and shall be accompanied by an Environmental Report required under subpart A of part 51 of this chapter.

Similarly, 10 CFR 70.23(a)(7), and (by reference) 10 CFR Part 51, require that:

> Where the proposed activity is processing and fuel fabrication, scrap recovery, conversion of uranium hexafluoride, uranium enrichment facility construction and operation, or any other activity which the Commission determines will significantly affect the quality of the environment, the Director of Nuclear Material Safety and Safeguards or his designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to subpart A of part 51 of this chapter, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to this conclusion is grounds for denial to possess and use special nuclear material in the plant or facility. As used in this paragraph, the term 'commencement of construction' means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, roads necessary for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

These two provisions capture many facilities for which the BDC and preliminary ISA requirements were intended; however, the provisions may not apply to certain new processes at existing facilities. The staff believes that for new facilities (i.e., new constructions), the license application and ISA Summary will be submitted pursuant to 10 CFR 70.65 before construction begins. Note that one of

the primary purposes of the preliminary ISA, as stated in SECY-98-185, was that it ". . . provides an opportunity for applicants to get early feedback [from NRC] 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." Because the ISA (the complete hazard analysis) will be completed and the ISA summary submitted before construction, NRC will have an opportunity to comment on the design adequacy before construction begins.

In general, the staff agrees with the approach recommended in NEI's comments submitted on March 26, 1999. However, the staff further believes that, absent a submittal, it is unnecessary to require performance of the preliminary PHA in the Part 70 licensing regulations. The staff believes that the preliminary ISA could be a valuable pre-licensing tool, but absent submittal or approval by NRC, the staff agrees with the comment submitted on the Website that the preliminary ISA does not perform a function in the licensing process.

The staff agrees with NEI that past pre-licensing communications between NRC and prospective applicants for new licenses or new processes have been adequate. A regulatory requirement to formalize this communication is, therefore, not necessary at this time. Although the staff encourages performance of the preliminary PHA because it should provide valuable information about the safety of the facility design; the decision to perform it and use it in pre-licensing communications with NRC (for example, to avoid later facility retrofits to satisfy NRC licensing requirements) is largely a business decision that the staff recommends be left to the applicant. If this is done, staff recommends that it be done early in the process (i.e., at the 30 percent conceptual design stage).

Issue 3: Decommissioning ISA

A. Contents of SECY-98-185

In SECY-98-185, the staff proposed the following requirement as 10 CFR 70.62(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."

B. Commission Direction in SRM to SECY-98-185

The Commission, in the SRM to SECY-98-185, directed the staff as follows:

> "The Commission may support the proposed requirement for the conduct of a decommissioning ISA if it can be justified on a health and safety or cost-benefit basis. However, the Commission is concerned that this requirement appears somewhat redundant with that required by NRC's 1997 decommissioning rule (Part 20) that applies to Part 70 as well as other licensees."

C. Comments received during public interaction on draft rule language

One comment was received on this issue during the period of public interaction on the staff's draft requirements. The NEI, in a December 22, 1998, letter, commented:

> NEI believes that a separate decommissioning ISA is not warranted. Decommissioning should be viewed as simply one, albeit the last, phase of operation of a licensed facility. As such, the facility's existing ISA program can be used to assess the potential hazards of activities and procedures proposed for use in the decommissioning phase. Any required changes to the ISA and facility operations to protect the health and safety of workers and the public during decommissioning can be implemented within the

framework of the existing ISA program. The ISA would be updated, as required, and changes to the ISA summary would be submitted to the NRC as currently practiced. There is, therefore, no need for a separate decommissioning ISA in the Part 70 rule.

The decommissioning plan submitted to the NRC in accordance with the schedule and requirements of §70.38(g) will include an ISA evaluation of the hazards posed by activities or procedures proposed for use in the decommissioning and recommendations for implementation of items relied on for safety and assurances to be placed on such controls.

The example cited in the draft language for §70.62(b)-- "…potentially hazardous activities such as chemical treatment of wastes…" -- may be inappropriate as the NRC-OSHA MOU does not grant NRC jurisdiction over management of purely chemical wastes.

NEI recommends that §70.62(b) be deleted from the proposed Part 70 revisions.

D. Staff response to SRM and disposition of comments

In accordance with the SRM direction, the staff reviewed the requirements for decommissioning in Part 20 as well as the existing requirements for decommissioning in 10 CFR 70.25 and 70.38. In addition, the staff considered the comments provided by NEI.

The staff did not identify redundancy of the ISA provisions with the decommissioning requirements of Part 20. However, the staff notes that 10 CFR 70.38(g)(4)(iii) requires that the decommissioning plan (DP) include, ". . . a description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning." Because the DP is submitted for NRC approval before initiation of "procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area," the staff believes that there is a measure of redundancy between 10 CFR 70.38 and the draft requirements in SECY-98-185 regarding submittal of decommissioning ISA results.

The staff agrees with NEI that the facility's existing ISA program can be used to assess the potential hazards of activities and procedures proposed for use in the decommissioning phase. In this respect, the ISA should provide valuable information with respect to developing the DP's ". . . description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning." The DP will be the vehicle for regulatory approval of the licensee's practices for protection of health and safety during decommissioning. Although the staff encourages the use of the ISA to aid in development of the DP, the staff believes that an explicit regulatory requirement to use the ISA in this manner is not warranted. Changes to 10 CFR 70.38 have not been considered in this rulemaking.

In the attached proposed Part 70 rule language, the requirements to perform an ISA with regards to decommissioning, and submit the results to NRC, have been deleted. The focus of Subpart H is limited to protection from accidents that are of sufficient credibility and consequence such that controls preventing or mitigating them have to be considered during operations. The staff believes that activities related to decommissioning are adequately regulated by existing requirements in Part 20 and 10 CFR 70.25 and 70.38. The applicability section -- §70.60 -- has been modified to indicate that requirements for decommissioning are addressed by those provisions. The addition of this sentence eliminates any potential redundancy in the regulations regarding decommissioning. Finally, because the staff's recommendation is to delete the requirement, the staff has not attempted to justify performance of a decommissioning ISA on a cost-benefit or health and safety basis.

Issue 4: Backfit

A. Contents of SECY 98-185

As part of its petition for rulemaking, NEI requested an immediately effective backfit for 10 CFR Part 70. In SECY 98-185, the staff recommended that the Commission defer a decision on backfit until after the safety basis, including the results of the Integrated Safety Analysis (ISA), are incorporated in the license, and the staff has gained sufficient experience with the ISA requirements. After completing the initial ISA, and the staff has gained experience with the ISA requirements, a baseline determination of risk could be established, as needed for a backfit analysis. This approach was initially approved by the Commission in their Staff Requirements Memorandum (SRM) dated August 22, 1997, in response to SECY 97-137.

B. Commission Direction in staff requirements memorandum (SRM) to SECY 98-185

The Commission, in the SRM to SECY 98-185, directed the staff as follows:

> "The Commission supports a requirement that any new backfit pass a cost-benefit test, without the 'substantial' increase in safety test. The Commission believes that modest increases in safety at minimal or inconsequential cost could be justified on a cost benefit basis."

C. Comments received during public interaction on draft rule language

In NEI's 1997 Petition for Rulemaking, NEI requested that the Commission include a backfit provision in the revisions to 10 CFR Part 70. The Petition for Rulemaking outlined the need for the backfit to be immediately effective and that, in order for the backfit to be implemented, it must substantially increase overall protection of the public health and safety and its cost must be justified by the increased protection it affords.

In a July 7, 1998 document, "Nuclear Energy Institute White Paper on Part 70 Regulation," provided to staff, NEI explained its basis for requesting that a backfit provision be made "immediately effective." In its paper, NEI stated that "it is critical that the backfit provision apply immediately upon the effective date of the rule change." NEI argues that the staff's basis for deferring a backfit regulation in SECY-

97-137 (i.e., licensee's do not have a "well-defined" licensing bases) was faulty. NEI believes that NRC possesses an ample basis to have licensed the Part 70 facilities in the past and to have permitted their continued operation. NEI stated that the NRC staff should be able to determine whether a proposed new requirement would "substantially increase" protection of the public health or safety or common defense and security, and whether the costs of such new requirements are justified. NEI also stated that if a licensee concludes that plant or program modification are needed based on the results of the ISA, the licensee will make those changes and no backfit issue arises; however, if the staff believes additional changes are necessary, those changes should be considered under the backfit rule. NEI does caveat these statements by adding that backfit analysis is "not required" if the staff concludes that the changes are required to implement applicable requirements, however, "this is very different from the staff's position that the backfit rule itself should not apply to plant changes based on the initial ISA's." This seems to indicate that although the ISA will be performed to comply with NRC regulations, if the licensee disagrees with any changes that the staff believes are necessary, as a result of the ISA, to comply with the regulations, then those changes would be subject to backfit. NEI completes its discussion regarding immediately effective backfit by addressing the delayed implementation of backfit in 10 CFR Part 76, for which it states a number of costly plant, program, and procedural changes were required by the staff without performing a rigorous backfit analysis. NEI asserts that if a backfit analysis had been performed, a number of the modifications may have been found to be unnecessary. Finally, concerning the staff's proposal to use a qualitative backfit, NEI states that this is not consistent with NUREG/BR-0058 Rev. 2 "Regulatory Analysis Guidance of the U.S. Nuclear Regulatory Commission" which makes it clear that quantitative analyses are much preferred over qualitative ones even if the values and impacts can not be expressed in "monetary terms." NEI states that "the Commission should specify that backfit analyses performed under Part 70 will use quantitative analyses to the maximum extent possible."

By letter dated February, 12, 1999, NEI reiterated their concerns on backfit as a result of NRC staff's discussion of backfit in SECY-98-185. The concerns were the same as those in the White Paper and supported through reference to the White Paper.

D. Staff response to SRM and disposition of comments

The staff continues to believe that backfit should not be considered until after experience is gained in implementing the revised rule and until a well documented safety basis is established. At that time,

if a backfit requirement were to be implemented, it would be consistent with the SECY-98-185 SRM direction and not require a "substantial" increase in safety test, i.e., modest increases in safety at a minimal or inconsequential cost would be permissible under backfit.

Backfit, as defined in §50.109(a)(1), is "the modification of or addition to systems, structures, components or design of a facility; or the procedures or organization required to design construct or operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position." A similar definition for backfit is found in 10 CFR Part 76. 10 CFR Part 72 is also similar, however, it does not limit backfit to new or amended Commission rules or a new or different interpretation of a staff position.

In its July 7, 1998, backfit white paper, NEI argues for the implementation of a quantitative backfit analysis versus the staff's intent to use a qualitative backfit analysis, if a backfit requirement were to be implemented. NEI argues that the use of a quantitative backfit analysis is consistent with NUREG/BR-0058 Rev. 2 which states quantitative analysis is much preferred over qualitative ones even if the values and impacts cannot be expressed in "monetary terms." The staff believes that a quantitative determination of incremental risk may require a Probabilistic Risk Assessment, to which the industry has strongly opposed in the past. Furthermore, it is not clear how a determination of incremental risk, as needed for backfit analysis, would be accomplished without an already determined baseline for the determination of risk. Currently, if backfit provisions were to be implemented, the staff intends to use the newly required ISAs to help develop the baseline; but without some level of PRA in the ISA, for which historical data may not be sufficient for these facilities, it would be difficult to quantify any backfit analysis.

NEI's interpretation of backfit also appears to be in conflict with the staff's. Although both parties agree that, if backfit were to be implemented, it would apply to changes in the regulations or interpretations of those regulations, there does seem to be some difference in opinion as to when backfit would apply to interpretations of the ISA results. Although NEI agrees that backfit would not apply to implementation of the regulations, the general nature of Part 70 will inevitably lead to differences of opinion about whether an action is necessary to implement the regulations. For example, NEI states that if the licensee concludes that plant or program modification are needed, it will make those changes and no backfit issue arises, but if the staff believes additional changes are necessary, the staff should be

required to consider such changes under the backfit rule. NRC staff believes that if, in its judgement, additional modifications are necessary to satisfy the performance requirements of the rule, it is a issue related to implementing the regulations, and that NRC should be responsible for interpreting the implementation of the regulations, not the licensee. In the past, differences of opinion related to implementation of the regulations have usually been successfully resolved through discussion at the staff level after the licensee has identified and justified their concern that an NRC request may be beyond what is required by the regulations. If the differences cannot be resolved at the staff level, as in the past, it will be elevated to higher levels of NRC and licensee management for resolution. If backfit is developed in Part 70 similar to the requirements in §50.109(a)(4)(i), the burden to show that an issue is related to implementing the regulations is placed upon the staff and thus the staff's implementation of Part 70 could result in the need for significantly larger resources if licensees attempt to argue regulatory interpretations based on the generality of the regulations in Part 70.

The current basis for licensing a Part 70 facility is the general regulations in 10 CFR Part 70, the licensee's application, and license conditions. Although the staff believes existing, operating facilities to be safe, there is not sufficient confidence in the margin of safety because of the absence of a well-defined, risk-informed safety basis. The staff has developed proposed revisions to 10 CFR Part 70 which require development of an ISA. The staff believes, and industry appears to agree, that development of an ISA would help define a risk-informed safety basis; however, industry believes that the current safety basis is sufficient to implement backfit. Staff view is that the current safety basis would not correspond to the performance requirements of the rule. In addition, staff believes that experience with ISAs, developed using the performance requirements of the rule, is necessary to ensure that the ISAs are sufficient to provide the appropriate safety basis. Therefore, the staff believes that backfit should be deferred until the safety basis corresponding to the revised rule is established.

Deferring backfit is also consistent with staff's implementation of Part 76 regulations where backfit was delayed until after certification was completed. The commitments in the Gaseous Diffusion Plant Compliance Plans were never subject to the backfit provision. Although NEI argues that a number of the modifications for GDPs may have been found to be unnecessary if backfit were applied, the staff required most of these modifications to bring the GDPs into compliance with existing DOE regulations prior to certification. Despite NEI's opinion, the staff believes that the backfit process would have likely shown that these modifications were issues related to implementing the regulations and not backfit issues; however, the regulatory burden to show that each issue was related to

implementing the regulations, instead of a backfit issue, would likely have been significant. Only after certification was completed, and experience was gained in implementing the Part 76 requirements, were backfit regulations implemented.

The above discussion clearly indicates that Part 70 regulations are much different than regulations to which backfit currently applies. As such, the staff continues to believe that backfit should only be considered after experience is gained in the implementation of the revisions to Part 70. Given the differences of opinion on this subject, the staff, however, plans to request public comment on its intent to defer the decision on a qualitative backfit provision in Part 70 in the Federal Register notice.

Issue 5: Reporting Requirements

A. Contents of SECY-98-185

In SECY-98-185, 10 CFR 70.74, and Appendix C, the staff proposed a graded approach for reporting licensee events. The rule specified three reporting classes and required specified events to be reported in 1, 4 and 24 hours from time of discovery. The approach was based on whether actual consequences had occurred, or whether a potential for such consequences existed. Serious events that had occurred were to be reported in 1 hour. Four-hour reporting was required for intermediate consequence events that had occurred; events that could potentially lead to consequences of concern; and events where controls could not be reestablished in 4 hours. If the controls could be reestablished in 4 hours, the event was to be reported within 24 hours.

B. Commission direction in SRM to SECY-98-185

The Commission, in the SRM to SECY-98-185, directed the staff as follows:

> "The rule should contain criteria for protection against the occurrence of certain consequences and require reporting of certain significant events to NRC because of their potential to impact worker or public health and safety."

C. Comments received during public interaction on draft rule language

NEI comments expressed five concerns with the rule language contained in SECY-98-185, as follows: 1) reporting requirements for fuel cycle facilities are already adequately addressed in the existing rule -- a new rule chapter is unnecessary; 2) the new 1-hour reporting timeframe for certain events is too restrictive; 3) a licensee should not be required to report all personnel hazardous chemical exposures; 4) a licensee should not be required to conduct continuous radiological monitoring in the unrestricted or controlled areas of its facility; and 5) emergency reporting of "potential deviations" from safe operating practices or "potentially unsafe conditions" should not be required, since the language is too subjective. NEI provided additional comments on the staff's revised draft proposed rule language. These comments were to eliminate duplication with other reporting requirements in Part 70 and to limit the reporting to two classes – serious events to be reported in 1 hour and significant events to be reported in 24 hours.

D. Staff response to SRM and disposition of comments

In response to the Commission direction and the comments received, the staff revised the reporting requirements in 10 CFR 70.74 and Appendix A, to: 1) require reporting of certain significant events to NRC because of their potential to impact worker or public health and safety, consistent with the performance requirements in 10 CFR 70.61; 2) limit reporting to two classes (i.e., serious events to be reported in 1 hour and significant events to be reported in 24 hours); 3) clarify that continuous radiological monitoring in the unrestricted or controlled areas of its facility is not required; 4) clarify that only reporting of chemical exposures consistent with the performance requirements in 10 CFR 70.61 is required, not all chemical exposures; and 5) eliminate subjective language.

Issue 6: Performance Requirements Related to Chemical and Radiological Safety

A. Contents of SECY-98-185

In SECY-98-185, 10 CFR 70.60(b), the staff proposed inclusion of specific consequences against which licensees must provide adequate protection. These consequences, applicable to workers and members of the public, were 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 staff proposed criteria that address both types of consequences. The staff-proposed rule in SECY-98-185 stated that the occurrence of any high-consequence event must be "highly unlikely," while the occurrence of any intermediate-consequence event must be "unlikely;" based on the draft Standard Review Plan definitions of the terms "highly unlikely" and "unlikely." This guidance is based on a combination of qualitative and quantitative indicators, but does not require a probabilistic risk assessment. The specific requirements are summarized in Table 6-1.

The chemical consequence criteria in SECY-98-185 were based on anticipated adverse health effects to humans from acute chemical exposures that were developed (or under development), by the National Advisory Committee for Acute Guideline Levels for Hazardous Substances (Acute Exposure Guideline Limits (AEGLs)) and the American Industrial Hygiene Association (Emergency Response Planning Guidelines (ERPGs)). SECY-98-185 proposed two appendices for Part 70 that listed the applicable concentrations for the EPRG or AEGL standards. The chemical risk standards were not limited to chemicals produced from radioactive materials.

TABLE 6-1 Radiological and Chemical Consequence Criteria

	Worker		Public	
Consequence	Radiological	Chemical	Radiological	Chemical
High	> 1 Sv (100 rem) or Nuclear Criticality	> 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)

B. Commission Direction in SRM to SECY-98-185

The Commission, in the SRM to SECY-98-185, directed the staff as follows:

> The rule should contain criteria for protection against the occurrence of certain consequences . . . because of their potential to impact worker or public health and safety. However, the Commission does not support the proposed rule with regard to chemical safety and consequence criteria. This issue warrants further discussion with affected agencies and industry to fully understand their respective authorities and the degree to which those authorities are implemented. The NRC should maintain its primary focus on its nuclear and radiological safety mandate. Consideration should be given to clarifying the basis for use of chemical safety and chemical consequence criteria in the rule, particularly within the context of Memoranda of Understanding with OSHA and other government agencies.

C. Comments received during public interaction on draft rule language

NEI provided several written comments on these issues during the period of public interaction on the staff's draft requirements. The U.S. Environmental Protection Agency and the Occupational Safety and Health Organization (OSHA) commented in response to a staff letter providing them the draft rule revisions. In addition, there were comments in the area of nuclear criticality posted on the World Wide Web discussion forum and in letters from both a member of the public and the American Nuclear Society. The wording for the performance requirements was a major topic of discussion at the three public meetings. The received written comments are described below.

In a November 4, 1998, letter, NEI commented that SECY-98-185 was deficient because it:

> . . . will provide NRC regulatory jurisdiction over all 'chemical hazards resulting from the processing of licensed' radioactive material. The breadth of this jurisdiction exceeds that described in SECY-98-185 and in the 1988 NRC/OSHA Memorandum of Understanding (MOU). Proposed language in Part 70 can be construed to extend NRC regulation to any chemical hazard at a licensed fuel fabrication facility. NEI's principal objection to the draft Part 70 language is its failure to clearly separate the regulatory responsibilities of the NRC and OSHA as established in the MOU. As written, the draft rule will result in redundant, overlapping regulatory oversight that will not improve public or worker health and safety.

NEI recommended that NRC jurisdiction be limited, by the rule text, consistent with the MOU. Specifically, NRC would regulate: (1) Special Nuclear Material (SNM), (2) radioactive compounds (e.g. UF_6), and (3) chemical compounds produced from radioactive materials during the processing of SNM (e.g. HF). NEI's November 4 letter also proposed several language changes including: a modification to the definition "hazardous chemicals"; addition of a definition for "hazardous chemicals produced from radioactive materials"; and deletion of the specific ERPG/AEGL values in Appendix B and C.

In a February 12, 1999, letter, NEI provided additional comments on the chemical safety risk standards, in response to staff revised rule language. NEI remarked, " the staff's proposed changes to the rule, for all intents and purposes, have resolved our concerns in the area of chemical safety. They constitute a major step forward in addressing our concerns that the rule be more "risk based" as opposed to "consequence' based."

In a response to an earlier NRC letter, OSHA commented on the staff's draft Part 70 revisions in a February 1, 1999 letter. OSHA noted that any regulation of chemical hazards or requirement to perform a hazards analysis is potentially preemptive of OSHA regulatory authority under the prevailing statute (i.e., the Occupational Safety and Health Act). The degree to which preemption would apply is largely dependent upon U.S. Circuit Court interpretations, which have exhibited regional variation. OSHA noted that this issue is independent of the division of responsibilities in the 1988 NRC-OSHA MOU, so, as the staff understands OSHA's opinion, implementing the MOU in the Part 70 rule may not be appropriate. In a March 2, 1999, letter, NEI provided its opinion on OSHA's jurisdictional letter, stating NEI believes "that the Staff's suggested changes to the chemical hazards portions of the draft rule are appropriate and would not preempt any legitimate OSHA authority over non-radiological

conditions at licensed Part 70 facilities. We again encourage you to incorporate the suggested modifications into the proposed rule." Also, at a February 25, 1999 meeting of NRC and OSHA staff, some clarifications and further information was provided at that meeting that resulted in some changes to the rule language to more clearly specify the scope of NRC involvement. However, these changes do not fully resolve the basic preemption issue. The problems identified with the rule are not unique, i.e., the preemption issue is generic and may already exist for any NRC-licensed facilities where there are requirements to analyze hazards. At the February 25 meeting, OSHA confirmed that the rule language is consistent with the October 21, 1988 MOU; indicated that they have no suggested changes to the MOU; and indicated that they are not opposed to the proposed rule.

The staff sent a similar letter to the U.S. Environmental Protection Agency (EPA) to solicit their views on the draft rule language. While OSHA has jurisdiction of workplace chemical safety, EPA regulates off-site (public) chemical safety. On May 24, 1999, EPA replied, noting that "EPA believes that the proposed revisions to NRC licensing regulations are consistent with the accident prevention portion of EPA's risk management program regulations and the general duty clause of the Clean Air Act." However, EPA requested that the rule contain an "explicit acknowledgment that [EPA] authority extends to applicable NRC-regulated facilities," that the preamble explain the relationship of the NRC and EPA rules similar to the explanation of OSHA rules (viz., the discussion on the NRC-OSHA MOU), and that NRC avoid any regulatory action that might inadvertently inhibit or restrict EPA's authority under 40 CFR Part 68.

In a December 17, 1998, letter, NEI commented on the nuclear criticality performance requirements. NEI recommended that the proposed revisions of 10 CFR 70 be clarified to reduce their ambiguity and the possibility of interpreting them to be 'consequence-based' rather than 'risk-based' regulations. While acknowledging that a nuclear criticality accident is an operating hazard whose risk must be adequately managed, NEI believed criticality should not be explicitly identified to be a "high consequence event" regardless of the resulting radiation doses. A letter from a member of the public, several submittals on the World Wide Web discussion forum, and by a December 1, 1998, letter from the Nuclear Criticality Safety Division of the American Nuclear Society advocated approaches that generally agreed with NEI's. In addition, NEI recommended that the rule permit industry to continue implementation of the double contingency principle as it has done without imposition of a probabilistic methodology, and Part 70 should be consistent with industry standards (American National Standards

Institute, American Nuclear Society Standards Committee, Subcommittee ANS-8) that uphold the basic definition of the double contingency principle as adequate and sufficient.

D. Staff response to SRM and disposition of comments

The staff believes that the clarifications to the draft rule text related to chemical risks, criticality, and the use of risk-informed language in establishing the performance requirements, are consistent with the Commission's direction provided in the SRM and address NEI's and industry's concerns in this area.

The staff clarified the performance requirements section by:

(1) consolidating the options that permit reducing the likelihood (prevention) or consequences (mitigation) in limiting the risk of accidents;

(2) separating, for clarity, the information on applicability into §70.60, and the requirements for a three element safety program (process safety information, integrated safety analysis, and management measures) into §70.62;

(3) providing a separate performance requirement for criticality using wording that matches the industry standards and stresses prevention of criticality, rather than including criticality within the subsection for high consequence events;

(4) adopting qualitative language related to chemical risks, and permit quantitative standards (ERPG/AEGL) for them to be adopted or developed by the applicant specific to its processes;

(5) defining "hazardous chemicals produced from licensed materials" such that the scope of the regulation is more clearly limited to the NRC's areas of responsibility consistent with the 1988 NRC-OSHA MOU;

(6) clearly stating the function of the ISA and the process for identifying items relied on for safety; and

(7) clarifying the use of the term "controlled area" that defines the location of evaluation against the performance requirements for impacts to members of the public.

The revised rule language retains the basic consequence and probability scheme for limiting the risk of accidents. The numerical consequences were not changed from those in SECY-98-185, as shown above in Table 6-1; however, the reference to the ERPG and AEGL values was deleted from the rule

in favor of qualitative language for chemical effects (the ERPG and AEGL techniques are listed in the standard review plan (SRP) as examples of acceptable approaches). Consequently, SECY-98-185 Appendices A and B, the chemical-by-chemical lists of ERPG and AEGL values, was deleted in agreement with the NEI comment. The SECY-98-185 version's reliance on qualitative language related to the probability component of the risk ("highly unlikely" and "unlikely") is retained. The applicant will be allowed to define his use of those terms, specific to that facility or process, in the application (i.e., in the ISA summary), and guidance is provided in the SRP.

The evaluation location for the accident standard for members of the public was specified in SECY-98-185 using the term "controlled site boundary" (meaning a physical barrier surrounding the facility). This became an issue during the public interaction period on the draft rule. Many commentors believed that NRC should incorporate the term, "controlled area" consistent with its use in 10 CFR Part 20. In response to this comment, the staff adopted the term "controlled area" in the performance requirements specified for the members of the public. The location at which compliance with the standard is evaluated is identified to be any point at or beyond the boundary of the "controlled area."

Section 70.61(f) requires licensees to identify a controlled area consistent with the use of that term in Part 20, and provides clarification regarding the activities that may occur inside the controlled area. The function of this term is to delimit an area over which the licensee exercises control of activities to meet regulatory requirements. Control includes the power to exclude individuals, if necessary. The size of the controlled area is not specified in the regulation because it will be dependent upon the particular activities that are conducted at the site and their relationship to the licensed activities. Within the controlled area will be a restricted area (as defined in §20.1003) access to which is controlled by the licensee for purposes of radiation safety. Anyone not receiving an *occupational dose* (per Part 20) in the controlled area will be subject to the dose limits for members of the public in 10 CFR 20.1301. However, the staff acknowledges that certain licensees may have ongoing activities on their site (i.e., within the controlled area) that are not related to the licensed activities. For example, a non-nuclear facility may be adjacent to the nuclear facility but both are within the controlled area (which may be defined similar to the site boundary). Protection of the individuals at the non-nuclear facility must consider that the nature of many potential accidents at a fuel cycle facility is such that they may not have substantive progression time during which to take action to exclude individuals from the controlled area. Therefore, for purposes of the ISA accident evaluation, the rule includes two

options for these individuals. In the first option, the ISA evaluates the risk at their location (as opposed to any point at or beyond the controlled area boundary) and determines that it meets the performance requirements for members of the public. In the second option, performance requirements for workers can be applied to individuals in the controlled area if the provisions of Section 70.61(f)(2) are satisfied. These conditions ensure that the individuals are aware of the risks to them from the potential accidents at the nuclear facility and have received appropriate training and access to information (e.g., the ISA). This parallels and is consistent with the use of the term, “Exclusion area”, by Parts 50 and 100, which state, “Activities unrelated to operation of the reactor may be permitted in an exclusion area under appropriate limitations, provided that no significant hazards to the public health and safety will result.”

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

Issue 7: Standard Review Plan Modifications

A. Contents of SECY-98-185

A draft standard review plan (SRP) was included in SECY-98-185. The purpose of the draft standard review plan is to provide guidance to the staff reviewers in the Office of Nuclear Material Safety and Safeguards who perform safety and environmental impact reviews of applications to construct or modify and operate fuel cycle facilities. The SRP facilitates the quality, uniformity, stability, and predictability of staff reviews. The SRP also makes information about the licensing acceptance criteria widely available to interested members of the public and the regulated industry.

B. Commission Direction in SRM to SECY-98-185

The Commission, in the SRM to SECY-98-185, directed the staff as follows:

> "The staff should critically review the Standard Review Plan in its entirety to ensure that, by providing specific acceptance criteria and program attributes to demonstrate compliance with the performance-based rule, it does not inadvertently prevent licensees or applicants from suggesting alternative means of demonstrating compliance."

C. Comments received during public interaction on draft rule language

In their November 25, 1998, letter to NRC, the Nuclear Energy Institute (NEI) provided the following:

> NEI is concerned that new prescriptive, programmatic criteria introduced in the SRP without any specific basis in 10 CFR Part 70 will become de facto regulatory requirements. Although we recognize the SRP is only intended to be a staff guidance document to ensure consistency in license application reviews, the SRP acceptance criteria can over time become minimum standards ('lowest rung on the acceptance ladder'). The prescriptiveness of the draft SRP language is of particular concern. Though possibly not intended, it often appears to prejudge the need to implement new programs and practices before an Integrated Safety Analysis (ISA) establishes their need. In accordance with a risk-informed, performance-based regulatory approach, the SRP should reflect the philosophy that the licensee will propose appropriate

programmatic activities based upon the risk significance identified in the ISA, and that the reviewer should expect a sound justification for each proposal from the licensee.

NEI provided other comments regarding quality assurance criteria, training and qualifications, fire safety, decommissioning, human-systems interface, organization and administration, emergency management, configuration management, maintenance, and criticality safety.

In letters dated December 17, 1998, and January 21, 1999, NEI provided criticality safety comments and an annotated mark-up of SRP Chapter 5, "Nuclear Criticality Safety."

In a letter dated April 12, 1999, NEI provided comments on decommissioning and an annotated markup of Chapter 10, "Decommissioning". In that letter, it states "...SRP Chapter 10 should be limited to a discussion of decommissioning funding plans, record retention requirements for new license applications, and waste/contamination plans."

NEI also provided comments in the form of an annotated markup of SRP Chapter 6, "Chemical Process Safety," in a letter dated March 2, 1999.

D. Staff response to SRM and disposition of comments

The staff has stated from the outset, that the SRP is expected to be used during reviews as guidance. As stated on page 2 of the June 1998 draft SRP, "The 'Acceptance Criteria' delineated in this SRP are intended to communicate the underlying objectives but not to represent the only means of satisfying that objective. If approaches different from the SRP are chosen, the applicant should identify the portions of its application that differ from the design approaches and acceptance criteria of the SRP and evaluate how the proposed alternatives provide an acceptable method of complying with the Commission's regulations." This approach is not different from the approach presented in NEI's November 25, 1998, comments stated in C above. The intent is that the acceptance criteria is only one specific approach, which if followed, is intended ensure acceptance by the reviewer in most, if not all, situations. However, because the proposed regulations allow a graded approach based upon the significance of the process being evaluated, the applicant may propose approaches different from that proposed in the acceptance criteria; these differing approaches may result in smaller programs or no program to meet the category under review. The applicant is only required to identify that they

are using a different approach from that presented in the SRP and based upon the applicant's evaluation, provide an explanation for the alternative approach used. This is consistent with NEI's statement "that the reviewer should expect a sound justification for each proposal from the licensee."

NEI has mentioned some concern that NRC's statements in the introduction of the SRP may be overlooked in the future and acceptance criteria may still become "de facto" requirements. As such, the acceptance criteria of each section will include a statement "the reviewed item should be considered acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative in the application."

The staff has revised the SRP to be consistent with the rule language and has incorporated many of the comments received on the SRP, especially in the chemical safety and criticality safety chapters.

Issue 8: Use of ISA Methodologies in the Licensing of New Technologies

A. Contents of SECY-98-185

In SECY-98-185, the ISA to be performed was described as a systematic analysis to identify plant and external hazards and their potential for initiating accidents; the potential accident sequences and their likelihood and consequences; and the items that are relied on for safety. Specific ISA methodologies that could be used were described in NUREG-1513, “Integrated Safety Analysis” guidance document. Flexibility was permitted in the ISA methodology chosen so that it would be appropriate to the process and technology being analyzed.

B. Commission Direction in SRM to SECY-98-185

The Commission, in the SRM to SECY-98-185, directed the staff as follows:

> "Also, in soliciting public comments, the staff should request input on how applicable ISA methodologies should be employed in the licensing of new technologies for use within new or existing facilities."

C. Comments received during public interaction on draft rule language

No comments were specifically received addressing this issue, nor were there any concerns expressed on the application of ISA methodologies to new technologies..

D. Staff response to SRM and disposition of comments

The ISA methodology described in this rule and SRP have not changed from that described in SECY-98-185. The ISA guidance document (NUREG-1513) also has not changed. The staff continues to believe that sufficient flexibility is permitted in the ISA methodology chosen to be able to accommodate a wide range of technologies. However, to better address the Commission concern, the draft Federal Register notice associated with this proposed rule specifically requests comments on this matter.

Revised Requirements for the Domestic Licensing of Special Nuclear Material (Part 70)

Comments in Document Library

Source	Citation	Comment	Response
NEI letter (042-0036), 11/4/98, on chemical safety.	Attachment 1 presents the changes that NEI recommends be incorporated to accurately reflect NRC's regulatory jurisdiction over hazardous chemicals.	1.The breadth of this jurisdiction exceeds that described in SECY-98-185 and in the 1988 NRC/OSHA Memorandum of Understanding (MOU).	Agree. Rule was revised to reflect MOU. New 70.60(b), (c), and 70.62(c) wording and defn., "Haz. chem..." parallel MOU.
		2. (i) The term "*hazardous chemicals*" should be replaced by "*radioactive materials or hazardous chemicals produced from radioactive materials*" This change would apply to §70.60(b)(1)(ii)(B), §70.60(b)(1)(iii)(c), §70.60(b)(2)(i)(B) and §70.60(b)(2)(ii)(B) of the draft rule and throughout SECY-98-185.	Agree. Language adopted (except uses "licensed" materials as opposed to "radioactive" materials.
		2. (ii)The proposed Rule revisions could be simplified by retaining references to the AEGL and ERPG standards, but deleting the actual tables of exposure limits which will be continually updated and modified.	Agree in part. AEGL/ERPG references removed from rule (will be in SRP); equivalent, qualitative language adopted in 70.60(b) & (c).
		2.(iii) "*Hazardous Chemicals*" definition should read as follows: "*Hazardous Chemicals means substances that are toxic, explosive, flammable, corrosive or reactive to the extent that they can endanger life if not adequately controlled.*"	Comment not applicable. Definition *hazardous chemicals* deleted from 70.4.

Source	Citation	Comment	Response
		2(iv) Add definition for "*Hazardous Chemicals Produced from Radioactive Materials*." The new definition should build upon the existing definition of Hazardous Chemicals and should read: *"Hazardous Chemicals Produced from Radioactive Materials means Hazardous Chemicals either having radioactive material(s) as precursor compound(s) or formed through interaction with radioactive materials. They do not include chemicals merely added to, or used in, or recycled from, the processing of special nuclear material (SNM)."*	Agree. Added a definition of *hazardous chemicals produced from radioactive materials* that is similar to comment
NEI 11/25/98 letter (042-0043). SRP New Programmatic Criteria	Cover letter, p.1	New prescriptive, programmatic criteria introduced in the SRP without any specific basis in 10 CFR Part 70 will become *de facto* regulatory requirements.	Disagree. The intent is to use the SRP as guidance only.
	Cover letter, p.2	The prescriptiveness of the draft SRP language is of particular concern. Though possibly not intended, it often appears to prejudge the need to implement new programs and practices before an Integrated Safety Analysis (ISA) establishes their need.	Disagree. The intent of including these topics is to be inclusive. The applicant, based upon his ISA, may find that a lesser grade or no program is sufficient.

Source	Citation	Comment		Response
	Cover letter, p.2	More clearly distinguish between what information is expected in a license application for a new fuel cycle operation versus that required for the renewal of an existing license, the guidance provided to the NRC reviewer in the SRP might be different and more in line with the current industry proposals.		Disagree. In general, outside of addressing baseline design criteria, the reviewer would be expected to consider the same areas.
	Enclosure, Section I	NEI also anticipated that the NRC would permit licensees to determine, based on the results of their own Integrated Safety Analyses (ISA), whether any changes would be required in their existing programs, procedures and practices in order to provide reasonable assurance that the consequences of concern set forth in §70.60(B) of the rule would not be exceeded.		Agree in Part. Licensees are expected to determine whether any changes are required in their existing programs based upon the ISA; however, the NRC reviewer will evaluate the implementation to see if the implementation is appropriate.
	Enclosure, Section II	1 Quality Assurance Criteria (Draft SRP §11.3):	The SRP mandates that all 18 NQA-1 criteria are to be addressed for both high and intermediate risk accident sequences, although their application is to be graded according to risk [Draft SRP §11.3.4.3].	Agree. Clarified to show that all 18 criteria are not required.
			Imposition of NQA-1 as a requirement for compliance with 10 CFR Part 70 is a new programmatic requirement.	Agree. Added other QA options to clarify that NQA-1 was not a requirement.
			The SRP “prejudges” that a licensee’s quality program, must conform to the NQA-1 criteria.	

Source	Citation		Comment	Response
			Imposition of NQA-1 on fuel facility licensees would necessitate radical changes in virtually all affected licensees' quality programs.	Disagree.
			The imposition of NQA-1 on Part 70 licensees, whether on a graded basis or otherwise, should not be injected as a new "expectation" either in an SRP, or through informal case-by-case licensing action, unless specifically included as a Part 70 rule requirement.	Disagree. NQA-1 is guidance; if included in rule it would be mandatory, which is not what NEI or NRC want.
			Reference to NUREG-1200 on "design" and "construction" activities creates QA criteria for design and construction of non-plutonium Part 70 facilities. This is a new programmatic requirement that is not consistent with licenses that have been issued. The creation of QA criteria for design and construction of Part 70 facilities is not a requirement of Part 70.	Agree. Deleted reference to NUREG-1200.
			The SRP does not address how existing licensed facilities would have to comply with these new design and construction requirements.	Disagree. Existing facilities would have to address.

Source	Citation	Comment		Response
			The number of NQA-1 criteria which an individual program must address – even for high and intermediate risk events – can only be established following completion of the appropriate ISA.	Agree.
		2. Training and Qualification (Draft SRP §11.4)	There is no requirement in the Part 70 rule which requires such a comprehensive level of staff training as that mandated in the SRP.	Agree in part. Training requirement is determined based on ISA.
			Risk-informed, performance-based regulation grants a licensee the latitude to establish the content, detail and comprehensiveness of its staff training and qualification program. A "Systems Approach to Training" (SAT) program may not be warranted.	Agree.
			The SRP does not justify how operator knowledge and skills in "design" and "construction" activities at non-plutonium licensed fuel cycle facilities enhances health and safety.	Agree. Rule revised.
			Adoption of such standards represents a significant departure from current licensing practice and the rulemaking package does not discuss the implications of this change.	Agree in part. Clarified to show that SAT not required.

Source	Citation	Comment		Response
			Different training requirements may be appropriate for new fuel cycle facilities, particularly if a new process or technology is to be used where there is a dearth of operating, safety and performance history. The SRP should differentiate between the staff training and qualification requirements for new and existing fuel cycle facilities.	Agree. SRP revised to reflect that training is based on ISA, whether new or existing facility.
			The Qualifications, Training and Human Performance Requirements detailed in the SRP: (a) are very prescriptive and cumbersome; (b) are inconsistent with current industry practice; and, (c) will result in only a marginal positive impact on the effectiveness of facility training programs. Such requirements should only be established by the licensee using the results of the ISA.	Agree in part. SRP clarified to show that training requirements are based on ISA.

Source	Citation	Comment		Response
		3. Fire Safety (Draft SRP §7.0)	The SRP requirement (acceptance criteria) for an "Fire Protection Program" (FPP), Fire Hazards Analyses (FHAs), and Pre-Fire Plans (PFP) constitutes a new set of programmatic requirements.	Agree in part. The SRP has been revised to clearly indicate that these concepts are guidance, and options for *one acceptable* approach, not additional requirements.
			Unless the risk of an accident sequence justifies, or a specific provision written into the Part 70 rule mandates this comprehensive level of fire safety, FPPs, FHAs and PFPs may not be warranted.	Agree. The results of the ISA will be used to determine the risks of credible accidents that include fires. An FHA is an option for including the information/concepts in the ISA. The concepts embodied by FHA and PFPs need to be considered in assessing those risks, be it in the ISA or a FHA.

Source	Citation	Comment		Response
			The listing of 58 NFPA codes and the statement that the "most current versions" of those codes will be utilized as the basis for Staff reviews clearly creates new regulatory expectations that may be very costly to achieve and may require licensees to continually upgrade their facilities to meet newly-developed industry codes without any commensurate reduction in risk.	Agree. Compliance with the code-of-record should be sufficient for existing facilities.
		4. Decommissioning (Draft SRP §10.0)	At the time of license application the SRP requires submission of a detailed decommissioning plan and detailed procedures to minimize contamination to the environment. This constitutes a new programmatic requirement. By contrast, at present, licensees at operating facilities must simply submit a cost estimate for decommissioning and provide financial assurance through a decommissioning funding plan, as part of a licensing submittal.	Agree in part - The SRP is to be used for new license applications as well as amendment applications. Staff agrees that the timing of submitting a DP was not clear. Language was revised to show that DP's are not required during new license application.

Source	Citation	Comment		Response
			Forecasting the methodologies or technologies to be used to decommission a facility 20 to 40 years in the future is an unreasonable requirement.	Agree. This is not required by the SRP which has been revised to make clear that DPs and detailed descriptions of decommissioning tech. is only required shortly before decommissioning actions begin.
			NEI believes that this entire chapter should be removed from the SRP and placed in a Regulatory Guidance document	Disagree - The SRP is intended to consolidate all guidance documents. This chapter is necessary and should not be deleted.

Source	Citation	Comment		Response
		5. Human-System Interfaces (Draft SRP §11.6)	The draft SRP requires ["formal evaluation of human-system interfaces" and requires licensees to have a formal process for "design, evaluation, implementation, maintenance, and modification of human-system interfaces . . . ." [Draft SRP §§ 11.6.3, 11.6.4.3]. This includes periodic human-system interface reviews, employment of human-system interface "specialists," development of human-system "standards" and creation of an "inventory" of such interfaces. This portion of the SRP is a new programmatic requirement.	Agree - These requirements were removed from the rule therefore this chapter was no longer needed and was removed from SRP.
			It creates an entirely new and complex set of criteria that will require licensees to establish detailed programs and procedures to formally analyze interfaces between personnel and systems.	Chapter was removed
			Additionally, it prejudges that control of human-system interfaces is needed, regardless of the results of the ISA.	Chapter was removed

Source	Citation	Comment		Response
		6. Organization and Administration (Draft SRP §2.0)	Licenses issued under Part 70 are not for the construction and operation of facilities, but rather for the possession and use of special nuclear material. Therefore, specifying policies on design and construction in the SRP is unwarranted. This represents a substantial change in policy and practice.	Disagree. Although Part 70 is for the possession of special nuclear material, sometimes the method to ensure its safe use is through specifying guidance on design and construction of the facility.
			Second, the SRP provides for NRC Staff review of the "experience" and "availability" of personnel for decommissioning of licensed facilities [Draft SRP §2.4.3]. Again, review of such details associated with the actual decommissioning process at the licensing stage is premature. What contractors and personnel will be available in 20 to 40 years to oversee decommissioning cannot reasonably be expected to be known now.	Agree.

Source	Citation	Comment		Response
			Imposing licensing standards for the maintenance of a "safety-conscious work environment" goes well beyond existing practice and requirements and is inconsistent with the Commission's February and September policy determinations.	Agree.
		7. Emergency Management (Draft SRP §8.0)	Part 70 currently does not require formal training of offsite fire, police, medical and other emergency personnel. The draft SRP appears to go beyond existing requirements.	Agree in Part. Part 70 does require the licensee to off such training, although the offsite agency is not required to accept it.
			NRC's own analysis did not identify significant off-site risks. The draft SRP suggests an emergency response training program that is more akin to those established for commercial nuclear power plants.	Disagree. The training requirements in the SRP are no different from and have not been expanded from past practice for fuel cycle facilities.

Source	Citation	Comment		Response
			Until such risks are assessed in an ISA, the components and requirements of an emergency management plan can not be accurately defined. The SRP must allow the licensee to establish appropriate emergency response measures and to determine the extent of training which should be provided to "offsite emergency response personnel."	Agree in Part. Part 70 does list some specific requirements related to the emergency management plan. However, other specifications in the SRP are guidance for the reviewer to examine, and appropriate justification for their lack of implementation is acceptable.
		8. Configuration Management (Draft SRP §11.1)	The expectation that licensees will be required to "reconstitute" their "designs" [Draft SRP §11.1.3(6), 11.1.5.26] constitutes a new programmatic requirement. Provisions for design bases reconstruction go well beyond existing requirements and, in fact, substantially exceed the requirements applied to nuclear power plants.	Agree in Part. The only expectation is for the licensee to ensure that their design basis documentation is current in respect to operating practice for those areas related to ISA development.

Source	Citation	Comment		Response
			Part 70 licenses do not "license" the design of a facility and so there should be no requirement to perform a reconstitution.	Disagree. The licensee still needs to show that the ISA is developed using current operating practices. If they have always used an appropriate configuration management program, this should not entail any additional effort.
			Operators of new and existing fuel cycle facilities should commit to a configuration management program in their licenses.	Agree.
		9. Maintenance (Draft SRP §11.2)	The discussion of preventive maintenance specifically discusses "requalification and retraining of personnel" [Draft SRP § 11.2.4.3]. This is a unique and to the best of our knowledge, unprecedented extension of the concept of a nuclear facility maintenance program. It is not clear what additional requirements this would add over the proposed training program criteria in SRP §11.4.	Agree. Clarified to reflect that "requalification and retraining," while important, are not part of preventive maintenance program.

Source	Citation	Comment		Response
			In the absence of a corresponding requirement to 10 CFR §50.65 in the Part 70 rule, the NRC should not attempt to impose a highly prescriptive maintenance program either through the SRP or as a license condition.	Agree. Revised so as not to be "highly" prescriptive.
			The draft SRP appears to require preventive maintenance and post maintenance functional tests, regardless of whether such activities are needed to ensure the proper functioning of items relied on for safety as identified by the ISA.	Agree in part. Activities are still included in SRP since they are necessary to show items relied on for safety are available and reliable.
		10. Nuclear Criticality Safety (Draft SRP §5.0)	The SRP goes well beyond accepted international and nuclear industry practice by assigning specific, quantitative, numerical frequencies to each of the two controlled parameters or controls as an acceptance criterion, presumably in order to determine that a particular nuclear criticality accident is "highly unlikely."	Agree. This quantitative specification has been removed from the SRP Chapter.

Source	Citation	Comment		Response
			Adoption of these new quantitative standards will add considerably to the cost and complexity of performing nuclear criticality safety analyses.	This comment is no longer applicable because the quantitative standards has been removed.
			In industry's view, if adherence to the double contingency protection principle is confirmed, then it follows that a nuclear criticality event would be "highly unlikely."	Agree.
	Enclosure, Section III, Conclusions	The rulemaking record is replete with explanations as to the purpose of the requirements to perform ISAs, to adopt consequences of concern, to identify items relied on for safety, and to assure that such items remain available and reliable. It does not, however, explain at all the bases for the determination that the wide range of new programmatic criteria in the draft SRP is necessary or appropriate.		The SRP was revised to make clear that the contents are guidance and not requirements.
NEI 12/17/98 letter (042-0046): criticality safety	Cover letter	NEI supports the NRC's efforts to make the Part 70 rule consistent with the ANSI/ANS-8 NCS standards. In this regard, some modification of the language of the proposed revisions is, however, required to focus on the risks, rather than the 'consequences' and 'quantified likelihood' of accident sequences that could lead to potential nuclear criticalities.		Agree. Separate criticality performance requirement in 70.61(d) uses very similar language as ANS 8.1.

Source	Citation	Comment	Response
		A Part 70 license should include license commitments to manage NCS in accordance with ANS-8 guidelines.	Agree in Part. Commitment to ANS-8 standards alone is not sufficient.
		It should define the broad, operational bases for a facility, within which limits the licensee may safely operate without additional NRC approval (or license amendment) and without burdensome reporting requirements.	Agree. The license and the NRC's evaluation of the facility safety basis through the ISA process will allow a licensee to operate without burdensome requirements.
		A licensee should have the latitude to focus its NCS resources on high-risk nuclear criticality accident sequence prevention and to address safety issues within a licensee's corrective action program.	Agree.
	Enclosure Section I (a) Risk-Informed Regulation	NCS revisions to Part 70 should consider application of a risk-informed, performance-based methodology to: ! evaluate the risk (i.e. consequences and likelihood) of potential nuclear criticality accidents whether initiated by external events, process deviations or internal events	Agree. 70.61 Performance requirements clarified to allow limiting risk by reducing consequence or likelihood, as appropriate.

Source	Citation	Comment	Response
		! establish appropriate risk-based (graded) levels of protection to prevent nuclear criticality accidents	Agree. Separate criticality performance requirement in 70.61(d) now uses very similar language as ANS 8.1 and Prevention of criticality is stressed.
		! establish appropriate risk-based (graded) levels of assurance for items relied on for safety to ensure their availability and reliability	Agree. 70.62(a) and (d) permit grading of the safety program
	Enclosure Section I (b) Double Contingency	The draft SRP requires assignment of specific, quantitative numerical frequencies to each of the controls to determine that a nuclear criticality accident is 'highly unlikely.' To determine whether there are at least two 'unlikely', independent and concurrent process changes necessary before a criticality might occur (i.e. double contingency protection), industry has relied instead on the expertise, experience and judgment of nuclear criticality experts on a deterministic basis.	Agree. The quantification specification for double contingency protection has been removed from the SRP Chapter.

Source	Citation	Comment	Response
		The SRP's definition of 'highly unlikely' as a frequency of 10^{-5} is arbitrary and forces differentiation of 10^{-2} and 10^{-3} between two 'unlikely' events in a criticality accident scenario.	Agree. The quantification specification for double contingency protection has been removed from the SRP Chapter. The rule requires licensees to include, in the ISA summary, their definitions of "highly unlikely" and "unlikely".
		Measuring compliance to these arbitrary, quantitative values is burdensome and problematic for both licensees and the NRC.	Agree. The SRP has been modified to allow use of double contigency protection or quantitative values.
		Quantification of NRC's expression of the principle of double contingency contradicts guidance of the American National Standard.	Agree. The quantification specification for double contingency protection has been removed from the SRP Chapter.
		NEI recommends that industry's current practice of detailed evaluation of credible accident sequences by experienced nuclear criticality engineers continue. Adherence to the ANS-8 guidance should also be continued.	Agree in Part. Detailed evaluation of credible accident sequences by experienced nuclear criticality engineers should continue. And commitment to ANS-8 standards alone is not sufficient.

Source	Citation	Comment	Response
	Enclosure Section I (c) Graded Level of Protection of Items Relied On For Safety	The wording of §70.60(c) should be modified to address the risk of a nuclear criticality accident (rather than its consequences and likelihood) and to assure that items relied on for safety are "…available and reliable when required to perform their safety functions," instead of continuously available and reliable.	Comment no longer applicable. Section referenced is now 70.61(d) Criticality Performance Requirement and uses very similar language as ANS 8.1.
		Section §70.60(c) incorrectly identifies only the likelihood of external events as an element of risk from a nuclear criticality accident, thereby excluding the likelihood of process deviations or other internal events as an element of the risk evaluation. The language of §70.60(c) should be clarified.	Comment no longer applicable. Section referenced is now 70.61(d) Criticality Performance Requirement and uses very similar language as ANS 8.1.
	Enclosure Section I (d) Nuclear Criticality: Quality Assurance	Draft SRP §5.4.4.1(1) incorrectly requires that all criticality safety controls be afforded the highest level of assurance, while §70.60(d)(3)(vi) and draft SRP §5.4.4.1(5) correctly require the assurance level be commensurate with the importance of the safety function.	Comment is no longer applicable. SRP has been revised to allow grading of criticality safety controls.
		The highest level of assurance would not necessarily be warranted for criticality controls in accident scenarios with double contingency protection.	Agree.
		The reliability of individual controls should be considered when determining the appropriate level of assurance for criticality safety controls.	Agree.

Source	Citation	Comment	Response
	Enclosure Section I (e) Historical Nuclear Criticality Data	As the NRC has on file, or available to them, voluminous information on all operational events, including nuclear criticality safety deviations, NEI sees little justification in submitting this information at the time of license application or renewal. NEI recommends that §70.65(c) be deleted from the Part 70 revisions.	Agree - The requirement to submit information on operational events which had a sign impact on the safety of the facility was removed. This information is already available to NRC.
	Enclosure Section II	NEI recommends that the proposed revisions of 10 CFR 70 be clarified to reduce their ambiguity and the possibility of interpreting them to be 'consequence-based' rather than 'risk-based' regulations.	Agree. 70.61 Performance requirements clarified to allow limiting risk by reducing consequence or likelihood, as appropriate.
		The rule should permit industry to continue implementation of the double contingency principle as it has done without imposition of a probabilistic methodology.	Agree. The Rule permits implementation of the double contingency principle as is currently being performed by industry.
		Part 70 should be consistent with American National Standard 8 that upholds the basic definition of the double contingency principle as adequate and sufficient.	Agree. Criticality Performance Requirement in 70.61(d) uses very similar language as ANS 8.1 and prevention of criticality is stressed.

Source	Citation	Comment	Response
		In support of risk-informed, performance-based regulation, the rule should grant a license applicant the flexibility to implement graded controls (and assurances) based on the results of the ISA.	Agree. 70.62(a) and (d) permit grading of safety program based on the item's importance to reducing risk
Dec. 2, 1998 letter (042-0048) LANL ESH-6-98-A DM-05	**"Risk informed and performance based regulation"**	Numerous uses of the term 'consequence criteria' [as opposed to risk].	Agree. Performance requirements is the term now used throughout the rule. The specific performance requirements are risk-informed and appear in 70.60(b)-(d).
		The attempt to have PRA or any other form of quantified risk assessment become a major part of the safety basis of nuclear criticality safety at any facility would be inappropriate at best. The data on which to base failure rates simply do not exist	Agree. Rewrite of SRP Chapter 5 explicitly does not require PRA or quantitative risk assessments for criticality evaluations.
	70.62 ISA Requirements	As a direct result of a criticality accident being labeled a 'high-consequence' event, there are potentially severe implications in the rule on required actions and documentation compared to how the DOE regulates criticality safety, the latter being consistent with the guidance and philosophy found in the ANS-8 standards.	Agree. 70.60 (d) now uses very similar as ANS 8.1. Criticality is no longer labeled a "high consequence event."

Source	Citation	Comment	Response
	"(B) For new processes submit the results of the ISA and any revisions as part of the application for amendment of the license under 70.34."	Concern that time delay inherent in compliance with this would result in enormous costs at no practical risk reduction. DOE does not review and approve criticality safety evaluations before the contractor can implement operations unless an Unreviewed Safety Question (USQ) is found.	Agree in part. Pre-approval by NRC of changes is addressed by 70.72, which has been completely revised. Only changes which result in changes to the safety (licensing) basis need pre-approval.

Source	Citation	Comment	Response
	"70.64 Baseline design criteria…. "(a) Licensees shall maintain….. unless…..not relied on for safety. "(1) Appropriate records of these items must be maintained….. throughout the life of the facility. "(2) … "	What does this mean? Would it include cans and process equipment such as 5-liter dissolution pots, 4-liter Erlenmayer flasks, 7-liter filter boats, etc. that are not fixed in place on a glovebox floor and that truly do provide meaningful criticality protection? What if there are several barriers to reaching the critical state, a combination of vessel geometry and administrative controls such that none are dominant as is the case in many DOE operations?	Agree in part. Rule rewrite makes it clear that the baseline design criteria apply only to major facility-level or systems-level changes (i.e., new processes that require NRC pre-approval). The examples given are component-level (possibly systems-level) changes that could be addressed through 70.72 without NRC pre-approval, even if the specific equipment is an "item relied on for safety."

Source	Citation	Comment	Response
	Appendix C to part 70 - Reportable Safety Events "II(4 hours)….a deviation from safe operating conditions….. has the potential, as identified in the ISA,…."	Not possible to include all gradations of upsets in ISA. Within the DOE there is the flexibility to use a graded approach such that the process upset can be judged to be of such little significance locally and of such little learning value globally that it is recorded and tracked internally only. The consequences of not using this common sense approach have been painfully and expensively documented within the DOE!	Agree in part. Reporting requirements have been revised.

Source	Citation	Comment	Response
	"Standard Review Plan, Chapter 5 "5.4.6 ISA Results "The nuclear criticality aspects of the applicant's ISA are acceptable if the following criteria are met: "1. The applicant conducts and maintains an ISA that identifies specific control parameters…."	Should this requirement be interpreted to mean that controls for every operation or process are identified in the ISA? If so, either the ISA would be continually out of date or the DOE contractors nationwide would be shut down. Due to hundreds of independent operations, processes and limits in larger facilities are changing weekly if not daily in some cases.	Disagree. The purpose of the ISA is to identify the hazards at a facility as well as the controls which prevent or mitigate these hazards. these controls must be identified so that they can be maintained and remain available and reliable as specified in the regulations.
	"7. a. At least one of the two controlled parameters…"	This implies that there are only two controlled parameters, a very rare situation, and implies a misunderstanding of the double-contingency principle.	Comment is no longer applicable. SRP has been revised.

Source	Citation	Comment	Response
	"5.4.5.2 NCS Limits "5.a controlled parameters: When using experimental data, the applicant applies industry-accepted safety factors……45%….75%….etc."	These 'industry-accepted' safety factors were never adopted by ANS-8, nor are they in any refereed publication. In fact I have no idea where they are documented except possibly in NRC guidance for licensees. The DOE has no such formal, specific limits since there is no indication that they would reduce accident frequency; they would clearly have a tremendous cost impact on many DOE sites.	Disagree. These values are found in current licenses based on industry data from experiments.

Source	Citation	Comment	Response
	5.5 Procedures for Review "5.5.2 Safety Evaluation "14. The reviewer will determine that ... maintains a NCS review of the ISA …that includes a review of identified potential accident sequences that result in an inadvertent nuclear criticality."	This does not state a 'representative worst-case' criticality scenario and thus it implies that this will be maintained for every operation in the ISA. This is contrary to the safety analysis guidance for DOE facilities and would be prohibitively expensive.	Agree. The licensee's ISA process will allow a licensee to operate with a current safety basis.

Source	Citation	Comment	Response
Dec. 1, 1998, letter (042-0049) from NCSD/ANS	Proposed 10 CFR 70.60(b) defines a nuclear criticality as a "high consequence" event.	The category of "high consequence" for a criticality accident should be consistent with the other events in this category and be limited to those accidents for which an exposure of over 100 rem is likely.	Agree. 70.60 (d) now uses language very similar to ANS 8.1. Criticality is no longer labeled a "high consequence event." The separation means that the Rule does not equate a criticality to any particular dose.
	The direction and bases provided in the SRP Section 5.4.5.2 for establishing nuclear criticality safety limits for controlled parameters and their respective controls is overly prescriptive, onerous, and confusing.	As properly validated and applied, the subcritical value of k_{eff} # "$k_{failure}$" should have no less certainty for defining a subcritical condition than an actual critical experiment. This is to say, that the selection of operational controls should be independent of the methods (i.e., experimental data versus validated analytical methods) used to establish parameter limits. Thus, we conclude that the Controlled Parameters and Controls methodologies in Subpart 5.b are inappropriate.	Comment is no longer applicable. SRP has been revised such that the methodology used does not affect the results.

Source	Citation	Comment	Response
	The SRP essentially requires the use of the probability risk assessment (PRA) method to determine if the double contingency principle is affirmed.	Concerned that more effort will be expended in calculating the probabilities than in demonstrating that the entire process is in fact subcritical as required by Section 4.1.2 of ANSI/ANS-8.1. Data bases simply do not exist to support PRA for equipment failures in fuel cycle facilities and we feel that this course of action could divert attention from operational safety.	Agree. The quantification specification for double contingency protection has been removed from the SRP Chapter and so PRA or quantitative risk assessments for criticality evaluations are not required.
	In principle, we support the integrated safety assessment (ISA) process proposed by the 10 CFR Part 70 rule change.	The reporting requirements appear to be quite burdensome. For example, DOE requires contractors to have criticality safety evaluations for all operations, but reporting is not required if the operations remain within the operating bases authorization. The NRC should consider this model.	The reporting requirements were revised to require reporting when criticality controls are lost.

Source	Citation	Comment	Response
NEI 12/22/98 letter (042-0053) on ISA & preliminary ISA	Cover letter	The results of the ISA should not be included in the license. The onus be placed on a licensee to perform and implement an ISA, the licensee commit to maintaining an updated and complete version of the ISA at the licensed facility and only a summary of the ISA results be provided to the NRC for placement on the docket. ! Materials License: would contain the licensee's commitments to conduct, maintain, implement and update the ISA ! ISA Summary: a synopsis of the results of the ISA would be submitted to the NRC for placement on the docket. This synopsis would outline the ISA methodology, identified high-risk accident sequences, implemented mitigative safety controls and control assurances. ! Complete ISA: would be maintained at the licensed facility for NRC inspection and for updating as the facility (or its processes) are modified.	Agree with this concept. The safety program information is specified in 70.62 and is maintained on site. The ISA summary is specified in 70.65, it is not part of the license but is submitted on the docket and reviewed with the license.

Source	Citation	Comment	Response
		NEI recommends that preliminary Process Hazards Analysis (PHA) terminology be used in the Part 70 revisions. A preliminary PHA would be submitted to the NRC at the conceptual engineering phase of the project. NRC could use the preliminary PHA for informational purposes, acknowledging that the process or facility design may undergo refinements and redesigns prior to its eventual construction and commissioning. The licensee's ISA would be based on the "as-built" facility and would incorporate some, if not all, of the results of the preliminary PHA.	Agree. Conforming change made. Note NEI comment of 3/26/99 changed this position, requesting (1) deletion of the PHA definition (taken), (2) PHA be performed but not be required to be submitted (taken); and (3) the word 'analysis' be replaced with 'evaluation' (Not taken).
	(a) Risk-Informed Regulation	Part 70 revisions should discuss the risk of an accident sequence rather than separately its consequences and likelihood.	Agree. The performance requirements in 70.60 have been clarified to permit limiting risk by reducing either consequence or likelihood, as appropriate

Source	Citation	Comment	Response
	(b) Inclusion of ISA in License Application	! Complete ISA: The detailed results of the ISA would be retained by the licensee at the facility to be used to safely manage it and to be available for NRC licensing reviews and compliance inspections. The ISA would be updated under the facility's Configuration Management Program as modifications to the facility or to processes are implemented. ! ISA Summary: A synopsis of the results of the ISA would be prepared and submitted to the NRC for placement on the docket. The ISA summary would identify the disciplines of expertise and minimum qualifications of the individuals who performed the ISA, outline the approach and methodologies used in performing it, describe any identified, credible accident sequences whose unmitigated consequences could exceed the consequences of concern in ¶70.60(b), the safety controls implemented to reduce the risk of such accidents and the measures used to ensure the availability and reliability of such controls. The ISA summary would be maintained as a reference on the licensing docket or as the safety demonstration in Part II of a traditional two-part license. It would be revised on an annual basis. ! Materials License: A license applicant's commitments to conduct, maintain, implement and update the ISA would be	Agree in part with the concepts in these statements. However, in the last bullet, it is not true to state that commitments to conduct, maintain, etc. the ISA are the "only" commitments in the license (e.g., licensees must show how they comply with Part 20, which is outside the scope of the ISA). As Stated previously, 70.65 which contains the required contents of the ISA summary has been revised to follow the basic concept presented by NEI. The summary would also be on the docket and not in the license.

Source	Citation	Comment	Response
		Licensees would be free to change their facility or process configurations in accordance with their approved internal change control process without prior NRC approval or license amendment.	Agree in part. Changes to the facility would still need to meet the requirements of 70.72.
		The following definition of an ISA summary is proposed for inclusion in §70.4 of the proposed revisions to Part 70: "ISA summary means a synopsis of the results of the ISA that succinctly describes the facility or its processes, identifies the disciplines of expertise and minimum qualifications of the individuals who performed the ISA and outlines the approach and methodologies used in performing it. The ISA summary identifies and describes those credible accident sequences, whose unmitigated consequences could exceed the consequences of concern elaborated in §70.60(b), the safety controls (or items relied on for safety) to mitigate the risk of such accidents to an acceptable level and the measures to ensure the availability and reliability of such controls. The ISA summary shall be placed on the docket and shall be updated annually by the licensee, but shall not constitute part of the license."	Agree in part. Consistent with a subsequent NEI comment, the definition the staff eventually adopted in 70.4 simply refers to 70.65, which lists the detailed contents of the ISA summary. There was no need to repeat the same information in the definition.

Source	Citation	Comment	Response
	(c) Decommissioning ISA	NEI recommends that §70.62(b) be deleted from the proposed Part 70 revisions. NEI believes that a separate decommissioning ISA is not warranted. The facility's existing ISA program can be used to assess the potential hazards of activities and procedures proposed for use in the decommissioning phase. Any required changes to the ISA and facility operations to protect the health and safety of workers and the public during decommissioning can be implemented within the framework of the existing ISA program.	Agree. Current relevant Section is 70.60. ISA does not apply to decommissioning, which is addressed by existing Part 20, 70.25 & 70.38 Agree - The requirement to perform decommissioning ISA was removed. An additional sentence was added that stated facilities must meet all other decommissioning requirements in Part 20 and 70.
		The example cited in the draft language for §70.62(b)-- "…potentially hazardous activities such as chemical treatment of wastes…" -- may be inappropriate as the NRC-OSHA MOU does not grant NRC jurisdiction over management of purely chemical wastes.	Comment no longer applies based on acceptance of comment to delete decommissioning ISA

Source	Citation	Comment	Response
	(e) Preliminary ISA (or Process Hazards Analysis)	NEI recommends that the PHA terminology be used throughout the proposed Part 70 revisions and that the following preliminary PHA definition be included in §70.4 of the rule: "Preliminary Process Hazards Analysis (PHA) means an analysis undertaken during the design or early development phases of a process to identify the principal potential hazards and to enable them to be eliminated, minimized or controlled with minimal cost or disruption. The analysis also assists in identification of potential corrective, mitigative or preventive measures."	Comment no longer applies. NEI subsequently commented that the requirement to submit the preliminary ISA (or PHA) be deleted. That comment accepted by the staff.
	(f) Persinko Chart	Some clarification of the wording in the right-hand column of the chart is recommended.	Comment no longer applicable. Chart has been abandoned.
	Concluding Remarks	ISA be used in the licensing process in three ways: ISA commitments in the license, ISA summary on the docket and active management of the complete ISA at the licensed facility.	Agree. Reflected in rule.
		NRC licensing and regulatory resources be focused on those high-risk accident sequences that could potentially have the greatest impact on the health and safety of workers and the public.	Agree. Reflected in rule.
		AIChE terminology for a preliminary hazards analysis be substituted for "preliminary ISA."	No longer applies - see above.
		A separate "decommissioning ISA" is not warranted.	Agree - see above.

Source	Citation	Comment	Response
NEI 1/26/99 letter (042-0058): reporting requirements ; change mechanisms; baseline design criteria	Cover letter	The existing incident reporting provisions in 10 CFR 20 and 10 CFR 70 are adequate for ensuring that the NRC is promptly informed of all safety-related incidents. Adding a new §70.74 to the existing §70.50 and 10 CFR 20 reporting requirements appears to be unnecessary.	Disagree. Although the reporting requirements in Part 20 still apply, additional requirements were necessary to conform to the new rule language.
		NEI proposes a change mechanism that would require NRC pre-approval only when that change could potentially threaten to degrade the effectiveness of a safety commitment in the license.	Disagree. A change mechanism has been developed which specifies criteria when pre-approval is required. NEI does not disagree with these criteria.
		Inclusion of baseline design criteria in the Part 70 licensing process is appropriate for new facilities. We do not, however, believe an existing fuel cycle facility should be subject to such criteria, either now or when application is made for renewal of its license. The criteria should, similarly, not apply to new processes or technologies installed at existing facilities.	Disagree. The design basis criteria are considered to be basic design tenants that are applicable to all new larger scale modifications whether or not being added to an existing facility.
	Enclosure: I. Reporting Requirements (§70.74) - (1) Adequacy of Existing Rules	Reporting requirements for fuel cycle facilities (10 CFR 20.2201-22.06 and 70.50) are already adequate; a new rule chapter is unnecessary. The need for modifying the current Part 20 and 70 reporting requirements and for including §70.74 and Appendix C in the rule, is not apparent.	Disagree. Although the reporting requirements in Part 20 still apply, additional requirements were necessary to conform to the new rule language.

Source	Citation	Comment	Response
	Enclosure: I. Reporting Requirements (§70.74) - (2) One-Hour Reporting	The new one-hour reporting time frame for certain events is too restrictive The justification for shortening the reporting period to one hour for an incident which §70.50 or §20.2202 now only requires a four-hour notification is not apparent.	The one-hour reporting requirements have been revised and do not conflict with §70.50 and §20.2202. The requirements in §70.50 and §20.2202 still apply.
		NEI is particularly concerned with the exhaustive list of information that must accompany a one-hour telephone notification to the NRC Operations Center.	The information to accompany a one-hour report has been revised to conform with §70.50 information.
		Some required information such as personnel radiation exposure data and chemical analyses of licensed material or hazardous chemicals produced from licensed materials ((¶V.(c)(3)) can not be provided within such a short time frame.	The information to accompany a one-hour report has been revised to conform with §70.50 information.
		The risk of providing the NRC with inaccurate preliminary information, which may in turn be publicly disseminated, is increased under the draft rule revisions.	Disagree. The information to accompany a one-hour report has been revised to conform with §70.50 information.
		During the first hour following a 'safety-significant' event the licensee must focus all its efforts on emergency response activities.	The information to accompany a one-hour report has been revised to conform with §70.50 information.

Source	Citation	Comment	Response
		NEI recommends that the one-hour time frame be limited to notification of the NRC of serious safety incidents and that all supplemental information be provided within the existing four or twenty-four hour reporting periods.	Agree. The one-hour reporting requirements have been revised to require reporting of only serious safety incidents. The information to accompany a one-hour report has been revised to conform with §70.50 information.
	Enclosure: I. Reporting Requirements (§70.74) - (3) Chemical Exposure Reporting:	Appendix C Sections I(a)(2)(ii), I(a)(3)(iii) and II(a)(1)(iii) and II(a)(2)(ii) should be appropriately corrected to correspond to the Part 70 revisions proposed by the NRC in December 1998. A licensee should not be required to report all personnel hazardous chemical exposures	Agree. The reporting requirements have been revised such that licensees are not required to report all personnel hazardous chemical exposures.
	Enclosure: I. Reporting Requirements (§70.74) - (4) Environmental Monitoring Program	Compliance with Appendix C ¶II(3) could be interpreted to require explicit, continuous, radiological monitoring and surveying of radiation levels in the unrestricted and controlled areas adjoining a licensed facility. Fuel cycle facilities have very benign impacts on the public. A licensee should not be required to conduct continuous radiological monitoring in the unrestricted or controlled areas of its facility.	Agree. The reporting requirements have been clarified to reflect that continuous radiological monitoring in the unrestricted and controlled areas is not required.

Source	Citation	Comment	Response
	Enclosure: I. Reporting Requirements (§70.74) - (5) Subjective Language	Emergency reporting of 'potential deviations' from safe operating practices or 'potentially unsafe conditions' should not be required. This language is too subjective.	The language has been revised to remove this subjective language.
		Appendix C ¶II(2)(b), ¶III(a), ¶III(c) and ¶IV(a) require notification to the NRC of "…deviations from safe operating conditions…" What constitutes a 'deviation' is not defined.	The reporting requirements have been revised and no longer use this term
		Reports to the NRC should be limited to 'deviations' that are safety-significant or that resulted in an accident. Reporting potential unsafe conditions should not be necessary.	The reporting requirements have been revised and do not require reporting of potential unsafe conditions.
	Enclosure: II. Change Mechanism (§70.72)	A licensee should have the flexibility to operate within the 'regulatory envelope' of the commitments and authorized activities contained in its license.	Agree - The 70.72 change process was revised to allow the license greater flexibility to make changes without NRC pre-approval.
		A licensee should be able to implement changes so long as they do not substantially degrade or decrease the effectiveness of any safety commitment in the license, do not approach or exceed a §70.60(b) consequence of concern, do not impair the licensee's ability to meet applicable federal regulations or do not conflict with any license conditions.	Agree in part. Section 70.72 was revised to require NRC pre-approval for the significant changes to the facility.
		The inherently qualitative nature of the ISA used to establish whether or not NRC pre-approval is needed for a change makes assessment of what constitutes "…a minimal increase…" a highly subjective call.	Agree - The change process was revised to remove the subjective wording.

Source	Citation	Comment	Response
		The onus would be placed on the licensee to identify and analyze the significance of potential hazards associated with a proposed change and to seek NRC pre-approval of a change whenever its analysis so dictates.	Agree in part. The change process has been revised to remove the subject nature of rewording and therefore it is clear when pre-approved is required.
		NRC pre-approval should be required for a change to the facility or operating procedures as described in the ISA that entails: 1. exceedance of, or approach to, a consequence of concern listed in §70.60(b) 2. activities not currently authorized by the license 3. substantial degradation or a decrease in the effectiveness of any safety commitment in the license 4. significant process or facility changes that either create new types of higher consequence accidents or require significant changes to the facility's environmental report prepared in accordance with 10 CFR 51 5. impairment in the licensee's ability to meet applicable federal regulations 6. a conflict with any license condition	Agree. The change process has been revised to follow this concept. Changes under Bullets 2. 3, 5 and 6 in NEI's proposal would require pre-approval by NRC without a change process. Requirements in license and regulations can not be changed without NRC approval. The new change process incorporated changes of the type discusses in Bullets 1, 3 and 4.

Source	Citation	Comment	Response
		The licensing basis on which the NRC establishes compliance with the rule and base licensing action approvals should be the commitments and authorized activities contained in the materials license. These would include, for example, commitments to protect health and minimize danger to life and property, to protect against nuclear criticalities, to implement fire and chemical safety programs, to conduct personnel and environmental monitoring programs, to implement management control systems and to conduct, implement and maintain an ISA for the facility. The commitment to perform, maintain, update and address vulnerabilities identified by the ISA would constitute an important licensing basis.	Agree.
		All changes implemented by the licensee would be incorporated into the facility's ISA and reported to the NRC in the annual ISA update. For changes not requiring NRC pre-approval the licensee would maintain written internal evaluations that provide the bases for determining that the changes do not require NRC pre-approval.	Agree in part. Since the change process allows the licensee greater flexibility is making changes without NRC pre-approval, then those changes should be reported to NRC. The rule was revised to require changes made without NRC pre-approval that affect the ISA summary to be submitted within 90 days. All other changes within 1 year.

Source	Citation	Comment	Response
	Enclosure III. Baseline Design Criteria (§70.64)	Proposed revision §70.74 should be revised to exclude existing licensees from adherence to these baseline design criteria, both for their existing facilities and for changes in process technology or operating procedures that may be implemented in the future	Disagree. NOTE: INTENDED REFERENCE IS 70.64. BDCs apply to new processes and new facilities equally. Meaning of new processes is clarified. Subsequent NEI comments supercede this comment to state that BDC do apply to existing licensees if an amendment for a new process is required by 70.72. Staff agrees with that approach
Jan. 21, 1999, (042-0059) letter and mark-up of draft SRP Chapter 5, Criticality Safety	Enclosure II. General Concerns (a) Degree of Prescriptiveness	The SRP often constrains a reviewer to one approach when several are possible. For example, §5.4.5.2(5) does not acknowledge that there are several ways to calculate failure limit and safety limit K_{eff} values; the SRP formulation is too specific and unnecessarily constraining.	Disagree. The SRP introduction states that other approaches are acceptable as long as they are appropriately justified by the applicant.
		§5.4.4.3 arbitrarily mandates weekly audit inspections of SNM process areas and quarterly safety audits without any justification for the selected frequencies.	Agree. SRP Chapter revised to state that other time periods are acceptable as justified by the ISA.
		The SRP language should avoid usage of all-inclusive language and connotations. It should not constrain a license reviewer's 'acceptance criteria' to a single approach presented in the SRP.	Agree in Part. The SRP is to be used as guidance and therefore no constraining of the approach by the SRP is expected.

Source	Citation	Comment	Response
		The SRP should be written at a level of detail commensurate with the ANSI/ANS-8 standards.	Disagree. ANS-8 standards alone do not provide adequate information and so the SRP allows multiple approaches and provides more detail than the standards.
		Each facility's license application should be allowed to provide a level of detail appropriate to its design features and unique characteristics.	Agree. The SRP does not prescribe any level of detail.
	Enclosure II. General Concerns (b) Graded Approach to Safety	The NRC's proposal to no longer single out a potential nuclear criticality as a 'high consequence' event is appropriate and reflects a correct application of the graded approach to safety. There are numerous examples in Chapter 5 where the graded approach should be applied. Three of these examples are: (i) §5.4.4.2 (4)performance-based training in NCS for all plant personnel regardless of their responsibilities (ii) §5.4.4.1(1) requires application of the "…highest quality assurance level…for all criticality controls…" (iii) §5.4.5.1(5) presumptively assumes that changes from a passive engineered control to an active engineered control will result in a significant increase in risk.	Agree. The SRP has been changed to permit a graded approach to safety.

Source	Citation	Comment	Response
	Enclosure II. General Concerns (c) Use of Probabilistic Methodologies	NEI recommends that all references to probabilistic techniques be eliminated from Chapter 5.	Agree. All probabilistic techniques have been eliminated from the SRP Chapter.
		The approach for performing evaluations of margins of safety in a system (§5.4.6) should be performed consistent with ANSI/ANS-8 guidance	Agree. The approach in the SRP is consistent with ANS-8 guidance.
	Enclosure II. General Concerns (d) Excessive Repetitiveness	Most chapters of the SRP contain subsections on 'Training Requirements', 'Quality Assurance', 'Management Control Systems, 'Audits, Assessments and Investigations', and 'Organizational Requirements'. Inappropriate inconsistencies would be eliminated and the SRP would be a much more user-friendly document if these subchapters were removed from each chapter of the SRP and replaced by a single chapter for each topic.	Agree. The SRP has been changed to cross-reference appropriate sections and chapters.
		Chapter 5 attempts to repeat, interpret or expand upon many topics adequately addressed in ANSI/ANS-8 standards. This is not necessary. NEI recommends Chapter 5 refer the license reviewer to ANSI/ANS-8 standards	Disagree. One purpose of the SRP is to provide NRC's interpretation and applicability of ANS-8 standards for NRC reviewers
	Enclosure II. General Concerns (e) Definition Redundancies	Definitions appear in Chapter 5 that are found elsewhere in the Part 70 rule, in the ANSI/ANS-8 standard, or in the SRP. Reference to these definitions should be made rather than attempting to redefine a term in a manner that is inconsistent with the Rule or ANSI/ANS-8 standard.	Agree. Definitions have been moved to a general glossary for the SRP.

Source	Citation	Comment	Response
		Redundant definitions also should be removed. For example, several terms defined in §5.4.0 do not appear to be used elsewhere in Chapter 5 (e.g. 'criticality control system').	Agree. These redundant definitions have been removed.
		Conversely, terms are used which are not defined and which are used in a manner that prompts confusion (e.g. 'safety margin').	Agree. Definitions will be provided to reduce confusion.
		The language of several definitions should be clarified to remove ambiguity. For example, the term 'adequate margin of safety' should be stated to be "adequate margin of sub-criticality' (§5.4.5.1 (7)).	Agree. Use of terms will be clarified.
		definitions of 'double contingency' and 'double contingency principle' in §5.4.0 are redundant.	Comment is no longer applicable as the terms double contingency principle and double contingency protection are now used and have different meanings.
		definition of 'dual sampling' is erroneous (see red-lined Chapter 5 for correction),	Agree in Part. The definition has been modified to clarify NRC's intent.
		definitions of 'items relied on for safety' contained in the rule and Chapter 5 are inconsistent	Agree. The definitions in the Rule and SRP are now consistent.
		NEI recommends that technical definitions (and acronyms) be consolidated into a single chapter of the SRP.	Agree. Definitions have been moved to a general glossary for the SRP.

Source	Citation	Comment	Response
	Enclosure II. General Concerns (f) Adherence to ANSI/ANS-8 Standards -- ANSI/ANS-8 References	additional requirements sought by the SRP over and above double contingency are unnecessary.	Agree in Part. Additional requirements unrelated to double contingency may sometimes be required. Also, alternatives to double contingency are also permitted.
		in those areas where double contingency is met with robust systems, there is no reason for assurance measures on such controls or controlled parameters to be 'of the highest standard.'	Agree. The SRP has been modified to more clearly allow grading of measures.
		Whenever the ANSI/ANS-8 standards are cited, specific reference to its applicable chapter and section should be cited to enable the reviewer to quickly consult the appropriate and applicable section of the standard.	Agree. To the extent possible, specific references to standards will be made.
	Enclosure II. General Concerns (g) Chapter Structure and Style	The structure of Chapter 5 often is difficult to follow. For example, the introduction to Chapter 5.3 identifies four areas of review. However, the four subsections §5.3.1-5.3.4 neither faithfully nor clearly follow how these four introductory topics are presented.	Agree. The SRP Chapter has been modified in its entirety to address structure and style concerns.
		The level of detail and 'how-to' prescriptiveness, repetitiveness of definitions and sub-topics common to several SRP chapters (e.g. management systems, training, audits, etc.) and adherence to Part 70 rule provisions substantially differ.	Agree. The SRP has been modified in its entirety to provide a better consistency between sections and chapters.
		Several instances occur in §5.4 'Acceptance Criteria' where controls are mentioned without there being a clear linkage back to any acceptance criterion.	Agree. The SRP Chapter has been modified in its entirety in order to ensure that linkages are clear.

Source	Citation	Comment	Response
		NEI recommends that the entire SRP be reviewed by technical editors to ensure consistency in language, degree of detail and structure among individual chapters prior to its final issuance.	Agree. Review by a technical editor will be performed prior to final publication of the SRP.
	Enclosure II. General Concerns (h) Breadth of License Application Review	The draft SRP prescribes a much broader and extensive review of NCS technical data than should be required. The SRP directs that detailed reviews be performed of internal NCS evaluations and assessments on specific systems and/or specific credible accident scenarios identified in the ISA. NRC reviewers should, in contrast, focus on reviewing the broader NCS program (basic commitments, adequately trained personnel, review procedures, etc.) and the specific highest risk sequences.	Agree. The SRP should focus the NCS program and high risk areas of concern.
		§5.4.5.1 states that the "…application specifies the basis of nuclear criticality for each process…" and that "…the applicant demonstrates for each system that could cause a nuclear criticality, that the system possesses double contingency…" Review of each process or system is not necessary and will be very time-consuming. Only those higher risk accident sequences reported in the ISA Summary should be reviewed at this level of detail.	Agree. The review should focus the NCS program and high risk areas of concern.
	III. Specific Concerns 5.1 PURPOSE OF REVIEW	The order in which the 4 purposes are presented should parallel the order in which they are discussed in the following subsections	Agree. The SRP Chapter has been modified in its entirety to address structure and style concerns.

Source	Citation	Comment	Response
		Purpose (1) of this review is incorrectly stated: the reviewer will not review all accident sequences addressed in the ISA, but only those higher risk sequences which are presented in the ISA Summary	Agree in Part. As necessary, the reviewer may review other accident scenarios in the ISA at the applicant's site.
	5.3.1 NCS Organizational Responsibilities	move this section to Chapter 2.0 of SRP, consolidate and remove redundancies and inconsistencies, and reference reviewer to that chapter	Agree. Only items unique to NCS will remain in the SRP Chapter.
	5.3.2 Management Control Systems for NCS	move this section to Chapter 11.0 of SRP, consolidate and remove redundancies and inconsistencies and reference reviewer to that chapter.	Agree. Only items unique to NCS will remain in the SRP Chapter.
		"2. Maintenance to ensure that controls identified in the ISA Summary as important to NCS are ~~continually~~ available and reliable when required to perform their functions."	Agree.
		Change "quality assurance" term to "management measures" (here and throughout the balance of Chapter 5): " 3 ~~Quality assurance~~ Management measures to ensure that components important to NCS are properly specified, obtained, installed, operated, and maintained."	Comment is no longer applicable, as all references to quality assurance in this Chapter have been removed.
	5.3.3 NCS Technical Practices	NRC staff review should focus on the NCS program (i.e. basic commitments, adequately trained personnel, procedures for review to ensure adequate NCS, etc.), rather than on detailed NCSEs of specific scenarios or systems.	Agree in Part. The reviewer may need to evaluate certain high risk NCS scenarios to ensure that the NCS program is adequate.
		Replace ISA with ISA summary	Agree.

Source	Citation	Comment	Response
		Controls should not have to be reviewed for "…each process, system and equipment function…", but only for those higher risk accident sequences identified in the ISA Summary. If the ISA determines that a nuclear criticality is not possible in a particular process, such a review will also be unnecessary.	Agree in Part. Occasionally, the reviewer may choose to evaluate accidents not considered "high risk" by the applicant to ensure that they are, in fact, not "high risk."
		"2. NCS controls and control parameters ~~limits on controls and controlled parameters~~ to ensure that an adequate safety margin of subcriticality exists."	Agree. However, the term has been changed to margin of subcriticality for safety in the Rule.
		Is it the intent of the NRC to perform independent technical reviews of computer code calculations? This should not be the case.	Agree in Part. There may be cases where the reviewer will evaluate the methodology of how the code will be used by the applicant.
		"6. Information describing implementation of special protective features, as applicable, and information describing any additional margins of subcriticality ~~safety~~ adopted as a result of the ISA process, for specific functions or activities." What is the definition of "special protective features"?	No longer applicable. This item has been removed from the Chapter.
		- SEE MARK-UP OF CHAPTER 5 FOR ADDITIONAL COMMENTS -	

Source	Citation	Comment	Response
NEI Feb. 12, 1999, letter (042-0061): comments on proposed revisions to 10 CFR Parts 70.60 and 70.62 and on nuclear criticality issues raised at the January 13, 1999 public meeting	**II. Comments on §70.60 and §70.62 Proposed Revisions** (a) Administrative and Engineered Controls	Definitions of 'administrative control' and 'engineered control' that are consistent with the ANSI/ANS Series 8 standards should be included in §70.4.	Disagree. These definitions are more appropriate for the different SRP Chapters because different standards (e.g., ANS-8 and NFPA) have different definitions of "administrative controls."
	(b) Decommissioning ISA	A separate decommissioning ISA is not warranted as facility changes during decommissioning can be processed through a facility's existing ISA program, just like operational changes. NEI recommends that §70.62(a)(3) be deleted.	Agree. Current relevant Section is 70.60. ISA does not apply to decommissioning, which is addressed by existing Part 20, 70.25 & 70.38
	(c) ISA Results and ISA Summary	The license should specifically contain a licensee's commitments to safety programs, including one to conduct, maintain, implement and update the ISA. An ISA Summary outlining the ISA methodology, identifying high-risk accident sequences and implemented safety controls and control assurances would be submitted to the NRC for placement on the licensee's docket and for use by the NRC staff in reviewing a license application. The complete ISA ('results of the ISA') would be maintained at the licensed facility for NRC inspection and updating when the facility or its processes are modified.	Agree, this is the approach in the rule. Generally, 70.62 specifies on-site information and 70.65 specifies submitted information (i.e., ISA summary)
		The way in which the ISA is to be used in the licensing process is not correctly portrayed in the *revisions-in-total* to §70.72.	§70.72 has been revised. Comment no longer applies.

Source	Citation	Comment	Response
		The definition of ISA Summary in §70.4 requires revision.	Comment no longer applies. Consistent with subsequent NEI comment, the definition refers to 70.65, which specifies the contents of the ISA summary
	(d) Design Basis for Items Relied on For Safety	§70.62(c)(vi) should be clarified to require detailed information only on the items relied on for safety for ISA Summary-identified accident sequences.	Disagree. The ISA (maintained on site) should assess the potential accidents for all the processes, before a decision is made if an item relied on for safety needs to be identified for that process
		Part 70 baseline design criteria would not apply to existing, licensed facilities or to changes that may be made to them in the future.	Disagree. BDCs continue to apply to new processes and new facilities equally. Meaning of new processes is clarified. Subsequent NEI comments supercede this comment to state that BDC do apply to existing licensees if an amendment for a new process is required by 70.72. Staff agrees with that approach

Source	Citation	Comment	Response
	(e) ISA Team Qualifications	§70.62(c)(2) is too prescriptive and does not grant a licensee the option of having contractor personnel with the desired expertise participate in the ISA. The term 'employee' should be replaced by 'person' throughout this section.	Agree. term 'employee' was replaced by 'person' throughout the paragraph
	(f) ISA Revalidation	§70.62(c)(3) is not consistent with the ISA being a 'living document'	Agree. Revalidation of ISA was deleted as unnecessary, since the 70.72 process governs the facility changes and updating of safety program/ISA documentation
	(g) Preliminary ISA	NEI recommends that the American Institute of Chemical Engineering (AIChE) terminology be employed ('preliminary Process Hazards Analysis') rather than 'preliminary ISA'	Comment no longer applies. NEI subsequently commented that the requirement to submit the preliminary ISA (or PHA) be deleted. That comment accepted by the staff
	(h) ISA Filing by Existing Licensees	NEI recommends that the term 'compliance plan' be replaced simply by 'program' in this subsection.	Agree in part. 'Plan' (not 'program') was adopted in place of 'compliance plan'
	(i) Management Measures	the eight measures appear overly prescriptive and should be relocated to ¶5.4.4 ('Management Measures') in the SRP as acceptable, 'possible' measures to provide the required assurance.	Agree in part. The prescriptive list was deleted from what is now 70.62(d). The topical areas were retained in a newly added definition of management measures.

Source	Citation	Comment	Response
		additional language should be added to assure the NRC that an item relied on for safety will have assurances of availability and reliability that are appropriate to the nuclear criticality risk it is designed to prevent or mitigate.	Agree. 70.62(d), on management measures now links directly to the performance requirements. Grading is permitted.
		NEI recommends that this sub-section be simplified to read: *"(d)* ***management measures****. Each licensee or applicant shall establish management measures to ensure that each item relied on for safety described in the ISA Summary will perform its intended function when needed. The assurance of availability and reliability of such an item relied on for safety may be graded to the risk it is designed to prevent or mitigate."*	Agree in part. Similar but slightly modified language was adopted into what is now 70.62(d). Definition of management measures was also added to 70.4
	(j) Unacceptable Vulnerabilities	term 'unacceptable vulnerabilities' be replaced by 'unacceptable performance deficiencies'	Agree. 'unacceptable vulnerabilities' replaced by 'unacceptable performance deficiencies' throughout

Source	Citation	Comment	Response
	(k) Definitions (§70.4)	The following definition proposed by NEI is recommended for inclusion in §70.4 instead of that proposed in the December 1998 NRC posting: "ISA summary means a synopsis of the results of the ISA that succinctly describes the facility or its processes, identifies the disciplines of expertise and minimum qualifications of the individuals who performed the ISA and outlines the approach and methodologies used in performing it. The ISA summary identifies and describes those credible accident sequences, whose unmitigated consequences could exceed the consequences of concern in §70.60(b), the safety controls (or items relied on for safety) to mitigate the risk of such accidents to an acceptable level and the measures to ensure the availability and reliability of such controls. The ISA summary shall be placed on the docket and shall be updated annually by the licensee, but shall not constitute part of the license."	Agree in principle. The current definition states: Integrated safety analysis summary means the document submitted with the license application, license amendment application, or license renewal application that provides a synopsis of the results of the integrated safety analysis and contains the information specified in §70.65(b). 70.65 lists of contents for the submitted ISA summary. The ISA summary will be updated within 90 days of a change which affects the summary. All other changes will be submitted annually.

Source	Citation	Comment	Response
	III. Comments on Nuclear Criticality Safety Issues (a) Historical NCS Data	NEI recommends that the list of operational events not be incorporated in the license. An acceptance criterion could, however, be inserted into the ISA chapter of the SRP that would require an applicant to examine ten years of operational events in preparing the ISA.	Agree. This requirement has been removed from the latest rule language.
	(b) Controls vs. Control Systems	NEI recommends that the term 'set of controls' or 'control system' be used throughout the rule to clarify the broader meaning of control. For example, §70.60(e), as amended by the December NRC modifications, should read: "*(e) Each engineered or administrative control or control system necessary to comply…*"	Agree. "... or control systems" added in several places in the rule. An item relied on for safety could include a system of controls.
NEI Feb. 12, 1999, letter (042-0062) on the need for inclusion of a Backfit Provision in the Part 70 rule.		NEI believes that the 'modest increase/minimal or inconsequential cost' standard is worthy of further consideration in a proposed rule	Agree in Part. Even minimal increase/minimal cost items may be considered.
		NEI strongly recommends that the proposed rule include an immediately effective backfit provision.	Disagree. The staff's position is outlined in the response to the SRM.
		NRC's proposed use of a qualitative, non-monetary methodology to derive the safety benefit of a backfit modification is inconsistent with NUREG/BR-0058 Rev. 2 ('Regulatory Analysis Guidance of the U.S. Nuclear Regulatory Commission'), which requires use of quantitative analyses to the maximum extent possible.	Disagree. If quantitative analysis is required, this would push backfit towards using PRA which NEI has historically been against for Part 70 licensees.

Source	Citation	Comment	Response
		provision should be immediately effective. It should require a documented, quantitative analysis of any proposed modification to demonstrate that the proposed backfit: (i) will increase the overall protection of the public health and safety, and (ii) will have a cost of implementation that can be justified by the increase protection the modification affords.	Disagree. See positions in backfit response to SRM.
		include a 'compliance exception' clause that would state that a backfit analysis would not be required if the NRC determines that a backfit modification is necessary to bring the facility into compliance with its license commitments or that it is needed to protect the health and safety of the public, common defense and security.	Agree in Part. Would implement if backfit is implemented.
Feb. 1, 1999, letter from OSHA		A rule that generically addresses chemical hazards at NRC-licensed facilities would preempt OSHA from enforcing any of its standards with respect to chemical hazards at these facilities, not only Process Safely Management but such things as respiratory protection, confined space entry, lockout/tagout, etc. The MOU may not reflect OSHA's current position.	
		Decommissioning: Most of the hazards involving demolition would be better addressed by OSHA.	
		Exposure limits should not permit exposures in excess of OSHA's PEL's.	

Source	Citation	Comment	Response
NEI March 2, 1999, (042-0069) comments on SRP Chapter 6, Chemical Process Safety", with redline/ strikeout markup.	Cover letter	There are instances in which the SRP does not correctly reflect revisions to the Part 70 Rule or the consensus achieved at NRC public meetings.	Agree. Comment was made based on SRP text prior to revision to reflect new rule language that codified MOU.
		The draft SRP does not adequately address the third MOU principle ('chemical risks produced from plant conditions that affect the safety of radioactive materials').	Agree. Comment was made based on SRP text prior to revision to reflect new rule language that codified MOU.
		The SRP should also be clarified to state that NRC Staff review of chemical process safety will be limited to those higher-risk sequences identified in the facility's ISA Summary.	Disagree. The meaning of the term Higher-risk is not clear. NRC will review those sequences that could exceed the performance requirements.
		The SRP should focus the reviewer on assessing the adequacy of an applicant's license commitments to chemical process safety, rather than evaluating detailed, process-specific information against unduly prescriptive acceptance criteria.	Agree. Comment was made based on SRP prior to revision. Latest revision may resolve this concern

Source	Citation	Comment	Response
		topics that are addressed in other SRP chapters should be expunged from Chapter 6. For example, the entire §6.4.3.4 ('Continuing Assurance of Chemical Process Safety') which addresses the reliability and availability of items relied on for safety, should more appropriately be reviewed in SRP Chapter 11 ('Management Measures').	Agree in part. Clarified that the information does not need to be repeated in the application. The SRP refers the reviewer to the appropriate section unless there is an aspect particular to that technical discipline.
	Redline/strikeout mark-up of SRP Chapter 6 ('CHEMICAL PROCESS SAFETY')	- SEE MARK-UP FOR SPECIFIC COMMENTS -	Adopted as appropriate. SRP chapter 6 was totally re-written based on the new rule and on NEI's mark-up.
NEI 3/2/99 (042-0070) in response to OSHA questions		The NRC/OSHA MOU is, in our view, consistent with the statutory allocation of jurisdiction between the NRC and OSHA, and serves as a useful frame of reference for discussing these issues.	No response necessary. The comment is a statement of opinion and support for no changes.
		We did not intend to, nor do we believe that the NRC's suggested changes to the draft rule would, encroach in any way on OSHA's traditional authority over non-radiological chemical hazards at NRC licensed facilities.	No response necessary. The comment is a statement of opinion and support for no changes.

Source	Citation	Comment	Response
NEI letter (042-0077), 3/26/99 letter, on rule revisions	Definitions: Available and Reliable	Replace “analysis” with “assessment”	Disagree. This term has been used since the original rulemaking.
		Add “when needed” after “safety function”	Agree.
		Replace “ensure continuous” with “provide reasonable assurance of” in “ensure continuos compliance with the performance requirements of 70.61.”	Disagree. “Ensure continuos” was kept because the licensee must meet the performance requirements of 70.61 at all times. The proposed change incorrectly implies that the regulation is simply a target or a goal and as revised would allow the licensee to be out of compliance with the 70.61. Same changes requested in 70.62(d).
	Definitions: Configuration Management	Delete “all”	Agree in Part. “All” deleted, but phrase “that might impact the ability of item relied on for safety to perform their function when needed” added to end of sentence.
		Replace “the site, structures... personnel” with “items relied of for safety”	Agree.
	Definitions: Controlled Site Boundary	Delete definition in its entirety.	Agree.

Source	Citation	Comment	Response
	Definitions: Critical Mass of Special Nuclear Material	Delete definition in its entirety.	Disagree. Despite NEI's comment that the term is no longer used, it is used twice in the revision reviewed by NEI. These two areas are: 1) the title of Subpart H and 2) in §70.66. In §70.76, the reference has been removed and instead changed to reference "an applicant subject to Subpart H"
	Definitions: Deviation from Safe Operating Conditions	Delete Definition in its entirety.	Agree.
	Definitions: Integrated Safety Analysis	Replace "analysis" with "assessment" (3 occasions)	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
		Replace "site, structures... personnel that are" with "items"	Agree.
	Definitions: Integrated Safety Analysis summary	Replace "analysis" with "assessment" (2 occasions)	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
		Delete "in conjunction".	Agree.
		Replace "informs the Commission...;and the evaluations for compliance with the performance requirements of §70.61" with "contains the information specified in §70.65(b)"	Agree.

Source	Citation	Comment	Response
	Definitions: Items relied on for safety	Add “or mitigate” after “prevent” and remove “or to mitigate their potential consequences” at end of sentence.	Disagree. An accident is not mitigated, but rather the consequences of the accident are what is mitigated.
		Add “that could result in non-compliance with the performance requirements in §70.61" to end of sentence	Agree. Added “However, this does not limit the licensee from identifying additional structures, systems, equipment, components, or activities of personnel (i.e., beyond those in the minimum set necessary for compliance with the performance requirements) as items relied on for safety.”
	Definitions: Management measures	Replace “analysis” with ”assessment” .	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion. However, deleted phrase “identified in the integrated safety analysis” to reduce original limited scope of definition, making comment no longer applicable.

Source	Citation	Comment	Response
		Replace “ensure” with “provide reasonable assurance that”	Disagree. Ensure was kept to be consistent with other regulatory language. The regulations must be met and the licensee’s must ensure that they are met. The reasonableness of the assurances provided is evaluated during the inspection and enforcement process.
		Replace “quality” with “safety” and Replace “systems” with “measures”	Disagree. Replaced “quality assurance systems” with “quality assurance elements” to make it clear that some of the items listed already relate to quality assurance.
	Definitions: New processes at existing facilities	Delete definition in its entirety.	Agree.
	Definitions: Preliminary process hazards analysis	Delete definition in its entirety.	Agree.
	Definitions: Unacceptable performance deficiencies	Add “management” before “measures”.	Agree.
		Delete “used to assure the items are available and reliable to perform their function when needed,”	Agree.

Source	Citation	Comment	Response
	70.60	Delete “decommissioning of facilities used for these activities”.	Agree. However, added new statement “The regulations in §70.61 through §70.74 do not apply to decommissioning activities performed pursuant to other applicable Commission regulations including §70.25 and §70.38 of this Part” to end of paragraph. This addition was necessary to clarify that the licensee must continue to follow current decommissioning regulations since decommissioning actions were specifically removed from Subpart H.
		Add “These regulations do not apply to Gaseous Diffusion Plants”	Agree in part. Will change to “Also, the regulations in §70.61 through §70.74 do not apply to activities that are certified by the Commission pursuant to Part 76 of this Chapter.”
	70.61(a)	Replace “demonstrate” with “evaluate”.	Agree.
		Replace “analysis” with ”assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
		Add “its” after “§70.62,”	Agree.

Source	Citation	Comment	Response
	70.61(b)	Replace “demonstrated” with “determined”	Disagree. The licensees must demonstrate to NRC that they meet the requirements of the regulation. For the licensee to simply “determine” that they meet the requirement does not provide NRC with the information necessary to determine the adequacy of the licensee’s safety basis. No justification for this change was provided.
	70.61(b)(2)	Delete “outside the controlled site boundary” and add “to a member of the public outside the controlled area...”	Agree in Part. Replaced term “outside the controlled site boundary” with “to any individual located outside the controlled area identified pursuant to paragraph (f) of this section” to be consistent with Part 20. Added new section §70.61(f) to require establishment of such an area.
	70.61(b)(3)	Delete “outside the controlled site boundary” and add “to a member of the public outside the controlled area...”	Agree in Part. Replaced term “outside the controlled site boundary” with “by any individual located outside the controlled area identified pursuant to paragraph (f) of this section” to be consistent with Part 20. Added new section §70.61(f) to require establishment of such an area.

Source	Citation	Comment	Response
	70.61(b)(4)	Delete “outside the controlled site boundary” and add “to a member of the public outside the controlled area...”	Agree in Part. Replaced term “outside the controlled site boundary” with “to any individual located outside the controlled area identified pursuant to paragraph (f) of this section” to be consistent with Part 20. Added new section §70.61(f) to require establishment of such an area.
		Replace “Part” with “part”.	Disagree. As it is referencing the rule language, it is NRC policy to capitalize “Part.”
	70.61(c)	Replace “demonstrated” with “determined”.	Disagree. The licensees must demonstrate to NRC that they meet the requirements of the regulation. For the licensee to simply “determine” that they meet the requirement does not provide NRC with the information necessary to determine the adequacy of the licensee’s safety basis. No justification for this change was provided.

Source	Citation	Comment	Response
	70.61(c)(2)	Delete “outside the controlled site boundary” and add “to a member of the public outside the controlled area...”	Agree in Part. Replaced term “outside the controlled site boundary” with “to any individual located outside the controlled area identified pursuant to paragraph (f) of this section” to be consistent with Part 20. Added new section §70.61(f) to require establishment of such an area.
	70.61(c)(3)	Delete “outside the restricted area” and add “to a member of the public outside the controlled area...”	Disagree. Wording kept to be consistent with §20.2202(a)(2).
	70.61(c)(4)	Delete “outside the controlled site boundary” and add “to a member of the public outside the controlled area...”	Agree in Part. Replaced term “outside the controlled site boundary” with “to any individual located outside the controlled area identified pursuant to paragraph (f) of this section” to be consistent with Part 20. Added new section §70.61(f) to require establishment of such an area.
		Add “licensed” before “material” in last sentence.	Disagree. Not all chemical exposures covered under this regulation would be from licensed material; it may instead be associated with such material.
		Replace “Part” with “part”.	Agree. In this case, the word part is not referring to the rule.

Source	Citation	Comment	Response
	70.61(e)	Replace “ensure that each” with “provide reasonable assurance that” and change “its” to “their”	Disagree. Ensure was kept to be consistent with other regulatory language. The regulations must be met and the licensee’s must ensure that they are met. The reasonableness of the assurances provided is evaluated during the inspection and enforcement process. The proposed change incorrectly implies that the regulation is simply a target or a goal.
	70.62(a)(1)	Replace “that ensures that actions taken...and of the environment” with “consisting of appropriate management... when needed”.	Agree in part. Agree to modify statement that is requested to be deleted; however, NEI’s change improperly characterizes the safety program as management measures only whereas the safety program also includes process safety information and the integrated safety analysis. Therefore statement will be changed to “that demonstrates compliance with the performance requirements of §70.61.”

Source	Citation	Comment	Response
		Delete “the safety program, including”.	Disagree. This again improperly attempting to characterize the safety program as management measures only. To clarify this point, the final sentence was changed to state “The three elements of the safety program, namely process safety information, integrated safety analysis, and management measures, are described in paragraphs (b) through (d) of this section.”
		Replace “analysis” with “assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
	70.62(b)	Delete “compile and” and delete “a set of”.	Agree.
		Replace “analysis” with “assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
	70.62(c)	Replace “analysis” with “assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
	70.62(c)(1)	Replace “analysis” with “assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.

Source	Citation	Comment	Response
	70.62(c)(1)(i)	Replace “hazards” with “risks”.	Disagree. Although the use of risks is consistent with the MOU with OSHA, the intent of the statement is to identify the hazard so that one can evaluate the risk.
	70.62(c)(1)(ii)	Replace “hazards” with “risks”.	Disagree. Although the use of risks is consistent with the MOU with OSHA, the intent of the statement is to identify the hazard so that one can evaluate the risk.
		Replace “or” with “and”.	Agree.
	70.62(c)(1)(iii)	Replace “hazards” with “risks”.	Disagree. Although the use of risks is consistent with the MOU with OSHA, the intent of the statement is to identify the hazard so that one can evaluate the risk.
		Delete “(e.g., chemical, fire,...)”.	Agree.
	70.62(c)(1)(vi)	Replace “Part” with “part”.	Disagree. As it is referencing the rule language, it is NRC policy to capitalize “Part.”

Source	Citation	Comment	Response
	70.62(c)(1)	Add “The integrated safety assessment need not be docketed...”	Disagree. Although this intent will be stated in the statement of considerations, all submittals to NRC must be docketed; however, there is no requirement to submit the ISA and thus docketing should not be an issue.
	70.62(c)(2)	Replace “analysis” with “assessment” (3 places).	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
	70.62(c)(3)(i)	Replace “6" with “twelve”.	Disagree. No justification for change was provided. As existing licensees are already significantly involved in the development of this rule and ISAs at their sites, development of a plan within 6 months of issuance of the final rule should not be a significant burden.
		Add “unless otherwise specified by the conditions of...”	Disagree. This is unnecessary rule language as NRC expects all licensees to meet the time period provided.
		Replace “analysis” with “assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.

Source	Citation	Comment	Response
		Delete “Pending the correction of unacceptable... adequate protection.”	Agree in Part. The statement will be removed from this section as it is not directly relevant to other discussion in §70.62(c)(3)(i); however, it will replaced in its entirety as a new item §70.62(c)(3)(iii).
	70.62(c)(3)(ii)	Replace “4" with “five”.	Disagree. No justification for change was provided. As existing licensees are already significantly involved in the development of this rule and ISAs at their sites, development of a plan within 4 years after approval of the licencee’s plan should not be a significant burden. (See next item)
		Replace “<effective date of this rule> with “date of approval of the licensee’s plan by the Commission”.	Disagree. No justification for change was provided. As existing licensees are already significantly involved in the development of this rule and ISAs at their sites, development of an ISA within 4 years of issuance of the final rule should not be a significant burden.
	70.62(d)	Replace “safety program management measures” with “management measures” (2 places).	Agree.

Source	Citation	Comment	Response
		Replace “continuing” with “reasonable” in ”establish management measures to provide continuing assurance of compliance with performance requirements of section 70.61".	Disagree. ‘Continuing’ was kept because the licensee must meet the performance requirements of 70.61 at all times. The proposed change incorrectly implies that the regulation is simply a target or a goal and as revised would allow the licensee to be out of compliance with the 70.61.
		Add “or control system” after “control” (3 places).	Agree.
		Add “items” before “relied on for safety”.	Agree.
		Replace “ensure” with “provide reasonable assurance that”.	Disagree. Ensure was kept to be consistent with other regulatory language. The regulations must be met and the licensee’s must ensure that they are met. The reasonableness of the assurances provided is evaluated during the inspection and enforcement process. The proposed change incorrectly implies that the regulation is simply a target or a goal.
	70.64(a)	Delete “of the type listed in §70.60 of this part”.	Agree.
		Replace “or” with “. Each existing licensee shall ... in the”.	Agree.
		Add “that require a license amendment under §70.72" to end of 2nd sentence.	Agree.

Source	Citation	Comment	Response
		Replace “their process design and description” with “the new facility or process”.	Agree in Part. Modification was made to delete sentence in its entirety.
		Add new sentence “The baseline design criteria... or process.”	Agree in Part. New sentence added to state “The baseline design criteria shall be applied to the design of new facilities and new processes, but shall not require retrofits to existing facilities or existing processes (e.g., those housing or adjacent to the new process); however, all facilities and processes must comply with the performance requirements in §70.61.”
	70.64(a)(1)	Replace “established” with “developed”.	Agree.
		Replace “a quality assurance program” with “established management measures”.	Agree.
	70.64(a)(5)	Replace “hazards that may impact the storage, ... exposure to an individual from licensed material or” with “risks produced from licensed material... and exposure to”.	Agree in part. Removed phrase “exposure to” from NEI request but made all other modifications requested.
	70.64(a)(7)	Delete “,including reliable and timely... for safety.”	Agree.
	70.64(a)(8).	Add “Monitoring” and Replace “provide for” with “consider the need for monitoring”.	Disagree. To be consistent with §60.131, Instrumentation and Controls will remain separated from this item.

Source	Citation	Comment	Response
		Replace “ensure” with “provide reasonable assurance”.	Disagree. Ensure was kept to be consistent with other regulatory language. The regulations must be met and the licensee’s must ensure that they are met. The reasonableness of the assurances provided is evaluated during the inspection and enforcement process. The proposed change incorrectly implies that the regulation is simply a target or a goal.
		Replace “continued function and readiness” with “availability and reliability when needed”.	Agree in part. Changed to “availability and reliability to perform their function when needed.”
	70.64(a)(10)	Delete item 10 in its entirety.	Disagree. To be consistent with §60.131, Instrumentation and Controls will remain as a separate item. Further, the proposed merging of this item with item number 8 does not include the role of control systems.

Source	Citation	Comment	Response
	70.64(b)	Delete 1st sentence.	Disagree. However, the term "defense in depth" will be clarified through the use of a footnote which states "As used in §70.64, defense-in-depth practices means a design philosophy, applied from the outset and through completion of the design, that is based on providing successive levels of protection such that health and safety will not be wholly dependent upon any single element of the design, construction, maintenance, or operation of the facility. The net effect of incorporating defense-in-depth practices is a conservatively designed facility and system that will exhibit greater tolerance to failures and external challenges. The risk insights obtained through performance of the integrated safety analysis can be then used to supplement the final design by focusing attention on the prevention and mitigation of the higher-risk potential accidents. "

Source	Citation	Comment	Response
		Replace “passive systems are selected over active systems” with “engineered controls or control systems are preferable to administrative controls or control systems” and replace “by reducing challenges... for safety.”	Agree in part. Sentence will now read “The design process shall incorporate, to the extent practicable: (1) preference for the selection of engineered controls over administrative controls to increase overall system reliability; and (2) features that enhance safety by reducing challenges to items relied on for safety.”
		Delete last sentence in its entirety.	Agree.
	70.64(c)	Replace “analysis” with “evaluation”.	Disagree. However, comment is moot since the section was deleted in its entirety.
		Add “that requires a license amendment under §70.72" before “shall:”.	Agree. However, comment is moot since the section was deleted in its entirety.
	70.64(c)(1)	Replace “satisfy, with incorporated margins for uncertainty,” with “address”.	Agree. However, comment is moot since the section was deleted in its entirety.
		Replace “§70.60" with “§70.61".	Agree. However, comment is moot since the section was deleted in its entirety.
	70.64(c)(2)	Replace “analysis” with “evaluation”.	Disagree. However, comment is moot since the section was deleted in its entirety.

Source	Citation	Comment	Response
	70.64(c)(3)	Replace “analysis” with “evaluation”.	Disagree. However, comment is moot since the section was deleted in its entirety.
	70.64(c)(3)(i)	Delete “defense-in-depth strategy and”.	Disagree. However, comment is moot since the section was deleted in its entirety.
		Add “and” at end of item.	Disagree. “And” is implicit. However, comment is moot since the section was deleted in its entirety.
	70.64(c)(3)(ii)	Delete item in its entirety.	Agree. However, comment is moot since the section was deleted in its entirety.
	70.64(c)(3)(iii)	Change to “ii”.	Agree. However, comment is moot since the section was deleted in its entirety.
	70.64(c)(4)	Delete item in its entirety.	Agree. However, comment is moot since the section was deleted in its entirety.
	70.64(c)(5)	Delete item in its entirety.	Agree. However, comment is moot since the section was deleted in its entirety.
	70.64(d)	Delete first sentence.	Agree. However, comment is moot since the section was deleted in its entirety.

Source	Citation	Comment	Response
		Add word “applicable” before “regulations.”	Agree. However, comment is moot since the section was deleted in its entirety.
	70.65(a)	Replace “a summary of the integrated...established to ensure”.	Agree in Part. Replaced “a summary of the integrated... and in the context of the performance requirements of §70.61" with “the integrated safety analysis summary and a description of the management measures.” This change should capture NEI’s comments while shortening the text by removing some text that is repeating already defined terms.
	70.65(b)	Replace “summary of the integrated safety analysis” with “summary” (2 occasions).	Agree in Part. Replaced “summary of the integrated safety analysis” with “integrated safety analysis summary” to use defined term.
		Delete “,” after “license”.	Agree.
		Replace “analysis” with “assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
	70.65(b)(1)	Add “general” before “description”.	Agree.
	70.65(b)(2)	Add “general” before “description”.	Agree.

Source	Citation	Comment	Response
	70.65(b)(3)	Replace “each process” with “processes”.	Disagree. NEI did not provide a reason for the requested change; however, NEI is likely concerned about the level of detail to describe “each” process. To account for this concern, a definition for process “(defined as a single reasonably simple integrated unit operation within an overall production line)” was included to better define level of detail expected.
		Replace “integrated safety analysis including the theory of operation” with “and a general description of the types of accident sequences for each that could exceed the performance criteria of §70.61".	Agree in Part. Replaced “integrated safety analysis including the theory of operation” with “integrated safety analysis in sufficient detail to understand the theory of operation; and, for each process, the hazards that were identified in the integrated safety analysis pursuant to §70.62(c)(1)(i)-(iii) and a general description of the types of accident sequences.” The changes to NEI’s proposed text are to better define what is requested.

Source	Citation	Comment	Response
		Move “information that demonstrates...alarms in §70.24" to a new item (4).	Agree in Part. Text moved to new item (4) as requested but modified to state “information that demonstrates the licensee’s compliance with: the performance requirements of §70.61; the requirements for criticality monitoring and alarms in §70.24; and, if applicable, the requirements of §70.64.”
	70.65(b)(4)	Change to 70.65(b)(5).	Agree.
		Delete “integrated safety analysis” before “team”.	Agree.
		Replace “analysis” with “assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
	70.65(b)(5)	Delete item in its entirety.	Agree in Part. Original item(5) deleted, but intent of item moved to additions in new items (3) and (4) of this section.

Source	Citation	Comment	Response
	70.65(b)(6)	Replace item in its entirety with “for the purpose of this integrated safety assessment summary... to understand their function in relation to the performance requirements of §70.61".	Agree in Part. Modified in entirety to state “a list briefly describing all items relied on for safety which are identified pursuant to §70.61(e) in sufficient detail to understand their functions in relation to the performance requirements of §70.61;” A list of items is essential to NRC’s determination that the ISA summary provides an adequate safety basis for licensing the facilities.
	70.65(b)(7)	Delete (7) in its entirety.	Agree.
		Add new item (7) that states “a description of the management measures applicable to such items relied on for safety”.	Disagree. This requirement is redundant with the requirement in 70.65(a) that requires a description of management measures to be included with the application. The intent is not to require the licensee to identify what management measures apply to each item relied on for safety, but rather to describe the programs used in more general terms so as to not be burdensome to applicants.
	70.65(b)(8)	Replace “material” with “materials”.	Agree. This item becomes item (7).

Source	Citation	Comment	Response
	70.65(b)(9)	Replace “item” with “items” (2 instances) and replace “is the” with “identifies”.	Agree in Part. Replaced first occurrence, but did not replace second since a “sole item” is being referred to. This item becomes item (8).
		Replace “is the” with “identifies”.	Agree in Part. Modified item to start “a descriptive list that identifies all items relied on for safety that are the sole item...”
	70.65(b)(10)	Replace “analysis” with “assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion. This item becomes item (9).
	70.72(a)(3)	Add “including any necessary training/retraining before operation”.	Agree; however, replaced “/” with “or”.
	70.72(a)(4)	Delete item in its entirety.	Agree.
	70.72(a)(7)	Replace “analysis” with “assessment” (2 instances).	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion. Note: this item becomes (6).
	70.72(c)	Delete item in its entirety.	Agree.

Source	Citation	Comment	Response
	70.72(d)(1) (Option1)	Replace item in its entirety with “does not: (i) create new types of accidents... has no prior experience”.	Agree in Part. Item replaced with “does not: (i) create new types of accident sequences, that unless mitigated or prevented, would exceed the performance requirements of section 70.61 and that have not previously been described in the integrated safety analysis summary; or (ii) use new processes, technologies, or control systems for which the licensee has no prior experience.” What is meant by the term “type” is described by a footnote.
	70.72(d)(2) (Option 1)	Replace “equivalent” with “a comparable”.	Agree in Part. Instead replaced” an equivalent replacement” with “at least an equivalent replacement of the safety function.” This change is to better define the fact the better replacements are acceptable; however, changes that reduce safety require pre-approval.

Source	Citation	Comment	Response
		Replace “item relied on for safety that is listed” with “any control or control system described”.	Disagree. NEI’s change in this section was to correspond to their change in §70.65(b)(6) which staff disagreed with. Since no change was made to that section, the text in this section remains the same to remain consistent with the fact that items relied on for safety are provided in the ISA summary.
	70.72(d)(3) (Option 1)	Replace “analysis” with “assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
		Replace “exceess” with “exceeds”.	Agree.
	70.72(e) (Option 1)	Replace (d) with (c).	Agree. However, comment is moot since the section was deleted in its entirety.
		Replace “[“ and “]” with “<“ and “>”, respectively.	Agree. However, comment is moot since the section was deleted in its entirety.
		Replace “analysis” with “assessment”.	Disagree. However, comment is moot since the section was deleted in its entirety.
	70.72(f) (Option 1)	Replace “(e)” with “(d)” and replace “(d)” with “(c)”.	Agree. However, comment is moot since the section was deleted in its entirety.

Source	Citation	Comment	Response
	70.72(g)(1)	Replace “analysis” with “assessment” (2 instances).	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
		Replace “within 90 days of the change” with “annually”.	Disagree. The ISA summary is intended to be a living document and therefore must be updated on a frequent basis. NRC staff needs to have a current safety basis on the docket in order to understand the facility, facility safety, and the changes made to the facility. Although Part 50 requires annual updates, the change process associated with that regulation is must more restrictive and NRC maintains knowledge about the facility and the changes to the facility through the change process. The change process proposed for Part 70 is less restrictive and allows the licensees to make changes with out NRC pre-approval. However, because of the flexibility allowed here, the ISA summary must be updated more frequently.

Source	Citation	Comment	Response
	70.72(g)(3)	Replace “process safety information, integrated safety analysis, or management measures” with “integrated safety assessment summary”.	Agree in Part. Replaced “process safety information, integrated safety analysis, or management measures required by section 70.62” with “records required by section 70.62(a)(2)”. Also added word “brief” before “summary”.
		Replace “every 6 months” with “annually”.	Agree in Part. Changed “every 6 months” to “every 12 months.”
	70.72(h)	Replace in item in its entirety with “If a change covered by §70.72 is made, the affected onsite documentation shall be updated promptly.”	Agree.
	70.72(i)	change “(d or e)” to “(c or d)”.	Agree.
	70.73	Delete 2nd sentence.	Agree.
	70.74(a)		Replaced references to “section (c) in Appendix A to Part 70" with “§70.50(c)(1)” to be consistent with NEI’s comments in Appendix A.
	70.74(b)		Replaced references to “section (d) in Appendix A to Part 70" with “§70.50(c)(2)” to be consistent with NEI’s comments in Appendix A.
	Appendix A (a)(1)	Replace “unintended” with “inadvertent”.	Agree.

Source	Citation	Comment	Response
	Appendix A (b)(1)	Move (b)(1) to (a)(4).	Agree in part. Moved, but modified to state: "An event or condition such that no items relied on for safety, as documented in the Integrated Safety Analysis summary, remain available and reliable, in an accident sequence evaluated in the Integrated Safety Analysis, to perform their function: (i) in the context of the performance requirements in §70.61(b) and §70.61(c), or (ii) prevent a nuclear criticality accident (i.e., loss of all controls in a particular sequence).
	Appendix A (b)(2)	Delete item in its entirety.	Disagree. The purpose of this item is to determine if accidents frequencies are classified correctly so that if a licensee takes credit for infrequency and the occurrence of the deviation is frequent, NRC is notified of the potential problem in the analysis technique. The item has also been relocated as item (5).
	Appendix A (b)(3)	Add ",was improperly analyzed" after "was not analyzed".	Agree.
		Delete first instance of "in the Integrated Safety Analysis".	Agree.

Source	Citation	Comment	Response
		Replace “Analysis” with “Assessment”.	Disagree. This term has been used since the original rulemaking and will remain the same to avoid confusion.
	Appendix A (b)(4)	Replace “has affected or may have affected the intended safety function and reliability of one or more items relied on for safety” with “affected the availability and reliability of one or more items relied on for safety and could have resulted in a failure to meet the performance requirements of §70.61.”	Disagree. The intent is to also have external events reported that may also have affected items relied on for safety but didn’t because either possible problems had not yet been detected or were mitigated or prevented by previously unreported items that were relied on to remain safe. Did, however, replace “availability and reliability” with “availability or reliability”.
	Appendix A (b)(6)	Replace “an” with “a sole”.	Agree. However, comment is moot as this item was deleted.
		Delete “This includes... perform the same safety function.”	Agree. However, comment is moot as this item was deleted.
	Appendix A (b)(7)	Replace “restricted” with “controlled area”.	Disagree. Wording kept to be consistent with §20.2202(a)(2). However comment is moot because item modified in its entirety to state “Loss or degradation of items relied on for safety that results in failure to meet the performance requirement of 70.61".

Source	Citation	Comment	Response
	Appendix A (b)(8)	Delete item in its entirety.	Disagree. However, item moved to new item (c) of Appendix A. NRC would like to be aware of communications which may result in inquiries from outside sources.
	Appendix A (c)	Delete item and all subitems in their entirety.	Agree.
	Appendix A (d)	Delete item and all subitems in their entirety.	Agree.

Comments Posted on Web Site "Threads" Page

Date	Author/ Affiliation	Topic	Subject	Comment	Response
Jan. 6, 1999	Steve Schilthelm/ BWXT	Separating the performance requirements from the descriptive requirements	70.62(c)(3) Integrated Safety Analysis Revalidation	an enhanced approach to change management which uses ISA evaluation techniques and team concepts with qualified reviewers would provide greater confidence in the continuing validity of the ISA results and would eliminate the need for periodic revalidation.	Agree. Revalidation of ISA was deleted as unnecessary, since the 70.72 process governs the facility changes and updating of safety program/ISA documentation
				BWXT believes the focus should be on quality configuration management and maintenance of a valid ISA rather than periodic revalidation and that this section should be deleted.	Agree. Revalidation of ISA was deleted as unnecessary, since the 70.72 process governs the facility changes and updating of safety program/ISA documentation
			70.4 Controlled Site Boundary	It appears that 10CFR20 definitions are adequate and that the ISA consequence criteria should be applied at the Controlled Area Boundary as defined in 10CFR20.	Agree in part. 70.61(f) was added to use the controlled area definition consistent with Part 20. However, in recognition that activities unrelated to licensed activities occur in the controlled area of some Part 70 facilities, some conditions were added.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			70.62(d) Management Measures	BWXT supports the concept of management measures as presented. Section (d)(6) however, implies that a QA program be implemented in addition to other management measures in 70.62(d), some of which are elements of a QA program. Section (d)(6) appears to be redundant and unnecessary and should be deleted.	The comment no longer applies because the list was deleted. In the definition management measures, the term "other QA elements" is used. QA and management measures are not synonymous. Management measures, could, for example, include a condition on operations in the event of a system's failure.
			70.4 Integrated Safety Analysis Summary	BWXT supports use of this terminology. This definition places the ISA Summary as part of the license application. Although this is contrary to Industry's position, BWXT believes the ISA Summary could be part of the license application (as BWXT is currently doing with a two part license) as long as it is clearly stated in the rule that changes to the process and the ISA Summary do not require license amendment. This would require some minor revision to this definition.	Agree in part. This terminology reflects the concept of the rule. 70.4 defines the ISA summary and states it will be submitted with the license application. Section 70.65 states that the summary will not be part of the license but will be on the docket. 70.72 specifies the changes that do not need pre-approval.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			70.72	To support the BWXT position on ISA Summary being part of the license application, the draft proposed language in 10CFR70.72 would be revised in order to clearly state when a license amendment is required for changes to the ISA Summary (Part 2 of the license). 70.72 should be consistent with the 12/1/98 SRM in that only "those few significant changes that currently would require license amendments" would require license amendments in the future.	Agree. 70.72 was revised as stated above. and does meet the intent of the SRM by requiring pre-approval for the most significant changes which inconsistent with past practices.
Feb. 2, 1999	Thomas P. McLaughlii nLANL	Criticality safety	General	I'm optimistic that the NEI's proposed revisions will be adopted essentially as is by the NRC.	Disagree. Much of NEI's comments were adopted; but not all and not in the form that NEI requested.
				I would also hope that the discussions that are now documented in the transcripts of these public meetings could be retained as evidence of the understanding and interpretation of the intent and flavor that the NRC intends for the words in the Rule and SRP.	Agree. Transcripts and letters received by NRC related to this rulemaking will be in the public record.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			Double Contingency Principle (DCP)	Section 4.1.2 of ANS-8.1 is the overriding SHALL statement while 4.2.2(DCP) is simply a SHOULD statement. It is essentially unanimous among the experienced practitioners nationwide that the NRC, and now the DOE, are misguided in their attempts to "better?" control criticality risks by making the DCP a SHALL statement.	Agree. The new, separated performance requirement for criticality, 70.61(d), uses language similar to section 4.1.2 of ANS-8.1 (the “shall” statement) and DCP is defined similar to section 4.2.2 of ANS-8.1 (the “should” statement).
			NCS Limits(Section 5.4.5.2)	these additional limit definitions could add significant paperwork and reduce operational flexibility but not enhance real safety.	No longer applicable. The NCS limit definitions have been removed from the SRP Chapter.
				It is misguided and likely dangerous to attempt to specify either a single, subcritical k-eff, such as 0.95, or a single delta k-eff such as 0.02, that is intended to be applied to all situations	No longer applicable. The quantification of subcritical limits has been replaced by Margin of Safety for Subcriticality.
Feb. 3, 1999	James S. Baker/LANL	Criticality safety	I urge the NRC to carefully review and act up the recommendations made by NEI and Dr. McLaughlin relative to the proposed 10CFR70 revisions.		Agree. NRC has reviewed and acted upon comments provided.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			The ANSI/ANS-8 series of standards provide terse, yet comprehensive guidelines for the practice of nuclear criticality safety (NCS). Deviating from these guidelines will almost always lead to wasted time and effort, and a decrease in real safety.		Agree in Part. Some ANS-8 standards are not completely clear and in such cases, NRC has attempted to provide an interpretation for NRC use.
Mar. 17, 1999	Steve Schilthelm/ BWXT	BWXT comments on 3/1 draft of 10CFR70	70.4 New Processes at Existing Facilities	The definition should only include Facility Level changes so that the requirements of 70.64 (c) & (d) are consistent with Commission directives in SECY 98-185.	Agree. Comment does not apply anymore. Consistent with a subsequent NEI comment, this definition was eliminated and 70.72 is used to identify the new processes at exiting facilities that need the application of 70.64 BDCs

Date	Author/ Affiliation	Topic	Subject	Comment	Response
				The value of 70.72 should also be considered given that 70.64 appears to define when a license amendment is required.	Disagree. 70.64 requires application of BDC's to new processes (i.e., major changes). 70.72 could require pre-approval of changes that are not necessarily new processes and would therefore not require application of the BDCs. 70.72 is important to define changes to the facility 70.75 is for new facilities and new processes.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
				BWXT has reviewed Facility, System, and Component Level changes initiated during 1998 under SNM-42. ... an additional 30 license amendments would have been required in 1998 under the proposed rule language.	Disagree. This was not the intent. Perhaps the meaning of "new process" was misunderstood. In any event, the subsequent changes based on the NEI 3/26/98 comments obviate this comment. The definition was deleted and 70.72 is used to identify the new processes at exiting facilities that need the application of 70.64 BDCs 70.72 was revised to attempt to limit the number of licence amendment required to approximately the number required prior to rule making

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			70.64 (c)(4)	providing a Preliminary Process Hazards Analysis to NRC prior to construction is an exercise which appears to have no function in the licensing process. ... an open-ended regulatory requirement is inappropriate.	Agree that Preliminary Hazards analysis os a pre-licensing tool, not a tool for the licensing process. See also response to NEI 3/26 comments on Preliminary PHA submittal.
			70.65(b)	This section implies ALL license amendments require an ISA summary. There are, however, administrative and programmatic commitments in the license application (e.g., Organization) which do not impact the ISA Summary. Flexibility should be provided for these types of amendments.	Agree. Section was revised to indicate not all amendments require ISA summary information.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			70.65(b)(1-10)	The ISA Summary content requirements appear to be expanded even beyond those presented in the draft SRP. This level of information in the ISA Summary will provide more detail than the review can digest and may mask the forest with the trees. Suggest a higher level summary.	Disagree- The revised ISA summary contents were modeled after the suggested ISA summary submitted by NEI in the December 3 and 4th meeting. The level of detail has been reduced from the previous draft rule and is at a level appropriate to provide useful information to NRC without being burdensome to the industry.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			70.65(b)(10)	These terms can be discussed in qualitative terms but the decision regarding where a particular event, failure, or occurrence fits in these terms MUST be based on the experience and judgement of qualified ISA team members. ... Attempts to define these terms implies a level of quantitative assessment that is simply not practical or necessary at fuel facilities.	Agree - this comment refers to the requirement in the ISA summary for the licensee to define how they used the terms likely, unlikely and highly unlikely in their analysis. It is up to the licensee to determine how best to define these terms and the determination concerning which category an event falls into should be based on the licensee's experience and judgment. However, the rule requires that certain events be shown to be unlikely or highly unlikely. If the license does not define these terms they can not then prove that they meet the rule. These definitions must be included in the ISA summary.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			70.72	Neither Option 1 or 2 of paragraph (d) is consistent with commission directive in SECY 98-185 which limits the types of changes requiring submittal for license amendment to "those few significant changes that currently would require a license amendment."	Disagree. Only one option, Option 1 remains in the rule. Option 2 has been removed. The staff believes Option 1 is consistence with Secy 98-185.
				It is also unclear how these options relate to the definition of New Processes at Existing Facilities and the requirements 70.64(c) & (d).	Rule revised to delete definition and cross reference §70.64 and §70.72
				NRC should limit the requirements for license amendments to facility level changes and changes to authorized activities. This would be consistent with Commission directives not to lower the license amendment threshold. 70.64(c) & (d) and 70.72 should be revised to clearly state.	Agree. These sections have been revised to incorporate this.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			70.72(g)	nearly every change to process safety information will require revision of the ISA Summary.	Disagree. The content of the ISA summary does not include detailed process information, and the level of detail in the summary determines the number of updates required. In addition, because the ISA and ISA summary are "living" documents changes to the information contained in these documents should be updated regularly. The number of changes which would require a change to the ISA summary is determined by the level of detail the licensee chooses to put in the summary

Date	Author/ Affiliation	Topic	Subject	Comment	Response
				given the level of detail in the ISA Summary, the 6-month notification of change to process safety information seems unnecessary... Notification of changed process safety information should be deleted.	Agree - The requirement to submit a brief summary of all changes to records required by 70.62(a) has been revised to an annual update, This would include a summary of changes to process safety information.
				BWXT recommends the ISA Summary be updated annually, or with each license amendment.	Disagree- The ISA summary is to be a living document which contains relatively current information. This information is to be used in licensing, inspection and emergency response. A one year update period or greater is not sufficient.
Mar. 24, 1999	Burton Rothleder/ DOE	References and terminology in the Criticality SRP Chapter	1. Update: ANSI/ANS-8.1-1998 is the latest revision of this endorsed ANSI/ANS standard.		Agree. However, NRC has not yet endorsed the 1998 revised standard ; this should be made in the next revision of NRC's Regulatory Guide.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			2. Correction to ANSI/ANS-8.6: In section 5.3, the "i.e." should be "e.g." This is not merely a typo correction since the used of "i.e." tacitly omits (n,2n) reactions as sources of neutrons. By endorsing this ANSI/ANS standard, I think that this error should be noted as part of the SRP		Disagree. The endorsement correction, if appropriate, should be made in the next revision of NRC's Regulatory Guide endorsing the standard rather than the SRP.
			3. Section 5.4.3.1: In section 5.4.3.1, paragraph 6.b., the sentence should read "... *deterministic computer codes, or stochastic computer codes which* ..." I have replaced "probabilistic" with "stochastic" in order to avoid confusion with PRA codes.		Agree in Part. The words have been changed in the SRP to accurately reflect the meaning.
3/29/99	Thomas P. McLaughlin/ LANL	Comments on Draft NUREG-1520, Chapter 5, Nuclear Criticality Safety (NCS) rev. March 15, 1999	General:	If the ISA is analogous to the SAR in the DOE, then the ISA should be the place for a Design Basis or Worst Credible criticality accident scenario in order for the applicant to demonstrate that criticality accidents are very unlikely and that they have essentially zero off-site consequences. I.e., they are worker safety issues and not a threat to the public or the environment.	Disagree. The ISA is expected to evaluate all potential accidents and those with a potential to exceed the performance criteria are to be reported in the ISA summary to NRC -- not just the bounding evaluations.
				Individual criticality safety evaluations (CSE) should be where each separate process is documented, not in the ISA.	Disagree. The ISA is expected to include the equivalent of the CSE.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
				Perhaps more so in the DOE world, but operations are continually changing and new ones are being added such that requiring regulatory approval except for those new or changed operations which represent a greater risk than that currently in the ISA, is not justified.	Disagree. The change process only requires pre-approval for certain changes as listed in 70.72.
				Similarly, the CSE is where the justification for active vs passive controls should be justified.	Agree. Because the ISA is expected to include the equivalent of the CSE, this justification would also be in the ISA.
				There is an over-emphasis on the Double Contingency Principle to the detriment of the control of criticality risks.	Disagree. The SRP Chapter makes it clear that there are alternatives to double contingency protection.
			5.4.1 (6) and repeated in 5.4.2 (1)(d)	"....*take no further action.*...." This seeming prohibition to not allow risk-reducing actions is inconsistent with the ANS-8 standards and the philosophy implicit in section 5.4.3.3 (8) - "....*because shutting down certain processes, even to make them safe, may carry a larger risk*....."	Disagree. The SRP Chapter is consistent with the industry understanding that only analyzed and approved NCS actions should be taken.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			5.4.2 (3) (b)	"*.....weekly walkthroughs of all operating.....all operating areas should be reviewed at least every two weeks*...." This frequency is far beyond that of most, if not all, DOE regulated facilities and is not supported on the basis of performance-based and risk-informed regulation . A commitment to walkthroughs based on performance and risk would be consistent with DOE practices.	Disagree. Although this is industry practice, the SRP allows grading to justify other frequencies based upon the ISA evaluation.
			5.4.3.1 (3)(a)	Reference to, and a commitment to have copies of, appropriate reports should be sufficient . Otherwise it is unnecessary duplication.	Disagree. It is necessary for the reviewer to have a summary of the methodology in order to ensure that the applicant is using the methodology appropriately.
			5.4.3.1 (3)(f)	"*.....plant specific benchmark experiments*....." is an unattainable ideal . If the intent is to require that the benchmark experiments chosen for code validation cover, to the extent available, the credible ranges of the process parameters, then that is realistic.	Agree. If the plant specific information exists, the applicant is expected to use it.
			5.4.3.1 (3)(i)	"*.....a verification process*....." What does this mean?	Clarification. It means that the process used to determine that the methodology chosen is appropriate.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			5.4.3.1 (4) all subparts	This section is duplication of the prior subpart but with a different application . I suggest that the applications (headings) be combined and then the body would not have to be repeated.	Disagree. The two subparts havd different functions and different requirements. One requires information for the application, the other information for the site.
			5.4.3.1 (6) (c & d)	Where are "NCS safety limits" and "NCS operating limits" defined? Can they be one and the same as they are at most, if not all DOE facilities?	Clarification. Failure limits are where you fail, safety limits are where the analysis determines you are safe, and operating limits are set below the safety limits to ensure that you operate safely.
			5.4.3.2 (3)	"...*provide justification in the ISA*." This should be a part of a CSE, not the ISA.	Disagree. The CSE is part of the ISA.
			5.4.3.2 (6)	"....*credible abnormal conditions*...." Certainly mass is the most common controlled parameter and yet it would generally not be considered "incredible" that a mass limit be violated, i.e., it would be considered credible . Thus the applicant could not meet this requirement.	Agree. Mass limit violation is a credible abnormal condition and by analyzing the scenario to its conclusion, you will have maintained the Controlled Parameter and met the SRP requirement.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			5.4.3.2 (9 & 10)	The numerical values (45%, 75%, 85%, 90%) have no basis in consensus standards or other recognized criticality documents. They should be deleted as they can only lead to a false sense of risk control. For example, "....*When double batching is possible...*" it would generally be also true that triple, quadruple, etc . batching is possible.	Disagree. These values are found in current licenses based on industry data from experiments.
			5.4.3.2.(12) (a)	"....*the SNM is segregated by enrichment*." Why would it be unacceptable for the applicant to have assumed in the CSE that the highest credible enrichment was always present?	Agree. It would be acceptable for the applicant to assume the highest credible enrichment in the CSE.
			5.4.3.2 (13) (a)	The *"one foot"* restriction has no technical basis; it should be deleted.	Disagree. This is only a recommendation and not a requirement.
			5.4.3.2 (15) (b)	*"High concentrations"* needs to be defined.	Disagree. The intent of the term is different depending upon what process is being used.
			5.4.3.3 (3) (a)	"....*shall be required in each area*...." This unilateral requirement does not allow for competing risks, or likelihoods that are judged to be in the incredible range, to be considered.	Disagree. This is part of the Rule itself and therefore a requirement.

Date	Author/ Affiliation	Topic	Subject	Comment	Response
			5.4.3.4	The repetition of the ANS-8 standards as requirements seems unnecessary.	Disagree. This is not repetition, but where the applicant commits to using the standards as an acceptable approach.
			5.4.3.4 (8)	I am not aware of a definition for *"administrative k-eff margins"*, but in general each process will have different margins of subcriticality and each will be highly judgmental based on the chosen conditions of analysis . These should be approved by line management and documented in the CSE . As stated under General, such information should not be in the ISA or otherwise require pre-approval outside of line management within the company.	Disagree. This value is pre-approved by NRC. For a particular process, the applicant may choose to use a higher margin which would be documented and approved by the applicant's management.
			5.4.3.5	This is another example of putting the recommendation, ANS-8.1, section 4.2.2, ahead of the requirement, section 4.1.2.	Disagree. This is part of the Rule itself and therefore a requirement.
			5.4.3.6 (3) (b)	Again, an over- and misleading-emphasis on Double contingency is evident.	Disagree. Double Contingency Protection is listed as an acceptable method, but not required.

Option 2 of Section §70.72(d)

In response to the SRM for SECY-98-185 and previous industry comments, the staff re-evaluated the §70.72 change process including the types of changes that can be made without NRC pre-approval. During this evaluation, two different options for §70.72(d) were developed and both were posted on the web for public comment. The rule language contained in §70.72 (d) of this rulemaking package represents option 1, and is explained in detail in the FRN and SRM issues papers, and is supported by both staff and NEI.

Option 2 mirrors the §50.59-type change process currently being considered for power reactors under revisions to Part 50. It should be noted that the revisions to §50.59 are being made to allow the greater flexibility in the change process at reactors and allows them to make more changes without NRC pre-approval. However, the staff believes that this type of change process is more restrictive for fuel cycle facilities and would require more changes to be pre-approved than has occurred in the past. NEI has indicated concern with this approach because: 1) determining which changes are ”more than minimal” is a highly subjective determination; 2) it is also more restrictive than past practice at fuel facilities; 3) it would require NRC pre-approval, and thereby issuance of license amendments for a large number of changes per year; 4) and it would be overly burdensome to both the industry and NRC.

Option 2 language for §70.72(d) is as follows:

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

i) a change to the license application or license condition is not required, and

ii) The change, test or experiment does not meet any of the criteria in Paragraph (d)(2) of this section.

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

i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the integrated safety analysis;

ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of an item relied on for safety previously evaluated in the integrated safety analysis;

iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the integrated safety analysis;

iv) Result in more than a minimal increase in the consequences of a malfunction of an item relied on for safety previously evaluated in the integrated safety analysis;

v) Create the possibility for an accident of a different type than previously evaluated in the integrated safety analysis;

vi) Create the possibility for a malfunction of an item relied on for safety with a different result than any previously evaluated in the integrated safety analysis; or

vii) Result in more than a minimal change in a method of analysis described in the integrated safety analysis."

All other sections of §70.72 remain the same and are not affected by Option 2.

Attachment 5

DRAFT

NUREG-1520

May 1999

Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility

Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

DRAFT

U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

ABSTRACT

The Standard Review Plan (SRP) (NUREG-1520) provides guidance to the staff reviewers in the Office of Nuclear Material Safety and Safeguards who perform safety and environmental impact reviews of applications to construct or modify and operate fuel cycle facilities. The SRP ensures the quality, uniformity, stability, and predictability of the staff reviews. It presents a defined basis from which to evaluate proposed changes in the scope and requirements of the staff reviews. The SRP makes information about licensing acceptance criteria widely available to interested members of the public and the regulated industry. Each SRP section addresses the responsibilities of persons performing the review, the matters that are reviewed, the Commission's regulations pertinent to specific technical matters, the acceptance criteria used by the staff, how the review is accomplished, and the conclusions that are appropriate to summarize the review.

An integrated safety analysis (ISA), required by a revised 10 CFR Part 70, is produced by an applicant for a new, renewed, or revised license under Part 70. An ISA summary and other ISA documentation become fundamental in the NRC staff's review process, and the NRC staff's expectations for this work is described fully in this SRP. The work that is recorded in the applicant's ISA and ISA summary informs the applicant and the NRC staff of the risks inherent in the plant design and operation, and will provide the basis for the application of the NRC acceptance criteria presented in this SRP.

(Note: Existing criteria for the review of the safeguards sections of license applications may be incorporated in this SRP at a later date. These criteria were developed earlier and are published in NUREGs 1280 and 1365.)

U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

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U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

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INTRODUCTION

The *Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility* provides U.S. Nuclear Regulatory Commission (NRC) guidance for the review and evaluation of health, safety, and environmental protection in applications for licenses to possess and use special nuclear material (SNM) to produce nuclear reactor fuel. The guidance is also applicable to the review and evaluation of proposed amendments and license renewal applications. Specific filing requirements for license applications, and for issuance of such licenses, are in 10 CFR 70, "Domestic Licensing of Special Nuclear Material."

The principal purpose of the Standard Review Plan (SRP) is to ensure the quality and uniformity of staff reviews and to present a well-defined base from which to evaluate proposed changes in the scope, level of detail, and acceptance criteria of reviews. The SRP also will be used as the basis for the review of requests by licensees for changes in their licenses. Thus, the SRP, at any point in time, provides the basis for the review of proposed new or renewal applications, and amendments to existing licenses, as well as modifications to the SRP resulting from new NRC requirements and licensee initiatives.

Another important purpose of the SRP is to make information about regulatory reviews widely available and to improve communication and understanding of the staff review process. Because the SRP describes the scope, level of detail, and acceptance criteria for reviewers, it serves as regulatory guidance for applicants who need to determine what information should be presented in a license application.

It is important to note that this SRP:
1) is a guidance document,
2) is for use during the review of license applications, license renewal applications, and amendment applications,
3) and does not prevent licensees or applicants from suggesting alternate means of demonstrating compliance.

The responsibility of the staff in the review of a license application, renewal application, or license amendment for a fuel cycle facility is to determine that there is reasonable assurance that the facility can and will be operated in a manner that will not be inimical to the common defense and security, and will provide adequate protection of the health and safety of workers and the public, and the environment. To carry out this responsibility, the staff evaluates information provided by an applicant and through independent assessments determines that the applicant has demonstrated an adequate safety program that is in accordance with regulatory requirements. To facilitate carrying out this responsibility, the SRP clearly states and identifies those standards, criteria, and bases that the staff will use in reaching licensing decisions.

NRC requirements in 10 CFR 70.61 require that an applicant submit a complete description of the safety program for the possession and use of SNM to show how compliance with the

applicable requirements will be accomplished. The Safety Program Description must be sufficiently detailed to permit the staff to obtain reasonable assurance that the facility is designed and will be operated without undue risk to the health and safety of workers or the public. Prior to submission of the program description, an applicant should have analyzed the facility in sufficient detail to conclude that it is designed and can be operated safely. The Safety Program Description is the principal document with which the applicant provides the information needed by staff to develop the basis for conclusion. When reviewed and approved by the staff, and incorporated in the NRC license by reference, the Safety Program Description, in its entirety and in its parts, is considered a binding commitment of the applicant regarding the design and operation of the licensed facility. The Safety Program Description is the safety basis on which the license is issued, and may not be changed except under circumstances defined in 10 CFR Part 70.

The requirements in 10 CFR 70 specify, in general terms, the information to be supplied in a Safety Program Description. The specific information to be submitted by an applicant and evaluated by staff is identified in this SRP. Prospective applicants should study the topic areas treated in this document (generally, chapter headings) and the subsections within each topic area, specifically the subsections headed "Areas of Review" and "Acceptance Criteria." A license application should contain a Safety Program Description that addresses all the topics in the Table of Contents of this SRP, in the same order as presented in this document. The appendix provides additional guidance on the format of applications.

In this SRP, information is provided to assist the licensing staff and the applicant in understanding the underlying objective of the regulatory requirements, the relationships among NRC requirements, the licensing process, the major guidance documents NRC staff has prepared for licensing fuel cycle facilities, and the details of the staff review process set out in individual SRP sections. Analyses by the staff are intended to provide regulatory confirmation of reasonable assurance of safe design and operation. A staff determination of reasonable assurance leads to a decision to issue or renew a license or to approve an amendment. In the case of a staff determination of inadequate description or commitments, the staff will inform the applicant of what is needed and the basis upon which the determination was made.

The "Acceptance Criteria" delineated in this SRP are intended to communicate the underlying objectives but not to represent the only means of satisfying that objective. An applicant should tailor its safety program to the features of its particular facility. If approaches different from the SRP are chosen, the applicant should identify in its license application the portions of its application that differ from the design approaches and acceptance criteria of the SRP and evaluate how the proposed alternatives provide an acceptable method of complying with the Commission's regulations. The staff retains the responsibility to make an independent determination of the adequacy of what is proposed.

The major topics addressed within the Safety Program Description of a facility license application are addressed in separate SRP sections; each of those sections, or chapters, includes subsections described below.

The applicant’s ISA is the central focus for the selection of design and operational safety measures and the management control systems that assure the availability and reliability of those measures. The ISA should provide a comprehensive evaluation and presentation, useful to both the applicant and the NRC, of the distribution of risk among the many activities ongoing at

a fuel cycle facility. The NRC expects to be able to use the ISA findings and conclusions to focus its resources on the dominant risks of facility design and operation and the safety controls and assurances necessary to ensure that those controls remain available and reliable. Accordingly, staff reviewers will conduct a coordinated review of the ISA and will focus on the information contained in the ISA summary applicable to each of the technical areas treated in the chapters of the SRP, although review of other ISA documentation may also be necessary. The acceptance criteria in each of the SRP chapters are the criteria that apply to the dominant risks of operation. The applicant has the opportunity to justify lesser criteria for those design and operational features that can be shown to represent lesser risk than the accident or failure sequences that pose the dominant risks.

While recognizing the fundamental importance of the ISA to understanding the risk at a facility, certain SRP chapters are less dependent on ISA outcomes than others. The chapters concerning radiation safety, environmental protection, emergency management, and decommissioning, for example, contain acceptance criteria that are set primarily by current regulations that have not been changed in issuing the revision to 10 CFR Part 70. Finally, for new facilities (that have not already been designed, built, licensed and operated), certain baseline design criteria have been specified in 10 CFR 70.64. These criteria apply prior to the NRC approval of an ISA for the complete, final design which may indicate that reduced levels of assurance are acceptable in certain instances. The acceptance criteria in the SRP chapters implement the baseline design criteria in 10 CFR 70.64(a). A more detailed description of the application of these criteria is given in the discussion of "Section 4. *Acceptance Criteria*" below.

Section 1. PURPOSE OF REVIEW

This section is a brief statement of the purpose for and objectives of reviewing the subject areas. It emphasizes the staff's evaluation of the ways the applicant will achieve identified performance objectives and ensures through the review that the applicant has used a multi-disciplinary, systems-oriented approach to establishing designs, controls, and procedures within individual technical areas.

Section 2. RESPONSIBILITY FOR REVIEW

This section identifies the organization and individuals by function, within NRC, responsible for evaluating the subject or functional area covered by the SRP. If reviewers with expertise in other areas are to participate in the evaluation, they are identified by function. In general, the Licensing Project Manager has responsibility for the total review product, a safety evaluation report for an application. However, an identified technical specialist will have primary responsibility for a particular review topic, usually an SRP chapter. One or more specialists may have supporting responsibility. In most situations the review is performed by a team of specialist reviewers including the lead reviewer for the ISA and the project manager. Although they individually perform their review tasks, the reviews are extensively coordinated and integrated to ensure consistency in approach and to ensure risk-informed reviews. The project manager oversees and directs the coordination of the reviewers. The reviewers' immediate line management has the responsibility to ensure that an adequate review is performed by qualified reviewers.

Section 3. AREAS OF REVIEW

This section describes the topics, functions, systems, components, analyses, data, or other information that should be reviewed as part of that particular subject area of the license application. Because the section identifies information to be reviewed in evaluating the adequacy of the application, it identifies the acceptable content of an applicant's submittal in the areas discussed. The areas of review identified in this section obviate the need for a separate Standard Format and Content Guide.

The topics identified in this section also set the content of the next two sections of the SRP. Both Section 4, "Acceptance Criteria," and Section 5, "Review Procedures," should address, in the same order, the topics set forth in this section as areas to be reviewed. This section also identifies the information needed or the review expected from other NRC individuals to permit the individual charged with primary review responsibility to complete the review.

Section 4. ACCEPTANCE CRITERIA

This section contains a statement of the applicable NRC criteria based on regulatory requirements, and the bases for determining the acceptability of the applicant's commitments relative to the design, programs, or functions within the scope of the particular SRP section. Technical bases consist of specific criteria such as NRC regulations, regulatory guides, NUREG reports, industry codes and standards, and branch technical positions. To the extent practicable, the acceptance criteria will identify, as objectively or quantitatively as is feasible, specific requirements and other technical bases that are to be satisfied. The acceptance criteria (including branch technical positions or other information) present positions and approaches that are acceptable to the staff. They are not considered the only acceptable positions or approaches. Others may be proposed by an applicant.

It is NRC's intent that the SRP presents acceptance criteria for each technical function area (e.g., nuclear criticality safety, fire safety, radiation safety), and for the management control systems (e.g., quality assurance, maintenance, audits and assessments), that allow an applicant to provide a level of protection commensurate with the accident risk inherent in the process activities proposed. For example, at process stations (or for an entire process or sub-process) for which the inherent risk to workers, the public, or the environment is demonstrably small, the applicant needs to provide only those design and operating controls which assure that small risk. The key elements in the regulatory transaction involving presentation by an applicant, and review and approval by the NRC, are an adequate demonstration of acceptable control of risk by the applicant, which then supports a competent and informed review by NRC staff. The starting point for the applicant's demonstration of acceptable control of risk is the ISA.

The applicant's ISA is the primary supporting rationale for the safety level of design and operational features. There are, however, design and operational features and management controls that may be required independent of the ISA. This is to meet the requirements of 10 CFR 70.64 for new facilities or new processes at existing facilities, or, for all facilities, other NRC requirements such as 10 CFR Parts 20 and 51. The level of detail presented in the ISA summary submitted to NRC and in other parts of the application represents the safety basis committed to by the applicant, and is the basis which is subject to the provisions of 10 CFR 70.72 regarding changes that a licensee may make to the facility without prior NRC approval.

NRC will find an application acceptable if an applicant commits to the design features and management measures defined by the acceptance criteria within this SRP. The criteria in this

SRP represent the design features or management measures that support an NRC finding of reasonable assurance of adequate protection, independent of any ISA findings or conclusions that could lead to NRC approval of reduced levels of assurance for certain design features or management measures where the associated risk does not warrant the same high level of assurance.

An applicant for license renewal or an amendment for an existing facility responding to the requirements of 10 CFR Part 70 may propose structures, systems, and components (SSC) or management measures that meet less stringent acceptance criteria than described in the SRP based on supporting analyses from the applicant's ISA. The ISA may be used to justify a reduced level of assurance for particular items relied on for safety, that are associated with lesser risk accident sequences, as defined by the applicant's analysis of likelihood and consequences pursuant to 10 CFR 70.61. The criteria shown in this SRP apply to those SSC and management measures that are involved in the higher risk accident sequences as defined in §70.61.

For proposed new facilities or amendments for new processes proposed at existing facilities, the acceptance criteria described in the SRP apply for design purposes and should be addressed in the applicant's licensing submittal for all SSC and management measures, in accordance with 10 CFR 70.64. During NRC review of the ISA summary, license application contents, and other ISA documentation as needed, the applicant may justify reduced criteria for some SSC and management measures based on the ISA findings or conclusions.

Applicants should recognize that substantial time and effort on the part of the staff have gone into the development of the acceptance criteria and that a significant amount of time and effort may be required to review and accept proposals that depart from the standard applications described in the SRP. Thus, applicants resolving safety issues or safety-related design areas in ways other than those described in the SRP should plan for longer review times and more extensive questioning in these areas.

Section 5. REVIEW PROCEDURES

This section describes how the review will be performed. It generally describes procedures that the reviewer should follow to achieve an acceptable scope and depth of review and to obtain reasonable assurance that the applicant has provided appropriate commitments to ensure that it will operate the facility safely. This includes identifying licensee commitments to verify and could include directing the reviewer to coordinate with others having review responsibilities for other portions of the application than that assigned to the reviewer. This section should provide whatever procedural guidance is necessary to evaluate the applicant's level of achievement of the acceptance criteria.

Section 6. EVALUATION FINDINGS

This section presents the type of positive conclusion that is sought for the particular review area to support a decision to grant a license or amendment. The review must be adequate to permit the reviewer to support this conclusion. For each section, a conclusion of this type will be included in the staff's Safety Evaluation Report (SER) in which the staff publishes the results of its review. The SER will also contain a description of the review, including aspects of the review that received special emphasis; matters that were modified by the applicant during the review; matters that require additional information or will be resolved in the future; aspects where the plant's design or the applicant's proposals deviate from the criteria in the SRP; and the bases for any deviations from the SRP or proposed exemptions from the regulations. Staff reviews may be documented in the form of draft SERs that identify open issues requiring resolution before the staff can make a positive finding in favor of the license issuance or amendment.

Section 7. REFERENCES

This section lists references that should be consulted in the review process. However, they may not always be relevant to the review, depending on the action and approaches proposed by the applicant.

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1.1 FACILITY AND PROCESS DESCRIPTION

1.1.1 PURPOSE OF REVIEW

The purpose of this review is to establish that the license application includes an overview of the facility layout and a summary description of the structures, systems, equipment, components, and actions of personnel (SSC) used in the processes that comprise the facility's operating objectives. This overview of the application will be used by all reviewers, NRC managers, and the general public to understand the purpose of the facility and its processes; a more detailed description of this information should be provided in appropriate sections of the ISA summary.

1.1.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: None

Supporting: None

1.1.3 AREAS OF REVIEW

The staff should review the general facility description and process descriptions provided by the applicant, which should include (1) scaled drawings showing the locations of facility buildings and other major structures, hazardous materials storage areas, on-site roadways, railroad spurs or sidings, and major ingress and egress routes for the site, (2) a text index with titles that are descriptive of the purpose of each feature, (3) the interrelationships of the features, (4) the relationship of facility features to site features, and (5) the movement of personnel, materials, and equipment during facility operations. This information should be consistent with and summarize the information provided in the applicant's ISA summary in response to the acceptance criteria of this SRP, Section 3.4.3 "Acceptance Criteria", and should also be consistent with information reviewed under the Environmental Protection and Emergency Management chapters of this SRP.

1.1.4 ACCEPTANCE CRITERIA

1.1.4.1 Regulatory Requirements

The regulation applicable to the areas of review in this SRP is 10 CFR 70.22, "Contents of Applications", §70.60, “Applicability”, and §70.61, “Safety Performance Requirements”.

1.1.4.2 Regulatory Guidance

There are no regulatory guides that apply to a general facility description for a fuel cycle facility.

1.1.4.3 Acceptance Criteria

The reviewer will determine that the applicant’s presentations with respect to this section of the SRP are acceptable if the following criteria are met:

1. The application presents the facility and process description at a level of detail appropriate for general familiarization and understanding of the proposed facility and processes.

2. The application presents a summary of the facility information presented in the application in response to the guidance described in Section 3.5, Item 2 of this SRP. This includes descriptions of the overall plant layout on scaled drawings, including site geographical features, and plant structural features such as buildings, towers, and tanks and transportation right of ways. The relationship of specific facility features to the major processes that will be ongoing at the facility is described.

3. The major chemical or mechanical processes involving SNM to be licensed are described in summary form, based in part on information presented in the application in response to the guidance described in Section 3.5, Item 3 of this SRP. This description should include reference to the building locations of major components of the processes, brief descriptions of the process steps, the chemical forms of SNM in process, the maximum amounts of SNM in process in various building locations, and the types, amounts, and discharge points of waste materials discharged to the environment from the processes.

4. The general description of the facility and processes is consistent with, yet less detailed than, information presented in the applicant’s ISA summary.

1.1.5 REVIEW PROCEDURES

1.1.5.1 Acceptance Review

The staff review starts with a determination by the primary reviewer that the content of the application as required by 10 CFR Part 70 regarding facility and process design for fuel cycle

facilities has been included, and that topics discussed in Section 1.1.3, "Areas of Review," have been included.

If significant deficiencies are identified in the application, the applicant should be requested to submit additional material before the start of the safety evaluation. The reviewer should then determine that the applicant has provided the information required. If necessary, a request for additional information should be prepared for issue to the applicant. With the complete submittal available, the reviewer should examine the summary data and determine acceptability by comparison with the acceptance criteria in section 1.1.4.3 above and information in the ISA summary.

1.1.5.2 Safety Evaluation

If the application is accepted for NRC review, the reviewer will proceed by comparing the application with the acceptance criteria. The material to be reviewed is informational in nature, and no technical analysis is required. The information to be reviewed is only used as background for the more detailed descriptions in later sections of the application. Therefore, the primary reviewer only confirms that the descriptive information presented is consistent with the information presented in the ISA summary.

1.1.6 EVALUATION FINDINGS

The staff's review verifies that sufficient information has been provided in the license application to satisfy the 10 CFR Part 70 requirements for this section and that the regulatory acceptance criteria in section 1.1.4.3 are appropriately satisfied. On the basis of this information, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the SER prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows:

The staff has reviewed the general facility description for [name of facility] according to the Standard Review Plan Section 1.1. The applicant has adequately described (1) the facility and processes so that the staff has an overall understanding of the relationships of the facility features and (2) the function of each feature. The applicant has cross-referenced its general description with the more detailed descriptions elsewhere in the application. The staff concludes that the applicant has complied with the general requirements of 10 CFR 70.22, "Contents of Applications", §70.60, “Applicability”, and with §70.61, “Safety Performance Requirements”, as applicable to this section.

1.1.7 REFERENCES

Code of Federal Regulations, Title 10, Part 70, Domestic Licensing of Special Nuclear Material, U.S. Government Printing Office, Washington, DC.

U.S. NUCLEAR REGULATORY COMMISSION

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1.2 INSTITUTIONAL INFORMATION

1.2.1 PURPOSE OF REVIEW

The purpose of this review is to establish that the license application includes adequate information identifying the applicant, the applicant's characteristics, and the proposed activity.

1.2.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: None

Supporting: Office of the General Counsel; Office of Administration/Division of Security

1.2.3 AREAS OF REVIEW

Information provided for review should include the identity and address of the applicant's facility and corporate headquarters; corporate information sufficient to show the relationship of the applicant's organization relative to other corporate entities; the existence and extent of foreign ownership or influence; financial information sufficient to indicate the resources available to the applicant to pursue the activities for which the license is sought; the site location as legally described in land records; a description of each proposed licensed activity in the form of requested authorized uses; the type of license being applied for; and the type, quantity, and form(s) of material(s) proposed to be licensed.

1.2.4 ACCEPTANCE CRITERIA

1.2.4.1 Regulatory Requirements

The regulations applicable to the areas of review in this SRP are 10 CFR 70.22, "Contents of applications", §70.23, "Requirements for the Approval of Applications", §70.61, "Performance Requirements", §70.65, "Additional Contents of Applications," 10 CFR 2.109 "Effect of Timely Renewal Application, " 10 CFR 70.33, "Renewal of Licenses," and 10 CFR 95, "Security Facility Approval and Safeguarding of National Security Information and Restricted Data."

1.2.4.2 Regulatory Guidance

There are no regulatory guides that apply to institutional information for a fuel cycle facility.

1.2.4.3 Regulatory Acceptance Criteria

The application is acceptable if the following criteria are met:

1. Corporate Identity

   The applicant has furnished its full name and address. The address of the fuel cycle facility is provided if it is different from that of the applicant. If the application is for renewal, the applicant identifies the number of the license to be renewed. A full description of the plant site location (State, county, and municipality) is given. The State where the applicant is incorporated or organized and the location of the principal office are indicated. If the applicant is a corporation or other entity, the names and citizenship of its principal officers are provided. The entity to be licensed is clearly described with respect to any higher level related corporate structure. The description clearly identifies and explains any proposed foreign ownership or control of activities, and shows that there is no foreign controlling interest. Primary ownership and relationships to other components of the same ownership are explicitly described. The presence and operations of any other company on the site to be licensed are fully described.

2. Financial Qualifications

   A description of financial qualifications demonstrates the applicant's current and continuing access to the financial resources necessary to engage in the proposed activity in accordance with §70.22(a)(8) and §70.23(a)(5).

3. Type, Quantity, and Form of Licensed Material

   The elemental name, maximum quantity, and specifications, including the chemical and physical form(s), of the special nuclear material the applicant proposes to acquire, deliver, receive, possess, produce, use, transfer or store are identified. For special nuclear material, the specifications include the isotopic content and amount of enrichment by weight percent. In addition, any trace impurities or contaminants, such as fission products or transuranics are characterized by identity and concentration. The applicant describes the amounts, if any, of Agreement State licensed radioactive material for the proposed facility. The proposed possession at the facility of any moderator or reflector with special characteristics, such as beryllium or graphite, is identified.

4. Authorized Uses

   Each activity or process in which special nuclear material is proposed to be acquired, delivered, received, possessed, produced, used, processed, transferred, or stored is described. The authorized uses are consistent with the Atomic Energy Act of 1954, et seq. The description is consistent with more detailed process descriptions submitted as part of the ISA summary reviewed under Section 3.0 of this SRP.

If the application is for a renewal, the applicant states the period of time for which license renewal is requested, and why the renewal application should be considered timely in accordance with 10 CFR 70.

5. Special Exemptions or Special Authorizations

Specific requests for exemptions or authorizations of an unusual nature should be listed in this section and justified in the appropriate technical section of the application.

6. Security of Classified Information

If applicable, applicant has requested and received a facility security clearance in accordance with 10 CFR 95.

1.2.5 REVIEW PROCEDURES

1.2.5.1 Acceptance Review

The staff review starts with a determination by the primary reviewer that the content of the application has been included as required by 10 CFR Part 70 regarding institutional information for fuel cycle facilities and that the information discussed in Subsection 1.2.3, "Areas of Review," has been included.

If significant deficiencies are identified in the application, the applicant will be requested to submit additional material before the start of the safety evaluation.

1.2.5.2 Safety Evaluation

If the application is accepted for review, the reviewer conducts the review with respect to the acceptance criteria in section 1.2.4 above. The material to be reviewed is for the most part informational in nature, except for information on financial qualifications and foreign ownership and control, and detailed technical analysis is generally not required beyond the acceptance criterion. The reviewer requests review assistance, as needed, from the Division of Security and the Office of the General Counsel in the review of corporate and financial information. The material provided by the applicant should satisfy the acceptance criteria of section 1.2.4. above.

1.2.6 EVALUATION FINDINGS

The staff's review will verify that sufficient information has been provided in the license application to satisfy the regulations listed under section 1.2.4.1 above with respect to institutional information and that the information provided is consistent with the guidance of this SRP. On the basis of this information, the staff will conclude that this evaluation is complete. The staff can document its review as follows:

The staff has reviewed the institutional information for [name of facility] according to Standard Review Plan Section 1.2. Based on the review, the NRC staff has determined that the applicant has adequately described and documented the corporate structure and financial information,

and that the applicant is in compliance with those parts of 10 CFR 70.22 and 70.65 relating to other institutional information. In addition, the applicant has adequately described the types, forms, quantities, and proposed authorized uses of licensable materials to be permitted at this facility as follows:

Material	Form	Quantity	Authorized Use(s)

The applicant's proposed activities are consistent with the Atomic Energy Act. The applicant has provided all institutional information necessary to understand the ownership, financial qualifications, location, planned activities, and nuclear materials to be handled in connection with the requested license.

1.2.7 REFERENCES

Code of Federal Regulations, Title 10, Part 70, Domestic Licensing of Special Nuclear Material, U.S. Government Printing Office, Washington, DC.

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1.3 SITE DESCRIPTION

1.3.1 PURPOSE OF REVIEW

The purpose of this review is to determine that the information provided by an applicant adequately describes the geographic, demographic, meteorologic, hydrologic, geologic, and seismologic characteristics of the site and the surrounding area. The site description is a summary of the information used by the applicant in preparing the Environmental Report, Emergency Plan, and the ISA summary, which identify hazards, potential credible accidents, and the consequences of those accidents.

1.3.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: ISA Reviewer, Environmental Protection Reviewer, and Emergency Plan Reviewer

Supporting: Fuel Facility Inspection staff

1.3.3 AREAS OF REVIEW

The types of information NRC staff will review include the following (as appropriate for the facility being reviewed):

1. Site Geography

   a. Site location: state, county, municipality, topographic quadrangle (71/2 minute series).
   b. Major nearby highways.
   c. Nearby bodies of water.
   d. Any other significant geographic feature that may impact accident analysis within one mile of the site (e.g., ridges, valleys, specific geologic structures).

2. Demographics

   a. Latest census results for area of concern.
   b. Description, distance, and direction to nearby population centers.
   c. Description, distance, and direction to nearby public facilities (e.g., schools, hospitals, parks).

d. Description, distance, and direction to nearby industrial areas or facilities that may present potential hazards (including other nearby nuclear facilities).
e. Uses of land within one mile of the facility (i.e., residential, industrial, commercial, agricultural).
f. Uses of nearby bodies of water.

3. Meteorology

a. Primary wind directions and average wind speeds.
b. Annual amount and forms of precipitation. The design basis values for accident analysis of maximum snow or ice load, probable maximum precipitation.
c. Type, frequency, and magnitude of severe weather (e.g., lightning, tornado, hurricane). Design basis event descriptions for accident analysis.

4. Hydrology

a. Characteristics of nearby rivers, streams, and bodies of water as appropriate.
b. Depth to the water table; potentiometric surface map.
c. Groundwater flow direction and velocity for the site.
d. Characteristics of the uppermost aquifer.
e. Design basis flood events used for accident analysis.

5. Geology

a. Characteristics of soil types and bedrock.
b. Design basis earthquake magnitudes used for accident analysis.
c. Description of other geologic hazards, e.g. mass wasting.

The above information complements and is consistent with the information presented in the Environmental Report, Emergency Plan, and ISA summary prepared by the applicant. In contrast to these more detailed descriptions, the summary site description reviewed under this section is less detailed and more brief.

1.3.4 ACCEPTANCE CRITERIA

The site description summary will be considered acceptable if the following is included:

1. A brief description of the site geography, including its location relative to prominent natural and man-made features such as mountains, rivers, airports, population centers, schools, commercial and manufacturing facilities, etc.

2. Population information based on the most current available census data to show population distribution as a function of distance from the facility.

3. Appropriate meteorologic data. Applicant's presentation or discussion includes design basis values for accident analysis of maximum snow or ice load, and probable maximum precipitation. The applicant presents appropriate design basis values for lightning, high winds, tornado, hurricane, and other severe weather conditions that are applicable to the

site.

4. A description of the hydrology, and geology, including seismicity, for the area. Applicant describes the design basis flood event for which the plant may be safely shut down. This event is at least the 100 year flood for the site, and is consistent with U.S. Army Corps of Engineers flood plain maps. The applicant describes the maximum earthquake magnitude and peak ground acceleration at the site and its expected likelihood, in terms of return period at which the plant processes can be shut down safely with acceptable risk of radiological exposure to workers, public, and the environment. Applicant compares the design basis earthquake with the maximum earthquake accelerations expected on the site with a return period of 10,000 years. The purpose of the comparison is to evaluate the likelihood of the design basis earthquake to ensure that such an event is properly considered in the applicant's ISA.

Applicant's descriptions are consistent with the more detailed information presented within the ISA information in Chapter 3 of the application, the Environmental Report, and the Emergency Plan, if applicable. The information in the description is based on official assessments prepared by Federal, State, or local authorities.

1.3.5 REVIEW PROCEDURES

1.3.4.1 Acceptance Review

The staff review starts with a determination by the primary reviewer that the application provides the content as required by 10 CFR Part 70 regarding the site description for fuel cycle facilities, and that topics discussed in Section 1.3.3, "Areas of Review," have been addressed. The information in this section provides a general summary of the bases for evaluations completed in the ISA section of the application and is consistent with the applicant's environmental report and emergency plan. The applicant may include references to the more detailed data used to complete evaluations in the ISA. The primary reviewer reviews the information in the application for completeness.

If significant deficiencies are identified in the application, the applicant will be requested to submit additional material before the start of the safety evaluation. The detailed information necessary to support the site description summary will be included in the ISA section of the application.

For license renewals, the details necessary to support the information in the site description summary may be referenced to prior submittals or material included else where in the renewal application.

1.3.4.2 Safety Evaluation

The material to be reviewed in this section is informational, summarizing the reports and information which provide the bases for the ISA evaluations. The primary reviewer verifies that the information is acceptable using the acceptance criteria of this SRP, and accurately portrays and is consistent with the information in the ISA summary, Environmental Report, Emergency Plan and other documents referenced by the applicant. No technical analysis is required, as the primary reference for the information is the ISA. If information being verified is found to be

inconsistent from the primary source, the applicant is requested to submit clarifying information or corrections. This section may also need to be updated by the applicant based upon any information changes made in response to the staff's environmental, emergency management, and ISA reviews.

1.3.6 EVALUATION FINDINGS

The staff's review verifies that sufficient information has been provided in the license application to satisfy 10 CFR Part 70.22, "Contents of Applications," requirements with respect to the site description and that the information provided is consistent with the guidance in this SRP and information contained in other sections of the application. On the basis of this information, the staff concludes that this evaluation is complete and the applicant's site description is acceptable. The staff can document its review as follows:

The staff has reviewed the site description for [name of facility] according to the Standard Review Plan Section 1.3. The applicant has adequately described and summarized general information pertaining to (1) the site geography, including its location relative to prominent natural and man-made features such as mountains, rivers, airports, population centers, schools, and commercial and manufacturing facilities; (2) population information based on the most current available census data to show population distribution as a function of distance from the facility; (3) meteorology, hydrology, and geology for the site; and (4) applicable design basis events. The reviewer verified the site description to be consistent with the information used as a basis for environmental, emergency management, and ISA analyses.

1.3.7 REFERENCES

Code of Federal Regulations, Title 10, Part 70, Domestic Licensing of Special Nuclear Material, U.S. Government Printing Office, Washington, DC.

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2.0 ORGANIZATION AND ADMINISTRATION

2.1 PURPOSE OF REVIEW

The purpose of the review of the applicant's organization and administration is to ensure that management systems and structures are in place that provide reasonable assurance that the licensee plans, implements, and controls site activities in a manner that ensures the safety of workers, the public, and the environment. The review also ensures that the qualifications for key management positions are adequate.

2.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: None

Supporting: Primary reviewers for other SRP Chapters, e.g., technical area chapters and management measures chapters; Fuel Facility Inspection staff

2.3 AREAS OF REVIEW

The organizational structure and associated administrative program proposed by the applicant should include administrative policies, procedures, and management measures, qualifications of key management positions, along with a description of how these are deemed adequate to provide reasonable assurance that the health, safety, and environmental protection (HS&E) functions will be effective.

For new applicants, or already licensed plants undergoing major modifications, the applicant should address the integration of authorities and responsibilities among the process designers, the architect-engineering firm, the construction contractor, and the plant operator, as applicable, to provide assurance that they will function as needed on the HS&E-related tasks.

The application should address how the management measures ensure the establishment and maintenance of design and operations. The administrative policies and management measures should describe the relationships among major plant safety functions such as the ISA, configuration management, maintenance, quality assurance (QA), training, radiation safety, nuclear criticality safety, fire safety, chemical safety, environmental monitoring, emergency planning, audits and assessments, and incident investigations. The applicant should also describe its qualification criteria for education, training, and experience for key management positions. Management positions for which such criteria should be described include the plant manager, operations manager, shift supervisor, and managers for various safety and environmental disciplines. Qualification criteria should be described generally, in terms of academic credentials, formal continuing education, and work experience. For example, "...bachelor's degree in nuclear engineering or related scientific or engineering field, with 5 years

experience managing the operations of a nuclear fuel manufacturing facility."

2.4 ACCEPTANCE CRITERIA

2.4.1 Regulatory Requirements

A management system and administrative procedures for the effective implementation of HS&E functions is required by 10 CFR Part 70.22, 70.23, and other sections of Part 70, as revised,[6] concerning the applicant's corporate organization, qualifications of the staff, and the adequacy of the proposed equipment, facilities, and procedures to provide adequate safety for workers, the public, and the environment.

2.4.2 Regulatory Guidance

There are no regulatory guides specific to the organization and administration description of fuel cycle facilities.

2.4.3 Regulatory Acceptance Criteria

The application is acceptable if the following criteria are met. Appropriate commitments relevant to these criteria should be included in the applicant's safety program description.

New Facilities or Facilities Undergoing Major Modifications (In addition to the criteria listed below for existing facilities):

1. The applicant has identified and functionally described the specific organizational groups responsible for designing, constructing and operating the facility. Organizational charts are included in the application.

2. Clear, unambiguous management control and communications exist among the organizational units responsible for the design and construction of the facility. A corporate officer is responsible for HS&E activities.

3. The personnel to design, construct, and operate the facility have substantive breadth and level of experience and are appropriately available. The qualifications, responsibilities, and authorities for key supervisory and management positions with HS&E responsibilities, including the plant manager, operations manager, shift supervisor, and HS&E managers (or similar positions), are clearly defined in position descriptions that are accessible to all affected personnel and to the NRC, upon request.

4. The applicant has described specific plans to transition from the design and construction phase to operations.

[6] This reference is to the draft revision to 10 CFR Part 70, subject to on-going dialogue.

Existing Facilities:

7. Applicant has identified and functionally described the specific organizational groups responsible for designing and operating the facility. Organizational charts should be included.

8. The qualifications, responsibilities, and authorities of key supervisory and management positions with HS&E responsibilities including the plant manager, operations manager, shift supervisor, and HS&E managers (or similar positions), are clearly defined in position descriptions that are accessible to affected persons and to the NRC, upon request. A corporate officer is responsible for HS&E activities.

9. In the organizational hierarchy, the HS&E organization(s) is independent of the operations organization(s), allowing it to provide objective HS&E audit, review, or control activities. "Independent" means that neither organization reports to the other in an administrative sense. Both may report to a common manager. Lines of responsibility and authority are clearly drawn.

10. The individual delegated overall responsibility for the HS&E functions has the authority to shut down operations if they appear to be unsafe, and must in that case approve restart of shutdown operations. Typically, this individual should be at as high a management level as the production or operations manager and have direct line responsibility to the plant manager.

11. The activities essential for effective implementation of the HS&E functions are documented in formally approved, written procedures, prepared in compliance with a formal document control program.

12. The applicant should commit to a simple mechanism for reporting potentially unsafe conditions or activities to the HS&E organization and/or to upper management that is available for use by any person in the plant. Reported concerns are investigated, assessed, and resolved promptly.

13. Effective lines of communication and authority among the organization units involved in the engineering, HS&E, and operations functions of the facility are clearly defined.

14. The applicant has committed to establish formal management measures including configuration management, maintenance, quality assurance (QA), training and qualification, procedures, human factors, audits and assessments, incident investigations, and records management, as necessary and appropriate to ensure the availability and reliability of controls relied on for safety. The detailed guidance for these functions is addressed in separate SRP sections on the specific topic. The applicant also describes how management assures, by formal procedures, that all applicable management measures are appropriately implemented for all structures, systems, and components that are considered items relied on for safety as defined by the safety program and its ISA.

15. Written agreements exist with off-site emergency resources such as fire, police, ambulance/rescue units, and medical services. This is addressed in more detail in Section 7.0, "Fire Safety," and Section 8.0, "Emergency Planning," of this SRP.

Commitments relevant to meeting the acceptance criteria described above are included in the applicant's safety program description.

2.5 REVIEW PROCEDURES

2.5.1 Acceptance Review

The primary reviewer should evaluate the application to determine whether it addresses the "Areas of Review" discussed in Section 2.3, above. If significant deficiencies are identified, the applicant should be requested to submit additional material before the start of the safety evaluation.

2.5.2 Safety Evaluation

After determining that the application is acceptable for review in accordance with Section 2.5.1, above, the primary reviewer should perform a safety evaluation against the acceptance criteria described in Section 2.4. The objective of the review is to ensure that the corporate-level management and technical support structure, as demonstrated by organizational charts and descriptions of functions and responsibilities, are clear with respect to assignments of primary responsibility. The primary reviewer consults with the NRC inspection staff to verify that the applicant's management positions are adequately defined in terms of both numbers of persons and their responsibilities, authorities, and required qualifications.

The review process should consist of:

1. An examination of the applicant's organizational structure and administration as described in the application.

2. Site visits by one or more reviewers (with support from the NRC inspection staff, as appropriate) to review, discuss, and verify implementation of the management structure, systems, and administrative procedures.

The supporting staff reviewers determine, on the basis of the foregoing, the overall acceptability of the applicant's management system, management qualifications, organizational structure, and administrative procedures. To facilitate the review of the applicant's proposed organization and administration program, the reviewers should examine organization charts, position descriptions, corporate and plant policies, and the descriptions of administrative procedures and guidance documents concerning HS&E. The reviewers should make a determination whether the acceptance criteria of Section 2.4 are satisfied and then prepare an SER in accordance with Section 2.6.

2.6 EVALUATION FINDINGS

The staff's evaluation should verify that the license application provides sufficient information to satisfy the regulatory requirements of Section 2.4.1 and that the regulatory acceptance criteria in Section 2.4.3 have been appropriately considered in satisfying the requirements. On the basis of this information, the staff should conclude that this evaluation is complete. The reviewer should write material suitable for inclusion in the SER prepared for the entire application. The SER should include a summary statement of what was evaluated and the basis for the reviewers' conclusions.

The staff can document the evaluation as follows:

The staff has reviewed the organization and administration for [name of facility] according to the Standard Review Plan Chapter 2.0.

[For new facilities] The applicant has described (1) clear responsibilities and associated resources for the design and construction of the facility and (2) its plans for management of the project. [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] The staff has reviewed these plans and commitments and concludes that they provide reasonable assurance that an acceptable organization, administrative policies, and sufficient competent resources have been established or are committed, to satisfy the applicant's commitments for the design and construction of the facility.

[For operating and new facilities] The applicant has described its organization and management policies for providing adequate safety management and management measures for the safe operation of the facility. [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] The staff has reviewed these measures and

concludes that the applicant has an acceptable organization, administrative policies, and sufficient competent resources are established to provide for the safe operation of the facility under both normal and abnormal conditions.

2.7 REFERENCES

1) Code of Federal Regulations, Title 10, Part 70, *Domestic Licensing of Special Nuclear Material,* U.S. Government Printing Office, Washington, DC.

2) Proposed Revision to Code of Federal Regulations, Title 10, Part 70, *Domestic Licensing of Special Nuclear Material,* as revised.

3) NUREG-1324, *Proposed Method for Regulating Major Materials Licensees*, Sections 3.1, Organization Plan, and 3.2, Managerial Controls and Oversight, U.S. Nuclear Regulatory Commission, 1992.

3.0 INTEGRATED SAFETY ANALYSIS (ISA)

3.1 PURPOSE OF REVIEW

The purpose of the ISA review is to establish reasonable assurance that the applicant or licensee has:

1. Performed a comprehensive ISA of the fuel cycle facility and its processes using effective systematic methods.

2. Identified and evaluated all hazards and credible accident sequences in the ISA involving process deviations or other events internal to the plant (e.g., explosions and fires), and credible external events (e.g., floods, high winds, and earthquakes) that could result in consequences to the public, worker, or the environment of the types specified in 10 CFR 70.61.

3. Designated engineered and administrative items relied on for safety, and evaluated the set of items for each accident sequence to provide reasonable assurance, through preventive or mitigative measures, that the safety performance requirements of 10 CFR 70.61 are met.

4. Used competent staff in the ISA process.

5. Provided a formal system to manage changes to the ISA.

3.2 RESPONSIBILITY FOR REVIEW

Primary: FCLB assigned reviewer

Secondary: Technical specialists in specific areas

Supporting: Fuel Facility Inspection Staff

3.3 AREAS OF REVIEW

Information about the licensee's ISA is contained in the license application, the ISA summary, and other ISA documentation. The application and the ISA summary are submitted to NRC whereas additional documentation of the ISA is available for NRC review at the facility site. The term "results of the ISA" includes all the ISA information that is submitted to NRC plus the additional supporting information that is found on-site. In general, the application contains information needed by the reviewer to understand the nature of the ISA process performed at the site, the qualifications of the team performing the ISA, the major results of the ISA, and the procedures for conducting and maintaining the ISA. The application provides licensee commitments that demonstrate the adequacy of the ISA program. The summary of the ISA provides a synopsis of the results of the ISA as specified in 70.65(b). Information contained in the ISA summary that also satisfies the information requirements in the application may be referenced in the application.

The staff reviews the application and the ISA results (ISA summary and other ISA documentation) to find reasonable assurance that the applicant has performed a systematic evaluation of the hazards and credible accident sequences. The review includes the makeup of the ISA team and the administrative and physical safety controls required to prevent or mitigate the consequences of accidents. The review boundary includes those accidents that result in a release of licensed radioactive material or an inadvertent nuclear criticality event. In addition, the staff reviews accidents involving hazardous chemicals when the chemicals are composed of, or produced from the processing of, licensed radioactive material; or if the accident has the potential to jeopardize the safety of regulated activities. An event sequence having consequences less than those identified in 10 CFR 70.61(c) would not require further consideration within the ISA. The areas of review are as follows:

1. The site description (see Section 1.3, "Site Description") concerning those factors that could affect safety, such as geography, meteorology (e.g., high winds and flood potential), seismology, and demography.

2. The facility description concerning features that could affect potential accidents and their consequences. Examples of these features are facility location, facility design information, and the location and arrangement of buildings on the facility site.

3. The description of each process analyzed as part of the ISA. Specific areas reviewed include basic process function and theory, major components ! their function and operation, process design and equipment, and process operating ranges and limits.

4. The applicant's commitment to compile and maintain a current and accurate set of process safety information (PSI) including information on the hazardous materials, technology, and equipment used in each process. The applicant should explain this activity in detail in the description of its configuration management program (Section 11.1, "Configuration Management").

5. The description of the applicant's requirements for ISA team training and qualifications (Section 11.3, "Training and Qualification").

6. The ISA method used for each individual process node and the justification for its selection. For purposes of this review, the ISA begins with an identification of hazards (chemicals,

radiological materials, fissile materials, etc.) that may present a potential threat to the public, facility workers, or the environment. Based on a systematic analysis of each plant process, the ISA Process Hazard Analysis (PHA) identifies a set of individual accident sequences or process upsets that could result from the hazards. The review of the ISA methodology includes evaluating the applicant's methods in the following specific areas:

a. Hazard identification.

b. Process hazard analysis (accident identification).

c. Accident sequence construction and evaluation.

d. Consequence determination and comparability to 10 CFR 70.61.

e. Likelihood categorization for determination of compliance with 10 CFR 70.61.

7. The narrative description, process hazard analysis documentation, and the tabular summary of the ISA results in the following specific areas:

   a. The list of hazardous materials and conditions resulting from the Hazard Identification task.

   b. The Hazard Interaction Matrix table [see reference AIChE 1992, section 3.3].

   c. Accident sequences identified by the ISA systematic Process Hazard Analysis.

   d. Unmitigated and mitigated consequences of each postulated accident to facility workers or the public.

   e. Comparisons of the consequences of each postulated accident to the consequences of concern identified in 10 CFR Part 70.61.

   f. Identification of engineered and administrative controls involved in each accident sequence.

   g. Assignment of accident sequences to likelihood categories and comparison to 10 CFR 70.61 requirements.

8. The description of the engineered and administrative safety controls, and mitigative barriers used to maintain safe operation of the facility to ensure that, for each accident sequence, the controls are commensurate with 10 CFR 70 requirements as interpreted in the acceptance criteria of section 3.4 below. These criteria are risk informed in that systems of controls applied to accident sequences having more severe consequences are to be correspondingly more reliable. The applicant should also commit to maintain safety controls and mitigative barriers available and reliable for high and intermediate risk accident sequences.

9. The management measures (see definition in Glossary) applied to each safety control needed to conform to the requirements of 10 CFR 70.62(d). Those management measures that are generically applied to all safety controls or to specified classes of controls may be described in Section 11, "Management Controls Systems," or in Sections 4 through 7 and 9,

which cover specific safety disciplines. However, since the ISA identifies the safety controls as such, and provides other information needed to apply management measures in a graded manner, the information from the ISA summary and other ISA documentation needed to implement these systems should be reviewed.

For accident sequences evaluated as potentially having the consequences specified in 70.61, but meeting the likelihood requirements of 10 CFR 70.61 without controls, staff reviews the basis for the applicant evaluation of the sequence as being of acceptably low likelihood. Typically such accident sequences involve very low likelihood natural phenomena or other initiating events.

10. The facility procedures for conducting and maintaining the ISA. The object of this review is to ensure the overall integrity of the ISA as a current and accurate safety basis for the facility. Specific review areas include the applicant's procedures for: (1) performing and updating the ISA, (2) review responsibility, (3) documentation (including provisions for updating NRC on changes to controls or seeking NRC approval of changes per 70.72, and (4) maintenance of ISA records per 70.62(a)(2). The integrity of the ISA procedures should be controlled by the applicant's configuration management program.

3.4 ACCEPTANCE CRITERIA

3.4.1 Regulatory Requirements

The requirement to perform an Integrated Safety Analysis (ISA) is specified in 10 CFR 70.62. 10 CFR 70.62(c) specifies requirements for the tasks comprising the ISA and the demonstration that items relied on for safety meet the safety performance requirements of 70.61. 10 CFR 70.72 states requirements for keeping the ISA and its documentation current when changes are made to systems, structures, and components.

3.4.2 Regulatory Guidance

Guidance applicable to performing an ISA and documenting the results is contained in NUREG-1513, "Integrated Safety Analysis Guidance Document." A sample ISA Summary for one process is also available to illustrate an acceptable form and content.

3.4.3 Regulatory Acceptance Criteria

The acceptance criteria for an ISA are based on meeting the relevant requirements in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." The ISA will form the basis for the safety program by identifying accidents of concern, designating controls and management measures, and evaluating the likelihood of each accident sequence for compliance with 70.61. The staff will accept the ISA, the designation of controls, and the management of the ISA process if the reviewer finds the following criteria are met:

1. The description of the site for processing nuclear material is considered acceptable if the applicant includes or references the following safety-related information in the application:

a. A description of the site geography, including its location from prominent natural and man-made features such as mountains, rivers, airports, population centers, possibly hazardous commercial and manufacturing facilities, etc. adequate to permit evaluation of the likelihood and magnitude of consequences of concern.

b. Population information, based on recent census data, that shows population distribution as a function of distance from the facility adequate to permit evaluation of regulatory requirements, including exposure of the public to consequences listed in 10 CFR 70.61.

c. Characterization of natural phenomena (e.g., tornadoes, hurricanes, and earthquakes) and other external events sufficient to assess their impact on plant safety and to assess their likelihood of occurrence. The discussion identifies the design basis events for the facility and indicates which events are considered incredible and the basis for that determination. The assessment also indicates which events could occur without adversely impacting safety.

The level of detail for this material is greater than that which would be acceptable in the general information in Chapter 1.

2. The description of the facility is considered acceptable if the applicant identifies and describes the general features that are relied on or required for safety. If such information is available elsewhere in the application, reference to the appropriate sections is considered acceptable. The information provided should adequately support an overall understanding of the facility structure and its general arrangement as it pertains to the ISA. As a minimum, the applicant adequately identifies and describes:

   a. The facility location and the distance from the site boundary in all directions, including the distance to the nearest resident and distance to boundaries in the prevailing wind directions.

   b. Design information regarding the resistance of the facility to failures caused by credible external events, when those failures may produce consequences of concern.

   c. The location and arrangement of buildings on the facility site.

3. The description of the processes analyzed as part of the ISA is considered acceptable if it describes the following features sufficiently to permit: 1) an evaluation of the completeness of the hazard (accident) identification task, and 2) an evaluation of the likelihood and consequences of the accidents identified. If the information is available elsewhere in the application and is adequate to support the ISA, reference to the appropriate sections is considered acceptable. The information provides an adequate explanation of how the safety controls reliably prevent the process from exceeding safety limits for each case identified in the ISA results where they are needed.

   a. Basic process function and theory. This information includes a general discussion of the basic theory of the process.

   b. Major components ! their function and operation. This information includes the general arrangement, function, and operation of major components in the process. It includes

process schematics showing the major components and instrumentation and, if appropriate, chemical flow sheets showing compositions of the various process streams.

c. Process design and equipment. This information includes a discussion of process design, equipment, and instrumentation that is sufficiently detailed to permit an adequate understanding of the results of the ISA. It includes schematics indicating safety interrelationships of parts of the process. In particular, either schematics or descriptions indicating the location and geometry of Special Nuclear Materials, moderators, and other materials in the process are sufficient to permit an understanding of the adequacy of controls on mass, geometry, moderation, reflection, and other criticality parameters affected by geometry.

d. Process operating ranges and limits. This information includes the operating ranges and limits for measured process variables (e.g., temperatures, pressures, flows, and compositions) used in engineered or administrative controls to ensure safe operation of the process. The process operating limits and ranges are considered acceptable if they are consistent with those evaluated as adequate for safety in the ISA. One acceptable way of presenting this information is as a tabular summary of all safety controls grouped according to hazard type, i.e. nuclear criticality, radiological hazards, chemical hazards, etc., as shown in Appendix A, Table A.3-7.

4. For purposes of conducting an ISA, the applicant's Process Safety Information is considered acceptable if the applicant commits to maintain, at a minimum, the following information current and accurate:

   a. Hazardous material information including toxicity information, permissible exposure limits, physical data, reactivity data, corrosivity data, and stability data (thermal and chemical).

   b. Process technology information including block flow diagrams or simplified process flow diagrams, process chemistry, maximum intended inventory, and safe upper and lower limits for parameters controlled for safety reasons, such as temperatures, pressures, flows, and compositions.

   c. Process equipment information including materials of construction, piping and instrumentation diagrams (P&IDs), electrical classification, relief system design and design basis, ventilation system design, design codes and standards used, material and energy balances, and safety systems (e.g., interlocks, detection systems, and suppression systems).

5. The ISA team for each process analyzed is considered acceptable if the following criteria are met:

   a. The ISA team has a team leader who is formally trained and knowledgeable in the ISA methodology chosen for the hazard and accident evaluations. In addition, the team leader can demonstrate an adequate understanding of all process operations and hazards under evaluation, but is not the cognizant engineer or expert for that process.

   b. At least one member of the ISA team has thorough, specific, and detailed experience in the process under evaluation.

c. The team represents a variety of process operating and engineering design experience, in particular, radiation safety, nuclear safety, fire protection, and chemical safety disciplines.

d. A manager provides overall administrative and technical direction for the ISA.

6. The descriptive summary of the ISA methodology is considered acceptable if it describes the methods used for each ISA task, and the basis for selection of each method, so that the adequacy of the method is clear and appropriate according to the criteria described in NUREG-1513 for selection of ISA methods. Specific acceptance criteria for the ISA methodology are as follows:

   a. The hazard identification method selected is considered acceptable if it:

      i. Provides a list of materials (radioactive, fissile, flammable, and toxic) or conditions that could result in hazardous situations (e.g., loss of containment of licensed nuclear material). The list includes maximum intended inventory amounts and the location of the hazardous materials at the facility.[7]

      ii. Determines potential interactions between materials or between materials and conditions that could result in hazardous situations.

   b. The process hazard analysis (accident sequence identification) method selected is considered acceptable if:

      i. Its selection is consistent with the guidance provided in NUREG-1513. For methods used by the applicant but not addressed in NUREG-1513, the applicant provides justification and references for their use.

      ii. It adequately address all the hazards identified in the hazard identification task of section 6.a above. The applicant identifies and justifies any hazards eliminated from further consideration.

      iii. It provides reasonable assurance that the applicant identifies all significant accident sequences (including the controls used to prevent or mitigate the accidents) that could result in consequences of concern identified in §70.61[8].

      iv. It takes into account the interactions of identified hazards and proposed controls, including system interactions, to ensure that the overall level of risk at the facility is consistent with the requirements of §70.61 and appropriately limited.

      v. It addresses all modes of operation including startup, normal operation, shutdown, and maintenance.

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[7] At least the following hazardous materials should be included in the inventory list if present on-site: ammonia, fines (UO_2 dust), flammable liquids and gases, fluorine, hydrofluoric acid, hydrogen, nitric acid, organic solvents, propane, uranium hexafluoride, and Zircalloy.

[8] The release of hazardous chemicals is of regulatory concern to NRC 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.

vi. It addresses hazards resulting from process deviations (e.g., high temperature, high pressure), initiating events internal to the facility (e.g., fires or explosions), and hazardous credible external events (e.g., floods, high winds, and earthquakes, airplane crashes). The applicant provides justification for its determination that certain events are incredible and, therefore, not subject to analysis in the ISA.

vii. It adequately considers initiation of, or contribution, to accident sequences by human error by appropriate use of human-systems interface analysis.

viii. It adequately considers common mode failures and system interactions in evaluating systems that are to be protected by double contingency.

c. The application demonstrates that valid consequence evaluation methods have been used, as described in the appropriate safety chapters of the license application (e.g., Section 5.0, "Nuclear Criticality Safety," Section 6.0, "Chemical Safety"). Acceptable methods of consequence evaluation are described in Nuclear Fuel Cycle Facility Accident Analysis Handbook, NUREG/CR-6410, March 1998.

d. The applicant uses, and submits adequate documentation of, an effective method for evaluating the adequacy of items relied on for safety in all identified accident sequences. This evaluation method is considered acceptable if:

i. For nuclear criticality accident sequences, it can demonstrate adherence to the double contingency principle, including reasonable assurance that common failure modes are accounted for (see Section 3.4.3.8), or

ii. It can demonstrate compliance with the graded protection criteria of 10 CFR 70.62(a) consistent with the guidance in the Appendix A. Or, for individual accident sequences not conforming to the guidance in Appendix A, specific and adequate justification showing conformance to 10 CFR 70.61 is provided.

7. ISA RESULTS: The documentation of the ISA results, consisting of both the ISA Summary and the in-plant documentation of results, is acceptable if it is sufficient to demonstrate that the following three top level criteria have been met:

a) completeness in identifying all accident sequences,
b) acceptable evaluation of consequences, and
c) acceptable evaluation of likelihood.

That is, the documentation of results is acceptable if it demonstrates:

(a) completeness of the ISA in identifying all hazards and accident sequences that might be capable of producing consequences of concern. This means that all accidents exceeding the minimum consequence levels of 10 CFR 70.61 including: those that involve releases of licensed material or hazardous chemicals produced from licensed material, all unplanned radiation exposures, and all nuclear criticality accidents have been identified. The primary criterion for completeness is that the systematic method chosen was correctly applied. During the PHA phase accidents will be identified whose consequences may initially be unknown, then later are analyzed and shown to be beneath the minima of concern. The ISA documentation must show which such accidents have been eliminated due to

insufficient consequences, otherwise the completeness of those identified cannot be evaluated. Large groups of events of a similar nature and clearly having consequences below the level of concern may be described as a single item, provided the definition of the group is sufficiently clear as to which accidents are included, so that completeness is evident;

(b) correct evaluation of the consequences of each accident sequence and comparison to the consequence levels of concern in 10 CFR 70.61, and

(c) evaluation showing, with adequate basis, compliance with the likelihood requirements of 10 CFR 70.61.

Supporting criteria for acceptable ways of complying with each of these three top level criteria follow.

a. COMPLETENESS.

The information submitted is acceptable for showing completeness in identifying accident sequences and evaluation of consequences if:

i. The summary of the hazard identification results provides:

1) A list of materials (radioactive, fissile, flammable, and toxic) or conditions that could result in hazardous situations. The list includes maximum intended inventory amounts and the location of the hazardous materials at the site.

2) A hazards interaction table showing potential interactions either between materials or between materials and conditions that could possibly result in hazardous situations.

ii. The ISA results documentation provides either:

1) A tabular summary description of the accident sequences identified in the process hazard analysis. The tabular description consists of one row for each accident sequence. Accident sequences initiated by the same type of event, and consisting of the same sequence of control failures, and resulting in the same consequence category are summarized as a single row. This row lists the initiating event, the controls or barriers that must fail in order for the accident to occur, and the level of unmitigated consequences, if all controls fail. The listing clearly indicates the sequence and linkage between each initiating event, the controls designed to prevent or mitigate consequences of concern, and the resulting consequences when these controls fail. The tabular summary identifies the severity level of each type of consequence (radiological, criticality, chemical, environmental) according to the values defined in 10 CFR 70.61. Information sufficient for evaluation of compliance with the likelihood requirements of 10 CFR 70.61, such as likelihood indices are tabulated. Appendix A, Table A-1, provides an acceptable way of presenting this information.

OR

2) A set of logic diagrams, such as fault trees or event trees for each process, presenting the same information as in 1) above.

In the tabular summary or diagrams showing accident sequences, it is not necessary to list as a separate sequence every conceivable permutation of the accidents. The listing has three purposes: 1) to show completeness, 2) to permit evaluation of likelihood (adequacy of controls), and 3) to identify controls relied on to prevent and mitigate accidents. Accidents having characteristics that all fall in the same categories can be grouped as a single line item in the table, if: a) the initiating events have the same type of effect on the system, b) they all consist of failure of the same controls, c) they all result in violation of the safety limit on the same parameter, and d) they all result in the same type and severity category of consequences. A primary purpose of showing completeness is to assure that existing safety controls are adequate. Once this has been shown for a class of accidents having the same characteristics, it is not necessary to distinguish among the different types. On the other hand, if a different initiating event poses a different type of challenge to a safety control, then it should be listed separately, because it may reveal a weakness of the control.

To demonstrate completeness, it may be necessary to describe certain accidents evaluated as incredible events, when this is not obvious. Justification for their evaluation as incredible should be provided.

b. CONSEQUENCES.

The information submitted is acceptable for showing adequate evaluation of consequences of accidents if:

i. The ISA results documentation at the plant includes a description of each accident that includes an estimate of its quantitative consequences (doses, chemical exposures, criticality) in a form that can be directly compared to the consequence levels in 10 CFR 70.61 or includes a reference to a calculated value that applies to that accident; and

ii. The ISA Summary includes a brief description of each process that also summarizes the accident consequences in that process by giving the maximum calculated exposure values for each type of chemical and the maximum radiological dose, other than from criticalities, to both workers and the offsite public, and whether a criticality accident was identified in that process.

The ISA results documentation must show that all accident sequences have a likelihood and consequences, such that the safety performance requirements of 10 CFR 70.61 are met. Showing the consequences for each accident can be done using a tabular summary as shown in Appendix A, Table A-1, by a narrative list of all accident sequences, or by annotated logic diagrams.

Consistent with the guidance in the following paragraph, criticality accidents will normally be high consequence events because the dose will exceed 100 rem to nearby workers (see Section 5.0, “Criticality Safety”). For processes with effective engineered shielding, criticalities may produce very low doses to workers. However, as stated in the regulation, notwithstanding the effectiveness of shielding or other mitigative features, primary reliance must be on prevention of

criticalities. However, when shielding is used, it is acceptable that preventive measures of lower reliability be used. That is, shielded criticality events need not be highly unlikely.

In assessing the consequences of nuclear criticality accidents to workers, since a typical criticality of 10^{17} fissions produces a dose of about 450 to 1000 rem at 2 meters, it is acceptable to assume that, absent shielding, criticalities will exceed the 100 rem threshold. Hence, all such criticalities would be categorized as "high consequence" accidents in the terminology of 10 CFR 70.61. Any reduction of the dose from a criticality accident to a value below 100 rem is acceptable if due to reliable engineered features, such as shielding. Administrative controls alone would not normally be considered of adequate reliability. In evaluating shielding, a criticality of a conservative credible magnitude must be assumed. The Nuclear Fuel Cycle Facility Accident Analysis Handbook, NUREG/CR-6410, March 1998, provides methods for estimating magnitudes of criticality events.

c. LIKELIHOOD

The ISA documentation is acceptable for showing compliance with 10 CFR 70.61 and 70.62(a) if:

1) It contains an evaluation of the likelihood of each accident that is adequately supported, and
2) these evaluated likelihoods comply with 70.61.

The likelihood requirements stated in 10 CFR 70.61 are that accidents resulting in consequences of concern in 70.61(b), "high consequences", be "highly unlikely"; and those resulting in consequences in 70.61(c), "intermediate consequences", be "unlikely".

Acceptance criterion 1 above means that, to be acceptable, the evaluation of the accidents must be supported by use of a methodology that provides reasonable assurance that the items relied on to prevent or mitigate the accident are sufficient to achieve the regulatory requirement of unlikeliness. Such methods must be systematic, consistent among different practitioners, consistent with the actual history of failure events at the plant, and consider all the factors that affect the reliability of items. As a minimum, the method should consider the factors of redundancy, independence, concurrency, and human error. To achieve consistency, objective written methods, data, and criteria should be established to be followed by ISA Team members evaluating likelihood compliance.

Acceptance criteria 2 above means that, ultimately, the conclusion of an evaluation must clearly assign the accident as "highly unlikely" or "unlikely" as required. This means that the terms, "unlikely" and "highly unlikely", require interpretation. The applicant may provide in the ISA submittal, a definition and basis for these terms. One basis acceptable to the staff is provided in the following.

The text and tables in Appendix A describe an acceptable method for establishing likelihoods based on estimated frequencies of failure.

LIKELIHOOD CRITERIA

The terms, "highly unlikely" and "unlikely", are inherently quantitative in nature. That is, the underlying concept is that events have a certain likelihood of occurrence in any one year; and

adequate safety performance means this likelihood be sufficiently low. The obvious questions are:

1) What annual frequency would qualify as “unlikely” or “highly unlikely” respectively?
2) How can compliance with the requirements be demonstrated?

10 CFR 70.61 safety performance likelihood requirements are stated in qualitative rather than quantitative form. Thus staff should not interpret these requirements as mandating that quantitative analysis be done to show compliance. However, quantitative analysis of likelihoods is one acceptable method of showing compliance. If quantitative analysis is performed, accident sequence frequencies should be determined using established methods and input values consistent with industry performance. Because quantitative methods would be acceptable, there follows a discussion of acceptable accident frequency values based on Commission guidance. Following this discussion of frequencies, criteria for acceptable non-quantitative methods will be given.

QUANTITATIVE LIKELIHOOD EVALUATION

Quantitative Evaluation Methods

Standard methods for quantitative evaluation of the frequency of accidents can be found in works on reliability engineering and probabilistic risk assessment. Such methods require input information concerning failure and repair rates for basic events. These basic events may be external or internal initiating events or failures of items relied on for safety. Quantitative credit should not be taken for the low likelihood of an event without justification. One justification is that the event is failure of an item relied on for safety that is subject to management measures (e.g. maintenance, training) to assure meeting its reliability goal. Another justification is that the event has inherently low likelihood that cannot reasonably be increased by human intervention.

Quantitative Acceptance Criteria

There are two safety performance measures established as part of the NRC Strategic Plan that bear on the question of how reliable safety controls must be. These goals thus bear directly on the question of acceptance criteria for safety controls identified in the ISA’s to be done at fuel cycle facilities. The two safety performance measures are: 1) No inadvertent nuclear criticalities, and 2) no increase in reportable radiation releases. Unshielded criticality events can be expected to produce doses to workers exceeding the 100 rem value defining “high consequences”. Hence, high consequence events are tied to this first safety performance measure. That is, an acceptable interpretation of the 70.61 requirement that high consequence events be “highly unlikely” should be consistent with the goal of “no inadvertent nuclear criticalities”. This cannot mean zero likelihood, but neither can it mean that criticalities are expected frequently.

The second Commission safety performance measure refers to the requirements for Abnormal Occurrence reports by the NRC to Congress of radiation releases. One of these Abnormal Occurrence reporting criteria is 25 rem exposure to any adult. In terms of 70.61, 25 rem is an intermediate consequence event for a worker, and a high consequence event for the offsite public. Hence, the 70.61requirement that intermediate consequence accidents be “unlikely” is constrained by the Commission goal of “no increase” in the rate of 25 rem doses.

The current 1997 five year average of reportable radiation exposures (25 rem) is 0.4 per year. If no increase is to be permitted, then the contribution of fuel cycle facilities, which in the past has likely been zero, should be at most a small fraction of this 0.4 per year. For example, let the fuel cycle industry be allocated 10% of this value, hence 0.04 per year. If there are about 10 fuel cycle facilities, this is 0.004 per facility per year.

Similarly, to achieve no inadvertent criticalities, the expected frequency per accident per year must be sufficiently low. Let us say that, for the whole industry we wish to have a likelihood of criticality no more than once in 100 years. This would appear to be about as high a value as is tolerable for be consistent with the Commission goal. For an industry of 10 facilities, 0.01 per year is 0.001 per facility per year. Note that this is less than the 0.004 per facility per year goal for offsite doses exceeding 25 rem derived above.

Considering the above, a consistent set of quantitative goals would require that the sum of the frequencies of all accident sequences at a facility be less than:
1) 0.001 per facility per year for high consequence events, and
2) 0.004 per facility per year for intermediate consequence events.

It should be noted that the safety performance requirements of 70.61 are applied to each individual accident identified in the ISA. If an applicant chooses to use quantitative methods for evaluating compliance with 70.61, then summing the accident frequencies for the whole facility and showing compliance with the above numerical goals is one acceptable way of demonstrating compliance with the requirements.

NON-QUANTITATIVE LIKELIHOOD EVALUATION

In order that each accident sequence have sufficiently low likelihood to comply with 70.61 it is necessary that the system of safety controls (IROFS) designed to make the likelihood low have certain reliability characteristics. These characteristics include redundancy, independence, low failure rate, rapid detection of failures, and rapid restoration or repair. Qualitatively, the system of controls preventing an accident is sufficient to make it highly unlikely if it has double contingency protection as interpreted by the NRC staff. Double contingency protection can be achieved by having two independent highly reliable controls, or a larger number of redundant controls of equivalent system reliability. Qualitatively, the system of controls preventing an accident is sufficient to make it unlikely if it has at least one highly reliable control, or multiple redundant controls of equivalent system reliability.

For an accident sequence with unmitigated consequences in the high consequence category of 70.61, adherence to double contingency is acceptable. Adherence to double contingency requires that at least two unlikely, independent, and concurrent changes in process conditions are necessary before a criticality accident can occur. If double contingency is not feasible, then the controls should exhibit sufficient redundancy and diversity to make criticality comparably unlikely.

For an accident sequence that results in the intermediate consequence category of 10 CFR 70.61, at least a single unlikely event must occur before the unmitigated consequences of the accident occur. The following is a logical deduction from the set of safety performance requirements; namely, that a mitigative control applied to a sequence must reduce the consequences below the limits defining the lower bound of the category in order to be credited in determining compliance with 70.61.

To show qualitative compliance with the likelihood requirements, the applicant must describe the qualitative likelihood evaluation method and criteria that have been used. The results of applying this method and criteria must then be documented for each accident sequence identified in the accident identification (PHA) phase of the ISA. The evaluation method must be systematic and sufficiently objective to allow different teams to produce consistent results. It is not adequate merely to have the ISA Team express a holistic judgement that the system of IROFS preventing a given accident makes it sufficiently unlikely. Such a method lacks consistency and objectivity and cannot be evaluated. The double contingency principle identifies the reliability characteristics required but does not provide criteria for when a process change is sufficiently "unlikely" to qualify.

The acceptance criterion for a non-quantitative likelihood evaluation method is that it include evaluation of each of the reliability characteristics of the system of controls. These characteristics to be evaluated are:

redundancy,
independence,
concurrency of the system,
likelihood of each of the individual "process changes".

Detailed acceptance criteria for each characteristic are given below.

Redundancy

Redundancy refers to process designs where multiple items relied on for safety must fail before an accident can occur. An effective way to make accidents highly unlikely is to provide sufficient redundancy. Double contingency is a concept that includes redundancy as one element. It may appear that double contingency only requires a twofold degree of redundancy. This is not strictly true. Some controls used to prevent accidents are not sufficiently reliable on their own to make the undesired process change qualify as "unlikely". This is particularly true when relying on administrative controls. By administrative is meant procedures requiring correct action by an operator. When using such low reliability controls, process parameters are often controlled by multiple redundant items. Though no one of them would qualify alone as "unlikely" to fail, taken together they make the process change unlikely. Thus, to achieve double contingency may require a degree of redundancy greater than two. Two highly reliable engineered controls may be sufficient, but a greater number of controls is needed if each is of lower reliability.

Independence

Independence must be evaluated when redundancy is relied upon. Two events are independent if the likelihood of occurrence of each does not depend on the other. If independence is not achieved, then the likelihood of both failures may not be as low as one estimates. Independence means no common cause, no shared elements, and nothing else that could cause loss of both functions. There are checklists and other methodological tools for performing common cause evaluations of sets of controls. Ideally these methods should be used. In any case, independence should be evaluated. Controls that act upon the same process parameter may be subject to a single point failure that bypasses or overwhelms both. Processes which rely on correct action by an operator may be vulnerable to a single point failure that is an incorrect action by that operator. Protecting against this type of operator error may require physical locks or other means of preventing any single individual from taking an action that could be incorrect.

Concurrency

Any non-quantitative method for evaluating redundant systems of safety controls should take credit for lack of concurrency of control failures. Accidents often require that two process changes occur, each a change in the state of the system. The first change places the system in a certain state, for example, a critical mass accumulates. The second change, for example, addition of moderator, must occur while this first state still exists. If the first state is detected and corrected rapidly, it is much less likely that the second event will occur while the system is vulnerable. Thus for such active redundant systems, the evaluation methodology should include evaluation of the time to detect and correct failures. These time periods are referred to as "surveillance intervals" and "repair times". The total of these two for the first failure should be much shorter than the mean time between failures of the second control.

Another way of saying the same thing is that systems having items that may fail during the life of the plant require at least annual surveillance. Similarly, systems containing items known to fail frequently must have virtually continuous surveillance. This is not necessarily difficult because many processes are continuously manned during operation, failures are obvious, and restoration is quick. It can also be achieved by fail safe devices or by continuous automatic monitoring. The point is that the evaluation must explicitly consider surveillance and repair times. Without surveillance, failure of redundant systems containing items which can fail cannot be considered highly unlikely.

Likelihood

As stated earlier, the number of redundant items needed to make an accident highly unlikely depends on how unlikely failure of each redundant item is. All items are not created equal. In general, certain types of items are less likely to fail than others. A better way of saying this is that items with certain characteristics can more easily be made reliable. The usual hierarchy is: passive engineered controls, active engineered controls, enhanced administrative controls, and simple administrative controls. Among administrative controls another such hierarchy is: enhanced prohibitions, simple prohibitions, enhanced positive actions, and simple positive actions required for safety. Although the reliability of safety items can be roughly categorized in this way, a better way is to define groups of items graded according to their safety significance. For instance the terms "safety equipment", "safety related equipment","high reliability equipment", "process features relied on for safety", etc. may be used. Equipment or features in these groups then receive sufficient management measures (e.g., maintenance, surveillance, configuration management) to assure that they achieve a reliability appropriate to their group. The point is that, to be acceptable, a method for non-quantitative evaluation of accident sequences requires that the reliability of individual safety items be assured by characteristics or measures whose presence and relative effectiveness can be objectively determined.

Appendix A describes a method for demonstrating compliance with the likelihood requirements of 10 CFR 70.61. This method, though derived from and related to underlying frequencies of failure, can be applied as a purely qualitative method.

8. The "list describing items relied on for safety" required by 10 CFR 70.62(c)(vi) is acceptable if:

   1) it includes all items relied on for safety in the identified accident sequences; and

2) the description of the items relied on for safety, their management measures, and the associated safety limits and margins is adequate to permit a determination of compliance with 10 CFR 70.62(c)(vi); and

3) information concerning the assignment of management measures to safety controls is adequate to show compliance with 10 CFR 70.62(d).

Acceptance criteria 1) through 3) above are explained in greater detail below.

1) ALL ITEMS: The primary function of the "list describing all items relied on for safety" is to document the safety basis of all processes in the facility to assist in assuring that these items are not degraded or removed without a justifying safety review. Thus the key feature of this list is that every item relied on for safety be included. No item, aspect, feature, or property of the processes that is needed to show compliance with the safety performance requirements of the regulation may be left off this list.

For example, if a process upset is required before an accident may occur, and if, in showing compliance with 70.61 reliance is placed on the fact that this process upset is an unlikely event, then those features of the process that assure that the upset is of low frequency are an item relied on for safety. Similarly, if the dimension or the material composition of a piece of process equipment is essential to preventing an accident, then that dimension or material is an item relied on for safety. In such cases, only those dimensions, features, or properties of the process that are essential to the safety function are items relied on for safety. It is essential that such process features be clearly identified so that a description of their safety function is available to safety reviewers for change control.

Items relied on for safety include both hardware safety controls and administrative controls. All such items must be listed, no matter how low their safety significance, if they are relied on to demonstrate compliance with the safety performance requirements of 70.61. Such items may assure compliance by making the accident unlikely or by mitigating its consequences.

2) THE DESCRIPTIONS OF ITEMS: The essential features of each item relied on for safety (IROFS) that are required to achieve adequate reliability should be described. Sufficient information should be provided about hardware controls to permit an evaluation that, in principle, controls of this type will have adequate reliability. If the IROFS is an administrative control, the nature of the action or prohibition involved must be described sufficiently to permit an understanding that, in principle, adherence to it should be reliable.

3) MANAGEMENT MEASURES: The description of each item must contain any information needed to identify how the management measures, such as maintenance, training, configuration management, etc. of 10 CFR 70.62(d) are applied to it. If a system of graded management measures is used, the grade applied to each control should be determinable from information provided. To show compliance with the performance requirements of 10 CFR 70.61, the description of the items relied on for safety and the management measures applied to them, must show how they meet all applicable provisions of the Baseline Design Criteria as described in Sections 4 through 7 and Section 11, or a lesser set of measures if justified. The primary justification for lesser management measures is lower risk significance.

One example of a tabular description of IROFS meeting these criteria is Table A-7 in Appendix A.

9. The description of the facility procedures for conducting and maintaining the ISA is acceptable if it includes: management policies, organizational responsibilities, administrative controls, and procedures governing the performance, review, and approval of the initial ISA and any revisions to the ISA. The applicant commits to evaluating the need for updating the ISA to reflect changes using a team with similar qualifications to the team that originally prepared the ISA for the system under review. In addition, the applicant commits to maintain the ISA under an adequate configuration management function. The applicant also identifies updates to the table on controls necessary to ensure safety, as well as seeks prior approval for any changes that raise unreviewed safety questions or increase the level of risk. Administrative controls ensure the independence of reviewing organizations and individual reviewers. The applicant establishes procedures to control records and supporting documentation concerning the ISA.

3.5 REVIEW PROCEDURES

3.5.1 Acceptance Review

The primary reviewer will review the application to determine if it contains the topics and information discussed in Section 3.3, "Areas of Review." If significant deficiencies are identified in the application, the applicant will be requested to submit additional information before the start of the safety evaluation. The primary reviewer will then determine that the applicant has provided the information required. If necessary, a request for additional information to the applicant will be prepared in conjunction with the licensing project manager.

3.5.2 Safety Evaluation

1. The staff reviews the applicant's description of the facility to determine if adequate information is presented to provide an understanding of those factors that could pose a hazard to the facility. The reviewer reviews the types, frequency, and severity of specific external hazards (such as locations of nearby airports, rail lines, port facilities, other nuclear or chemical facilities, dams, rivers, etc.) identified in the application. The reviewer similarly reviews natural external event hazards, such as severe weather conditions, hurricanes, earthquakes, floods, tornadoes, that are specific threats to the site.

2. The staff reviews the applicant's description of the facility to determine that the applicant has adequately discussed the features that could affect potential accidents and their consequences. The reviewer should verify that the applicant has provided information describing the location and arrangement of buildings at the site and their distance from the site boundary and nearby population. The reviewer should also determine that design criteria for the facility are justified on the basis that (1) they are sufficient to withstand the effects of credible external events that could occur at the site or (2) the consequences of such credible external events are acceptable, given their expected frequency of occurrence.

3. The staff reviews the applicant's description of each process analyzed in the ISA to determine that it provides an adequate understanding of process function and theory, as well as major component function and operation. The staff also reviews information

provided on process design, equipment, and instrumentation to determine that it is sufficient to understand the results of the ISA.

4. The staff reviews the applicant's commitment to compile and maintain current and accurate process safety information on hazardous materials, process technology, and process equipment.

5. The staff reviews the applicant's description of the ISA team to determine the adequacy of the makeup of the team and qualifications of the team leader and team members. The reviewer should determine that the qualifications of the team meet the acceptance criteria in Section 3.4.3.5.

6. The staff reviews the applicant's description of the ISA methodology selected to verify that the applicant has cogently described the methodology (i.e., the methods used for hazard identification, hazard analysis and accident identification, accident consequence determination, and accident sequence evaluation) and the bases for its choice. The reviewer also verifies that the acceptance criteria in Section 3.4.3.6 are satisfied.

7. The staff reviews the narrative and tabular summary of the results of the ISA to determine if the information provided is complete and satisfies the acceptance criteria in Section 3.4.3.7 and Appendix A. The information reviewed includes:

   a. a listing of hazardous materials and conditions and a table showing interactions between materials and between materials and conditions that could result in a hazardous situation; and

   b. either:
   (i) A tabular summary listing of each accident sequence that could result in radiological or chemical exposures to workers or the public, or environmental consequences. This tabular summary identifies for each sequence, the events that occur, including initiating event, and failures of safety controls, and the unmitigated consequences resulting. Staff reviews this list following the procedures in Appendix A; or, (ii) a set of logic diagrams that identify the all combinations and sequences of failure events that would cause consequences of concern.

8. The staff reviews the tabular list describing the administrative and engineered safety controls identified in the accident sequences as being relied on for safety. The review determines if the controls satisfy the acceptance criteria provided in Section 3.4.3.8 and its appendix. These criteria specify the redundancy, independence, quality, and reliability of the controls needed to assure that the likelihood and consequences of identified accidents meet the safety performance requirements of 10 CFR 70.61.

   The risk significance of accident sequences will be evaluated by staff using the risk indices from Table A-1 in Appendix A. The procedure for evaluating risk significance is described in the last section of Appendix A. Accident sequences will be placed in categories. Safety controls appearing in those sequences in the category of highest risk significance will each be reviewed in detail. Independent evaluation or site visits will be performed, if warranted. For accident sequences categorized as lower risk significance, staff will select a representative sample (e.g., 5 to 10%) of sequences for specific evaluation, while the remainder receive a less detailed review.

9. The staff reviews the management practices proposed by the applicant to ensure that the ISA is used so as to assure safety, and is kept current and accurate. The reviewer verifies that the applicant practices mandate adequate procedures for ISA performance, update, review responsibility, documentation, and record maintenance.

3.6 EVALUATION FINDINGS

The reviewer verifies that the information submitted by the applicant is sufficiently complete so that compliance with 10 CFR Part 70 can be evaluated. The reviewer also verifies that the applicant's submittal contains sufficient information and that the staff review supports statements and conclusions of the following type, which the staff should include in the SER:

> Many hazards and potential accidents can result in unintended exposure of persons to radiation, radioactive materials, or toxic chemicals associated with licensed materials. The applicant has performed an Integrated Safety Analysis (ISA) to identify and evaluate those hazards and potential accidents, and to establish safety controls to ensure facility operation within the bounds of the ISA. The NRC staff has reviewed those postulated accidents resulting from the facility hazards that may be anticipated to occur (or are considered unlikely or highly unlikely). To ensure that the limits in 10 CFR Part 70 are met, the applicant has adequately established both administrative and engineered safety controls. The staff has reviewed these safety controls and finds them acceptable based on the ISA evaluation and other supporting information.
>
> The staff concludes that (1) the identification and evaluation of the hazards and accidents as part of the ISA and (2) the establishment of controls to maintain safe facility operation from their consequences meet the requirements of 10 CFR Part 70, and provide reasonable assurance that the health and safety of the public will be adequately protected.

3.7 REFERENCES

AIChE, *Guidelines for Hazard Evaluation Procedures*, *Second Edition with Worked Examples*, American Institute of Chemical Engineers, New York, September 1992.

American National Standards Institute, ANSI/ANS-8.1-1983, "Nuclear Criticality Safety in Operations With Fissionable Materials Outside Reactors," American Nuclear Society, La Grange Park, IL, 1983.

American National Standards Institute, ANSI/ANS-51.1-1983, "Nuclear Safety Criteria for the Design of Stationary Pressurized Water Reactor Plants," American Nuclear Society, La Grange Park, IL, 1983.

Code of Federal Regulations , Title 10, Part 70, Domestic Licensing of Special Nuclear Material, U.S. Government Printing Office, Washington, DC.

NUREG-1513, *Integrated Safety Analysis Guidance Document*, 1995.

U.S. Dept. of Commerce, Bureau of the Census, Statistical Abstract of the United States 1995, Table No. 688.

APPENDIX A

EXAMPLE PROCEDURE FOR RISK EVALUATION

NRC requirements in 10 CFR 70.61 require that the occurrence of consequences of concern, defined in 70.61, be sufficiently unlikely. In addition, 10 CFR 70.62(c) requires that the applicant perform an ISA to identify all potential accident sequences and to assess their consequences. These two requirements are related. The consequences of concern result from accident sequences identified in the ISA. Thus, to show that the likelihood of occurrence of the consequences is sufficiently low, it is necessary to show that for each of the accident sequences identified in the ISA, the resulting consequences are sufficiently unlikely.

As defined in 10 CFR 70.61, the required likelihood is graded according to the severity of the consequences of the accident. Accidents in the intermediate consequence category of 70.61(c) must be "unlikely", while those in the high consequence category of 70.61(b) must be "highly unlikely". The procedure described in this appendix is one way by which the applicant may use the ISA results to demonstrate that the requirements of 10 CFR 70.61 have been met. If the licensee evaluates accidents using a different method, the method should produce similar results in terms of how accidents are categorized. This method should be regarded as a screening method, not as a definitive method of proving the adequacy or inadequacy of the controls for any particular accident. The method requires the licensee to identify and evaluate the characteristics of controls used to limit accident sequences in a consistent manner. This will permit identification of accident sequences with defects in the combination of controls used. Such controls can then be further evaluated or improved to establish adequacy. The procedure also ensures the consistent evaluation of similar controls by different ISA teams. Sequences or controls that have risk significance, and are evaluated as marginally acceptable, are good candidates for more detailed evaluation by the applicant and the reviewer.

The tabular accident summary resulting from the ISA should identify, for each sequence, what safety controls must fail for consequences of concern in 10 CFR 70.61 to occur. Section 3.4.3.8 specifies acceptance criteria for these safety controls, such that the performance requirements of 70.61 are met. These criteria require that safety controls be sufficiently unlikely to fail. However, the criteria of 3.4.3.8 do not provide for a method for assessing likelihood. This appendix describes an acceptable procedure for this required assessment of likelihood.

A.1DETERMINING COMPLIANCE WITH GRADED PROTECTION REQUIREMENTS

Section 70.61 of 10 CFR Part 70 describes requirements for a graded system of protection sufficient to bound the risk of identified accidents by making accidents of higher potential consequences have a proportionately lower likelihood of occurrence. The regulation specifies two categories of consequences of concern into which an accident may fall. The first category is referred to in 70.61 as "high consequences", the second as "intermediate consequences". Implicitly there is a third category; namely, those accidents that produce consequences less than "intermediate". These will be referred to as "low consequence" accidents. Since the primary purpose of Process Hazard Analysis is to identify all accidents having consequences of concern, it will, in some cases, be necessary to identify accidents that produce radioactive or chemical exposures, then subsequently determine that some of these exceed the threshold values of the regulation. For this reason, the list of accidents resulting from such analysis will

include such low consequence accidents in order to show that they have been considered. Otherwise, the analysis will not have demonstrated its completeness.

The limits defining the three accident consequence categories are given below. Note that the categories are numbered in ascending order of the magnitude of their consequences. The usefulness of this numbering will be evident later. The symbols AEGL and ERPG refer to chemical exposure levels from accidents sufficient to produce certain effects. AEGL-3 and ERPG-3 levels are life threatening.

Consequence Category 3- High Consequences: An accident resulting in any consequence specified in 70.61(b); that is: an acute worker exposure of 1 Sievert (100 rem)[9] or greater TEDE*, or a chemical exposure that could endanger the life of a worker (above AEGL-3 or ERPG-3); or acute exposure of a member of the public outside the controlled area to a radiation dose of 0.25 Sievert (25 rem) or greater TEDE, a 30 mg soluble uranium intake, or a chemical exposure that could lead to irreversible or other serious long-lasting health effects (exceeding AEGL-2 or ERPG-2).

Consequence Category 2- Intermediate Consequences: An accident resulting in any consequence specified in 70.61(c). That is, acute exposure of a worker to a radiation dose between 0.25 Sievert and 1 Sievert TEDE, or chemical exposure that could lead to irreversible or other serious long-lasting health effects (above AEGL-2 or ERPG-2); or acute exposure of a member of the public outside the controlled area to a radiation dose between 0.05 and 0.25 Sievert TEDE, or a chemical exposure that could cause mild transient health effects (exceeding AEGL-1 or ERPG-1); or prompt release of radiation outside the restricted area that would, if averaged over a 24 hour period, exceed 5000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20.

Consequence Category 1- Low Consequences: Any accident with potential adverse radiological or chemical consequences but at exposures less than Categories 3 and 2 above.

* TEDE is Total Effective Dose Equivalent (see 10 CFR Part 20)

This system of consequence categories is shown in the following table. In the table, D signifies the TEDE from an acute accidental radiation exposure.

[9] A nuclear criticality would normally be considered a high consequence event because of the potential for producing a high radiation dose to a worker.

CONSEQUENCE SEVERITY CATEGORIES BASED ON 10 CFR 70.61

	Workers	Offsite Public	Environment
Consequence Category 3: high	D>1 Sv (100 rem) >AEGL3, ERPG3	D>.25 Sv (25 rem) 30 mg sol U intake >AEGL2, ERPG2	
Consequence Category 2: intermediate	.25 Sv<D# 1 Sv >AEGL2, ERPG2 but <AEGL3, ERPG3	.05 Sv<D# .25 Sv >AEGL1, ERPG1 but <AEGL2, ERPG2	radioactive release >5000 x Table 2 App B 10 CFR 20
Consequence Category 1: low	accidents of lesser radiological and chemical exposures to workers than those above in this column	accidents of lesser radiological and chemical exposures to the public than those above in this column	radioactive releases producing effects less than those specified above in this column

Corresponding to the two consequence categories of the rule (Categories 2 and 3 above), 70.61 requires corresponding levels of graded protection, that is, safety controls and management measures, sufficient to ensure that the likelihood of these adverse events is correspondingly low. The two categories of likelihood thus prescribed are:

Likelihood Category 1: Consequence Category 3 accidents must be “highly unlikely”, and

Likelihood Category 2: Consequence Category 2 accidents must be “unlikely.”

Implicitly there is a third category into which an accident could fall, that is it could fail to be “unlikely.” This category will be referred to in this document as:

Likelihood Category 3: “not unlikely.”

Although this category includes unintended events that might actually be expected to happen, others might be less frequent. For this reason the term “likely” was not used for these events.

A major purpose of the ISA is to show compliance with the above system of graded protection. This can be done by using the required tabular summary of identified accident sequences. One acceptable way of doing so is for the applicant to assign two category numbers to each accident sequence, one based on its consequences and one for likelihood. The product of these two category numbers is then used as a risk index. Listing this calculated risk index in the tabular summary provides a simple method for showing that the graded protection requirements have been met for each accident sequence. A risk index value less than or equal to “4" means the sequence is acceptable. If the applicant provides this risk index in one column of the tabular summary, the reviewer can quickly scan this column to confirm that each accident conforms to the safety performance requirements of 10 CFR 70.61. This system is equivalent to assigning

each accident to a cell in a 3 by 3 matrix. This conceptual matrix is shown below. The values in the matrix cells are the risk index numbers.

RISK MATRIX

	Likelihood Category 1: highly unlikely	Likelihood Category 2: unlikely	Likelihood Category 3: not unlikely
Consequence Cat. 3 High	3 acceptable	6 unacceptable	9 unacceptable
Consequence Cat. 2 Intermediate	2 acceptable	4 acceptable	6 unacceptable
Consequence Cat. 1 Low	1 acceptable	2 acceptable	3 acceptable

To demonstrate compliance with the system described above, the applicant needs to assign consequence categories to each identified accident in order to determine which likelihood requirement applies. Then those accident sequences identified as high or intermediate consequences must be assigned to a likelihood category. To be acceptable, these assigned consequences and likelihoods must have a valid basis, and the applicant must demonstrate this basis in the documentation submitted in the application. The following sections describe an acceptable method for making these assignments.

A.2 CONSEQUENCE CATEGORY ASSIGNMENT

The assignment of consequence categories is based on estimated consequences of prototype accidents. Criteria for the presentation of these estimates by the applicant is described in Section 3.4.3.7. Although consequences of accidents can be determined by actual calculations, it is not necessary that such a calculation be performed for each individual accident sequence listed. Accident consequences may be estimated by comparison to similar events for which reasonably bounding conservative calculations have been made. The applicant should document the bases for bounding calculations of the consequence assignment in the submittal. NUREG/CR-6410, Nuclear Fuel Cycle Facility Accident Analysis Handbook, describes valid methods and data to be used by the applicant and may be used for confirmatory evaluations by the reviewer.

A.3 LIKELIHOOD CATEGORY ASSIGNMENT

An assignment of an accident sequence to a likelihood category is acceptable if it is based on the record of failures at the facility or other methods that have objective validity. Because sequences leading to accidents often involve multiple failures, a combination of failure frequency and probability values determines the likelihood of the whole sequence. These values include the frequencies of initiating events and failure likelihoods of safety controls. An acceptable method is described below by which the applicant can make an estimate of an approximate likelihood category for an accident sequence by considering all the events involved. This method

makes use of the number, type, independence, and observed failure history of safety controls. However a correct evaluation of the appropriate likelihood of accidents using such a qualitative system depends on the informed judgement of the analyst. Safety controls, even those of the same types, have a wide range of reliability. The ultimate criterion for acceptability, is that the frequencies of initiating events and the likelihood of failure of safety controls involved is sufficiently low so that the entire accident sequence is "highly unlikely" or "unlikely" as required by 10 CFR 70.61. The virtue of the structure is that it requires explicit consideration of some of the underlying events and factors that affect the likelihood of the accident. Another virtue is that, the more explicit the criteria for assignment are, the more consistent are the results.

Underlying any evaluation of an accident sequence as "unlikely" or "highly unlikely" is an implied assessment of its "likelihood" or frequency of occurrence. The structured procedure described below will indicate which likelihood category may be appropriate for an event. In order to maintain internal consistency in evaluating different control systems and accidents, it was necessary to derive this structured procedure based on the underlying frequencies of events. The following numerical guidelines were thus used to obtain consistency:

Likelihood Category 1: highly unlikely, a frequency of less than 10^{-5} per accident per year

Likelihood Category 2: unlikely, a frequency of less than 10^{-2} per accident per year (but more frequent than 10^{-5})

Likelihood Category 3: not unlikely, more frequent than 10^{-2} per accident per year

In assessing the adequacy of safety controls, individual accidents frequencies greater than 10^{-5} per year may not be "highly unlikely". The NRC has a strategic safety performance measure of no inadvertent nuclear criticalities. For this reason, the acceptability of any given frequency depends on the total number of accidents that may be identified. Since the total number and consequences of all potential accidents at a facility is not accurately known until its ISA is completed, it is difficult to establish a definitive acceptable frequency. Individual accidents may need to be limited to lower values in order to achieve an overall acceptable risk. On the other hand, the fact that a particular accident sequence is below this value does not automatically mean that it is clearly acceptable. The frequency value is to be used as a guideline in developing more consistent and objective standards for safety control features. The value of 10^{-5} per year per accident is such that a plant with 100 potential Consequence Category 3 accidents would have a frequency of: 100 accidents times 10^{-5} per year per accident = 10^{-3} per year. These Category 3 accidents generally result in fatalities. The average statistic for all manufacturing industries is that a plant with 250 manufacturing workers would expect 10^{-2} on-the-job deaths per year (see References, Statistical Abstract of the U.S.).

Similarly, accident sequences having frequencies more than 10^{-2} per year per accident are not considered "unlikely." Again this value should not be taken as a definitive criterion for acceptability. It is a guideline value to assure consistency. It may need to be adjusted based on the numbers and severity of accidents. The rationale for the value 10^{-2} is that accidents of the corresponding severity, Consequence Category 2, are not common and should remain so. To achieve this, the product of this frequency per accident per year with the assessed number of potential accidents should provide adequate confidence that such accidents will not occur. Note again that these values of 10^{-5} and 10^{-2} are per accident per year.

The accident evaluation method described below does not preclude the need to comply with the double contingency principle for sequences leading to criticality. Although exceptions are permitted with compensatory measures, double contingency, should, in general, be applied. The reason double contingency is needed is the fact that there is usually insufficient firm data as to the reliability of the control equipment and administrative control procedures used in criticality safety. If only one item were relied on to prevent a criticality, and it proved to be less reliable than expected, then the first time it failed a criticality accident would result. For this reason, it is prudent to require two independent controls. Inadequate controls can then be determined by observing their failure, without also suffering the consequence of a criticality. Even with double contingency it is essential that each item relied on for safety be itself sufficiently unlikely to fail. This is so that, if one of the two items that establish double contingency is actually ineffective, criticality will still be unlikely.

A.4RISK INDEX EVALUATION SUMMARY

As previously mentioned, an acceptable way for the applicant to present the results of the ISA is a tabular summary of the identified accident sequences. Table A-1 is an acceptable format for such a table. This table lists several example accident sequences for a powder blender at a typical facility. Table A-1 summarizes two sets of information: (1) the accident sequences identified in the ISA, and (2) a risk index calculated for each sequence to show compliance with the regulation. A summary of the risk index calculation will be given below.

Accident sequences result from initiating events, followed by failure of one or more controls. Thus there are columns in Table A-1 for the initiating event and for controls. Controls may be mitigative or preventive. Mitigative controls are measures that reduce the consequences of an accident. The phrase “unmitigated consequences” describes the results when the system of preventive controls fails and mitigation also fails. Mitigated consequences result when the preventive controls fail, but mitigative measures succeed. These are abbreviated in the table as “unmit.” and “mitig.”, respectively. Index numbers are assigned to initiating events, control failure events, and mitigation failure events, based on the reliability characteristics of these items.

With redundant safety controls and in certain other cases, there are sequences where an initiating event occurs that places the system in a vulnerable state. While the system is in this vulnerable state, a safety control must fail in order for the accident to result. Thus the frequency of the accident depends on the frequency of the first event, the duration of vulnerability, and the frequency of the (second) control failure. For this reason, it is necessary to consider the duration of the vulnerable state, and to assign it a duration index. The values of all index numbers for a sequence, depending on the number of events involved, are added to obtain a total likelihood index, T. Sequences are then assigned to one of the three likelihood categories of the Risk Matrix depending on the value of this index in accordance with Table A-2.

The values of index numbers in sequences are assigned considering the criteria in Tables A-3 through A-5. Each table applies to a different type of event. Table A-3 applies to events which have frequencies of occurrence, such as initiating events and certain control failures. When failure probabilities are required for the event, Table A-4 provides the index values. Table A-5 provides index numbers for durations of failure. These are used in certain accident sequences where two controls must simultaneously be in a failed state. In this case, one of the two controlled parameters will fail first. It is then necessary to consider the duration that the system remains susceptible to failure of the second. The reverse sequence, where the second control fails first, should also be considered as a separate accident sequence. This is necessary

because the duration of failure of the second control will usually differ from that of the first. The values of these duration indices are not merely judgmental. They are directly related to the time interval of surveillance monitoring for failures. That is, the duration of a failure is the time until it is detected plus the time to restore the system to a state where it is not vulnerable to the second failure.

For all these index numbers, the more negative the number is, the less likely is the failure. Accident sequences may consist of varying numbers of events, starting with an initiating event. The total likelihood index is the sum of the indices for all the events in the sequence, including those for duration.

Consequences are assigned to one of the three consequence categories of the Risk Matrix based on calculations or estimates of the actual consequences of the accident sequence. The consequences of concern are those of 10 CFR 70.61. Multiple types of consequences can result from the same event. The consequence category is chosen for the most severe consequence.

As shown in the first row of Table A-1, the failure duration index can make a large contribution to the total likelihood index. Therefore, the reviewer should verify that there is adequate justification that the failure will be corrected in the time ascribed to the duration index. In general, duration indices with values less than minus one (-1), corresponding to 36 days, to be acceptable, should be based on the existence of intentional monitoring of the process. The duration of failure for an unmonitored process should be conservatively estimated.

Table A-1 provides two risk indices for each sequence in order to permit evaluation of the risk significance of the controls involved. To measure whether a control has high risk significance, the Table provides an “uncontrolled risk index”, determined by modeling the sequence with all controls as failed (i.e., not contributing to a lower likelihood). In addition, a “controlled risk index” is also calculated, taking credit for the low likelihood and duration of control failures. When an accident sequence has an uncontrolled risk index exceeding 4, but a controlled index of less than 4, then the safety controls involved have a high risk significance in that they are relied on to achieve acceptable safety performance. Thus use of these indices permits evaluation of the possible benefit of improving controls, and also where a relaxation may be acceptable.

Table A-6 provides a more detailed description of the accident sequences used in the example of Table A-1. The reviewer needs the information in Table A-6 to understand the nature of the accident sequences listed in Table A-1. Table A-1 lacks sufficient room to explain any but the simplest failure events.

Table A-7 is used to explain the safety controls and external initiating events that appear in the accident sequences in Table A-1. The reviewer needs the information in Table A-7 to understand why the initiating events and safety controls listed in Table A-1 have the low likelihood indices assigned. Thus Table A-7 needs to address such information as: the margins to safety limits, the redundancy of a control, the measures taken to assure adequate reliability of a control. Table A-7 must also justify why those external events, which are not obviously extremely unlikely, have the low likelihoods which are being relied on for safety. The applicant should provide separate tables to list the controls for criticality, chemical, fire, radiological, and environmental accidents.

Definitions and explanations of the terms used in the following tables will follow the last table.

TABLE A-1: EXAMPLE ACCIDENT SEQUENCE SUMMARY AND RISK INDEX ASSIGNMENT

Process: UO2 Powder Preparation (PP) Unit Process: Additive Blending Node: Blender Hopper Node (PPB2)

Accident Sequence	Initiating Event (a)	Preventive Control 1 (b)	Preventive Control 2 (c)	Mitigation Control (d)	Likelihood* Index T (e) uncontrolled controlled	Likelihood Category (f)	Conse quence Evaluation Reference	Conse-quence Category (g)	Risk Indices (h=f x g) uncontrolled controlled	Comments & Recommendations
PPB2-1A (Criticality from blender leak of UO_2)	see Control 1 (note 1)	PPB2-C1: Mass Control Failure: Blender leaks UO_2 onto floor, critical mass exceeded frq1 = -1 dur1 = -4	PPB2-C2: Moderation Failure: Suffic. water for criticality introduced while UO_2 on floor frq2 = -2	N/A	unc T = -1 con T = -7	unc 3 con 1	rad 35	3 (crit: 3, rad: 0)	9 3	criticality, consequences = 3 Control 2 fails while Control 1 is in failed state. T = -1-4-2 = -7
PPB2-1B (Rad. release from blender leak of UO_2)	blender leaks UO2 frqi = -1	PPB2-C1: Mass Control success: leaked UO_2 below critical mass, OR	PPB2-C2: Moderation success: no moderator	Ventilation Failure: Ventilated blender enclosure frqm = -2	unc T = -1 con T = -3 con T = -1	unc 3 unmit. 2 mitig. 3	rad 36	unc 2 unmit. 2 mitig. 1	6 unmit. 4 mitig. 3	rad consequences, no criticality unmitigated sequence: control 1 & mitigation fail. T= -1-2 = -3 mitig.: Control 1 fails, mitig. control does not fail. T = -1
PPB2-1C	see Control 1 (note 1)	PPB2-C2: Moderation Failure: Suffic. water for criticality on floor under UO_2 blender frq1 = -2 dur1 = -3	PPB2-C1: Mass Control Failure: Blender leaks UO_2 on floor while water present frq2 = -1	N/A	unc T = -2 con T = -6	unc 2 con 1	rad 35	3 (crit: 3, rad: 0)	6 3	criticality by reverse sequence of PPB2-1A, moderation fails first. Note different likelihood T = -6
PPB2-2	Fire in Blender Room frqi = -2	Fire Suppression Failure: Fails on demand: prf1 = -1	N/A	N/A	unc T = -2 con T = -3	unc 2 con 2	rad 37	2 (rad) 1	4 2	Event sequence is just initiating event plus one control failure on demand

*Likelihood index T is a sum. uncontrolled: T=frqi or frq1; controlled: includes all indices T=a+b+c+d

Note 1: For these sequences the initiating event is failure of one of the controls, hence the frequency is assigned under that control.

TABLE A-2: DETERMINATION OF LIKELIHOOD CATEGORY

LIKELIHOOD CATEGORY	LIKELIHOOD INDEX T (= sum of index numbers)
1	T # -5
2	-5 < T # -2
3	-2 < T

TABLE A-3: FAILURE FREQUENCY INDEX NUMBERS

FREQUENCY INDEX NUMBER	BASED ON EVIDENCE	BASED ON TYPE OF CONTROL**	COMMENTS
-6 *	external event with freq. < 10^{-6} /yr		If initiating event, no controls needed
-4 *	no failures in 30 yrs for hundreds of similar controls in industry	exceptionally robust passive engineered control (PEC), or an inherently safe process, or 2 independent AEC, PEC, or enhanced admin. controls	rarely can be justified by evidence, since few systems are found in such large numbers. Further, most types of single control have been observed to fail.
-3 *	no failures in 30 years for tens of similar controls in industry	a single control with redundant parts, each a PEC or AEC	
-2 *	no failure of this type in this plant in 30 years	a single PEC	
-1	a few failures may occur during plant lifetime	a single AEC, an enhanced administrative control, an admin. control with large margin, or a redundant admin. control	
0	failures occur every 1 - 3 years	a single administrative control	
1	several occurrences per year	a frequent event	not for safety controls, just initiating events
2	occurs every week or more often	frequent event, an inadequate control	not for safety controls, just initiating events

* Indices less than (more negative than) “-1" should not be assigned to controls unless the configuration management, auditing, and other management measures are of high quality, because, without these measures, the controls may be changed or not maintained.
** The index value assigned to a control of a given type in column 3 may be one value higher or lower than the value given in column 1. Criteria justifying assignment of the lower (more negative) value should be given in the narrative describing ISA methods. Exceptions require individual justification.

TABLE A-4: FAILURE PROBABILITY INDEX NUMBERS

PROBABILITY INDEX NUMBER	PROBABILITY OF FAILURE ON DEMAND	BASED ON TYPE OF CONTROL	COMMENTS
-6 *	10^{-6}		If initiating event, no controls needed
-4 or -5*	10^{-4} - 10^{-5}	exceptionally robust passive engineered control (PEC), or an inherently safe process, or 2 redundant controls better than simple admin controls (AEC, PEC, or enhanced admin)	rarely can be justified by evidence, since few systems are found in such large numbers . Further, most types of single control have been observed to fail.
-3 or -4*	10^{-3} - 10^{-4}	a single passive engineered ctrl. (PEC) or an active engineered control (AEC) with high availability	
-2 or -3 *	10^{-2} - 10^{-3}	a single active engineered control, or an enhanced admin control, or an admin control for routine planned operations	
-1 or -2	10^{-1} - 10^{-2}	an admin control that must be performed in response to a rare unplanned demand	

* Indices less than (more negative than) “-1" should not be assigned to controls unless the configuration management, auditing, and other management measures are of high quality, because, without these measures, the controls may be changed or not maintained.

TABLE A-5: FAILURE DURATION INDEX NUMBERS

DURATION INDEX NUMBER	AVG. FAILURE DURATION	DURATION IN YEARS	COMMENTS
1	more than 3 years	10	
0	one year	1	
-1	one month	0.1	Formal monitoring to justify indices less than “-1"
-2	a few days	0.01	
-3	8 hours	0.001	
-4	1 hour	10^{-4}	
-5	5 minutes	10^{-5}	

TABLE A-6: ACCIDENT SEQUENCE DESCRIPTIONS

Process: UO2 Powder Preparation (PP) Unit Process: Additive Blending
Node: Blender Hopper Node (PPB2)

Accident Sequence (see Table A-1)	DESCRIPTION
PPB2-1A Blender UO_2 leak criticality	The initial failure is a blender leak of UO_2 that results in a mass sufficient for criticality on the floor. (This event is not a small leak.) Before UO_2 can be removed, moderator sufficient to cause criticality is introduced. Duration of critical mass UO_2 on floor estimated to be one hour.
PPB2-1B Blender UO_2 leak, rad. release	The initial failure is a blender leak of UO_2 that results in a mass insufficient for criticality on the floor, or mass sufficient for criticality but moderation failure does not occur. Consequences are radiological, not a criticality. A ventilated enclosure should mitigate the radiological release of UO_2. If it fails during cleanup or is not working, unmitigated consequences occur.
PPB2-1C	The events of PPB2-1A occur in reverse sequence. The initial failure is introduction of water onto the floor under the blender. Duration of this flooded condition is 8 hours. During this time, blender leaks a critical mass of UO_2 onto the floor. Criticality occurs.
PPB2-2	Initiating event is a fire in the blender room. Fire is not extinguished in time. Release of UO_2 from process equipment occurs. Offsite dose estimated to exceed 100 mrem.

TABLE A-7: CRITICALITY SAFETY LIMITS AND CONTROLS

Process: UO2 Powder Preparation (PP) Unit Process: Additive Blending
Node: Blender Hopper Node (PPB2)

Safety Control Identifier	Safety Parameter and Limits	Safety Controls Description	max value of other parameters	Reliability Management measures	QA Grade
PPB2-C1	Mass Outside Hopper: zero	Mass Outside Hopper: Hopper and outlet design prevent UO_2 leaks, double gasket at outlet.	Full Water Reflection, Enrichment 5%	surveillance for leaked UO2 each shift	A
PPB2-C2	Moderation: in UO_2 < 1.5 wt. % External Water in area: zero	Moderation In UO_2 : Two sample measurements by two persons before transfer to hopper. External Water: Posting excluding water, double piping in room, floor drains, roof integrity	Full Water Reflection, Enrichment 5%	drain, roof, and piping are under safety grade maintenance	A

Note: In addition to engineered controls, this table should include descriptions of external initiating events whose low likelihood is relied on to achieve acceptable risk, especially those which are assigned frequency indices lower than -4. The descriptions of these initiating events should contain information supporting the frequency index value selected by the applicant.

ACCIDENT SUMMARY AND RISK INDEX ASSIGNMENT FOR TABLE A-1

The definitions for the contents of each column in the accident summary tabulation, Table A-1, are provided below.

Accident Sequence

This column is provided to list the accident sequences identified by the applicant in the ISA. It is important to the proper documentation of the ISA that the applicant subdivides the plant into a set of uniquely identified units, referred to here as "nodes". The applicant should give symbols, names, or numbers to these nodes that permit them to be uniquely identified. For example, the "Blender Hopper" node described In Table A-1 has the unique identifying symbol PPB2. Additional identifier characters have been added to form the identifier, PPB2-1, to identify the first accident sequence identified in that node. Because the applicant should list all the plant safety controls of significance used elsewhere in the ISA, tabulations of the unique node (and accident) identifier can be used to find the accidents that these safety controls have been shown to prevent. By reviewing this table, the reviewer can then evaluate (1) the adequacy of the controls for preventing accidents and (2) the bases for making the consequence and likelihood assignments in the table.

Initiating Event or Control Failure

This column is provided to list initiating events or control failures, typically identified in the Process Hazard Analysis phase of the ISA, that may lead to consequences of concern. Initiating events are of several distinct types: (1) external events, such as hurricanes and earthquakes, (2) plant events external to the node being analyzed (e.g., fires, explosions, failures of other equipment, flooding from plant water sources), (3) deviations from normal of the process in the node (i.e., credible abnormal events), and (4) failures of safety controls of the node. The tabulated initiating events should only consist of those that involve an actual or threatened failure of safety controls, or that cause a demand requiring controls to function in order to prevent consequences of concern. The frequency index number for initiating events is referred to in the table using the symbol "frqi". Table A-3 provides criteria for assigning a value to frqi. Usually, insufficient room is present in a tabular presentation like Table A-1 to describe accurately the events indicated. Consequently, the applicant should provide supplementary narrative information to adequately describe each accident sequence of Table A-1. Cross referencing between this information and the table should be adequate, for instance, the unique symbolic accident sequence identifiers can be used. Table A-6 is an example of a list of supplementary accident sequence descriptions corresponding to Table A-1.

Preventive Control 1

This column is provided to list a control designed to prevent consequences of concern. If separate controls are used to prevent different consequences, separate rows in the table should be defined corresponding to each type of consequence. Table A-1 contains an example of a set of related sequences so separated. Sequences where two controls must simultaneously be in a failed state require assignment of three index numbers: the failure frequency of the first control, frq1, the duration of this failure, dur1, and the failure frequency of the second control, frq2. For such sequences, the initiating event is failure of the first control. In these cases, frq1 is assigned using Table A-3. The failure duration of the first control is assigned using Table A-5. Other sequences may be more easily described as a failure of the safety controls on demand after the occurrence of an initiating event. In these cases, the failure probability index number, prf1, is assigned using Table A-4. The symbol "b" is used in the column heading for the indices associated with this control.

Preventive Control 2
This column is provided in case a second preventive control exists. The failure frequency or failure probability on demand is assigned as for Preventive Control 1. The symbol “c” is used in the column heading for the indices associated with this control.

Mitigation Control
This column is provided in case controls are available to mitigate the accident. That is, they reduce, but do not eliminate, the consequences of a sequence. A control that eliminates all adverse consequences should be considered preventive. The symbol “d” is used in the column heading for the indices associated with this control.

Likelihood Category
This column is provided to list the likelihood category number for the risk matrix, which is based on the total likelihood index for a sequence. The total likelihood index, T, is the sum of the indices for those events that comprise a sequence. These events normally consist of the initiating event, and failure of one or more controls, including any failure duration indices. However, accident sequences may consist of varying numbers and types of undesired events. Methods for deciding what frequencies and failure durations need to be considered will be described later in this appendix. Based on the sum of these indices, the likelihood category number for the risk matrix is assigned using Table A-2. The symbol “e” is used for this category number in the column heading.

Consequence Evaluation Reference
This column permits identification of the consequence calculations that relate to this accident sequence. Multiple references may be required to refer to calculations of the different types of consequences, radiological, various chemicals, etc..

Consequence Category
This column is provided to assign the consequence category numbers based on estimating the consequences of all types (i.e., radiological, criticality, chemical, and environmental) that may occur. Based on this estimate, accidents can be assigned to the categories defined in 10 CFR 70.61. The symbol “f” is used for this category number in the column heading. Sequences having controls to mitigate consequences must be divided into two cases, one where the mitigation succeeds, and one where it fails, each with different consequences. The two cases may be tabulated in one row of Table A-1, but the mitigated and unmitigated consequences should be separately indicated. Unless the mitigated case results in consequences below those of concern in 10 CFR 70.61, both cases must satisfy the likelihood requirements as shown by the risk matrix.

Risk Index
This column is provided to list the risk index, which is calculated as the product of the likelihood category and consequence category numbers. This is shown in the column heading by the formula “g = e x f”. Sequences with values of “g” less than or equal to “4" are acceptable. Another risk index can also be calculated as the product of the consequence category number times the likelihood category associated with only the failure frequency index for the initiating event. The resulting product can be referred to as the “unmitigated” risk index. It is unmitigated in the sense that no credit is taken for the functioning of any subsequent controls. For example, in the first three cases in Table A-1, the initiating event is failure of Preventive Control 1. In these cases, the failure frequency of Preventive Control 1 is used to determine the likelihood category when calculating the unmitigated risk index.

Comments and Recommendations

This column is needed to record ISA team recommendations, especially when the existing system of controls is evaluated as being deficient. This may happen because a newly identified accident sequence is not addressed by existing controls, or because a deficiency has been found in the existing controls.

DETERMINATION OF LIKELIHOOD CATEGORY IN TABLE A-2

The likelihood category is determined by calculating the likelihood index, T, then using this table. The term T is calculated as the sum of the indices for the events in the accident sequence.

DETERMINATION OF FAILURE FREQUENCY INDEX NUMBERS IN TABLE A-3

Table A-3 is used to assign frequency index numbers to plant initiating events and control system failures as found in the columns of Table A-1. The term failure must be understood to mean not merely failure of the control device or procedure, but also as violation of the safety limit by the process. In the example in Table A-1, accident sequence PPB2-1A involves loss of mass control over UO_2 in a blender. If criticality is the concern, failure does not occur unless UO_2 accumulates to a critical mass before the leak is stopped. For radiological consequences, any amount leaked may cause exposure. In assessing the frequency index, this factor should be considered because many control failures do not cause safety limits to be exceeded.

Table A-3 provides two columns with two sets of criteria for assigning an index value, one based on type of control, the other directly on observed failure frequencies. The types of controls are administrative, active engineered, passive engineered, etc. Since controls of a given type have a wide range of failure frequencies, assignment of index values based on this table should be done with caution. Due consideration should be given as to whether the control will actually achieve the corresponding failure frequency in the next column. Based on operational experience, more refined criteria for judging failure frequencies may be developed by an individual applicant. In the column labeled “Based on Type of Control”, references to redundancy allow for controls that may themselves have internal redundancy to achieve a necessary level of reliability.

Another objective basis for assignment of an index value is actual observations of failure events. These actual events may have occurred in the applicant plant or in a comparable process elsewhere. Justification for specific assignments may be noted in the Comments column of Table A-1.

As previously noted, the definition of failure of a safety control to be used in assigning indices is, for non-redundant controls, a failure severe enough to cause an accident with consequences. For redundant controls, it is a failure such that, if no credit is taken for functionality of the other control, an accident with consequences would result. If most control malfunctions would qualify as such failures, then the index assignments of this table are appropriate. If true failure is substantially less frequent, then credit should be taken and adequate justification provided.

Note that indices less than (more negative than) “-1" should not be assigned to controls unless the configuration management, auditing, and other required management measures are of high quality, because, without these measures, the controls may be changed or inadequately maintained. The reviewer should be able to determine this from a tabular summary of safety controls provided in the application. This summary should include identification of the process

parameters to be controlled and their safety limits, and a thorough description of the control and its applied management measures.

DETERMINATION OF FAILURE PROBABILITY INDEX NUMBERS IN TABLE A-4

Occasionally, information concerning the reliability of a safety control may be available as a probability on demand. That is, a history may exist of tests or incidents where the system in question is demanded to function. To quantify such accident sequences it is necessary then to know the demand frequency, the initiating event, and the demand failure probability of the safety control. This table provides an assignment of index numbers for such controls in a way that is consistent with Table A-3. The probability of failure on demand may be the likelihood that it is in a failed state when demanded (availability), or that it fails to remain functional for a sufficient time to complete its mission.

DETERMINING MANAGEMENT MEASURES FOR SAFETY CONTROLS

Table A-7 is an acceptable way of listing those items relied on for safety in all the accident sequences leading to consequences of concern. The items listed should include all safety controls and all external events whose low likelihood is relied upon to meet the performance requirements of 10 CFR 70.61. Staff reviews this list to determine whether measures have been applied to each safety control adequate to assure their continual availability and reliability in conformance to 10 CFR 70.62(d). The types of management measures include maintenance, training, configuration management, audits and assessments, quality assurance, etc. These management measures are indicated in the Baseline Design Criteria and described in greater detail in Chapters 4 through 7 and Chapter 11. Safety controls meeting all the provisions of these chapters have acceptable management measures, that is, they comply with 70.62(d). Safety controls may, with justification, have lesser management measures than those described. However, every item relied on for safety in accident sequences leading to consequence categories 2 or 3 should be assigned at least a minimal set of management measures. Specifically, in order to defend against common mode failure of all controls on a process, this minimal set of measures must include an adequate degree of: a) configuration management, b) regular auditing for the continued effectiveness of the control, c) adequate labeling, training, or written procedures to assure the awareness of the operating staff of the safety function performed, d) surveillance and corrective maintenance, and e) preventive maintenance, if applicable.

If lesser or graded management measures are applied to some controls, Tables A-1 and A-7 and the narratives preceding them, in order to be acceptable, must identify to which controls these lesser measures are applied. In addition, information indicating that acceptable reliability can be achieved with these lesser measures must be presented. It is not necessary that the specifics of these measures, such as the surveillance interval, type of maintenance, or type of testing, be described as applied to each control. It is recognized that such specific measures must be applied differently to each control to whatever degree is necessary to achieve adequate reliability. It is the formality, documentation, and QA requirements applied to these direct management measures that may be graded generically in a risk-informed manner.

The following describes the application of management measures to items relied on for safety based on the risk importance of the item in an accident sequence, as defined by (1) the “uncontrolled” risk index shown in Appendix A to this Chapter, and (2) the failure likelihood index, “T”, also described in Appendix A. In summary, items relied on to prevent or mitigate accidents

with unmitigated consequences in the two highest categories identified in 70.61 should satisfy the Baseline Design Requirements of 70.64 that apply.

1. For those sequences that are reduced in risk from initially high risk (an "uncontrolled" risk index of 6 or 9) to an acceptable risk ("controlled" risk index of less than or equal to 4):

Items relied on for safety must have satisfied all applicable Baseline Design Requirements of Section 70.64.

2. For those sequences that are initially evaluated as being in an acceptable risk category (an "uncontrolled" risk index of less than or equal to 4):

2A. If the initiating event is not a control failure, then assurances for items relied on for safety are not necessary. No additional risk reduction is required. However, for sequences claimed to be highly unlikely, the assessment that the initiating event has such a low frequency must be adequately justified in the application. Further, for accident sequences resulting in nuclear criticality, double contingency should still be achieved, thus requiring at least one more item relied on for safety, typically a control, in addition to the initiating event. This control must have satisfied all applicable Baseline Design Requirements of Section 70.64

2B. If the initiating event is a control failure, and if the likelihood of that failure is taken to be at least a few times per plant lifetime (T is greater than -2), then assurances for that item relied on may be less than Baseline Design Requirements of 70.64, as defined by the applicant and approved by the NRC. Any subsequent items in the accident sequence will be unregulated.

[Rationale: Since T is greater than -2, the likelihood category is 3. Therefore the consequence category is no greater than 1, to limit the uncontrolled risk index to at most 4. Since the consequence category is low, the assurance level can be reduced]

2C. If the initiating event is a control failure, and if the likelihood of that failure is taken to be less than a few times per plant lifetime (T is less than or equal to -2), then assurance for this control must satisfy the full Baseline Design Requirements. No regulation of subsequent controls in the sequence is necessary.

[Rationale: Since T is less than or equal to -2, the likelihood category must be 1 or 2. Therefore, the consequence category must be no greater than 2, in order to limit the uncontrolled risk index to at most 4. In this case, the uncertainty in determining a low failure likelihood requires compensatory measures in the form of increased assurances (high level criteria) that the control is indeed kept at a low failure likelihood]

RISK-INFORMED REVIEW OF SAFETY CONTROLS

Staff reviews the safety controls and external events listed in Table A-7 in a risk-informed manner as described in Section 3.5.8. The procedure for identifying systems of safety controls having higher risk significance is described in this section. These controls will be subject to a more detailed review by staff to assure their adequacy.

The final results column of Table A-1 gives the risk indices for each accident sequence that was identified in the ISA. There are two indices, uncontrolled and controlled. The controlled index is a measure of risk without credit for the safety controls. If the uncontrolled risk index is a 6 or 9, while the controlled index is an acceptable value (less than 5), the set of safety controls involved are significant in achieving acceptable risk. That is, these controls have high risk significance. The uncontrolled risk index will be used by staff to identify all risk significant sets of controls. These sets of controls will be reviewed with greater scrutiny than controls established to prevent or mitigate accident sequences of low risk.

U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

4.0 RADIATION SAFETY

4.1 PURPOSE OF REVIEW

The purpose of this review is to determine whether the applicant's radiation protection program is adequate to protect the radiological health and safety of workers and to comply with the regulatory requirements in 10 CFR Parts 19, 20, and 70. The content and level of detail in this chapter is more detailed because this chapter provides acceptance criteria for evaluating compliance with 10 CFR Part 20, which has very specific requirements. Review procedures and acceptance criteria for the applicant's program for protecting members of the public and the control of effluent releases is not included in this chapter, but is in Chapter 9, "Environmental Protection," of this SRP.

4.2 RESPONSIBILITY FOR REVIEW

Primary: Health Physicist

Secondary: Licensing Project Manager, Environmental Reviewer, and ISA Reviewer.

Supporting: Fuel Cycle Facility Inspector

4.3 AREAS OF REVIEW

A radiation protection program is required to be established and implemented per 10 CFR 20.1101. The areas of the radiation protection program that the staff will review include: As Low As Reasonably Achievable (ALARA), organizational relationships and personnel qualifications, radiation safety procedures and radiation work permits (RWPs), training, ventilation systems, air sampling, contamination control, external exposure, internal exposure, summing internal and external exposures, respiratory protection, and instrumentation. In addition to reviewing the radiation protection program, the staff will also review the radiation safety consequences to workers and associated items relied on for safety that are identified in the applicant's ISA summary and other ISA documentation as needed.

1. ALARA

   The staff will review the applicant's policy and procedures that are used to ensure that occupational radiological exposures are maintained ALARA including: (a) the organization structure and how units interact to maintain ALARA; (b) internal and external audits; (c) integration with the ISA; and (d) trend analysis to examine the historical patterns of exposures, concentrations of airborne radioactivity, contamination levels, instrumentation performance, respiratory protection equipment performance, and filter performance.

2. Organizational Relationships and Personnel Qualifications

The staff will review the applicant's organization of the radiological protection program, the qualification requirements for the radiological protection personnel, and the assignment of specific responsibilities and authorities for key functions.

rmits (RWPs)3.

The staff will review the applicant's commitments regarding the need for, the development and control of, and the use of approved written radiation safety procedures and RWPs for activities related to radiological safety.

Trainin4g

The staff will review the applicant's radiological safety training for all personnel who have authorized access to a restricted area. The review will include training objectives, management oversight, methodology of training, who receives the training, a description and the frequency of the training and refresher training, and the effectiveness of the training. Further aspects of training are covered in Section 11.3 of this SRP.

5. Ventilation Systems

The staff will review the applicant's requirements of and operation of the ventilation systems including the minimum flow velocity at hood openings, the types of filters and the maximum differential pressure across filters, and the frequency and types of tests required to measure ventilation system performance.

6. Air Sampling

The staff will review the applicant's radiological air sampling objectives and procedures, including: (a) the frequency and methods of analysis of airborne concentrations, (b) sampling methods and frequency, (c) counting techniques,
(d) lower limits of detection for specific radionuclides, (e) action levels and actions to be taken when the levels are exceeded, and (f) location of continuous air monitors (CAMs), if used, and annunciators and alarms associated with CAMs.

7. Contamination Control

The staff will review the applicant's control of radiological contamination within the facility including the types and frequencies of surveys, limits for contamination levels, the methods and choice of instruments used in the surveys, and the action levels and actions to be taken when the actions levels are exceeded. In addition, the staff will review the design features of the facility that control access including: (a) the types and availability of contamination monitoring equipment; (b) specific limits established for personnel contamination; (c) minimum provisions for personnel decontamination; (d) minimum types of protective clothing necessary for individuals to enter restricted areas; (e) technical criteria and levels for defining contamination areas; (f) release criteria for radiological contaminated material, and (g) frequency of periodic reviews of all aspects of access control.

8. External Exposure

The staff will review the applicant's program for monitoring personnel external radiation exposure including the means to measure, assess, and record personnel exposure to radiation. In addition, the staff will review the type, range, sensitivity, accuracy, and frequency for analyzing personnel dosimeters and the action levels and actions to be taken when the actions levels are exceeded.

9. Internal Exposure

The staff will review the applicant's program for monitoring personnel internal radiation exposure, including: (a) the criteria for determining when it is necessary to monitor an individual's internal exposure; (b) methods for determining the worker intake; (c) frequency of analysis; (d) minimum detection levels; and (e) action levels and actions to be taken based on the results.

10. Summing Internal and External Exposure

The staff will review the applicant's program for summing internal and external exposure in order to demonstrate compliance with the dose limits, including the procedure used for assessing worker's exposures in accordance with NRC regulatory requirements.

11. Respiratory Protection

The staff will review the applicant's respiratory protection program, including the equipment to be used, the conditions under which respiratory protection will be required for routine and nonroutine operations, the protection factors that will be applied when respirators are being used, and the locations of respiratory equipment within the plant.

12. Instrumentation

The staff will review the applicant's requirements for radiological measurement instrumentation, including the policy for the maintenance and use of operating

instrumentation and the types of instruments that are available, including their ranges, counting mode, sensitivity, alarm setpoints, planned use, and frequency of calibration.

13. Integrated Safety Analysis (ISA)

In addition to the radiation protection program elements discussed above, the primary reviewer will review a sample of the postulated, higher-risk accidents in the ISA summary and other ISA documentation as needed which have radiation safety consequences for the workers (See Section 3.0, "Integrated Safety Analysis."). At a minimum, the review of the ISA summary and other ISA documentation as needed will include a review of a sample of the higher risk accident sequences that result in worker radiation exposures of concern before any controls are applied. The methodology in assessing the accident consequences, likelihood, and risk index associated with each of these accident sequences will be reviewed. Items relied on for safety established by the applicant to prevent or mitigate each accident sequence, and the levels of assurance applied to the items relied on for safety will be reviewed.

4.4 ACCEPTANCE CRITERIA

The applicant's radiation protection program is acceptable if the applicant provides data and information that meet the acceptance criteria for each element in this section.

4.4.1 ALARA (As Low As Is Reasonably Achievable)

4.4.1.1 Regulatory Requirements

Regulations applicable to the ALARA program are the following from Title 10, CFR:

1.	Section 19.12	"Instructions to workers"
2.	Section 20.1101	"Radiation protection programs"
3.	Section 20.2102	"Records of radiation protection programs"
4.	Section 20.2110	"Form of records"
5.	Section 20.2105	"Records of Planned Special Exposures"

4.4.1.2 Regulatory Guidance

NRC regulatory guides applicable to the ALARA program that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.1.1 are:

1. Regulatory Guide 8.2 February 2, 1973	*Guide for Administrative Practice in Radiation Monitoring*
2. Regulatory Guide 8.10,	*Operating Philosophy for Maintaining Occupational*

Rev. 1-R, May 1977	*Radiation Exposures As Low As Is Reasonably Achievable*
3. Regulatory Guide 8.13, Rev. 3 Draft DG 8014, October 1994	*Instructions Concerning Prenatal Radiation* Exposure
4. Regulatory Guide 8.29 February 1996	*Instructions Concerning Risks from Occupational Radiation Exposure*

4.4.1.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's ALARA program is acceptable if it fulfills the following criteria: (1) the applicant commits to a comprehensive, effective, and written ALARA program; (2) the ALARA committee is evidenced by an organizational structure in which radiation protection personnel interact, in a timely manner, with production personnel to ensure that methods and techniques for reducing occupational radiation exposure are incorporated in facility operation and design; (3) the ALARA committee, or other similar safety committee, is responsible for conducting periodic reviews of the radiation protection program at least annually and documenting their results. The committee's membership includes management representatives of radiation protection, environmental, safety, and production; (4) the ALARA committee considers the ISA in determining whether further reduction in occupational radiation exposures are reasonable; and (5) the recommendations of the ALARA committee are documented and tracked to completion.

The committee's review includes evaluation of the results of audits made by the radiation protection organization, reports of radiation levels, contamination levels, employee exposures, waste management, and effluent releases. The review determines:

1. If there are any upward trends in personnel exposure for identified categories of workers or types of operations, or effluent releases.

2. If exposures and releases are being lowered or maintained in accordance with the ALARA concept.

3. If equipment for effluent and exposure controls is being properly used, maintained, and inspected.

Trend analysis is performed in the following areas:

1. Radiation exposures of plant workers and members of the public.

2. Concentrations of airborne radioactivity in plant areas.

quid effluents.3

4. Radioactive contamination in plant areas and on equipment.

5. Operation of radiation measurement instrumentation.

6. Operation of respiratory protection equipment.

7. Operation of effluent filtration systems.

4.4.2 Organizational Relationships and Personnel Qualifications

4.4.2.1 Regulatory Requirements

Regulations applicable to organizational relationships and personnel qualifications of the radiological protection staff are the following from Title 10CFR:

1. Section 70.22 "Contents of applications."

2. Section 70.23 “Requirements for the approval of applications”

4.4.2.2 Regulatory Guidance

NRC regulatory guides applicable to organizational relationships and personnel qualifications that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.2.1 are:

1. Regulatory Guide 8.2 February 1973 — *"Guide for Administrative Practice in Radiation Monitoring"*

2. Regulatory Guide 8.10, Rev. 1-R, May 1977 — *"Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable"*

4.4.2.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's radiation safety program organizational relationships and personnel qualifications are acceptable if they fulfill the following criteria: (1) the applicant identifies and includes the authority and responsibility of each position identified; (2) the applicant describes the organizational relationships that are to exist between the individual positions responsible for the radiation safety program and other line managers; (3) the Plant Manager, or equivalent, has overall responsibility and authority for safety; (4) the Radiation Safety Manager, or equivalent, has direct responsibility for establishing and implementing the radiation protection program and has direct access to the Plant Manager; and (5) Radiation Safety Specialist(s) are responsible for specific activities assigned to the radiation safety program with radiation safety technicians implementing these functions. Certain radiation safety technical support and/or audit activities may be supplied by qualified off-site corporate or consultant organizations.

Radiation Protection personnel meet the following education and experience criteria:

1. The Radiation Safety Manager has a bachelor's degree in Science or Engineering, at least 5 years experience as a Health Physicist, and at least 1 year of experience as a Health Physicist in a uranium fuel fabrication facility.

2. Radiation safety specialist has a bachelor's degree in Science or Engineering and at least 1 year of applied health physics experience at a nuclear facility.

3. Radiation safety technicians have a high school diploma or equivalent and certification in a technician trainee program.

4.4.3 Radiation Safety Procedures and Radiation Work Permits (RWPs)

4.4.3.1 Regulatory Requirements

The regulations applicable to approved operating procedures and RWPs are the following from Title 10, CFR:

1. Section 70.22 "Contents of applications"

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

4.4.3.2 Regulatory Guidance

Regulatory guidance applicable to procedures and RWPs that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.3.1. is Regulatory Guide 8.10, Rev., 1-R, May 1977, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable."

4.4.3.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's radiation safety procedures and RWPs are acceptable if they fulfill the following criteria: (1) written, approved radiation safety procedures and RWPs are used to carry out activities related to the radiation safety program and the procedures and RWPs are reviewed, revised, and updated periodically; (2) a mechanism for providing a current copy of the procedures to personnel is established; (3) procedures are reviewed and approved by the Radiation Safety Manager, or an individual who has the qualifications of the Radiation Safety Manager, and at intervals no longer than every 2 years, the procedures are revised and updated as necessary; (4) the applicant makes a commitment to use special reviews and approvals before conducting an activity involving licensed materials with an RWP that is not covered by a written radiation safety procedure; (5) the applicant specifies how the determination is made to use an RWP, the positions within the organization authorized to approve and issue an RWP, the types of information that will be included in an RWP, the provisions for updating and terminating an RWP, and the records to be kept for the RWPs; (6) the applicant specifies the levels of approval necessary for an RWP before it can become effective and that the RWP is approved and signed by a supervisor or specialist in radiation protection; (7) approvals are required from other involved groups to ensure that the provisions of the RWP cover all potential hazards and that the operations are conducted according to proper standards; and (8) the applicant commits to a system that ensures that RWPs are not used past their termination dates. The system includes what types of records are to be kept, the retention times for these records, and the final disposition of the RWP. The record system is sufficient to allow independent auditors to reconstruct the circumstances necessitating the RWP, the factors included, and the results.

The applicant commits to using RWPs for specific purposes only and RWPs are reissued when significant changes in the task or changes that affect the safety of the worker are made. The applicant states that the RWP includes a list of the safety requirements for work conducted under the authorization and includes at least the following, as applicable: (1) the type and frequency of personal monitoring to be conducted; (2) the total time allotted for the authorization; (3) special shielding or ventilation to be used; (4) personal protective equipment; (5) work limitations; (6) radiological conditions; and (7) special instructions.

4.4.4 Training

4.4.4.1 Regulatory Requirements

Regulations applicable to the radiation safety training program are the following from Title 10, CFR:

1.	Section 19.12	"Instructions to workers"
2.	Section 20.2110	"Form of records"

4.4.4.2 Regulatory Guidance

NRC regulatory guides and ANSI and American Society for Testing and Materials (ASTM) standards provide information, recommendations and guidance, and, in general, describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.4.1. are:

1.	Regulatory Guide 8.10, Rev. 1-R May 1977	*"Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable"*
2.	Regulatory Guide 8.13, *Draft DG-801 proposed* R-3 October 1994	*"Instructions Concerning Prenatal Radiation Exposure"*
3.	Regulatory Guide 8.29, *Draft DG-8012 proposed* R-1 December 1994	*"Instructions Concerning Risks from Occupational Radiation Exposure"*
4.	ASTM C986-89 Reapproved 1995	"Developing Training Programs in the Nuclear Fuel Cycle"
5.	ASTM E1168-95	"Radiological Protection Training for Nuclear Facility Workers"

4.4.4.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's training program is acceptable if it fulfills the following criteria: (1) all personnel and visitors entering restricted areas either receive training in radiation protection or are escorted by an individual who has received such training; (2) the technical content of the training program is commensurate with the potential radiological health protection problems in the restricted area and meets the requirements of 10 CFR Parts 19 and 20; (3) the training covers the following areas, as appropriate, in sufficient depth for the specific types of functions: (a) access and egress controls and escort procedures; (b) radiation safety principles, policies, and procedures; (c) monitoring for internal and external exposures; (d) personnel dosimeters; (e) monitoring instruments; (f) contamination control, including protective

clothing and equipment; (g) radiation area and airborne radioactive area; (h) use, storage, and transfer of radioactive materials; (i) posting and labeling requirements; (j) ALARA and exposure limits; (k) radiation hazards and health risks; (l) practical training; and (m) emergency response requirements for individuals; (4) refresher training is completed not later than 2 years following the most recent training and consists of a condensed version of the initial training, with emphasis on changes in policies, procedures, requirements, and facilities; and (5) the effectiveness of the training program is evaluated by written tests or other methodologies and includes evaluation of the curriculum and the instructor's qualifications.

4.4.5 Ventilation Systems

4.4.5.1 Regulatory Requirements

Regulations applicable for the ventilation system are the following from Title 10, CFR:

1. Section 20.1701 *Use of process or other engineering controls*

2. Section 20.2110 *Form of records*

4.4.5.2 Regulatory Guidance

NRC regulatory guides, ANSI standards, and National Council on Radiation Protection and Measurements (NCRP) report applicable to the regulatory requirements related to the ventilation system that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.5.1. are:

1. Regulatory Guide 8.24, Rev. 1 October 1979 *"Health Physics Surveys during Enriched Uranium-235 Processing and Fuel Fabrication"*

2. ANSI N510-1980 "Testing of Nuclear Air Cleaning Systems"

3. ERDA 76-21 "Nuclear Air Cleaning Handbook," C. A. Burchsted, A. B. Fuller, J. E. Kahn

4. NCRP Report No. 59 December 15, 1978 "Operational Radiation Safety Program"

4.4.5.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's ventilation systems are acceptable if they fulfill the following criteria: (1) the applicant commits to a policy for designing and operating the ventilation systems in the facility in a manner that protects workers and the public from airborne radioactive material and assures that the limits of 10 CFR Part 20 are not exceeded during normal operations; (2) the applicant specifies criteria for the ventilation systems, including minimum flow velocity at openings of hoods, maximum differential pressure across filters, and types of filters to be used, where applicable; (3) the applicant specifies the frequency and types of tests required to measure ventilation system performance, the acceptance criteria, and the

actions to be taken when the acceptance criteria are not satisfied; (4) the applicant describes the maintenance, QA, fire safety, criticality safety, and chemical process safety activities associated with the ventilation systems' structures, systems, and components that are identified in the ISA summary as items relied on for safety; (5) airflow patterns are from areas of lesser contamination potential to areas of greater contamination potential; and (6) engineering controls are used to limit the intake of radioactive material, including portable filtration systems used to control airborne contaminants and containment structures to protect personnel working in adjacent areas, when feasible.

4.4.6 Air Sampling

4.4.6.1 Regulatory Requirements

NRC regulations applicable to the air sampling/monitoring program are the following from Title 10, CFR:

1.	Section 20.1204	*Determination of internal exposure*
2.	Section 20.1703	*Use of individual respiratory protection equipment*
3.	Section 20.1902	*Posting requirements of airborne radioactive areas*
4.	Section 20.2103	*Records of surveys*
5.	Section 20.2110	*Form of records*
6.	Section 20.2203(a)(3)(i) and (ii), (b), and (d)	*Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits*

4.4.6.2 Regulatory Guidance

NRC regulatory guides, and NUREGs, and ANSI standards applicable to the air sampling/monitoring program that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.6.1. are:

1.	Regulatory Guide 8.2 February 1973	*"Guide for Administrative Practice in Radiation Monitoring"*
2.	Regulatory Guide 8.24, Rev. 1 October 1979	"Health Physics Surveys During Enriched *Uranium-235 Processing and Fuel Fabrication"*
3.	Regulatory Guide 8.25, Rev. 1 June 1992	*"Air Sampling in the Workplace"*
4.	NUREG-1400 September 1993	*"Air Sampling in the Workplace"*
5.	ANSI N13.1-1969 Reaffirmed 1993	*"Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities"*

4.4.6.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's air sampling program is acceptable if it fulfills the following criteria: (1) the applicant commits to provide representative air sampling for all areas in which a potential exists for airborne radioactive materials; (2) the air sampling data is provided that demonstrates exposures do not exceed established limits and that exposures are maintained ALARA; (3) the applicant provides for each work area a determination that the frequency for analyzing the airborne level of radioactivity, the counting techniques, and the method for determining the airborne concentration are adequate; (3) the calibration methods and frequencies that ensure proper operation of the instrumentation, including the operation of flow rate meters, and the calculations of airborne concentrations, in various areas, to obtain the airborne levels, are described; (4) the application contains a description of action levels, alarm setpoints, frequency of measurements, and action to be taken when action levels are exceeded; (5) the application includes a description of where CAMs are used, the readouts, annunciators, and alarms; and (6) the applicant demonstrates that the action levels used are based on appropriate technical criteria to determine the necessary controls. The demonstration includes the minimum detectable activities (MDAs) for the specific radionuclides of interest.

4.4.7 Contamination Control

4.4.7.1 Regulatory Requirements

NRC regulations applicable to the contamination control program are the following from Title 10, CFR:

1.	Section 20.1501(a)(2)(ii) and (iii)	“Surveys and Monitoring - General”
2.	Section 20.1703(a)(3)(ii)	"Use of individual respiratory protection equipment"
3.	Section 20.1901	"Caution signs"
4.	Section 20.1902(e)	"Posting requirements"
5.	Section 20.1904	"Labeling containers"
6.	Section 20.1906	"Procedures for receiving and opening packages"
7.	Section 20.2103	"Records of surveys"
8.	Section 20.2110	"Form of records"
9.	Section 20.2203(a)(3)(i) and (ii), and (b)	"Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits"

4.4.7.2 Regulatory Guidance

NRC regulatory guides, NRC Branch Technical Positions, and ANSI standards applicable to the contamination control program that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.7.1 are:

1.	Regulatory Guide 8.1 February 1973	*Radiation Symbol*
2.	Regulatory Guide 8.2 February 1973	*Guide for Administrative Practice in Radiation Monitoring*
3.	Regulatory Guide 8.24, Rev. 1 October 1979	*Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication*
4.	ANSI N328-1978	*Radiation Protection Instrumentation Test and Calibration*

5.	ANSI N512-1974, Appendix A	*Protective Coatings (Paints) for the Nuclear Industry*, *Leak Test Methods*
6.	ANSI N542-1977	*Sealed Radioactive Sources Classification*
7.	NRC Branch Technical Position	*License Condition for Leak Testing Sealed Byproduct Material Sources, April 1993*
8.	NRC Branch Technical Position	*License Condition for Leak Testing Sealed Plutonium Sources, April 1993*
9.	NRC Branch Technical Position	*License Condition for Plutonium Alpha Sources, April 1993*
10.	NRC Branch Technical Position	*License Condition for Leak Testing Sealed Source Which Contains Alpha and/or Beta-Gamma Emitters, April 1993*
11.	NRC Branch Technical Position	*License Condition for Leak Testing Sealed Uranium Sources, April 1993*
12.	NRC Branch Technical Position	*Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material, April 1993*

4.4.7.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's contamination control program is acceptable if it fulfills the following criteria: (1) the applicant commits to establishing a contamination survey program, based on the specifications in Regulatory Guide 8.24, that includes the types and frequencies of surveys, limits for contamination levels, and methods and instruments used in the surveys; (2) contamination surveys are conducted routinely for the areas of the plant site where contamination is likely, and the methods and types of instruments used in the surveys are adequate to allow accurate assessment of working conditions; (3) information is provided about survey frequency for each area, the types of radiation, the criteria for contamination levels for both removable and fixed contamination and the action levels and actions (including the time frame for action initiation and completion) to be taken when the levels are exceeded; (4) instruments with sufficient sensitivity to measure contamination at or below the action level are available for use; (5) the features of the facility that help control contamination including step-off pads, personal monitoring equipment at exits, and change rooms are described; (6) the following are specified: (a) the types and availability of contamination monitoring equipment, (b) the specific limits established for personnel contamination, (c) the minimum provisions for personnel decontamination, (d) the minimum types of protective clothing necessary for individuals to enter restricted areas, and (e) the technical criteria and levels for defining contamination areas; and (7) the policy on the use of personnel monitoring equipment is stated and personnel perform a whole body survey each time they leave known contaminated areas, or

a minimum of a hand and shoe survey each time they leave restricted areas that are potentially contaminated.

The applicant's sealed sources are leak tested on a regular basis in accordance with NRC's Branch Technical Positions: (1) "License Condition for Leak Testing Sealed Byproduct Material Sources," April 1993; (2) "License Condition for Leak Testing Sealed Plutonium Sources," April 1993; (3) "License Condition for Plutonium Alpha Sources," April 1993; (4) "License Condition for Leak Testing Sealed Source Which Contains Alpha and/or Beta-Gamma Emitters," April 1993; and (5) "License Condition for Leak Testing Sealed Uranium Sources," April 1993. The applicant has written procedures for leak testing sealed sources in accordance with NRC's Branch Technical Positions described above. The procedures include at least the acceptable contamination levels, test frequencies, and actions to be followed, if limits are exceeded.

The applicant commits to a periodic review of all aspects of access control to determine that: (1) signs, labels, and other access controls are properly posted and operative; (2) restricted areas established to prevent the spread of contamination are identified with appropriate signs; and (3) step-off pads, change facilities, protective clothing facilities, and personnel monitoring instruments are provided in sufficient numbers and locations. The reviews are documented, along with any deficiencies, and the corrective actions taken.

A system is established to ensure that equipment and materials removed from contaminated areas are not contaminated above specified release levels. The radiological contamination levels of items (e.g., tools, equipment, material, premises, or scrap) given clearance for release for unrestricted use are in accordance with NRC's Branch Technical Position, "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material," dated April 1993. Maximum permissible personnel contamination levels (skin and clothing) are established. Detected contamination in excess of these levels is investigated and documented as to source, probable cause, and other pertinent information. Records of these investigations are maintained and reviewed by radiation protection management for trends and corrective action taken, as necessary.

4.4.8 External Exposure

4.4.8.1 Regulatory Requirements

NRC regulations applicable to the measuring, documenting, and maintaining the external exposure of personnel are the following from Title 10, CFR:

1.	Section 19.13	*Notifications and reports to individuals*
2.	Section 20.1201(a)(1)(2) and (c)	*Occupational dose limits for adults*
3.	Section 20.1301(a)(1) and (2), (b) and (c)	*Dose limits for individual members of the public*

4.	Section 20.1302 (a), (b)(1), and (b)(2)(ii)	*Compliance with dose limits for individual members of the public*
5.	Section 20.1501(a)(2)(i) and (c)	*Surveys and Monitoring ! General*
6.	Section 20.1502(a)	*Conditions requiring individual monitoring of external and internal occupational dose*
7.	Section 20.1601	*Control of access to high radiation areas*
8.	Section 20.1901	*Caution signs*
9.	Section 20.1902(a)	*Posting requirements*
10.	Section 20.1906	*Procedures for receiving and opening packages*
11.	Section 20.2101	*Records ! General Provisions*
12.	Section 20.2103	*Records of surveys*
13.	Section 20.2106	*Records of individual monitoring results*
14	Section 20.2110	*Form of records*
15.	Section 20.2202(a), (b), (c), and (d)	*Notification of incidents*
16.	Section 20.2203(a)(2), (a)(3)(i) and (ii), (b), and (d)	*Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits*
17.	Section 20.2206	*Reports of individual monitoring*

4.4.8.2 Regulatory Guidance

NRC regulatory guides and ANSI standards applicable to measuring, documenting, and maintaining the external exposure of personnel below the applicable external exposure limits that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.8.1. are:

1.	Regulatory Guide 8.1 February 1973	*Radiation Symbol*
2.	Regulatory Guide 8.2 February 1973	*Guide for Administrative Practice in Radiation Monitoring*

3.	Regulatory Guide 8.4 February 1973	*Direct-Reading and Indirect-Reading Pocket* Dosimeters
4.	Regulatory Guide 8.7, *Rev. 1 June 1992*	*Instructions for Recording and Reporting Occupational Radiation Exposure Data*
5.	Regulatory Guide 8.24, *Rev. 1 October 1979*	*Health Physics Survey During Enriched Uranium-235 Processing and Fuel Fabrication*
6.	Regulatory Guide 8.34 July 1992	*Monitoring Criteria and Methods to Calculate Occupational Radiation Doses*
7.	ANSI N13.11-1983	*Dosimetry ! Personnel Dosimetry Performance ! Criteria for Testing*
8.	ANSI N13.15-1985	*Radiation Detectors ! Personnel Thermoluminescence Dosimetry Systems ! Performance*
9.	ANSI N13.27-1981	*Performance Requirements for Pocket-Sized Alarm Dosimeters and Alarm Ratemeters*

10.	ANSI N322-1977	*Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters*

4.4.8.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's external exposure program is acceptable if it fulfills the following criteria: (1) the applicant commits to a personnel monitoring program for external radiation, that provides a method to measure, assess, and record personnel exposure to radiation and commits to an ALARA philosophy; (2) the types of monitoring equipment that are used and the types of radiation that are measured are described and justified.. Regulatory Guide 8.34, *"Monitoring Criteria and Methods to Calculate Occupational Radiation Doses"*, provides guidance for determining who is required to wear personnel monitoring dosimeters; (3) the type, range, sensitivity, accuracy, and frequency for reading personnel dosimeters and recording the radiation dose of the dosimeter reading are stated and justified; (4) the use of dosimetry results as a guide to operational planning are described and justified; (5) the specific exposure levels below the regulatory requirements at which action are taken to investigate the cause of the exposures and to reduce exposures are specified; and (6) all personnel dosimeters (except for those specified in 10 CFR 20.1501(c)) are processed and evaluated by a dosimetry processor holding accreditation from the National Voluntary Laboratory Accreditation Program of the National Institute of Standards and Technology.

4.4.9 Internal Exposure

4.4.9.1 Regulatory Requirements

NRC regulations applicable to the measuring, documenting, and maintaining the internal exposure of personnel below the applicable internal exposure limits are the following from Title 10, CFR:

1.	Section 19.13	*Notifications and reports to* individuals
2.	Section 20.1201 a(1),(d), and (e)	*Occupational dose limits for adults*
3.	Section 20.1204	*Determination of internal exposure*
4.	Section 20.1301(a)(1), (b),(c)	*Dose limits for individual members of the public*
5.	Section 20.1302(a) and (b)(1)	*Compliance with dose limits for individual members of the public*
6.	Section 20.1502(b)	*Conditions requiring individual monitoring of external and internal occupational dose*
7.	Section 20.1703(a)(3)(ii) and (b)	*Use of individual respiratory protection equipment*

8.	Section 20.1901	*Caution signs*
9.	Section 20.1902(d)	*Posting requirements*
10.	Section 20.2101	*Records ! General Provisions*
11.	Section 20.2103	*Records of surveys*
12.	Section 20.2106	*Records of individual monitoring results*
13.	Section 20.2110	*Form of records*
14.	Section 20.2202(a), (b), (c), and (d)	*Notification of incidents*
15.	Section 20.2203(a)(2), (b), and (d)	*Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits*
16.	Section 20.2206	*Reports of individual monitoring*

4.4.9.2 Regulatory Guidance

NRC regulatory guides and ANSI standard applicable to the measuring, documenting, and maintaining the internal exposure of personnel below the applicable internal exposure limits that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.9.1. are:

1.	Regulatory Guide 8.1 February 1973	*Radiation Symbol*
2.	Regulatory Guide 8.2 February 1973	*Guide for Administrative Practice in Radiation Monitoring*
3.	Regulatory Guide 8.7, *Rev. 1 June 1992*	*Instructions for Recording and Reporting Occupational Radiation Exposure Data*
4.	Regulatory Guide 8.9, *Rev. 1* July 1993	*Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program*
5.	Regulatory Guide 8.24, *Rev. 1 October 1979*	*Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication*
6.	Regulatory Guide 8.25, Rev. 1 June 1992	*Air Sampling in the Workplace*
7.	Regulatory Guide 8.34	*Monitoring Criteria and Methods to Calculate*

	July 1992	*Occupational Radiation Doses*
8.	ANSI.HPSN 13.22, 1995	*"Bioassay Program for Uranium"*
9.	ANSI.HPSN 13.30, 1996	"Performance Criteria for Radiobioassay"

4.4.9.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's program for internal exposure is acceptable if the applicant meets the requirements of 10 CFR 20.1201, 20.1204, and 20.1502(b). Regulatory Guides 8.25, *"Air Sampling in the Workplace"*; 8.34, *"Monitoring Criteria and Methods to Calculate Occupational Radiation Doses"*; 8.9, Rev. 1, *"Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program"* and ANSI.HPSN 13.22, 1995, "Bioassay Program for Uranium" provide information, recommendations, and guidance and a basis acceptable to the staff for implementing the internal exposure program.

The applicant establishes a program for monitoring worker internal exposures. The program specifies the criteria for participation, the frequency of measurements, the methods to be used, the frequency of analysis, the minimum detection levels, and the action levels and actions to be taken on the results. In addition, the program specifies: (1) the methods for determining if monitoring of worker internal exposure is needed; (2) the criteria for determining when it is necessary to monitor an individual's internal exposure during work hours; and (3) the methods for determining the worker intake from (a) the concentrations of radioactive materials in the work area air, (b) the quantities of radionuclides in the body, (c) the quantities of radionuclides excreted from the body, or (d) any combination of the above methods as may be necessary for determining the intake. If soluble uranium material is present in work area air, action levels based on the chemical toxicity is established.

When air sampling measurement results are used for determining worker intake, the applicant specifies the frequency of sampling and data analysis, the minimum detection levels, and the action levels and actions to be taken on the results.

When bioassay results are used for determining worker intake, the applicant specifies the types of bioassay to be used, the frequency of data collection for each type of measurement, the minimum detection levels, and the action levels and actions to be taken on the results. The applicant commits to a continuing quality assurance and control programs on all phases of its bioassay program, including such items as sample collection, qualifications of laboratory personnel, laboratory intercomparisons, computational checks, and use of appropriate blanks and standards.

4.4.10 Summing Internal and External Exposure

4.4.10.1 Regulatory Requirements

NRC regulations applicable to summing internal and external exposures are the following from Title 10, CFR:

1.	Section 20.1201(a)(1) and (f)	*Occupational dose limits for adults*
2.	Section 20.1202	*Compliance with requirements for summation of external and internal doses*
3.	Section 20.1207	*Occupational dose limits for minors*
4.	Section 20.1208	*Dose to an embryo/fetus*
5.	Section 20.2101	*Records ! General Provisions*
6.	Section 20.2103	*Records of surveys*
7.	Section 20.2104	*Determination of prior occupational dose*
8.	Section 20.2106	*Records of individual monitoring results*
9.	Section 20.2110	*Form of records*
10.	Section 20.2202(a), (b), (c), and (d)	*Notification of incidents*
11.	Section 20.2203(a)(2), (b), and (d)	*Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits*
12.	Section 20.2206	*Reports of individual monitoring*
13.	Section 20, Subpart D	*Radiation Dose Limits for Individual Members of the Public*

4.4.10.2 Regulatory Guidance

NRC regulatory guides, and ANSI standards applicable to the summing of internal and external exposures that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.10.1 are:

1.	Regulatory Guide 8.2 February 1973	*Guide for Administrative Practice in Radiation Monitoring*
2.	Regulatory Guide 8.7, *Rev. 1 June 1992*	*Instructions for Recording and Reporting Occupational Radiation Exposure Data*
3.	Regulatory Guide 8.34 July 1992	*Monitoring Criteria and Methods to Calculate Occupational Radiation Doses*

4.	Regulatory Guide 8.36 July 1992	*Radiation Dose to the Embryo/Fetus*
5.	ANSI N13.6-1966 Reaffirmed 1989	"Practice for Occupational Radiation Exposure *Records Systems"*

4.4.10.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's method for summing internal and external exposures is acceptable if the applicant commits to a procedure for combining internal and external exposures in accordance with Regulatory Guide 8.7, Rev. 1, *"Instructions for Recording and Reporting Occupational Radiation Exposure Data"*; 8.34, *"Monitoring Criteria and Methods to Calculate Occupational Radiation Doses"*; and 8.36, *"Radiation Dose to the Embryo/Fetus"*.

4.4.11 Respiratory Protection

4.4.11.1 Regulatory Requirements

NRC regulations applicable to respiratory protection are the following from Title 10, CFR:

1.	Section 20.1701	*Use of process or other engineering controls*
2.	Section 20.1702	*Use of other controls*
3.	Section 20.1703(a), (c), and (d)	*Use of individual respiratory protection equipment*
4.	Section 20.2110	*Form of records*

4.4.11.2 Regulatory Guidance

The NRC regulatory guide and ANSI standards applicable to the respiratory protection program that in general describe a basis acceptable to the staff for implementing the regulatory requirements Section 4.4.11.1 are:

1.	Regulatory Guide 8.15 October 1976	*Acceptable Programs for Respiratory Protection*
2.	ANSI Z88.2-1992	*Practices for Respiratory Protection*

4.4.11.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's respiratory protection program is acceptable if it fulfills the following criteria: (1) the applicant commits to establishing a respiratory program that meets the requirements of 10 CFR Part 20, Subpart H; (2) the application describes the equipment to be used, the conditions under which respiratory protection are required for routine and nonroutine operations, the protection factors that are applied when respirators are being

used, and the locations of respiratory equipment within the plant. ANSI Z88.2, which defines responsibilities and requirements in the areas of (a) training, (b) control and use of respiratory equipment, (c) mask-fit testing, and (d) breathing-air purity, may be used as guidance; (3) the applicant describes: (a) the types of engineering and administrative controls that have been implemented to reduce the risk of internal exposure without the need for respiratory protection and (b) the methods for determining exposure while an individual is using respiratory protection to ensure that a proper estimate of exposure and internal dose is made. Factors that are critical in this calculation include the time of exposure to airborne radioactive materials, the protection factor for the respirator, the proper fitting of the equipment before use, and the measurement of the concentrations of radioactive material during the exposure.

4.4.12 Instrumentation

4.4.12.1 Regulatory Requirements

NRC regulations applicable to the instrumentation program are the following from Title 10, CFR:

1.	Section 20.1501(b)(c)	*Surveys and Monitoring ! General*
2.	Section 20.2103	*Records of survey*

4.4.12.2 Regulatory Guidance

NRC regulatory guides and ANSI standards applicable to the instrumentation program that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.12.1 are:

1.	Regulatory Guide 8.24, Rev. 1, October 1979	*Health Physics Surveys during Enriched Uranium-235 Processing and Fuel Fabrication*
2.	ANSI N13.4-1971	*Specification of Portable X- or Gamma-Radiation Survey Instruments*
3.	ANSI N42.12-1980	*Calibration and Usage of Sodium Iodide Detector Systems*
4.	ANSI N42.15-1980	*Performance Verification of Liquid-Scintillation Counting Systems*
5.	ANSI N42.17A-1989	*Performance Specifications for Health Physics Instrumentation ! Portable Instrumentation for Use in Normal Environmental Conditions*
6.	ANSI N42.17B-1989	*Performance Specifications for Health Physics Instrumentation ! Occupational Airborne Radioactivity Monitoring Instrumentation*

7.	ANSI N323-1978	*Radiation Protection Instrumentation Test and Calibration*

4.4.12.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's instrumentation is acceptable if it fulfills the following criteria: (1) the applicant commits to a policy for the maintenance and use of operating instruments in sufficient number and types to meet the requirements specified in 10 CFR Part 20; (2) the applicant has adequate radiation measuring instruments for routine and emergency operations and includes a listing of the types of instruments that are available, including ranges, counting mode, sensitivity, alarm setpoints, planned use, and frequency of calibration; (3) the applicant commits to calibrate instruments at least annually, preferably semiannually, and recalibrates instruments if the equipment is repaired such that the accuracy of the reading is affected; (4) the applicant justifies the criteria for selecting radiation measurement instruments for: (a) performing radiation and contamination surveys, (b) sampling airborne radioactivity, (c) monitoring area radiation, (d) monitoring personnel, and (e) performing radioactive analyses; (5) instrument calibrations are traceable to a recognized standard such as National Institute of Standards and Technology (NIST); and (6) the applicant describes the (a) instrument storage, calibration, and maintenance facilities; and (b) the laboratory facilities for radiological analyses. Guidance on instrumentation and instrumentation calibration is provided in ANSI N42.17A and ANSI N323.

4.4.13 Integrated Safety Analysis (ISA)

4.4.13.1 Regulatory Requirements

The regulation applicable to the ISA is 10 CFR Part 70.62.

4.4.13.2 Regulatory Guidance

The NRC NUREGs applicable to the ISA that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.13.1 are:

1.	NUREG - 1513	Integrated Safety Analysis Guidance Document
2.	NUREG/CR-6410 April 1998	Nuclear Fuel Cycle Facility Accident Analysis Handbook

4.4.13.3 Regulatory Acceptance Criteria

The applicant considers accident sequences that could result in radiological consequences of concern as defined in 10 CFR 70.61 as part of the ISA. Radiological safety assessments that support the ISA (1) use appropriate and verified assessment methods, computer codes, and literature values, (2) consider a complete range of credible accident sequences that could adversely affect radiological exposures and cause the consequences of concern, (3) reasonably estimate radiological consequences of accident sequences, (4) identify items relied on for safety to prevent and mitigate accident sequences and radiological consequences of concern, and (5)

describe and commit to appropriate management measures to ensure the availability and reliability of items relied on for safety to perform their functions when needed.

This information will likely appear in the information provided in response to SRP Section 3. The radiation safety reviewer reviews this information, regardless of where it appears in the applicant's submittal. Information provided in one section of the application need not be repeated elsewhere.

4.5 REVIEW PROCEDURES

4.5.1 Acceptance Review

The primary reviewer will review the application to determine if it contains the topics and information discussed in Section 4.3 "Areas of Review." If significant deficiencies are identified in the application, the applicant will be requested to submit additional information before the start of the safety evaluation. The primary reviewer will then determine that the applicant has provided the information required. If necessary, a request for additional information to the applicant will be prepared in conjunction with the licensing project manager.

4.5.2 Safety Evaluation

When an acceptable application is received from the applicant, the primary reviewer will conduct a complete review of the application and determine its acceptability in accordance with Section 4.4, "Acceptance Criteria." For existing facilities, the reviewer will consult with the cognizant radiation protection NRC inspector to identify and resolve any issues of concern related to the licensing review. The final step for the primary reviewer will be to prepare a safety evaluation report (SER) in accordance with Section 4.6 "Evaluation Findings." The SER will be provided to the Licensing Project Manager for the supporting licensing action.

4.6 EVALUATION FINDINGS

The reviewer will write an SER addressing each topic reviewed and explain why the NRC staff has reasonable assurance that the radiation protection part of the application is acceptable and that the health and safety of the workers is adequately protected. License conditions may be proposed to impose requirements where the application is deficient. The following kinds of statements and conclusions will be included in the staff's SER:

> The applicant has committed to an acceptable radiation safety program that includes: (1) an effective documented program to ensure that occupational radiological exposures are ALARA; (2) an organization with adequate qualification requirements for the radiation safety personnel; (3) approved written radiation safety procedures or RWPs for radiation safety activities; (4) radiation safety training for all personnel who have access to restricted areas; (5) requirements for the ventilation systems; (6) requirements for radiological air sampling; (7) requirements for control of radiological contamination within the facility; (8) programs for monitoring personnel external and

internal radiation exposure; (9) a respiratory protection program; (10) requirements for radiological measurement instrumentation; and (11) appropriate radiation controls based on the ISA.

The NRC staff concludes that the applicant's radiation safety program is adequate and that the applicant has the necessary technical staff to administer an effective radiation safety program that meets the requirements of 10 CFR Parts 19, 20, and 70. Conformance to the application and license conditions will ensure safe operation and will provide early detection of unfavorable trends to allow prompt corrective action.

4.7 REFERENCES

Code of Federal Regulations, Title 10, Part 70, "Domestic Licensing of Special Nuclear Material," U.S. Government Printing Office, Washington, DC.

Code of Federal Regulations, Title 10, Part 20, “Standards for Protection Against Radiation,” U. S. Government Printing Office, Washington, DC.

U.S. Nuclear Regulatory Commission, Branch Technical Position, "License Condition for Leak Testing Sealed Plutonium Sources," April 1993.

U.S. Nuclear Regulatory Commission, Branch Technical Position, "License Condition for Plutonium Alpha Sources," April 1993.

U.S. Nuclear Regulatory Commission, Branch Technical Position, "License Condition for Leak Testing Sealed Source Which Contains Alpha and/or Beta-Gamma Emitters," April 1993.

U.S. Nuclear Regulatory Commission, Branch Technical Position, "License Condition for Leak Testing Sealed Uranium Sources," April 1993.

U.S. Nuclear Regulatory Commission, Branch Technical Position, "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material," April 1993.

5.0 NUCLEAR CRITICALITY SAFETY (NCS)

5.1 PURPOSE OF REVIEW

The purpose of this review is to determine whether the applicant, in the license application and supported by materials on the docket, has made the appropriate commitments to develop, implement, and maintain an NCS program in support of safe operation of the facility as required generally by Federal Regulations and specifically by 10 CFR 70.24, 70.61, 70.62, 70.64, and 70.65.

5.2 RESPONSIBILITY FOR REVIEW

Primary: Nuclear Process Engineer (NCS Reviewer)

Secondary: None

Supporting: Project Manager and Fuel Cycle Inspector (As needed.)

5.3 AREAS OF REVIEW

The staff should review the application to determine whether (1) the applicant has identified and committed to the responsibilities and authorities for individuals to develop and implement the NCS program; (2) the facility management measures described in 10 CFR 70.62 have been committed to and will support implementing and maintaining the NCS program; (3) an adequate NCS program is described which includes identifying and committing to the Methodologies and Technical Practices used to ensure the safe operation of the facility as required by 10 CFR 70.24 [Criticality Accident Alarm System (CAAS)], 10 CFR 70.61 [Subcriticality of Operations and Margin of Safety for Subcriticality], 10 CFR 70.64 [Baseline Design Criteria (BDC)], and 10 CFR 70.65 [ISA Summary].

The specific areas for review are as follows:

5.3.1 Organization and Administration

The Primary Reviewer should review the application to determine whether the Organization and Administration has identified and committed to the responsibilities and authorities for individuals to develop and implement the NCS program. The following areas of the application related to the applicant's Organization and Administration should be reviewed:

4) For familiarity, the general Organization and Administration methods used by the applicant (see Section 2.0).
5) The areas of review listed in Section 2.3.1 (Organization and Administration) as they relate to NCS.
6) Experience and education requirements of NCS management positions.

5.3.2 Management Measures

The Primary Reviewer should review the application to determine whether the facility management measures in 10 CFR 70.62 have been committed to by the applicant and whether they demonstrate the applicant's ability to implement and maintain the NCS program. The following areas of the application related to the applicant's Management Measures should be reviewed:

1. Configuration Management, Procedures, Audits and Assessments, Incident Investigations, and other quality assurance elements used by the applicant (see SRP Sections 11.1 through 11.8).

2. The Training, Procedures, and Audits and Assessments programs specifically related to NCS.

5.3.3 Methodologies and Technical Practices

The Primary Reviewer should review the application to determine whether the applicant has implemented NCS Methodologies and NCS Technical Practices used to make NCS determinations to ensure the safe operation of the facility as required by 10 CFR 70.24 [CAAS], 10 CFR 70.61(d) [Subcriticality of Operations and Margin of Safety for Subcriticality], 10 CFR 70.64(a)(9) [BDC], and 10 CFR 70.65(b) [ISA Summary]. The following areas of the application related to the applicant's NCS Methodologies and NCS Technical Practices should be reviewed:

1. The commitment to use the NCS Methodologies identified by the applicant's NCS program.
2. The commitment to use the NCS Technical Practices identified by the applicant's NCS program.

3. The commitment to fulfill the requirements of 10 CFR 70.24 (CAAS) and to have a CAAS that has been incorporated into the Management Measures.

4. The commitment to detect an inadvertent nuclear criticality and promptly notify personnel which should ensure that the radiation exposure to workers shall be minimized.

5. The commitment to the requirements of 10 CFR 70.61 (Subcriticality of Operations and Margin of Subcriticality for Safety).

6. The commitment to the requirements in 10 CFR 70.64 (BDC) as they relate to NCS.

7. The areas of review listed in Section 3.3 (ISA Summary) as they relate to NCS.

5.4 ACCEPTANCE CRITERIA

To provide for NCS, the applicant's use of standards should be considered acceptable if the applicant has met the following Acceptance Criteria:

If an applicant intends to conduct activities where a standard applies and the standard has been endorsed by an NRC Regulatory Guide, then a commitment to comply with all of the requirements (i.e., "shalls") and the appropriate recommendations (i.e., "shoulds") of the standard should constitute an acceptable program under the NRC regulations with respect to the safety aspects addressed by the standard. Notwithstanding such a general commitment to a standard, the licensee should clarify broad requirements in the standard by more specific commitments in the application. Any variations from the requirements of the standard should be identified and justified in the application.

Individual commitments to the Acceptance Criteria are expected only when the Acceptance Criteria are relevant to the operations and materials to be licensed.

5.4.1 Regulatory Requirements

The regulatory basis for the review should be the general and additional contents of an application as required by 10 CFR 70.22 and 70.65, respectively. In addition, the NCS review should be conducted to ensure compliance with 10 CFR 70.24, 70.61, and 70.62.

5.4.2 Regulatory Guidance

The NRC Regulatory Guide (RG) 3.71,*"Nuclear Criticality Safety Standards for Fuels and Materials Facilities,"* August 1998, endorses the ANSI/ANS-8 national standards listed below in part or in full.

1. ANSI/ANS-8.1-1983 (Reaffirmed in 1988), *"Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors."*

2. ANSI/ANS-8.3-1997, *"Criticality Accident Alarm System."*

3. ANSI/ANS-8.5-1996, *"Use of Borosilicate-Glass Raschig Rings as a Neutron Absorber in Solutions of Fissile Material."*

4. ANSI/ANS-8.6-1983 (Reaffirmed in 1995), *"Safety in Conducting Subcritical Neutron-Multiplication Measurements In Situ."*

5. ANSI/ANS-8.7-1975 (Reaffirmed in 1987), *"Guide for Nuclear Criticality Safety in the Storage of Fissile Materials."*

6. ANSI/ANS-8.9-1987 (Reaffirmed in 1995), *"Nuclear Criticality Safety Criteria for Steel-Pipe Intersections Containing Aqueous Solutions of Fissile Materials."*

7. ANSI/ANS-8.10-1983 (Reaffirmed in 1988), *"Criteria for Nuclear Criticality Safety Controls in Operations With Shielding and Confinement."*

8. ANSI/ANS-8.12-1987 (Reaffirmed in 1993), *"Nuclear Criticality Control and Safety of Plutonium-Uranium Fuel Mixtures Outside Reactors."*

9. ANSI/ANS-8.15-1981 (Reaffirmed in 1995), *"Nuclear Criticality Control of Special Actinide Elements."*

10. ANSI/ANS-8.17-1984 (Reaffirmed in 1997), *"Criticality Safety Criteria for the Handling, Storage, and Transportation of LWR Fuel Outside Reactors."*

11. ANSI/ANS-8.19-1996, *"Administrative Practices for Nuclear Criticality Safety."*

12. ANSI/ANS-8.20-1991, *"Nuclear Criticality Safety Training."*

13. ANSI/ANS-8.21-1995, *"Use of Fixed Neutron Absorbers in Nuclear Facilities Outside Reactors."*

14. ANSI/ANS-8.22-1997, *"Nuclear Criticality Safety Based on Limiting and Controlling Moderators."*

15. ANSI/ANS-8.23-1997, *"Nuclear Criticality Accident Emergency Planning and Response."*

5.4.3 Regulatory Acceptance Criteria

5.4.3.1 Organization and Administration

To provide for NCS, the applicant's Organization and Administration should be considered acceptable if the applicant has met the following Acceptance Criteria or has identified and justified an alternative in the application (information related to these Acceptance Criteria may be consolidated with other Organization and Administration descriptions elsewhere in the application in response to Chapter 2.0):

1. The applicant meets the Acceptance Criteria related to NCS in Section 2.4.1 (Organization and Administration).

2. The applicant commits to the requirements in ANSI/ANS-8.1-1983, *"Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors."*

3. The applicant commits to the requirements in ANSI/ANS-8.19-1996, *"Administrative Practices for Nuclear Criticality Safety."*

4. The applicant commits to the intent of Section 4.11 of ANSI/ANS-8.1-1983, which is: The applicant shall commit to the use of personnel, skilled in the interpretation of data pertinent to NCS and familiar with the operation of the facility, as a resource in NCS management decisions. These specialists should be independent of operations supervision.

5. The applicant commits to provide NCS postings for areas, operations, work stations, and storage locations that provide operators a reference for ensuring conformance and safe operation.

6. The applicant commits to the policy that: "All personnel shall report defective NCS conditions to the NCS function and take no further action not specified by approved written procedures until NCS has analyzed the situation."

5.4.3.2 Management Measures

To provide for NCS, the applicant's Management Measures required by 10 CFR 70.62 should be considered acceptable if the applicant has met the following Acceptance Criteria or has identified and justified an alternative in the application:

1. Training (information related to these Acceptance Criteria may be consolidated with other Training descriptions in the application in response to SRP Section 11.3):

   a. The applicant commits to the requirements in both ANSI/ANS-8.19-1996, *"Administrative Practices for Nuclear Criticality Safety"* and ANSI/ANS-8.20-1991, *"Nuclear Criticality Safety Training."*

   b. The applicant commits to provide instruction in the Training program regarding the use of Process Variables as NCS controls.

   c. The applicant commits to provide instruction in the Training program regarding all personnel to (1) recognize the CAAS signal and (2) evacuate promptly to a safe area.

   d. The applicant commits to provide instruction in the Training program regarding the policy that: "All personnel shall report defective NCS conditions to the NCS function and take no further action not specified by approved written procedures until NCS has analyzed the situation."

2. Procedures (information related to these Acceptance Criteria may be consolidated with other Procedures descriptions elsewhere in the application in response to Section 11.4):

   a. The applicant commits to the requirements in ANSI/ANS-8.19-1996, *"Administrative Practices for Nuclear Criticality Safety."*

   b. The applicant commits to the policy that: "No single, inadvertent departure from a procedure could cause an inadvertent nuclear criticality."

3. Audits and Assessments (information related to these Acceptance Criteria may be consolidated with other Audit and Assessment descriptions elsewhere in the application in response to Section 11.5):

   a. The applicant commits to the requirements in ANSI/ANS-8.19-1996, *"Administrative Practices for Nuclear Criticality Safety."*

   b. The applicant commits to conducting and documenting Weekly NCS Walkthroughs (e.g., checklists) of all operating SNM process areas such that all operating SNM process areas should be reviewed at least every two weeks. Identified weaknesses should be incorporated into the facility Corrective Actions Program and should be promptly and effectively resolved. A graded approach may be used to justify an alternate plan based on the ISA.

   c. The applicant commits to conducting and documenting Quarterly NCS Audits such that all NCS aspects of Management Measures (see Sections 11.1 through 11.8) should be

audited at least every 2 years. A graded approach may be used to justify an alternate plan based on the ISA.

5.4.3.3 Methodologies and Technical Practices

5.4.3.3.1 Methodologies

To provide for NCS, the applicant's commitment to NCS Methodologies should be considered acceptable if the applicant has met the following Acceptance Criteria or has identified and justified an alternative in the application:

1. The applicant commits to the requirements in ANSI/ANS-8.1-1983, *"Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors."*

2. The applicant commits to the intent of the requirement in Regulatory Guide 3.71, *"Nuclear Criticality Safety Standards for Fuels and Materials Facilities"* related to validation reports which is: The applicant should demonstrate: (1) the adequacy of the Margin of Subcriticality for Safety by assuring that the margin is large compared to the uncertainty in the calculated value of k-eff, (2) that the calculation of k-eff is based on a set of variables whose values lie in a range for which the methodology used to determine k-eff has been validated, and (3) that trends in the bias support the extension of the methodology to areas outside the Area(s) of Applicability.

3. The applicant includes a reference to (including date and revision number) and summary description of either a manual or a documented, reviewed, and approved validation report (by NCS and Management) for each methodology which will be used to make an NCS determination (e.g., experimental data, reference books, hand calculations, deterministic computer codes, probabilistic computer codes). The summary description of the reference manual or validation report should have:

   a. a summary of the theory of the methodology in sufficient detail, clarity, and lack of ambiguity that allows understanding of the methodology.

   b. a commitment to apply the methodology only in the Area(s) of Applicability or provide justifications for applying the methodology outside the Area(s) of Applicability.

   c. a commitment to use pertinent computer codes, assumptions, and techniques in the methodology.

   d. a commitment to use proper functioning of the mathematical operations in the methodology.

   e. a commitment to use the data consistently with reliable experimental measurements.

   f. a commitment to use plant specific benchmark experiments and data derived therefrom that will be used to validate the methodology.

   g. a commitment to determine the bias, uncertainty in the bias, uncertainty in the methodology, uncertainty in the data, uncertainty in the benchmark experiments, and Margin of Subcriticality for Safety, when using the methodology.

h. a commitment to use controlled software and hardware when using the methodology.

i. a commitment to use a verification process when using the methodology.

4. The applicant commits to have, at the facility, the reference manual or documented, reviewed, and approved validation report (by NCS and Management) for each methodology used to make an NCS determination. The manual or validation report should have:

a. a description of the theory of the methodology in sufficient detail, clarity, and lack of ambiguity that allows understanding of the methodology and independent duplication of results.

b. a description of the Area(s) of Applicability which identifies the range of values for which valid results have been obtained for the parameters used in the methodology. In accordance with the provisions in ANSI/ANS-8.1-1983, *"Nuclear Criticality Safety in Operations With Fissionable Material Outside Reactors,"* any extrapolation beyond the Area(s) of Applicability should be supported by an established mathematical methodology.

c. a description of the use of pertinent computer codes, assumptions, and techniques in the methodology.

d. a description of the proper functioning of the mathematical operations in the methodology (e.g., mathematical testing).

e. a description of the data used in the methodology consistent with reliable experimental measurements.

f. a description of the plant specific benchmark experiments and data derived therefrom that were used for validating the methodology.

g. a description of the bias, uncertainty in the bias, uncertainty in the methodology, uncertainty in the data, uncertainty in the benchmark experiments, and Margin of Subcriticality for Safety, as well as the basis for these items, as used in the methodology. If the bias is determined to be advantageous to the applicant, the applicant shall use a bias of 0.0 (e.g., in a critical experiment where the k-eff is known to be 1.0 and the code calculates 1.02, the applicant cannot use a bias of 0.02 to allow calculations to be made above the value of 1.0).

h. a description of the software and hardware that will use the methodology.

i. a description of the verification process and results.

5. The applicant commits to incorporate each reference manual or documented, reviewed, and approved validation report (by NCS and Management) for a methodology as well as assumptions used into the facility Configuration Management program.

6. The applicant commits to performing NCS determinations using specified methods. The applicant should commit to incorporating these methods into the facility Management Measures:

   a. The applicant should commit to assuming credible optimum conditions (i.e., most reactive conditions physically possible or limited by written commitments to regulatory agencies) for each Controlled Parameter unless specified controls are implemented to limit the Controlled Parameter to a certain range of values.

   b. The applicant should commit to set NCS operating and safety limits derived from experimental data, reference books, hand calculations, deterministic computer codes, or probabilistic computer codes which have either a reference manual or a documented, reviewed, and approved validation report (by NCS and Management).

   c. The applicant should commit to consider the variability and uncertainty in a process and the NCS subcritical limit when setting NCS safety limits.

   d. The applicant should commit to consider the variability and uncertainty in a process and the NCS safety limit when setting NCS operating limits.

5.4.3.3.2 Technical Practices

To provide for NCS, the applicant's commitment to NCS Technical Practices should be considered acceptable if the applicant has met the following Acceptance Criteria or has identified and justified an alternative in the application:

1. Although the applicant may use a single NCS control to maintain the values of two or more Controlled Parameters, this use constitutes only one component necessary for Double Contingency Protection.

2. Based on the Performance Requirements in 10 CFR 70.61, the applicant commits to the policy that: “No single credible event or failure could result in a criticality accident.”

3. The applicant commits to the preferred use of Passive-Engineered controls to ensure NCS. The applicant should commit to the following preference, in general, for controls to ensure NCS: (1) Passive-Engineered, (2) Active-Engineered, (3) Augmented-Administrative, and (4) Simple-Administrative. When choosing not to use a Passive-Engineered control, the applicant commits to identify and provide justification in the ISA.

4. When evaluating a Controlled Parameter, heterogeneous effects are considered. Heterogeneous effects are particularly relevant for low-enriched uranium processes, where, when all other parameters are equal, heterogeneous systems are more reactive than homogeneous systems.

5. The applicant commits to incorporate Controlled Parameters into the facility Management Measures of 10 CFR 70.62.

6. The applicant commits to perform an evaluation, for all Controlled Parameters, that shows that during both normal and credible abnormal conditions, the Controlled Parameter will be maintained.

7. The applicant commits to describe Controlled Parameters used as NCS control. Examples of Controlled Parameters available for NCS control are: Mass, Geometry, Density, Enrichment, Reflection, Moderation, Concentration, Interaction, Neutron Absorber, and Volume.

8. When Controlled Parameters are controlled for safety reasons by measurement, reliable methods and instruments should be used. It is acceptable if the applicant commits to representative sampling, reliable measurement instruments and methods, and dual independent measurements where there is significant susceptibility to human error.

9. The use of Mass as a Controlled Parameter should be considered acceptable if:

   a. When a given Mass of material has been determined, a percentage factor is used to determine the Mass percentage of SNM in that material.

   b. When fixed geometric devices are used to limit the Mass of SNM, a conservative process density is used.

   c. When physical measurement of the Mass is needed, the measurement is obtained by using instrumentation.

   d. When double batching of SNM is possible, the Mass of SNM is limited to no more than 45% of the minimum critical Mass based on spherical geometry.

   e. When double batching of SNM is not possible, the Mass of SNM is limited to no more than 75% of the critical Mass.

10. The use of Geometry as a Controlled Parameter should be considered acceptable if:

   a. Before beginning operations, all dimensions and nuclear properties which use Geometry control are verified. The facility Configuration Management program should be used to maintain these dimensions and nuclear properties.

   b. When using large single units, the Margins of Safety are 90% of the minimum critical cylinder diameter, 85% of the minimum critical slab thickness, and 75% of the minimum critical sphere volume.

11. The use of Density as a Controlled Parameter should be considered acceptable if:

   a. When Process Variables can affect the Density, the Process Variables are identified as items relied on for safety (IROFS) in the ISA Summary.

   b. When physical measurement of the Density is needed, the measurement is obtained by using instrumentation.

12. The use of Enrichment as a Controlled Parameter should be considered acceptable if:
   a. When using SNM with differing Enrichment, the SNM is segregated by Enrichment.

b. When physical measurement of the Enrichment is needed, the measurement is obtained by using instrumentation.

13. The use of Reflection as a Controlled Parameter should be considered acceptable if:

a. When investigating an individual unit, the wall thickness of the unit and all reflecting adjacent materials of the unit are considered. The adjacent materials should be farther than one foot away from the unit.

b. After identifying potential reflectors, the controls to prevent the presence of the potential reflectors are identified as IROFS in the ISA Summary.

14. The use of Moderation as a Controlled Parameter should be considered acceptable if:

a. When using Moderation, the applicant commits to the requirements in ANSI/ANS-8.22-1997, *"Nuclear Criticality Safety Based on Limiting and Controlling Moderators."*

b. When Process Variables can affect the Moderation, the Process Variables are identified as IROFS in the ISA Summary.

c. When physical measurement of the Moderation is needed, the measurement is obtained by using instrumentation.

d. When designing physical structures, the design precludes the ingress of Moderation.

e. When sampling of the Moderation is needed, the sampling program uses dual independent sampling methods.

f. When developing firefighting procedures for use in a Moderation controlled area, restrictions are placed on the use of Moderator material.

g. After evaluating all credible sources of Moderation for the potential for intrusion into a Moderation controlled area, the ingress of Moderation is precluded or controlled.

15. The use of Concentration as a Controlled Parameter should be considered acceptable if:

a. When Process Variables can affect the Concentration, the Process Variables are identified as IROFS in the ISA Summary.

b. High Concentrations of SNM in a process are precluded.

c. When using a tank containing Concentration controlled solution, the tank is normally closed.

d. When sampling of the Concentration is needed, the sampling program uses dual independent sampling methods.

e. After identifying possible precipitating agents, precautions are taken to ensure that such agents will not be inadvertently introduced.

16. The use of Interaction as a Controlled Parameter should be considered acceptable if:

    a. When maintaining a physical separation between units, engineered devices (i.e., spacers) with a minimum spacing are used. The structural integrity of the spacers should be sufficient for normal and credible abnormal conditions.

17. The use of Neutron Absorber as a Controlled Parameter should be considered acceptable if:

    a. When using Borosilicate-Glass Raschig Rings, the applicant commits to the requirements in ANSI/ANS-8.5-1996, *"Use of Borosilicate-Glass Raschig Rings as a Neutron Absorber in Solutions of Fissile Material."*

    b. When using Fixed Neutron Absorbers, the applicant commits to the requirements in ANSI/ANS-8.21-1995, *"Use of Fixed Neutron Absorbers in Nuclear Facilities Outside Reactors."*

    c. When evaluating absorber effectiveness, neutron spectra are considered (e.g., cadmium is an effective absorber for thermal neutrons, but ineffective for fast neutrons).

18. The use of Volume as a Controlled Parameter should be considered acceptable if:

    a. When using Volume control, geometrical devices are used to restrict the Volume of SNM and engineered devices should limit the accumulation of SNM.

    b. When physical measurement of the Volume is needed, the measurement is obtained by using instrumentation.

5.4.3.3.3 Requirements of 10 CFR 70.24 (CAAS)

To provide for NCS, the applicant's commitment to the CAAS requirements in 10 CFR 70.24 should be considered acceptable if the applicant has met the following Acceptance Criteria or has identified and justified an alternative in the application:

1. The applicant has documented that the facility CAAS meets the requirements of 10 CFR 70.24.

2. The applicant commits to the requirements in ANSI/ANS-8.3-1997, *"Criticality Accident Alarm System."*

3. The applicant commits to the requirements in Regulatory Guide 3.71, *"Nuclear Criticality Safety Standards for Fuels and Materials Facilities"* which effect the ANSI/ANS-8.3 standard:

    a. At or above the 10 CFR 70.24 mass limits, CAAS coverage shall be required in each area in which SNM is handled, stored, or used.

    b. 10 CFR 70.24 requires that each area that needs CAAS coverage to be covered by two detectors.

c. 10 CFR 70.24 requires that a CAAS be capable of detecting a nuclear criticality that produces an absorbed dose in soft tissue of 20 rads of combined neutron and gamma radiation at an unshielded distance of 2 meters from the reacting material within 1 minute.

4. The applicant commits to having a CAAS that is uniform throughout the facility for the type of radiation detected, the mode of detection, the alarm signal, and the system dependability.

5. The applicant commits to having a CAAS that is designed to remain operational during credible events such as a seismic shock equivalent to the site-specific design-basis earthquake or the equivalent value specified by the Uniform Building Code.

6. The applicant commits to having a CAAS that is designed to remain operational during credible events such as a fire, an explosion, a corrosive atmosphere, and other credible conditions.

7. The applicant commits to having a CAAS alarm that is clearly audible areas that must be evacuated or provides alternate notification methods that are documented to be effective in notifying personnel that evacuation is necessary.

8. The applicant commits to rendering operations safe, by shutdown and quarantine if necessary, in any area where CAAS coverage has been lost and not restored within a specified number of hours. The number of hours should be determined on a process by process basis because shutting down certain processes, even to make them safe, may carry a larger risk, than being without a CAAS for a short time. The applicant should commit to compensatory measures (e.g., limit access, halt SNM movement) when the CAAS system is not functioning due to Maintenance.

9. Emergency Management (information related to these Acceptance Criteria may be consolidated with other emergency management descriptions elsewhere in the application in response to Chapter 8.0):

   a. The applicant commits to the requirements in ANSI/ANS-8.23-1997, *"Nuclear Criticality Accident Emergency Planning and Response."*

   b. The applicant either has an Emergency Plan or satisfies the alternate requirements found in 70.22.(h)(1)(i).

   c. The applicant commits to provide fixed and personnel accident dosimeters in areas that require a CAAS, as well as a method for prompt onsite dosimeter readouts. These dosimeters should be readily available to personnel responding to an emergency.

   d. The applicant commits to provide emergency power for the CAAS.

5.4.3.3.4 Requirements of 10 CFR 70.61 (Subcriticality of Operations and Margin of Subcriticality for Safety)

To provide for NCS, the applicant's commitment to the Subcriticality of Operations and Margin of Safety for Subcriticality requirements in 10 CFR 70.61 should be considered acceptable if the applicant has met the following Acceptance Criteria or has identified and justified an alternative in the application:

1. The applicant commits to the use of NCS controls and Controlled Parameters to ensure both Subcriticality of Operations and Margin of Subcriticality for Safety. As required by ANSI/ANS-8.1-1983, *"Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors,"* process specifications shall incorporate margins to protect against uncertainties in process variables and against a limit being accidentally exceeded."

2. The applicant commits to the requirements in ANSI/ANS-8.7-1975, *"Guide for Nuclear Criticality Safety in the Storage of Fissile Materials."*

3. The applicant commits to the requirements in ANSI/ANS-8.9-1987, *"Nuclear Criticality Safety Criteria for Steel-Pipe Intersections Containing Aqueous Solutions of Fissile Materials."*

4. The applicant commits to the requirements in ANSI/ANS-8.10-1983, *"Criteria for Nuclear Criticality Safety Controls in Operations With Shielding and Confinement."*

5. The applicant commits to the requirements in ANSI/ANS-8.12-1987, *"Nuclear Criticality Control and Safety of Plutonium-Uranium Fuel Mixtures Outside Reactors."*

6. The applicant commits to the requirements in ANSI/ANS-8.15-1981, *"Nuclear Criticality Control of Special Actinide Elements."*

7. The applicant commits to the requirements in ANSI/ANS-8.17-1984, *"Criticality Safety Criteria for the Handling, Storage, and Transportation of LWR Fuel Outside Reactors."*

8. If the applicant intends to use administrative k-eff margins for normal and credible abnormal conditions, the applicant commits to NRC pre-approval of the administrative margins.

9. The applicant commits to the use of controls or control barriers on IROFS to ensure that an inadvertent nuclear criticality will not occur.

10. The applicant commits to incorporating controls and control barriers into the facility Management Measures of 10 CFR 70.62.

11. The applicant commits to determining subcritical limits for k-eff calculations such that : k-subcritical = 1.0 - bias-margin, where margin includes adequate allowance for uncertainty in the methodology, data, and bias to assure subcriticality.

12. The applicant commits to performing studies to correlate the change in a value of a Controlled Parameter and its k-eff value. The studies should also include changing the value of one Controlled Parameter and determining its effect on another Controlled Parameter and k-eff.

13. The applicant meets the Acceptance Criteria in Section 3.4.1 (ISA Summary) as they relate to Subcriticality of Operations and Margin of Subcriticality for Safety.

Note: This is the Acceptance Criteria to review the High-Risk Accident Sequences and a cross-section of Low-Risk Accident Sequences.

5.4.3.3.5 Requirements of 10 CFR 70.64 (BDC) [for new facilities and processes only]

To provide for NCS, the applicant's commitment to the BDC requirements in 10 CFR 70.64 should be considered acceptable if the applicant has met the following Acceptance Criteria or has identified and justified an alternative in the application:

1. The applicant commits to the Double Contingency Principle in determining NCS controls in the design of new facilities or new processes at existing facilities.

5.4.3.3.6 Requirements of 10 CFR 70.65 (ISA Summary)

The applicant is required to meet the performance criteria in 10 CFR 70.61(b) and (c) as well as the performance requirements in 70.61(d), which include the requirement to limit the risk of an inadvertent nuclear criticality by assuring that all nuclear processes remain subcritical. The applicant's evaluation of NCS Accident Sequences should be performed in a manner consistent with the applicant's evaluation of non-NCS Accident Sequences used to meet 10 CFR 70.61(b) and (c); however 10 CFR 70.61(d) requires the applicant to use prevention methods as the primary means to meet the performance requirements of 10 CFR 70.61(b) and (c).

To provide for NCS, the applicant's commitment to the ISA requirements in 10 CFR 70.65 should be considered acceptable if the applicant has met the following Acceptance Criteria or has identified and justified an alternative in the application:

1. Accident Sequences:

   a. The applicant meets the Acceptance Criteria in Section 3.4.1 (ISA Summary) related to Accident Sequences for NCS.

   b. The applicant commits to use Appendix A of ANSI/ANS-8.1-1983, *"Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors"* in determining Accident Sequences.

2. Consequences:

   a. The applicant meets the Acceptance Criteria in Section 3.4.1 (ISA Summary) related to Consequences for NCS.

   b. The applicant commits to the requirements in ANSI/ANS-8.10-1983, *"Criteria for Nuclear Criticality Safety Controls in Operations With Shielding and Confinement."* In addition, the applicant should commit to the requirements in RG 3.71, *"Nuclear Criticality Safety Standards for Fuels and Materials Facilities"* which effect the ANSI/ANS 8.10 standard.

3. Likelihoods:

a. The applicant meets the Acceptance Criteria in Section 3.4.1 (ISA Summary) related to Likelihoods for NCS.

b. The applicant commits to implement an NCS program that ensures Double Contingency Protection when practicable. When evaluating Double Contingency Protection, the term "unlikely" should be used in a manner consistent with ANSI/ANS-8.1-1983.

1. Adherence to Double Contingency Protection: Each process which could have an inadvertent nuclear criticality should have Double Contingency Protection. Double Contingency Protection may be provided by either (a) At Least Two Parameter Control: the control of at least two independent process parameters or (b) Single Parameter Control: a system of multiple independent controls on a single process parameter. The At Least Two Parameter Control method is the preferred approach due to the difficulty of preventing common-mode failure when controlling only one parameter.

2. As used in Double Contingency Protection, the term "concurrent" means that the effect of the first process change persists until a second change occurs, at which point the process could have an inadvertent nuclear criticality. It does not mean that the two events initiating the change must occur simultaneously. The possibility of an inadvertent nuclear criticality can be markedly reduced if failures of NCS controls are rapidly detected and the processes rendered safe. If not, processes can remain vulnerable to a second failure for extended periods of time.

3. If the applicant adheres to Double Contingency Protection for an NCS Accident Sequence, then the Likelihood requirements of 10 CFR 70.61(b) should be considered satisfied for that Accident Sequence.

4. Exceptions to Double Contingency Protection: There may be processes where Double Contingency Protection is not practicable. In those processes, the facility should implement sufficient Redundancy and Diversity in Controlled Parameters such that at least two unlikely and concurrent events, errors, accidents, or equipment malfunctions, are necessary before an inadvertent nuclear criticality is possible. The applicant should commit in the license application to identify and provide justification in the ISA for exceptions to Double Contingency Protection.

4. Risk:

a. The applicant meets the Acceptance Criteria in Section 3.4.1 (ISA Summary) related to Risks for NCS.

5. IROFS:

a. The applicant meets the Acceptance Criteria in Section 3.4.1 (ISA Summary) related to IROFS for NCS.

5.5 REVIEW PROCEDURES

The reviewer should use the Regulatory Guidance of this chapter; references in this chapter; the applicant's 91-01, 70.50, and 70.74 reports; and 10 CFR Part 70 Appendix A reporting requirements.

5.5.1 Acceptance Review

The Primary Reviewer should review the applicant's NCS information for completeness with respect to the requirements in 10 CFR 70.22, 70.24, 70.61, 70.62, 70.65 and the Acceptance Criteria in Section 5.4. Using guidance in the "FCLB Materials Licensing Procedures Manual," if deficiencies are identified, then either the applicant should be requested to submit additional material prior to the start of the safety evaluation or the application should be denied.

5.5.2 Safety Evaluation

When an acceptable application is received from the applicant, the primary reviewer will conduct a complete review of the application and determine its acceptability, consulting with the supporting reviewers to identify and resolve any issues of concern related to the licensing review. The primary reviewer (acting as a secondary or supporting reviewer) should also coordinate with other reviewers concerning NCS regarding the following:

1. In support of the primary reviewer for Section 2.0, the NCS reviewer should determine whether the Acceptance Criteria in Section 2.0 have been met as they relate to NCS.

2. In support of the primary reviewer for Sections 11.1 through 11.8, the NCS reviewer should determine whether the Acceptance Criteria in Sections 11.1 through 11.8 have been met as they relate to NCS.

3. In support of the primary reviewer for Section 3.0, the NCS reviewer should determine whether the Acceptance Criteria in Chapter 3.0 have been met as they relate to NCS.

4. In support of the primary reviewer for Section 8.0, the NCS reviewer should determine whether the Acceptance Criteria in Section 8.0 have been met as they relate to NCS.

The primary reviewer should determine whether the Acceptance Criteria in Section 5.4 have been met and should prepare the SER NCS chapter in accordance with Section 5.6.

5.6 EVALUATION FINDINGS

If the staff's review verifies that sufficient information has been provided in the safety program description to satisfy the Acceptance Criteria in Section 5.4, the staff should document its review as follows:

The staff has reviewed the Nuclear Criticality Safety (NCS) program for *[name of facility*] according to Chapter 5.0 of the Standard Review Plan. The staff has reasonable assurance that:

1. The applicant will have in place a staff of managers, supervisors, engineers, process operators, and other support personnel who are qualified to develop, implement, and

maintain the NCS program in accordance with the facility Organization, Administration, and Management Measures.

2. The applicant's conduct of operations will be based on NCS Methodologies and NCS Technical Practices which will ensure that the fissile material will be possessed, stored, and used safely according to the requirements in 10 CFR Part 70.

3. The applicant will develop, implement, and maintain a Criticality Accident Alarm System in accordance with the requirements in 10 CFR 70.24 and in accordance with its Emergency Management Program.

4. The applicant will have in place an NCS program in accordance with the Subcriticality of Operations and Margin of Subcriticality for Safety requirements in 10 CFR 70.61 and Baseline Design Criteria requirements in 10 CFR 70.64.

5. Based on this review, the staff concludes that the applicant's NCS program meets the requirements of 10 CFR Part 70 and provides reasonable assurance for the protection of public health and safety, including workers and the environment.

Note: The Evaluation Finding for the ISA Summary requirements for 10 CFR 70.65 should be in SRP Section 3.6.

5.7 REFERENCES

Code of Federal Regulations, Title 10, "Energy," Part 70, `Domestic Licensing of Special Nuclear Material,' U.S. Government Printing Office, Washington, DC.

LA-10860-MS, *Critical Dimensions of Systems Containing ^{235}U, ^{239}Pu, and ^{233}U*, H. C. Paxton and N. L. Pruvost, Los Alamos National Laboratory, Los Alamos, NM, 1987.

LA-12808/UC-714, *Nuclear Criticality Safety Guide*, N. L. Pruvost and H. C. Paxton, Los Alamos National Laboratory, Los Alamos, NM, 1996.

DP-1014, *Maximum Safe Limits for Slightly Enriched Uranium and Uranium Oxide*, H. K. Clark, Du Pont de Nemours and Co., Aiken, SC, 1966.

DOE/NCT-04, A Review of Criticality Accidents, W. R. Stratton, Revised by D. R. Smith, U.S. Dept. of Energy, March 1989.

Nuclear Criticality Safety -- Theory and Practice, R. A. Knief, American Nuclear Society, La Grange Park, IL, 1985.

DOE Order 420.1 (Change 2), *Facility Safety*, October 24, 1996.

U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

6.0 CHEMICAL PROCESS SAFETY

6.1 PURPOSE OF REVIEW

The primary purpose of the review is to determine with reasonable assurance that the applicant's facility, process design, and commitments to implement and maintain a chemical safety function will adequately protect the health and safety of workers and the public from chemical risks produced by licensed material, hazardous chemicals produced from licensed material, and from plant conditions that affect the safety of radioactive materials and thus present an increased radiation risk; during normal operations, anticipated (off-normal) events, and during accidents. This chapter facilitates the review of the chemical safety aspects for normal operations and for accidents that are analyzed in the integrated safety analysis (ISA), through interfaces with SRP Sections 3.0 and 11.0.

An additional purpose of the review is to verify with reasonable assurance that the areas of NRC responsibility, as specified in the NRC-OSHA Memorandum of Understanding (MOU) dated October 31, 1988, in the area of chemical process safety, are properly implemented by the applicant.

6.2 RESPONSIBILITY FOR REVIEW

Primary: Chemical Process Safety Reviewer (all sections of this chapter)

Secondary: None

Supporting: Project Manager and Fuel Facility Inspection Staff (as needed)
Health Physicist (for Part 20 uranium toxicity issues)

6.3 AREAS OF REVIEW

The regulation, 10 CFR 70.62, requires that a safety program be established and maintained that will provide adequate protection from licensed materials, for worker and public health and safety and the environment. A separate chemical process safety program is not required to provide chemical process safety. Applicants are required to conduct an ISA, identify accident sequences along with items relied on for safety, identify management measures that ensure items are available and reliable, maintain records that demonstrate chemical process safety compliance to the regulation and provide reporting commitments for chemical process releases if applicable.

The staff's chemical safety review should focus on the chemical safety-related accident sequences described in the ISA Summary (some of the relevant information may appear in SRP Section 3.0) and the interfaces with management measures (some of the relevant information

may appear in SRP Section 11.0) to confirm that the applicant's equipment, facilities and procedures are adequate to protect against releases and chemical exposures of licensed material, hazardous chemicals produced from licensed material and chemical risks produced from plant conditions that affect the safety of radioactive materials. Also to be reviewed is the applicant's evidence that items identified as relied on for safety would adequately mitigate or prevent such accident sequences. The review will verify that the grading of both the controls and assurances applied to such controls are appropriate for the accident risk that the controls are designed to reduce.

An additional area of review is the applicant's application of the principles of the MOU, in identifying the hazards to be evaluated in the ISA and controlled by items and management measures. The MOU delineates the areas of federal agency responsibility for chemical process safety at NRC licensed nuclear facilities. NRC is responsible for regulating: (a) radiation risk produced by radioactive materials; (b) chemical risk produced by radioactive materials; and (c) plant conditions which affect the safety of radioactive materials and thus present an increased radiation risk. Occupational risks both from plant conditions that do not affect the safety of licensed materials and from substances prior to process addition to licensed material or after process separation from licensed material are not subject to NRC regulatory oversight; therefore, these risks are not required by Part 70 to be addressed in the ISA, ISA summary, or management measures (although addressing these risks is not required, the applicant could *choose* to include them in the ISA if, for example, the ISA is also used to comply with OSHA regulatory requirements).

Specific areas to be reviewed by the staff, for commitments to protect workers and the public, and address chemical process accident sequences in the application or ISA summary, include:

6. The narrative description of the site, facility, and processes with respect to chemical safety for normal operations. This applies to substances addressed in the *NRC-OSHA* MOU.

7. The description of the unmitigated accident sequences and the applicant's quantitative interpretation of the qualitative chemical risk levels.

8. The identification and description of the adequacy of items relied on for (chemical) safety.

9. The management measures to assure the reliability and availability of items relied on for (chemical) safety.

10. The grading of safety controls and assurances placed on such controls.

11. The interface between chemical process safety and management measures and emergency management.

12. Records for chemical process safety compliance and reporting commitments for chemical releases.

13. Use of chemical baseline design criteria for new facilities or new processes (as applicable).

6.4 ACCEPTANCE CRITERIA

An applicant who has met the following acceptance criteria, should be considered to have an acceptable chemical process safety function.

6.4.1 Regulatory Requirements

The regulatory basis for the review should be the general and additional contents of an application as required by 10 CFR 70.22 and 70.65. In addition, the chemical process safety review should be conducted to provide reasonable assurance of compliance with 10 CFR 70.61, 70.62, as well as 10 CFR 70.64, for new facilities or new processes.

6.4.2 Regulatory Guidance

Relevant regulatory guidance for chemical process safety includes:

1. NUREG/CR-6410, *"Nuclear Fuel Cycle Facility Accident Analysis Handbook"*, 1998.

2. NUREG-1513, *"Integrated Safety Analysis Guidance Document"*, latest revision.

3. NUREG-1601, *"Chemical Process Safety at Fuel Cycle Facilities",* 1997.

6.4.3 Regulatory Acceptance Criteria

Applicant's license application may address these criterion by reference to information supplied to satisfy SRP Section 3.0 (ISA) or other chapters of this SRP (information need not be repeated). The chemical safety reviewer reviews the application, ISA summary, and other ISA documentation as needed with respect to these acceptance criteria regardless of where the information appears. NRC should find the applicant's chemical process safety approach or function acceptable if license commitments provide chemical process safety for the workers, the public and the environment, and satisfy the following criteria:

6.4.3.1 Process Chemical Risk and Accident Sequences

The applicant provides an adequate process description that provides sufficient detail to allow an independent assessment of the chemical hazards and potential chemical accident sequences. This information should be included in the ISA summary. Additional criteria that should be addressed in an acceptable ISA summary are:

1. Process descriptions of sufficient detail are provided to support an understanding of chemical process hazards (including radiological hazards caused by or involving chemical accidents) and to allow development of potential accident sequences.

2. The applicant provides an adequate list of the consequences and likelihoods of accident sequences identified in the ISA summary involving hazardous chemicals produced from licensed material, and chemical risks produced by plant conditions that effect the safety of radioactive materials. Each accident sequence should include the chemical hazard evaluation that identifies potential interactions of process chemicals with associated

confinement vessels, process equipment, and plant personnel. The hazard evaluation should use appropriate, accepted methods.

3. The applicant identifies and uses appropriate techniques and valid assumptions in estimating the concentrations of hazardous chemicals produced from licensed material or predicting the "toxic" footprint for releases from abnormal plant condition that affects the safety of radioactive materials for comparison with the "Performance Requirements", as described in 10 CFR 70.61(b) and 70.61(c).

4. Source term and vapor dispersion models used to calculate the concentration of UF_6 and its reaction products conform to guidance on the applicability of models provided in NUREG/CR-6481, *Review of Models Used for Determining Consequences of UF_6 Release*.

5. If dispersion models are used to determine whether a release of chemicals might affect worker or public health and safety, the applicant provides evidence that the models used are appropriate to the application and that the assumed input data leads to a conservative estimate of potential consequences. Consequence analyses conform to the guidance on atmospheric and consequence modeling found in NUREG/CR-6410, *Nuclear Fuel Cycle Facility Accident Analysis Handbook*, 1998.

6. The applicant proposes appropriate chemical exposure standards to assess chemical consequences. Acceptable exposure standards include, but are not limited to, Emergency Response Planning Guidelines (ERPGs) established by the American Industrial Hygiene Association, Acute Exposure Guideline Levels (AEGLs) established by the National Advisory Committee for Acute Guideline Levels for Hazardous Substances, exposure limits established by the Occupational Safety and Health Administration or exposure limits contained in international standards organization (ISO) standards. If the applicant does not use a published exposure standard, or if a chemical has an unknown exposure standard, the applicant may propose an alternate exposure standard accompanied by supporting documentation to justify selection of such alternative. Note: 10 CFR 70.61, "Performance Requirements" are for "acute chemical exposures", and OSHA permissible exposure limits (PELS) are typically time weighted average (TWA) values. Consequently, for ISA purposes only, acute chemical release limits may not be adjusted using the TWA calculation where concentration and time of exposure are used, unless a rational basis is provided in the ISA summary.

6.4.3.2 Items Relied on for Safety and Management Measures

The application should identify the design basis that provides safety for normal operations. A description could include specified features such as materials of construction, sizing, system fabrication, and process control schemes. Based upon a comparison of the unmitigated chemical consequences determined in 6.4.3.1 above, to the standards developed, in accordance with §70.61, the applicant should identify (in the ISA summary) chemical process safety controls (i.e., items relied on for safety) suitable to prevent or mitigate potential accidents. Items relied on for safety also should be identified for those accident sequences containing a chemical system/process failure that ultimately lead to radiological consequences that exceed the performance requirements (basis: MOU item (c)). Management measures to assure the availability and reliability of such items relied on for safety when they are required to perform their

safety functions must also be described in the application. With respect to chemical safety, acceptability of the application and ISA summary should be based upon the degree to which each satisfies the following criteria.

1. The application should describe the engineering approach, basis or schemes employed for maintaining safety in normal operations.

2. The ISA summary includes the following information: identification of the administrative and engineered controls to prevent or mitigate chemical process risks and the risk category. If applicable, the applicant should also explain how the controls and management measures have been graded commensurate with the reduction in risk that the controls are designed to achieve.

3. The application should describe the management measures proposed to assure items relied on for safety are available and reliable when required by satisfying the following criteria:

   a) Engineered Controls: procedures to ensure the reliable operation of engineered controls should be briefly described (e.g., inspection and testing procedures and frequencies, calibration programs, functional tests, corrective and preventive maintenance programs, criteria for acceptable test results, etc.)

   b) Administrative Controls: procedures to ensure that administrative controls will be correctly implemented when required should be briefly described (e.g., employee training an qualification in operating procedures, periodic retraining, safety work practices, development of standard operating procedures, training program evaluation, etc.)

6.4.3.3 Requirements for New Facilities or New Processes at Existing Facilities

The application should address the baseline design criteria (BDC) for new facilities or new processes at existing facilities. NUREG-1601,Section 2.4, Design Basis, contains a list if items that should be considered in an adequate facility design. With respect to chemical safety, acceptability of the application should be based upon it providing the following information:

A. A brief description of how the ISA was performed for the new process, including it's use and relationship to the performance requirements in 10 CFR 70.61, the BDC, and a defense-in-depth strategy for higher-risk accident sequences. Acceptable principles for defense-in-depth of the chemical design would be those that support hierarchy of controls with preference for prevention, mitigation, and operator intervention (in that order). For example, limiting inventory of on-site chemicals would be a preferred, preventive practice for limiting chemical safety-related accidents.

B. The descriptions of proposed facility-specific or process-specific relaxations or additions to BDC along with justification for relaxation.

C. In the ISA summary a description of how the chemical safety BDC were applied in establishing the design principles, features, and control systems of the new process.

6.5 REVIEW PROCEDURES

The reviewer should use the Regulatory Guidance stated in this chapter; references in this chapter; the applicant's 91-01, 70.50, and 70.74 reports; and 10 CFR Part 70 Appendix A reporting requirements.

6.5.1 Technical Review

The Primary Reviewer should review the applicant's chemical process safety information for completeness with respect to the requirements in 10 CFR 70.22, 70.24, 70.61, 70.62, 70.65 and the Acceptance Criteria in Section 6.4. Using guidance in the "FCLB Materials Licensing Procedures Manual," if deficiencies are identified, the applicant should either be requested to submit additional material, or the application should be denied for further safety evaluation under section 6.5.2..

6.5.2 Safety Evaluation

When an acceptable application is received from the applicant, the primary reviewer will conduct a complete review of the application and determine its acceptability, consulting with the supporting reviewers to identify and resolve any issues of concern related to the licensing review. The primary reviewer (acting as a secondary or supporting reviewer) should also coordinate with other reviewers concerning chemical safety regarding the following:

1. In support of the Primary Reviewer for Chapter 2.0, the chemical process safety reviewer should determine whether the Acceptance Criteria in Chapter 2.0 have been met as they relate to chemical process safety.

2. In support of the Primary Reviewer for Sections 11.1 through 11.8, the chemical process safety reviewer should determine whether the Acceptance Criteria in Sections 11.1 through 11.8 have been met as they relate to chemical process safety.

3. In support of the Primary Reviewer for Chapter 3.0, the chemical process safety reviewer should determine whether the Acceptance Criteria in Chapter 3.0 have been met as they relate to chemical process safety.

4. In support of the Primary Reviewer for Chapter 8.0, the chemical process safety reviewer should determine whether the Acceptance Criteria in Chapter 8.0 have been met as they relate to chemical process safety.

The Primary Reviewer should determine whether the Acceptance Criteria in Section 6.4 have been met using the review procedures in the following sections, then the reviewer should prepare the SER NCS chapter in accordance with Section 6.6

The applicant is not required to duplicate information in separate locations. For existing licensees (renewals and amendments) the chemical safety reviewer should interface with the fuel cycle facility inspection staff to obtain any insights particular to the applicant's operations that are relevant to the chemical process safety review.

6.5.2.1 Process Chemical Risks and Accident Sequences

The staff reviews the chemical risks identified in the ISA Summary against acceptance criteria in 6.4.3.1. The applicant's process safety information is reviewed and compared to the acceptance criteria in SRP Chapter 3.0, ISA. Verification of selected chemical, and physical properties and chemical incompatibilities may require the use of engineering and chemistry handbooks. NUREG-1601 may be used to determine if the safety information provided by the applicant is adequate for chemical process safety purposes.

The reviewer will make an independent judgment of the comparative risks assigned by the applicant to accident sequences identified in the ISA summary based on risk relative to other sequences (competing risks), the complexity of the sequence, plant operating history, and general industry performance. The focus will be on sequences which would exceed the performance requirements of 70.61 if they were not mitigated or prevented by one or more items relied on for safety. The review may encompass examination of a selected number of lower risk chemical safety-related accident sequences not contained in the ISA summary to validate the risk threshold criteria used by the applicant in assigning sequences to the ISA summary.

6.5.2.2 Items Relied on for Safety and Management Measures

The staff reviews the chemical process safety controls to ensure that adequate controls have been identified and will be reliable and available in accordance with criteria in 6.4.3.2. The review assures the adequacy of controls for all unmitigated sequences identified in the ISA. The chemical process safety review should be coordinated with the ISA (SRP Section 3.0), Nuclear Criticality Safety (SRP Section 5.0), Fire Safety (SRP Section 7.0), Emergency Management (SRP Section 8.0), Environmental Protection (SRP Section 9.0) and Management Measures (SRP Section 11.0) reviewers to achieve thoroughness.

For items relied on for safety the applicant should apply the graded approach, i.e. provide controls or management measures commensurate with risk. For example, the applicant should consider reliance on passive controls over active systems and consider defense-in-depth. To reduce common mode failures, the applicant should favor design features that utilize independent sources of motive force for items like: control actuators, jet pumps, eductors, and ejectors. Fail-safe controls are preferred unless safety concerns preclude this approach. The graded approach should also be applied to management measures.

If procedures are used by an applicant as an item relied on for safety for higher risk accident sequences, verify for chemical process safety that the applicant identifies the importance of procedure adherence for both worker and/or public safety. Verify the same for alarm response procedures that require operators to initiate actions to prevent or mitigate any higher risk accident sequences.

6.5.2.3 Requirements for New Facilities or New Processes at Existing Facilities

The staff reviews information required in 6.4.3.3 Acceptance Criteria, using the review methods in 6.5.2.1 and 6.5.2.2.

When the safety evaluation is complete, the staff reviewer documents the safety review in a Safety Evaluation Report (SER) for chemical process safety, as described in section 6.6.

6.6 EVALUATION FINDINGS

The reviewer verifies that the information submitted by the applicant is in accordance with 10 CFR Part 70. In the staff's Safety Evaluation Report (SER), the reviewer documents the basis for determining the adequacy of the application with respect to chemical process safety. The reviewer also describes the applicant's approach to ensuring the availability and reliability of the controls. Based on the review of the application, statements and conclusions of the following type should be included in the staff's draft SER as appropriate:

> Based on the review of the license application, the NRC staff concluded that the applicant has adequately described and assessed accident consequences with significant chemical consequences that could result from the handling, storage, or processing of special nuclear material. A hazard analysis has been conducted that identified and evaluated those chemical process hazards and potential accidents and established safety controls to ensure safe facility operation. To ensure that the limits in 10 CFR Part 70 are met, the applicant will ensure that controls are maintained available and reliable when required to perform their safety functions. The staff has reviewed these safety controls and the applicant's plan for managing chemical process safety and finds them acceptable.
>
> The staff concludes that the applicant's plan for managing chemical process safety and the chemical process safety controls meet the requirements of 10 CFR Part 70, and provide reasonable assurance that the health and safety of the public will be protected.

In cases where the SER is drafted in advance of resolving all outstanding chemical process safety issues, the reviewer documents the review as described above and includes a list of open issues that require resolution prior to the staff finding of reasonable assurance. For partial reviews, revisions, and process changes, the reviewer will use applicable sections of the acceptance criteria and the SER will be written to reflect what portions were not reviewed and the chemical process safety significance, if any. Upon completion of the review, NRC staff may impose temporary or one-time license conditions to authorize short duration activities. For certain functions and requirements that concern safety or regulatory issues, a license condition may be imposed and remain in effect until removed by an amendment or license renewal.

6.7 REFERENCES

Chemical Manufacturers Association, *"Responsible Care®, Process Safety Code of Management Practices"*, Washington, 1990.

Center for Chemical Process Safety, *"Guidelines for the Technical Management of Chemical Process Safety"*, American Institute of Chemical Engineers, New York, 1989, Chapter 11, as revised.

Code of Federal Regulations, Title 10, Part 70*, "Domestic Licensing of Special Nuclear Material"*, U.S. Government Printing Office, Washington, D.C., as revised.

Code of Federal Regulations, Title 29, Part 1910.119, *"Process Safety Management of Highly Hazardous Chemicals"*, U.S. Government Printing Office, Washington, D.C., as revised.

Manual Chapter 2603, *"Inspection of the Nuclear Chemical Process Safety Program at Fuel Cycle Facilities"*, as revised.

Memorandum of Understanding between the Nuclear Regulatory Commission and the Occupational Safety and Health Administration, "*Worker Protection at NRC-Licensed Facilities",* Federal Register No. 53, October 31, 1988.

NUREG/CR-6410, *"Nuclear Fuel Cycle Facility Accident Analysis Handbook"*, 1998.

NUREG-1601, *"Chemical Process Safety at Fuel Cycle Facilities"*, 1997.

NUREG/CR-6481, *"Review of Models Used for Determining Consequences of UF_6 Release"*, as revised.

U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

7.0 FIRE SAFETY

7.1 PURPOSE OF REVIEW

The purpose of this review is to determine with reasonable assurance that an applicant has appropriately analyzed the fire and explosion risks, which could effect the safety of licensed materials and thus present an increased radiological risk, and provided mitigative systems and controls to protect the workers, the public health and safety, and the environment.

7.2 RESPONSIBILITY FOR REVIEW

Primary: Fire Protection Reviewer

Secondary: Criticality Reviewer
Environmental Reviewer
Chemical Safety Reviewer
Physical Security Reviewer

Supporting: Region or Fuel Facility Inspection Staff and Resident Inspector

7.3 AREAS OF REVIEW

The regulation, 10 CFR 70.62, requires that each licensee establish and maintain a safety program that demonstrates compliance with the performance requirements in §70.61. A separate fire safety program is not required, however, the licensee shall demonstrate that the facility's safety function includes the following (as appropriate):

Fire Safety Management: This includes safety organization, engineering review, fire prevention, inspection, testing, and maintenance, prefire plans, and qualifications, drills, and training.

Fire Risk Identification: This includes a Fire Hazards Analysis (FHA) and an Integrated Safety Analyses (ISA).

Facility Design: This includes information on building construction, fire areas, life safety, ventilation, and electrical system design. Consideration of competing requirements among fire safety and security, criticality, and environmental concerns should be accounted for.

Process Fire Safety: This involves design consideration to prevent an accident or mitigate the consequences from using process chemicals, combustible metals, flammable and combustible liquids and gasses, high temperature equipment, hot cells and glove boxes, and laboratories.

Fire Protection Systems: This includes the specified application of fire detection, alarm, and suppression systems, portable extinguishers, water supply, and emergency response organization.

7.4 ACCEPTANCE CRITERIA

An applicant that has met the following acceptance criteria, or has provided an acceptable alternative, should be considered to have an acceptable fire safety function.

7.4.1 Regulatory Requirements

The regulatory basis for the review should be the general and additional contents of an application as required by 10 CFR 70.22 and 70.65. In addition, the fire safety review should be conducted to provide reasonable assurance of compliance with 10 CFR 70.61, 70.62, and 10 CFR 70.64 for new facilities or new processes.

7.4.2 Regulatory Guidance

Relevant regulatory guidance for fire safety includes:

5) NUREG/CR-6410, *"Nuclear Fuel Cycle Facility Accident Analysis Handbook,"* 1998.

6) NUREG-1513, *"Integrated Safety Analysis Guidance Document."* latest edition.

7.4.3 Regulatory Acceptance Criteria

The acceptability of the application and the ISA summary will be based on the NRC staff's review of the applicant's commitments to control and mitigate fire hazards. The staff will focus on an application that is risk informed, has addressed maintaining an acceptable level of nuclear safety, and demonstrates that an applicant is prepared to react quickly and safely to extinguish fires when they occur. An applicant may use a graded approach for defining fire safety, but sufficient documentation and commitments must be made to assure the protection of workers, the public, and the environment from fire events.

These criteria may be incorporated in the information supplied to satisfy SRP Section 3.0 (ISA) or other sections of this SRP with references provided (information need not be repeated). The fire safety reviewer reviews the application, ISA summary and other ISA documentation as needed with respect to these acceptance criteria regardless of where the information appears.

Nationally recognized codes and standards are used to assure fire safety. These include, but are not limited to, the National Fire Protection Association (NFPA) National Fire Codes, Factory Mutual (FM) Data Sheets and Approval Guide, Underwriters Laboratories (UL) Standards and Building Material Directory, American National Standards Institute (ANSI) Standards, and American Society for Testing Materials (ASTM) Standards. The NRC staff will review the application against the following acceptance criteria:

7.4.3.1 Fire Safety Management Measures

An adequate application documents how fire safety is administered and assured at the licensed facility. The application should reflect a commitment to assure the items relied upon for safety as identified in the Integrated Safety Analysis (ISA) summary, Section 3.0, are available and reliable, fire safety awareness among employees is maintained, transient ignition sources and combustibles are controlled, and the facility maintains a readiness to extinguish or limit the consequences of fire. The application will be reviewed by a staff fire protection engineer and will address fire safety management measures. These measures are unique to fire safety and are therefore not included in the acceptance criteria for SRP Section 11, Management Measures.

An adequate application identifies a senior level manager who has the authority and staff to ensure that fire safety receives appropriate priority. A Plant or Fire Safety Review Committee staffed by different discipline managers should integrate plant modifications. Day-to-day supervision of fire safety should be by an individual with sufficient practical fire safety experience (that is described in the application) in nuclear facilities.

The Standard for Fire Protection for Facilities Handling Radioactive Materials, NFPA 801, specifies the following fire safety management measures: fire prevention, inspection, testing, and maintenance of fire protection systems, emergency response organization qualifications, drills, and training, and prefire plans. An adequate application documents the fire safety management measures in sufficient detail to identify their relationship to, and functions for, normal operations, anticipated (off-normal) events, and accident safety (i.e., items relied on for safety).

7.4.3.2 Fire Risk Analysis

Knowing the fire risk allows a licensee to apply the appropriate level of fire protection to assure the safety of workers, the public, and the environment. To be risk informed, a licensee should conduct Fire Hazards Analyses (FHA) for high risk facilities. The FHA should develop bounding credible fire scenarios for each process fire area with significant fire loading, then assess or model the consequences of an unmitigated fire. NFPA 801 provides further guidance that is acceptable to the NRC staff for conducting FHAs. With respect to fire safety, the ISA summary is acceptable if the credible facility fire hazards (e.g., from the FHA) are identified for each process area, and information is provided detailing how that fire hazard was considered and addressed (i.e., the management measures and/or items relied on for safety) for each process such that the performance requirements in §70.61 are satisfied. A summary of the FHA is acceptable if it includes a description, by fire area, of the fuel loading, fire scenarios, methods of consequence analysis, the consequences, and a description of the mitigative controls.

7.4.3.3 Facility Design

NFPA 801 specifies facility design considerations that are acceptable to the NRC staff. Building construction, fire area determination, electrical installation, life safety, ventilation, drainage, and lightning protection are a few of the areas covered. An adequate application documents the fire safety considerations used in the general facility design of the licensed facilities. The following are other specific areas of concern:

Criticality: Criticality concerns may exclude water extinguishing systems from process areas. However during major fire events, the fire may overcome the extinguishing capability of portable extinguishers and hose lines may be needed. Consideration should be given to total flooding gaseous systems in water exclusion areas with significant fire risks. An adequate application should address the methodology used for extinguishing fires in water exclusion areas. The staff's fire safety and criticality specialist will review for adequacy.

Environmental Concerns: Thousands of gallons of fire water can be contaminated with nuclear material during a fire event. Diked areas and drainage of process facilities need to be properly sized to accommodate this run-off. The amount of runoff can be calculated using guidance in NFPA 801. An adequate application documents fire water run-off containment. The staff's fire safety and environmental specialists will review for adequacy.

Physical Security Concerns: Buildings and facilities should be designed to provide safe egress in the event of a fire, chemical, or radiological emergency. Physical security of SNM may inadvertently institute controls that delay worker egress and fire fighter access. Physical security procedures need to allow off-site fire departments quick and efficient access to the fire emergency. NFPA 801 specifies design features acceptable to the NRC and an adequate application documents the criteria used for worker egress and procedures for firefighter access. The staff's fire safety and physical security specialists will review for adequacy.

7.4.3.4 Process Fire Safety

Many hazardous chemicals used by fuel cycle facilities contribute to the fire hazard. The licensee should identify these chemicals and their effect on fire safety. In fire areas containing radiological material, NFPA 801 provides design criteria that is acceptable to the NRC staff for laboratories, high temperature equipment, hots cells, and glove boxes. The staff's fire safety and chemical safety specialists will review the application for adequacy.

The following are a few of the more common hazardous substances used at fuel cycle facilities:

Anhydrous Ammonia: Explosive, flammable, and toxic gas used to make hydrogen.
Fluorine: Reacts violently with organic material or metal powders and water vapor.
Hydrogen: Explosive and flammable gas used in reduction processes.
Hydrogen Peroxide: Off-gases hydrogen and oxygen, incompatible with some extinguishers.
Nitric Acid: Nitrates organic material, lowering the ignition temperature of combustibles.
Sulfuric Acid: Absorbs water from organic material in an exothermic reaction, causing ignition.
Zirconium: Combustible metal that burns at elevated temperatures.

7.4.3.5 Fire Protection and Emergency Response

The application should document the fire detection, alarm, and suppression systems and emergency response organizations provided for licensed facilities. The ISA summary (see SRP Section 3.0) should identify and list the items relied upon for fire safety. NFPA 801 provides criteria that is acceptable to the NRC staff for the design, installation, testing, and maintenance of the fire protection systems and the requirements for an effective emergency response organization. An adequate application should describe the fire protection provided in all process areas.

Facilities with significant fire risks may need a fire emergency response team in accordance with NFPA 600, “Industrial Fire Brigades.” If the off-site fire department is depended upon for plant safety, periodic training with the fire department is necessary to become familiar with facility access procedures, plant layout, and pre-fire plans. A memorandum of understanding (MOU) between the applicant and the fire departments may be necessary to define the protection required.

7.5 REVIEW PROCEDURES

7.5.1 Acceptance Review

During the acceptance review, the primary reviewer evaluates the application for completeness as required by 10 CFR Part 70 regarding fire safety for fuel cycle facilities and whether necessary criteria discussed in Section 7.3 “Areas of Review,” have been addressed. If significant deficiencies are identified in the application, the application should be returned or additional information should be requested before the start of the safety evaluation.

7.5.2 Safety Evaluation

During the Safety Evaluation, the primary and secondary reviewers evaluate the adequacy of the application to comprehensively describe the fire safety of the licensed activity as covered in Section 7.3 “Areas of Review” and the commitments made to the criteria specified in Section 7.4 “Acceptance Criteria.” The staff may request the applicant or licensee to provide additional information or modify the submittal to meet the acceptance criteria.

Reviewers should note that NFPA 801 uses "administrative control" in a different sense than Part 70 and elsewhere in this SRP. In Part 70 an administrative control, which is a subset of items relied on for safety, is the human action necessary to meet safety performance requirements. It is supported by management measures (training, QA, procedures, ...) that ensure the action will be taken if needed. In NFPA 801, administrative controls are the training, qualifications, procedures, etc. behind the human action. These elements are "Management Measures" in Part 70.

7.6 EVALUATION FINDINGS

The staff’s review should verify that sufficient information has been provided in the license application to satisfy the intent of 10 CFR Part 70 requirements relating to the overall safety program and is consistent with the fire safety criteria in this SRP. On the basis of this information, the staff should be able to evaluate the application in meeting the appropriate criteria. The staff will document the fire safety review as follows.

The applicant has established a Fire Protection Program meeting the acceptance criteria of the SRP. The program includes a Plant Safety Review Committee responsible for integrating modifications to the facility and a Fire Safety Manager responsible for the day to day program implementation. Fire prevention, inspection, testing, and maintenance of fire protection systems, and the qualification, drills, and training of plant personnel are in accordance with

applicable NFPA codes and standards. (Note: fire protection training requirements may be described in this section of the SRP or in SRP Section 11.3)

The applicant has conducted risk analysis in accordance with NFPA 801. The FHAs identified credible fire scenarios that bound the fire risk. The ISA used these scenarios and identified fire protection items important to safety. In particular, wet pipe sprinkling the process areas, isolating high temperature equipment within fire barriers, and a fire brigade meeting NFPA 600. An MOU with the fire department documents the protection required and the annual exercises. Procedures are in-place to allow efficient access by the fire department to plant process areas during fire emergencies.

Accordingly, the staff concludes that the applicant's description of fire safety complies with applicable NRC regulations and industry standards and can be implemented for the specific phases identified in the facility application.

7.7 REFERENCES

Code of Federal Regulations, 29 CFR 1910, “Occupational Safety and Health Standards.”

National Fire Protection Association, “National Fire Codes.”

U.S. Nuclear Regulatory Commission, Information Notice No. 92-14, ”Uranium Oxide Fires at Fuel Cycle Facilities,” February 21, 1992.

U.S. Nuclear Regulatory Commission, Information Notice No. 97-23, ”Evaluation and Reporting of Fires and Unplanned Chemical Reaction Events at Fuel Cycle Facilities,” May 7, 1997.

8.0 EMERGENCY MANAGEMENT

8.1 PURPOSE OF REVIEW

The review should determine if the applicant has established, before the start of operations, adequate emergency management facilities and procedures to protect the public, the workers, and the environment.

An emergency plan is required when an evaluation shows that the maximum dose to a member of the public offsite due to a release of radioactive materials would exceed 1 rem (0.01 Sv) effective dose equivalent. This section applies to facilities authorized to possess enriched uranium (U) or plutonium (Pu) for which a criticality accident alarm system is required, uranium hexafluoride (UF_6) in excess of 50 kg (110 lb) in a single container or 1000 kg (2200 lb) total, or in excess of 2 Ci of Pu in unsealed form or on foils or plated sources.

Emergency capability is incorporated into the baseline design criteria (BDC) of 10 CFR Part 70, as revised, and is intended to ensure control of licensed material, evacuation of personnel, and availability of emergency facilities.

8.2 RESPONSIBILITY FOR REVIEW

Primary: Assigned FCLB staff

Secondary: Licensing Project Manager

Supporting: Regional Emergency Preparedness Inspector
ISA Reviewer
Fuel Facility Inspection staff

8.3 AREAS OF REVIEW

The NRC staff should review the applicant's submittal for an acceptable level of evidence of planning for emergency preparedness directed at situations involving real or potential radiological hazards. The review should address those design features, facilities, functions, and equipment that may affect some aspect of emergency planning or the capability of an applicant to cope with plant emergencies. In addition, the review should address coordination with offsite organizations. The staff should either review the emergency plan made in accordance with 10 CFR 70.22(i)(1)(ii) and with the guidance contained in the acceptance criteria below, or should

review the applicant's evaluation that an emergency plan is not needed in accordance with 10 CFR 70.22(i)(1)(i).

The NRC staff reviewer should address the material presented, as described below.

8.3.1 Evaluation That No Emergency Plan is Required

If the applicant submits an evaluation, to demonstrate that an emergency plan is not required, the staff should review the evaluation against 10 CFR 70.22(i)(1)(i), and NUREG-1140, "A Regulatory Analysis of Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees." NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook," also contains useful information. Areas to be evaluated should include the following:

1. A description of the facility,
2. Types of materials used, including both radioactive material and hazardous chemicals,
3. Types of accidents,
4. Detection of accidents,
5. Site specific information used to support the evaluation, and
6. An evaluation of the consequences, both onsite and offsite, of accidents including radioactive and hazardous chemicals. The evaluation shows that the maximum dose to a member of the public offsite due to a release of radioactive materials would not exceed 1 rem (0.01 Sv) effective dose equivalent or an intake of 2 milligrams of soluble uranium in accordance with 10 CFR 70.22(i)(1)(i).
7. The evaluation should address one or more of the factors provided in 10 CFR 70.22(i)(2).

8.3.2 Emergency Plan

If the applicant submits an emergency plan, the staff should evaluate the emergency management program against 10 CFR 70.22(i)(1)(ii) and Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," which provides a standard format and content for an emergency plan. Elements in the emergency plan to be reviewed should include the following:

1. Facility description (including both onsite and offsite emergency facilities),
2. Types of accidents,
3. Classification of accidents,
4. Detection of accidents,
5. Mitigation of consequences (and safe shutdown),
6. Assessment of releases (both radioactive materials and hazards chemicals),
7. Responsibilities of licensee,
8. Notification and coordination,
9. Information to be communicated and parties to be contacted,
10. Training,
11. Safe shutdown (recovery and plant restoration),
12. Exercises (and drills),
13. Hazardous chemicals inventories and locations, and
14. Responsibilities for developing and maintaining the emergency program and its procedures.

8.4
ACCEPTANCE CRITERIA

8.4.1 Regulatory Requirements

10 CFR Part 70.22(i)(1)(i) specifies when an emergency plan does not have to be submitted to the NRC and, if an emergency plan is required to be submitted, 10 CFR Part 70.22(i)(3), contains the information that must be included in the emergency plan.

10 CFR Part 70.64(a)(6) requires that applicants address the control of licensed material, evacuation of personnel, and availability of emergency facilities for the design of new facilities.

8.4.2 Regulatory Guidance

Regulatory guidance for preparing an emergency plan includes:

1. Regulatory Guide 3.67, "*Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities,"* January 1992.

2. NUREG-1140, “A Regulatory Analysis of Emergency Preparedness for Fuel Cycle and Other Radioactive Materials,” January 1988.

3. NUREG/CR-6410, “Nuclear Fuel Cycle Facility Accident Analysis Handbook,” 1998.

8.4.3 Regulatory Acceptance Criteria

8.4.3.1 Evaluation That No Emergency Plan Is Required

The adequacy of the evaluation that no emergency plan is required should be evaluated by the reviewer against the requirements in 10 CFR Part 70.22(i)(2), and the specific criteria given in the following sections of the SRP. This evaluation should be acceptable if the regulatory requirements and the following criteria are met:

8.4.3.1.1 Facility Description

The evaluation includes a description of the facility and site, the area near the site, and the licensed activities conducted at the facility sufficient to support the evaluation. The description includes the following:

1. A detailed drawing of the site showing (1) onsite and near offsite (within 1 mile) structures with building numbers and labels, (2) roads and parking lots onsite and main roads near the site, (3) site boundaries, showing fences and gates, (4) major site features, (5) water bodies within approximately 1 mile, and (6) the location(s) of nearest residents.

2. The stack heights, typical stack flow rates, and the efficiencies of any emission control devices.

3. A general description of licensed and other major activities conducted at the facility, and the type, form, and quantities of radioactive and other hazardous material normally onsite.

8.4.3.1.2 Types of Accidents

The evaluation describes each type of accident identified by the ISA that has the maximum offsite consequences exceeding the limit of 10 CFR 70.22(i)(1)(i). The description includes:

1. The process and physical location where it could occur,

2. Complicating factors and possible onsite and offsite consequences, including non-radioactive hazardous material released,

3. The accident sequence that has the potential for the greatest radiological and toxic chemical impact.

8.4.3.1.3 Detection of Accidents

The evaluation described for each type of accident identified the following:

1. The means of detecting the accident,

2. The means of detecting any release of radioactive or other hazardous material,

3. The means of alerting the operating staff, and

4. The anticipated response of the operating staff.

8.4.3.1.4 Evaluation of Maximum Public Exposure

In order to demonstrate that no emergency plan is required, an applicant may either (1) request that its total possession limit for radioactive material be reduced below the emergency plan threshold in 10 CFR 70.22(i)(1), or (2) perform a site specific evaluation that demonstrates maximum public exposure is less than the limits in 70.22(i)(1)(i).

The evaluation should include a description of the following information sufficient to allow for independent verification:

1. Type of accident (e.g., fire, exposure, chemical release, nuclear criticality),
2. Location of accident,
3. Maximum source term,
4. Solubility of material,
5. Facility design or engineered safety features in the facility and the proposed release fraction,

6. Location and distance of nearest member of the public to the facility,
7. Dose model used and the process used to verify the reliability of the model and validity of the assumptions,
8. Assumed worst case weather condition, and
9. Maximum calculated dose to a member of the public at the facility boundary.

The evaluation should include a list and a description of the factors in 10 CFR 70.22(i)(2) considered in evaluating maximum dose to members of the public. The applicant should demonstrate why the factors used in the evaluation are appropriate when compared to the factors in NUREG-1140. If the factors and evaluation show that the maximum dose to a member of the public offsite due to a release of radioactive materials could not exceed 1 rem (0.01 Sv) effective dose equivalent or the intake of soluble uranium of 2 milligrams, no emergency plan is required in accordance with 10 CFR 70.22(i)(1)(i).

8.4.3.2 Emergency Plan

The adequacy of the proposed emergency plan should be evaluated by the reviewer against the requirements in 10 CFR Part 70.22(i)(3), and the specific criteria given in the following sections of the SRP. The applicant's emergency plan should be acceptable, if the regulatory requirements and the following criteria are met:

8.4.3.2.1 Facility Description

8.4.3.2.1.1 Operational Facilities

The emergency plan should include a description of the facility and site, the area near the site, and the licensed activities conducted at the facility sufficient to support emergency management activities. The description should include the following:

1. A detailed drawing of the site showing:

   a. onsite and near offsite (within 1 mile) structures with building numbers and labels,
   b. roads and parking lots onsite and main roads near the site,
   c. site boundaries, showing fences and gates,
   d. major site features, and
   e. water bodies within approximately 1 mile.

2. A general area map (approximately 16.09 km [10-mile] radius), a United States Geological Survey topographical quadrangle (7 ½ minute series; including the adjacent quadrangle(s) if site is located less than 1.609 km (1 mile) from the edge of the quadrangle), and a map or aerial photograph indicating onsite structures and near-site structures (about 1.609 km [1-mile] radius). The map should include the location of sensitive facilities near the site such as hospitals, schools, nursing homes, nearest residents, fire department, prisons, and environmental sampling locations, and other structures and facilities important to emergency management.

3. The stack heights, typical stack flow rates, and the efficiencies of any emission control devices.

4. A general description of licensed and other major activities conducted at the facility, and the type, form, and quantities of radioactive and other hazardous materials normally onsite, by location (use and storage) and building, and hazardous characteristics (exposure rates, pH, temperature, and other characteristics) important to emergency management.

5. Certification that the applicant has met responsibilities under Emergency Planning and Community Right To Know Act of 1986, Title III, Public Law 99-499, in accordance with 10 CFR 70.22(i)(3)(xiii).

8.4.3.2.2 Onsite and Offsite Emergency Facilities

The emergency plan should include a list and description of onsite and offsite facilities that could be relied upon in the event of an emergency. The description should include the following:

1. A list and description of both onsite and offsite emergency facilities by location and purpose of the facility.

2. A description of emergency monitoring equipment which is available for personnel and area monitoring, as well as that for assessing the release of radioactive or hazardous materials to the environment.

3. A description of the onsite and offsite services which support emergency response operations. The following are included:

   a. decontamination facilities,
   b. medical treatment facilities,
   c. first aid personnel,
   d. fire fighters,
   e. law enforcement assistance, and
   f. ambulance services.

4. In addition, the applicant should have emergency facilities, equipment, and resources, which are ready to support emergency response operations, including the following:

   a. Facilities of adequate size and appropriate location that are designated, equipped, and ready for emergency use,

   b. Adequate backup facilities required by the emergency plan and supporting documents that are available and ready for use,

   c. Appropriate equipment and supplies necessary to support emergency response activities that are accessible during accident conditions,

   d. Emergency equipment that is inventoried, tested, and serviced on a periodic basis to ensure accountability and reliability,

   e. Sufficient reliable primary and backup communications channels that are available to accommodate emergency needs,

f. Offsite emergency resources and services that are identified, and are ready to ensure their timely mobilization and use,

g. Operational engineering information, such as current as-built drawings and procedures, that are readily available in the emergency facilities,

h. Sufficient equipment for personnel protection and monitoring, and

i. Systems in place to alert onsite and offsite personnel in the event of an emergency.

8.4.3.2.3 Types of Accidents

The emergency plan should include a description for each accident identified by the ISA for which protective actions may be needed. The description should include:

1. The process and physical location(s) where the accidents could occur,

2. Complicating factors and possible onsite and offsite consequences, including nonradioactive hazardous material releases that could impact emergency response efforts,

3. The accident sequence that has the potential for the greatest radiological and toxic chemical impact, and

4. Figure(s) projecting dose and toxic substance concentration as a function of distance and time for various meteorological stability classes.

8.4.3.2.4 Classification of Accidents

1. The emergency plan classification system should include the following two classifications:

   - "Alert": Events that may occur, are in progress, or have occurred that could lead to a release of radioactive material or hazardous chemicals incident to the process, but the release is not expected to require a response by an offsite response organization to protect persons offsite.

   - "Site area emergency": Events that may occur, are in progress, or have occurred that could lead to a significant release of radioactive material or hazardous chemicals incident to the process that could require a response by offsite emergency response organizations to protect persons offsite.

2. For each accident in the emergency plan, the classification (alert or site area emergency) that is expected for each accident is identified.

3. The emergency plan should specify emergency action levels (EALs) at which an alert or site area emergency will be declared. EALs are specific conditions that require emergency response measures to be performed. The applicant's EALs are consistent with Appendix A of Regulatory Guide 3.67 and are compared with the Environmental Protection Agency's Protective Action Guides (EPA 400-R-92-001, May 1992 Revision). Transportation accidents more than 1 mile from the facility are not classified.

4. The emergency plan should designate the personnel positions and alternates with the responsibility for accident classification during normal and back shift hours.

8.4.3.2.5 Detection of Accidents

The emergency plan should describe, for each type of accident identified, the following:

1. The means of detecting the accident,

2. The means of detecting any release of radioactive or other hazardous material,

3. The means of alerting the operating staff, and

4. The anticipated response of the operating staff.

8.4.3.2.6 Mitigation of Consequences

1. The emergency plan should describe for each accident identified, adequate measures and equipment for safe shutdown and for mitigating the consequences to workers onsite and offsite as well as to the public offsite.

2. For impending danger from an accident initiator, the application should describe the following:

   a. The criteria that will be used to determine whether a single process or the entire facility will be shut down,

   b. The steps that will be taken to ensure a safe orderly shutdown of a single process or the entire facility,

   c. The approximate time required to accomplish a safe shutdown of processes, and

   d. The compensatory measures required for safety during the shutdown period following an accident.

8.4.3.2.7 Assessment of Releases

1. The emergency plan should describe the applicant's procedures to be used to promptly and effectively assess the release of radioactive material or hazardous chemicals associated with the processing of radioactive material. The description includes:

a. The procedures for estimating or measuring the release rate or source term,

b. Valid computer codes used to project doses or concentrations to the public or environment and associated assumptions, along with adequate justifications to show the validity of the assumptions,

c. The types, methods, frequencies, implementation time, and other details of onsite and offsite sampling and monitoring that will be performed to assess a release of radioactive material or hazardous chemicals, and

d. Method for assessing collateral damage to the facility, especially safety controls.

2. The emergency plan should describe the applicant's procedure for validating any code used to assess releases of radioactive material or hazardous chemicals.

8.4.3.2.8 Responsibilities

The emergency plan should describe the emergency response organization and administration which ensures effective planning, implementation, and control of emergency preparedness activities and meet the following criteria:

1. The organizational structure and chain of command are clearly defined,

2. Staffing and resources are sufficient to accomplish assigned tasks,

3. Responsibilities and authority for each management, supervisory, and professional position are clearly defined. Responsibility is assigned for the coordination of onsite and offsite radiation/hazardous material emergency response preparedness,

4. Interfaces with supporting groups, both onsite and offsite, are clearly defined,

5. Mutual cooperation agreements exist with local agencies such as fire, police, ambulance/rescue, and medical units,

6. Plant management measures include audit and assessment (SRP Section 11.5) of emergency preparedness to ensure site readiness to handle emergencies and to identify and correct problems,

7. The onsite emergency response organization as described provides reasonable assurance of effective command and control of the site during the assessment, mitigation, and recovery phase of an accident,

8. The emergency public information staff provides advance and ongoing information to the media and public on subjects that would be discussed during an emergency, such as radiation hazards, chemical hazards, site operation, and site emergency plans, and

9. The schedule of emergency preparedness procedure development provides for availability of procedures to support start-up and operation of new processes/facilities onsite.

8.4.3.2.9 Notification and Coordination

1. The emergency plan should provide reasonable assurance that emergency notification procedures will enable the emergency organization to correctly classify emergencies, notify emergency response personnel, and initiate or recommend appropriate actions in a timely manner, based on the following:

   a. Classification of emergency events are based on the current emergency plan.

   b. Notification procedures minimize distractions of shift operating personnel and include concise, preformatted messages. Appropriate follow-up messages to offsite authorities are issued in a timely manner.

   c. Information on the nature and magnitude of the hazards are made available to appropriate emergency response personnel.

   d. Radiological and chemical source term data are available to the command post, technical support center, emergency operation center, and appropriate State personnel, in cooperation with NRC.

   e. When available, offsite field monitoring data are logged, compared with source term data, and used in the protective action recommendation process.

   f. Protective Action Guides are available and used by appropriate personnel in a timely manner.

   g. The emergency public information program ensures timely dissemination of accurate, reliable, and understandable information.

   h. Systems are in place, if required, to alert, notify, and mobilize onsite and offsite response personnel in the event of an emergency.

   i. Notification and coordination with responsible parties when some personnel, equipment, and facility components are not available.

2. The emergency plan should describe how and by whom the following actions will promptly and effectively be taken:

   a. Decision to declare an alert or site area emergency,

   b. Activation of onsite emergency response organization during all shifts,

c. Prompt notification of offsite response authorities that an alert or site area emergency has been declared, including the licensee's initial recommendation for offsite protective actions (normally within 15 minutes),

d. Notification to the NRC Operations Center (as soon as possible and, in any case, no later than one hour after a declared emergency),

e. Decision on what onsite protective actions to initiate,

f. Decision on what offsite protective actions to recommend,

g. Decision to request support from offsite organizations, and

h. Decision to terminate the emergency or enter recovery mode.

8.4.3.2.10 Information To Be Communicated

The emergency plan should describe the information to be communicated during an emergency including the following:

1. A standard reporting checklist to facilitate timely notification,

2. The types of information to be provided concerning facility status, radioactive or hazardous chemical releases, and protective action recommendations,

3. A description of preplanned protective action recommendations to be made to each appropriate offsite organization,

4. The offsite officials to be notified, as a function of the classification of the event,

5. The recommended actions to be implemented by offsite organizations for each accident treated in the emergency plan.

8.4.3.2.11 Training

The emergency plan should include an adequate training program for onsite and offsite emergency response personnel to ensure knowledge of the emergency plan, assigned duties, and effectively respond to an actual emergency. The description includes:

1. The topics and general content of training programs used for training the onsite and offsite emergency response personnel to satisfy the objectives described above,

2. The administration of the training program, including responsibility for training, the positions to be trained, the schedules for training, the frequency of retraining, use of team training and the estimated number of hours of initial training and retraining,

3. The training to be provided on the use of protective equipment such as respirators, protective clothing, monitoring devices, and other equipment used in emergency response,

4. The training program for onsite personnel who are not members of the emergency response staff, and

5. The instructions and tours that will be offered to fire, police, medical, and other emergency personnel to the extent necessary commensurate with the results of the ISA.

8.4.3.2.12 Safe Shutdown (recovery and plant restoration)

The emergency plan should describe the plans for adequately restoring the facility to a safe status after an accident and recovery after an emergency. The description should include:

1. Appropriate methods and responsibilities for assessing the damage to and the status of the facility's capabilities to safely control radioactive material or hazardous chemicals associated with the process,

2. Procedures for promptly determining the actions necessary to reduce any ongoing releases of radioactive or other hazardous chemicals and to prevent further incidents,

3. Provisions for promptly and effectively accomplishing required restoration action, and

4. Describing the key positions in the recovery organization.

8.4.3.2.13 Exercises and Drills

The emergency plan should commit to conducting exercises and drills in a manner that demonstrates the capability of the organization to plan and perform an effective response to an emergency. An adequate plan should demonstrate the following:

1. Task-related knowledge is demonstrated through periodic participation by all qualified individuals for each position in the emergency response organization,

2. Drill performance is assessed against specific scenario objectives, using postulated accidents, that adequately test personnel, equipment, and resources, including previously identified weaknesses,

3. Effective player, controller, evaluator, and observer pre-drill briefings are conducted,

4. Scenario data and exercise messages provided by the controllers effectively maintain the time line and do not interfere with the emergency organization's response to exercise scenario events, except where safety considerations are involved,

5. Trained evaluators are used to identify and record participant performance, scenario strengths and deficiencies, and equipment problems,

6. Prestaging of equipment and personnel is minimized to realistically test the activation and staffing of emergency facilities,

7. Critiques are conducted in a timely manner and include a follow-up plan for correcting identified weaknesses and improving training effectiveness,

8. Emergency drills demonstrate that resources are effectively used to control the site, to mitigate further damage, and to control radiological/chemical releases, to perform required onsite activities under simulated radiation/airborne and other emergency conditions, to provide accurate assessments and status during an accident, and to initiate recovery,

9. Emergency drills demonstrate personnel protection measures, including controlling and minimizing hazards to individuals during events such as fires, medical emergencies, mitigation activities, search and rescue, and other similar events,

10. The emergency drill demonstrates that onsite communications effectively support emergency response activities,

11. The emergency drill demonstrates that the emergency public information organization disseminates accurate, reliable, timely, and understandable information,

12. Provisions are made for conducting quarterly communications checks with offsite response organizations, and

13. Offsite organizations are invited to participate in the biennial onsite exercise that tests the major elements of the emergency plan and response organizations.

8.4.3.2.14 Responsibilities for Developing and Maintaining Current the Emergency Program and Its Procedures

The emergency plan should describe the responsibilities for developing and maintaining the emergency program and its procedures. The description should include:

1. The means for ensuring that the revisions to the emergency plan and the procedures which implement the emergency plan are adequately prepared, kept up to date normally (within 30 days of any changes), and distributed to all affected parties including the NRC, and

2. The provisions for approval of the implementing emergency procedures, making and distributing changes to the procedures, and ensuring that each person responsible for an emergency response function has immediate access to a current copy of emergency procedures. Provisions for approval of changes to the emergency plan and the procedures and those individuals authorized to make these changes are clearly stated.

3. Procedures for allowing offsite response organizations 60 days to comment on the emergency plan before submitting it to the NRC, and to provide NRC any comments received within 60 days along with the plan.

4. Procedures for modifying the emergency plan in accordance with 10 CFR 70.32(i).

8.5 REVIEW PROCEDURES

8.5.1 Acceptance Review

The primary reviewer should evaluate the application to determine whether it addresses the "Areas of Review" discussed in Section 8.3, above. If significant deficiencies are identified, the applicant should be requested to submit additional material before the start of the safety evaluation.

8.5.2 Safety Evaluation

After determining that the application is acceptable for review in accordance with Section 8.5.1, above, the primary reviewer should perform a safety evaluation against the acceptance criteria described in Section 8.4. If during the course of the safety evaluation, the primary reviewer determines the need for additional information, the primary reviewer should coordinate a request for additional information with the licensing project manager.

8.5.2.1 Evaluation That No Emergency Plan Is Required

The primary reviewer should verify that the evaluation is consistent with the potential accident sequences described in the ISA. The ISA reviewer and the primary reviewer should coordinate to assure the resolution of any issues concerning the evaluation relative to ISA information. The final step for the primary reviewer should be to prepare a safety evaluation report (SER) in accordance with Section 8.6 which either agrees with the applicant's conclusion that no emergency plan is required or indicates that the staff does not accept the applicant's evaluation and recommends that an emergency plan be required by the applicant.

8.5.2.2 Emergency Plan

After it is determined that an acceptable application containing an emergency plan has been received from the applicant, the primary reviewer should conduct a complete review and determine its acceptability in accordance with Section 8.4.3.2. The reviewer should verify that emergency planning is consistent with the potential accident sequences described in the ISA. The ISA reviewer and emergency plan reviewer should coordinate to assure the resolution of any issues concerning the emergency plan relative to ISA information.

Although the bulk of this information should be found in the Emergency Management program section of the licensee's submittal, the primary and secondary reviewers should gain familiarity with the site, including the emergency planning zones, demography, land use, plant design and layout, and major accidents postulated by the applicant presented in relevant sections of the SAR. The primary and secondary reviewers should also gain familiarity with proposed radiation protection activities and other operational matters that interface with emergency plans, particularly the programs reviewed against SRP Chapters 4 and 11. Draft and final environmental statements for the proposed facility should be consulted. This information may be supplemented by a personal visit to the site by the reviewer and meetings with the applicant. Consultation with FEMA with respect to the relevant state and local government emergency response capabilities may also be necessary.

The final step for the primary reviewer should be to prepare an SER in accordance with Section 8.6, “Evaluation Findings.”

8.6 EVALUATION FINDINGS

The primary reviewer writes an SER section addressing each topic reviewed under this SRP Chapter and explains why the NRC staff has reasonable assurance that the emergency management part of the application is acceptable. License conditions may be proposed to impose requirements where the application is deficient. The report includes a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.

The staff can document the evaluation as follows:

The staff has evaluated ..... [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] In accordance with 10 CFR 70.22(i), the licensee commits to maintaining and executing an emergency plan for responding to the radiological hazards resulting from a release of radioactive material and to any associated chemical process hazards. The NRC staff reviewed the emergency plan with respect to 10 CFR 70.22(i) and the acceptance criteria in 8.4.3 of the SRP. NRC staff determined that the applicant’s emergency plan is adequate to demonstrate compliance with 10 CFR 70.22(i), including: (1) the plant is properly configured to limit releases of radioactive materials in the event of an accident, (2) a capability exists for measuring and assessing the significance of accidental releases of radioactive materials, (3) appropriate emergency equipment and procedures are provided onsite to protect workers against radiation and other chemical hazards that might be encountered following an accident, (4) a notification system has been established for notifying Federal, State, and local government agencies and recommending appropriate protective actions to protect members of the public, and (5) necessary recovery actions are established for returning the plant to a safe condition following an accident.

The requirements of the emergency plan are implemented through approved written procedures. Changes which decrease the effectiveness of the emergency plan may not be made without NRC approval. The NRC will be notified of other changes which do not decrease the effectiveness of the emergency plan within six months of the changes.

8.7 REFERENCES

1. U.S. Nuclear Regulatory Commission, *Part 30 Statements of Consideration and Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees*, Federal Register 54, 14051, 1989.

2. NUREG/CR-6410, *Nuclear Fuel Cycle Accident Analysis Handbook*, U.S. Nuclear Regulatory Commission, 1998.

3. NUREG/BR-0150, Vol. 1, Rev. 4, *RTM-96 Response Technical Manual*, U.S. Nuclear Regulatory Commission, 1996.

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

U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

9.0 ENVIRONMENTAL PROTECTION

9.1 PURPOSE OF REVIEW

The purpose of this review is to determine whether the applicant's proposed environmental protection measures are adequate to protect public health and the environment and comply with the regulatory requirements imposed by the Commission in 10 CFR Parts 20, 51, and 70. In addition, the staff will determine if the applicant submits an environmental report which is adequate for staff use in preparation of an Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) or an Environmental Impact Statement (EIS) pursuant to 10 CFR Part 51.

9.2 RESPONSIBILITY FOR REVIEW

Primary: Environmental Engineer/Scientist

Secondary: Licensing Project Manager

Supporting: Fuel Cycle Facility Inspector
Radiation Safety Reviewer
ISA Lead Reviewer

9.3 AREAS OF REVIEW

There are two distinct components of the application that require an environmental review. These are (1) the environmental report and (2) the description of environmental protection measures. The review of environmental protection measures includes a review of the applicant's integrated safety analysis (ISA) summary. The following subsections identify the areas of review for each of these components. Greater detail on each component is provided in Section 9.4, which specifies the review acceptance criteria.

9.3.1 Environmental Report

The regulatory requirements for the environmental report are contained in 10 CFR Part 51. These regulations were promulgated by the Commission to implement the National Environmental Policy Act (NEPA) of 1969, which requires an assessment of the environmental impacts for all major Federal actions. The NRC staff conducts an independent assessment for all licensing actions that may have a significant effect on the environment, based on the information provided by the applicant in the environmental report. This assessment is documented in an EA or EIS. Actions listed in 10 CFR Part 51.22(c) have been determined by the Commission to have insignificant environmental impacts and are categorically excluded

from the requirement for an environmental assessment and an environmental report. However, the

applicant may be required to submit information to the NRC to justify the applicability of the categorical exclusion.

The areas of review for the environmental report correspond to the content specified in 10 CFR 51.45:

- Date of Application
- Environmental Considerations
  - Description of the proposed action
  - Purpose of the proposed action
  - Description of the affected environment
  - Discussion of considerations (including environmental impacts and alternatives to the proposed action)
- Analysis
- Status of Compliance
- Adverse Information

The environmental report may include or reference information submitted to the NRC for prior licensing actions.

9.3.2 Environmental Protection Measures

The regulatory requirements for environmental protection are contained in 10 CFR Parts 20, 51, and 70. The NRC staff environmental review is focused on that part of the applicant's plant-wide safety program that is established to control and assess the level of radioactive and nonradioactive releases (gaseous, liquid, and solid) to the environment. Therefore, aspects of the applicant's radiation protection program for effluent control, as well as effluent and environmental monitoring practices, are reviewed. In addition, the plant-wide safety program is reviewed to ensure that the management controls specified to ensure that these activities meet license objectives.

To receive authorization to possess a critical quantity of special nuclear material, as defined in 10 CFR 70.4, an applicant must also perform an ISA in accordance with 10 CFR 70.60(d)(1). Guidance on the ISA is covered in Section 3.0 of this Standard Review Plan. The environmental safety review of the ISA summary will include a review of the identified potential accident sequences that result in radiological and nonradiological releases to the environment, as well as the controls specified by the applicant to reduce the risk of these accidents.

Thus, environmental protection includes three main components: (1) the radiation protection program, (2) effluent and environmental monitoring, and (3) the ISA summary and other ISA documentation as neded. The areas of review include:

9.3.2.1 Radiation Protection

- ALARA goals for effluent control

- Procedures, engineering controls, and process controls to maintain public doses ALARA
- ALARA reviews and reports to management
- Waste minimization practices and for new operations, design plans for waste minimization

9.3.2.2 Effluent and Environmental Monitoring

- In-place filter testing procedures for air cleaning systems
- Known or expected concentrations of radionuclides in effluents
- Physical and chemical characteristics of radionuclides in discharges
- Discharge locations
- Environmental media to be monitored and the sample locations
- Sampling collection and analysis procedures, including the minimum detectable concentrations of radionuclides
- Action levels and actions to be taken when the levels are exceeded
- Permits, including air discharge and National Pollutant Discharge and Elimination System permits
- Leak detection systems for ponds, lagoons, and tanks
- Pathways analysis methods to estimate public doses
- Recording and reporting procedures
- Solid waste handling and disposal programs

9.3.2.3 Integrated Safety Analysis

- Accident sequences (and associated facility processes) which, if unmitigated, result in releases to the environment
- Likelihood and environmental consequences of these accident sequences
- Controls relied on to reduce the unmitigated risk from “high” risk to an acceptable level
- Availability and reliability of controls

9.4 ACCEPTANCE CRITERIA

Acceptance criteria for the environmental report and for the environmental protection measures are described in Sections 9.4.1 and 9.4.2, respectively.

9.4.1 Environmental Report (or Categorical Exclusion Information)

The acceptance criteria for the environmental report are discussed in Section 9.4.1.1. For licensing actions which meet the requirements for a categorical exclusion as defined in 10 CFR 51.22(c), an environmental report is not required. However, if the action involves an amendment to licenses for fuel cycle plants, radioactive waste disposal sites, and other materials licenses identified in 10 CFR 51.60(b)(1) that involve changes in process operations or equipment, the applicant must justify that the action will not result in significant effects on the environment. The acceptance criteria for this demonstration are given in Section 9.4.1.2.

9.4.1.1 Environmental Report

A. Date of Application

The date of an application for a license to possess and use special nuclear material for processing and fuel fabrication, scrap recovery, conversion of uranium hexafluoride, or for the conduct of any other activity, which the NRC has determined pursuant to 10 CFR 51 Subpart A will significantly affect the quality of the environment, is acceptable if the application is submitted at least 9 months before the commencement of construction, as required by 10 CFR Part 70.21(f).

B. Environmental Considerations

An adequate environmental report addresses the requirements of 10 CFR 51.45(b), as described below.

1. Description of the proposed action

The summary of the proposed action includes a brief description of the significant characteristics of the proposed facility, including the major site features and the major plant design and operating parameters. The description includes a complete discussion about how special nuclear material will be processed at the facility. If future construction is proposed, the description includes a proposed project schedule showing the dates for initiation of site preparation, plant construction, and operation.

2. Purpose of the proposed action

The statement of purpose demonstrates a need for the proposed project. This demonstration provides at least the following information: (a) the quantities of special nuclear material used for domestic benefit, (b) a projection of national and foreign requirements for the services, and (c) alternative sources of supply for the proposed facility's services. If delay of the proposed project would have effects on the nation's energy program or on the applicant's business (such as loss of contracts, jobs, or future business), these effects are discussed.

3. Description of the affected environment

The description of the affected environment includes:

a. Site location (including longitude and latitude) and facility layout
b. Regional demography and land use
c. Socioeconomic information**,** including low-income and minority populations within a 50 mile radius
d. Regional historic, archaeological, architectural, scenic, cultural, and natural landmarks
e. Local meteorology and air quality
f. Local surface water and groundwater hydrology
g. Regional geology and seismology

h. Local terrestrial and aquatic ecology

To the extent possible, this information reflects observations and measurements made over a period of years, especially for conditions that are expected to vary seasonally (e.g., precipitations, wind speed and direction, and groundwater levels).

4. Discussion of considerations

The discussion of considerations includes (a) the impact of the proposed action on the environment, (b) the adverse environmental effects of the proposed action and alternatives to the proposed action, (c) the relationship between short-term uses and long-term productivity, and (d) irreversible or irretrievable commitments of resources. The discussion of these points is acceptable if it includes the following considerations:

a. Impact of the proposed action on the environment

- Effects of site preparation and construction on land use and water use
- Effects of plant operation on the human population (including consideration of occupational and public radiation exposure) and important biota
- Any irreversible commitments of resources because of site preparation and plant construction and operation, such as destruction of wildlife habitat, removal of land from agricultural use, and diversion of electrical power
- Plans and policies regarding decommissioning and dismantling at the end of the plant's useful life
- Environmental effects of the transportation of radioactive materials to and from the site
- Environmental effects of accidents
- Impacts on air and water quality
- Impacts on cultural and historic resources

This section of the environmental report discusses the impacts on the environment in proportion to their significance. In addition, accident analyses provided in the report are consistent with the applicant's ISA.

b. Adverse environmental effects

The information submitted describes any adverse environmental effects that cannot be avoided should the proposal be implemented. This description is presented in quantitative terms to the maximum extent possible. This discussion makes clear which of these effects are unavoidable and subject to later amelioration and which are unavoidable and irreversible. The description includes specific measures that the applicant could take or plan to take to mitigate adverse effects.

c. Alternatives to the proposed action

The discussion of alternatives to the proposed action is sufficiently complete to aid NRC in developing and exploring, pursuant to Section 102(2)(E) of NEPA, "appropriate alternatives to recommended courses of action in any proposal which involves unresolved conflicts concerning alternative uses of available resources." To

the extent practicable, the environmental impacts of the proposal and the alternatives are presented in comparative form.

The discussion of alternatives includes siting alternatives and design alternatives. Comparable levels of information on each site need not be presented as long as the applicant presents sufficient information to facilitate a fair and reasonable comparison. The following factors are considered when comparing alternative sites:

- Physical characteristics of the area, including demographic, geological, hydrological, meteorological, and seismological conditions of the site and surrounding area
- Location of power sources and transmission lines
- Location of the major product market
- Location of raw materials, components, and sources of supply
- Availability of air, rail, roads, and water for transport of raw materials and supplies, finished products, and solid wastes
- Commitment of natural resources for site preparation and plant construction, including but not limited to the destruction or diminution of wildlife habitats, flora, woodlands, and marshlands
- Commitment of capital for site preparation and plant construction
- Cost of operation, including consideration of labor supply, prevailing wage rates, and other recurring or nonrecurring costs
- Availability of municipal services and facilities or, conversely, the cost of providing services such as water and sewage treatment
- Requirements for relocating homes and families
- Existing and projected land use and economic status of the community (e.g., urban, industrial, stable)

d. Relationship between short-term uses and long-term productivity

The relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity is discussed. Short-term uses are considered to be those that occur during the active life of the facility. Long-term productivity represents the use of the environment beyond decommissioning of the facility.

e. Irreversible or irretrievable commitments of resources

Any irreversible environmental commitments and irretrievable material resources that would be involved in the proposed action are discussed.

C. Analysis of Environmental Effects of Proposed Action and Alternatives

An adequate environmental report analyzes the environmental effects of the proposed action and alternatives. In accordance with 10 CFR 51.45(c), the analysis considers and balances the environmental effects of the proposed action and the alternatives available

for reducing or avoiding adverse environmental effects, as well as the environmental, economic, social, and other benefits of the proposed action.

This analysis quantifies, to the fullest extent practicable, the various factors considered. If the application involves renewal or amendment of a current license, environmental impacts are quantified using environmental monitoring data collected by the licensee. To the extent that there are important qualitative considerations or factors that cannot be quantified, the analysis discusses those considerations and factors in qualitative terms. The analysis contains sufficient data to aid the staff in its development of an independent analysis.

D. Status of Compliance

As required by 10 CFR 51.45(d), the applicant should list all Federal permits, licenses, approvals, and other entitlements, which must be obtained in connection with the proposed action. The list is acceptable if it is complete and current as of the application date.

In addition, 10 CFR 51.45(d) requires that the environmental report include a discussion of the status of compliance with applicable environmental quality standards and requirements including, but not limited to, applicable zoning and land-use regulations, and thermal and other water pollution limitations or requirements which have been imposed by Federal, State, regional, and local agencies having responsibility for environmental protection. The discussion is acceptable if it includes a discussion of whether each alternative will comply with such applicable environmental quality standards and requirements. The discussion include's, but is not limited to, the following federal laws:

- The National Historic Preservation Act of 1966
- The Fish and Wildlife Coordination Act of 1966
- The Wild and Scenic Rivers Act of 1968
- The Endangered Species Act Amendments of 1978
- The Coastal Zone Management and Improvement Act of 1990

E. Adverse Information

In accordance with 10 CFR 51.45(e), the preceding discussions and analyses are acceptable if they include information that is adverse to the proposed actions as well as information supporting the proposed action.

9.4.1.2 Categorical Exclusion

An environmental report is not required for actions identified in 10 CFR 51.60(b)(1) that involve an amendment to licenses for fuel cycle plants, radioactive waste disposal sites, and other materials licenses, which are not expected to result in significant environmental impacts. However, since these amendments involve changes in process operations or equipment, the applicant needs to justify that the changes will not result in significant environmental effects.

The information provided by the applicant to justify the categorical exclusion determination is acceptable if it demonstrates the following as specified in 10 CFR 51.22(c)(11):

- There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite
- There is no significant increase in individual or cumulative occupational radiation exposure
- There is no significant construction impact
- There is no significant increase in the potential for or consequences from radiological accidents

9.4.2 Environmental Protection

An applicant's proposed actions for environmental protection are acceptable if they provide for qualified and trained staff, effluent control, and effluent and environmental monitoring in accordance with NRC requirements. Using the acceptance criteria provided in Chapter 11 of this Standard Review Plan, the NRC staff will review the training and qualifications for plant personnel associated with environmental protection as described in the license application. This will include the training and qualification of managers, supervisors, technical staff, operators, technicians, maintenance personnel whose level of knowledge is important to maintain protection of public health and the environment. Managers and staff will be expected to have levels of education and experience commensurate with the responsibilities of their positions.

The acceptance criteria for the radiation protection program, and effluent and environmental monitoring, are given in Sections 9.4.2.1, 9.4.2.2, and 9.4.2.3, respectively.

9.4.2.1 Radiation Protection

In accordance with 10 CFR 20 Subpart B, each licensee must implement a radiation protection program, which is discussed in detail in Chapter 4 of this Standard Review Plan. The environmental review of the radiation protection program focuses on the applicant's methods to maintain public doses ALARA in accordance with 10 CFR 20.1101. NRC guidance on compliance with these regulations can be found in Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," July 1993.

Specifically, 10 CFR 20.1101(d) requires the applicant to establish a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its decay products, such that the individual member of the public likely to receive the highest dose will not be expected to receive a TEDE in excess of 10 mrem (0.1 mSv) per year from these emissions. The applicant must have procedures to report when this dose constraint is exceeded to the NRC in accordance with 10 CFR 20.2203 and take prompt appropriate corrective action to ensure against recurrence. NRC guidance on compliance with this regulation can be found in Regulatory Guide 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," December 1996.

The environmental review of the radiation protection program also focusses on the applicant's waste minimization practices. Applicant's for new licenses are required to comply with 10 CFR 20.1406, which states that the applicant must describe how facility design procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste. Applicant's requesting

amendment or renewal of existing licenses must minimize and control waste generation during operations as part of the radiation protection program in accordance with 10 CFR 20.1101 [62 FR 39082].

Guidance for waste minimization programs can be found in NRC Information Notice No. 94-23: "Guidance to Hazardous, Radioactive and Mixed Waste Generators on the Elements of a Waste Minimization Program," March 25, 1994. More information on compliance with the decommissioning aspects of the waste minimization regulations can be found in Chapter 10.0 of this Standard Review Plan.

The proposed radiation protection program is acceptable if it satisfies the following criteria:

1. ALARA Goals for Effluent Control

   ALARA goals are set at a modest fraction (10% to 20%) of the values in Appendix B, Table 2, Columns 1 and 2 and Table 3 and the external exposure limit in 20.1302(b)(2)(ii), or the dose limit for members of the public, if the applicant proposes to demonstrate compliance with 10 CFR 20.1301 through a calculation of the total effective dose equivalent (TEDE) to the individual likely to receive the highest dose.

   An applicant's constraint approach is acceptable if it is consistent with guidance found in Regulatory Guide 4.20 and the applicant's description of the constraint approach provides sufficient detail to demonstrate specific application of the guidance to proposed operations.

2. Procedures, Engineering Controls, and Process Controls

   The applicant uses procedures, engineering controls, and process controls to achieve ALARA goals for effluent minimization. Common control practices include filtration, encapsulation, adsorption, containment, recycling, leakage reduction, and the storage of materials for radioactive decay. Practices for large, diffuse sources such as contaminated soils or surfaces include covers, wetting during operations, and the application of stabilizers. The applicant demonstrates a commitment to reducing unnecessary exposure to members of the public and releases to the environment.

   Engineering options which do not result in a substantial reduction in collective dose and require unreasonable costs are not required. Reasonableness can be based on a qualitative or quantitative cost/benefit analysis. Quantitative analyses may use a $2000 per person-cSv (man-rem) value, as discussed in NUREG-1530, "Reassessment of the NRC's Dollar per Person-Rem Conversion Factor Policy."

3. ALARA Reviews and Reports to Management

   The applicant commits to annual review of the content and implementation of the radiation protection program, which includes the ALARA effluent control program. This review includes analysis of trends in release concentrations, environmental monitoring data, and radionuclide usage, determines whether operational changes

are needed to achieve the ALARA effluent goals, and evaluates all designs for system installations or modifications. The applicant also includes a commitment to report the results to senior

management along with recommendations for changes in facilities or procedures that are necessary to achieve ALARA goals.

4. Waste minimization

Applications for new licenses are acceptable if they contain a description of how facility design procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, and minimize, to the extent practicable, the generation of radioactive waste. Waste minimizations programs proposed by applicants for both new and existing licenses are acceptable if the programs include:

- top management support
- methods to characterize waste generation, including types and amounts, and waste management costs, including costs of regulatory compliance, paperwork, transportation, treatment, storage, disposal, etc.
- periodic waste minimization assessments to identify waste minimization opportunities and solicit employee or external recommendations
- provisions for technology transfer to seek and exchange technical information on waste minimization
- methods for implementation and evaluation of waste minimization recommendations

9.4.2.2 Effluent and Environmental Controls and Monitoring

The following regulations require effluent control and effluent and environmental monitoring measures for applicants requesting use of special nuclear material:

10 CFR Part 20

The applicant must establish effluent control and treatment measures in order to meet the dose limits and dose constraints for members of the public specified in 10 CFR Part 20, Subparts D and F. The applicant must also comply with the survey requirements of 10 CFR 20 Subpart F, the waste disposal requirements of Subpart K, the records requirements of Subpart L, and the reporting requirements of Subpart M.

10 CFR Part 51

The applicant must establish effluent and environmental monitoring systems to provide the information required by 10 CFR 51.60(a). 10 CFR 51.60(a) states that the environmental report or supplement to the environmental report submitted to support renewal or amendment of a license must include documentation of significant environmental changes, including changes resulting from operational experience or a change in operations.

10 CFR Part 70

In accordance with 10 CFR 70.22(a)(7) and 70.23(a)(3), the applicant must demonstrate that proposed facilities and equipment, including measuring and monitoring instruments and devices for the disposal of radioactive effluents and wastes, are adequate to protect public health and the environment. In addition, pursuant to 10 CFR 70.65(d), each application for a license to posses a critical mass of special nuclear material must contain a description of the environmental monitoring measures established by the applicant to assess the impact of licensed activities in accordance with 10 CFR Part 20.

Guidance documents on implementing these regulations includes the following publications:

- ANSI N13.1-1982, "Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities"
- ANSI N42.18-1980, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents"
- NCRP Report No. 123, "Screening Models for Releases of Radionuclides to Atmosphere, Surface Water, and Ground," January 1996
- NRC Information Notice 94-07, “Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20,” January 28, 1994
- NRC Regulatory Guide 4.15, "Quality Assurance for Radiological Monitoring Programs (Normal Operations) ! Effluent Streams and the Environment"
- NRC Regulatory Guide 4.16, "Monitoring and Reporting Radioactivity in Releases of Radioactive Materials in Liquid and Gaseous Effluents from Nuclear Fuel Processing and Fabrication Plants and Uranium Hexafluoride Production Plants"

A. Effluent Control and Monitoring

The applicant’s effluent monitoring is acceptable if it meets the following criteria:

1. The known or expected concentrations of radioactive materials in airborne and liquid effluents are below the limits in 10 CFR Part 20, Appendix B, Table 2 or below site specific limits established in accordance with 20.1302(c) and are ALARA.

2. All liquid and airborne effluent discharge locations are identified and monitored.

   Airborne effluents from all operations associated with the plant, including areas not used for processing special nuclear material such as laboratories, experimental areas, storage areas, and fuel element assembly areas, are continuously sampled. For liquid effluents, representative samples are taken at each release point for the determination of concentrations and quantities of radionuclides released to an unrestricted area, including discharges to sewage systems. For continuous

releases, samples are continuously collected at each release point. For batch releases, a representative sample of each batch is collected. If periodic sampling is used in lieu of continual sampling, the applicant shows that the samples are representative of actual releases.

Effluents are sampled unless the applicant has established, by periodic sampling or other means, that radioactivity in the effluent is insignificant and will remain so. In such cases, the effluent is sampled at least quarterly to confirm that effluents are not significant. Radionuclide analyses are performed more frequently than usual whenever a process change or other circumstance might cause a significant variation in the radionuclide composition. For the purposes of this Standard Review Plan, an effluent is significant if the concentration averaged over a calendar quarter is equal to 10% or more of the appropriate concentration listed in Table 2 of Appendix B to 10 CFR Part 20.

4. Radionuclide specific analyses are performed on selected composited samples unless (1) the gross alpha and gross beta activities are so low that individual radionuclides could not be present in concentrations greater than 10 percent of the concentrations specified in Table 2 or 3 of Appendix B to 10 CFR Part 20, or (2) the radionuclide composition of the sample is known through operational data, such as the composition of the feed material. Monitoring reports in which estimates of quantities of individual radionuclides are based on methods other than direct measurement include an explanation and justification of how the results were obtained.

   Examples of cases in which operational data may not be adequate for the determination of radionuclide concentration are (1) plants processing uranium in which extraction, ammonium diuranate precipitation, ion exchange, or other separation processes could result in concentration of thorium isotopes (principally Th-234); (2) plants in which uranium of varying enrichments is processed; and (3) plants processing plutonium in which significant variation in the Pu-238/Pu-239 ratio among batches and the continuous in-growth of Am-241 would preclude the use of feed material data to determine the radionuclide composition of effluents.

   Radionuclide analyses are performed more frequently than usual under three circumstances: (1) at the beginning of the monitoring program until a predictable radionuclide composition in effluents is established; (2) whenever there is a significant unexplained increase in gross radioactivity in effluents; or (3) whenever a process change or other circumstance might cause a significant variation in the radionuclide composition.

5. The sample collection and analysis methods and frequencies are appropriate for the effluent medium and the radionuclide(s) being sampled. Sampling methods ensure that representative samples are obtained by use of appropriate sampling equipment and sample collection and storage procedures. Monitoring instruments are calibrated at least annually, or more frequently if suggested by the manufacturer.

6. The proposed action levels and actions to be taken if the levels are exceeded are appropriate. The action levels are incremental, such that each increasing action level results in a more aggressive action to assure and control effluents. A slightly higher than normal concentration of a radionuclide in effluent triggers an investigation into the cause of the increase. An action level is specified that will result in the shutdown of an operation if this level is exceeded. These action levels are selected based on the likelihood that a measured increase in concentration could indicate potential violation of the effluent limits.

7. The minimum detectable concentration (MDC) for sample analyses is not more than 5 percent of the concentration limits listed in Table 2 of Appendix B to 10 CFR Part 20. If the actual concentrations of radionuclides in samples are known to be higher than 5 percent of the 10 CFR Part 20 limits, the analysis methods need only be adequate to measure the actual concentration. However, in such cases, the MDC is low enough to accommodate fluctuations in the concentrations of the effluent and the uncertainty of the MDC.

8. The laboratory quality control procedures are adequate to support the validity of the analytical results. These QC procedures include the use of established standards such as those provided by the National Institute of Standards and Technology (NIST), as well as standard analytical procedures, such as those established by the National Environmental Laboratory Accreditation Conference.

9. The descriptions of applicable Federal and/or State standards for discharges and any permits issued by local, State, or Federal governments for gaseous and liquid effluents are complete and accurate.

10. If the applicant proposes to adjust the effluent concentrations in Appendix B to 10 CFR 20 in accordance with 20.1302(c) to take into account the actual physical and chemical characteristics of the effluents, the information related to aerosol size distributions, solubility, density, radioactive decay equilibrium, and chemical form is complete and accurate for the radioactive materials to justify the derivation and application of the alternative concentration limits.

11. The systems for the detection of leakage from ponds, lagoons, and tanks are adequate to detect and assure against any unplanned releases to groundwater, surface water, or soil.

12. Releases to sewer systems are controlled and maintained to meet the requirements of 10 CFR 20.2003, including (i) the material is water soluble; (ii) known or expected discharges meet the effluent limits of 10 CFR 20 Appendix B, Table 3; and (iii) the known or expected total quantity of radioactive material released into the sewer system in a year does not exceed 5 Ci (185 GBq) of ^{3}H, 1 Ci (37 GBq) of ^{14}C, and 1 Ci (37 GBq) of all other radioactive materials combined. Solubility is determined in accordance with the procedure described in NRC Information Notice 94-07.

13. Reporting procedures comply with the requirements of 10 CFR 70.59 and the guidance specified in Regulatory Guide 4.16. Reports of the concentrations of principal radionuclides released to unrestricted areas in liquid and gaseous effluents are provided and include the MDC for the analysis and the error for each data point.

14. If the licensee proposes to demonstrate compliance with 10 CFR 20.1301 through a calculation of the total effective dose equivalent (TEDE) to the individual likely to receive the highest dose in accordance with 20.1302(b)(1), calculation of the TEDE by pathways analyses uses appropriate models and codes and assumptions that accurately represent the facility, the site, and the surrounding area; assumptions are reasonable; input data is accurate; all applicable pathways are considered; and the results are interpreted correctly.

    NCRP Report No. 123, "Screening Models for Releases of Radionuclides to Atmosphere, Surface Water, and Ground," January 1996, provides acceptable methods for calculating the dose from radioactive effluents. Computer codes are acceptable tools for pathways analysis if the applicant is able to demonstrate that the code has undergone validation and verification to demonstrate the validity of estimates developed using the code for established input sets. Dose conversion factors used in the pathways analyses are acceptable if they are based on the methodology described in ICRP 30, "Limits for Intakes of Radionuclides by Workers" as reflected in Federal Guidance Report 11.

15. The applicant's procedures and facilities for solid waste handling, storage and monitoring result in safe storage of the material and timely disposition.

B. Environmental Monitoring

The scope of the applicant's environmental monitoring is acceptable if it is commensurate with the scope of activities at the facility and the expected impacts of operations as identified in the environmental report and meets the following criteria:

1. Background and baseline concentrations of radionuclides in environmental media have been established through sampling and analysis.
2. Monitoring includes sampling and analyses for monitoring of air, surface water, groundwater, soil, sediments, and vegetation, as appropriate.

3. The description of monitoring identifies adequate and appropriate sampling locations and frequencies for each environmental medium, the frequency of sampling, and the analyses to be performed on each medium.

4. Monitoring procedures employ acceptable analytical methods and instrumentation to be used. The applicant commits to a program of instrument maintenance and calibration appropriate to the instrumentation, as well as participation in round-robin measurement comparisons if the applicant proposes use of its own analytical laboratory for analysis of environmental samples.

5. Appropriate action levels and actions to be taken if the levels are exceeded are specified for each environmental medium and radionuclide.

Action levels are selected based upon a pathways analysis that demonstrates that below those concentrations, doses to the public will be below the limits in 10 CFR Part 20, Subpart B, and are ALARA. The action levels specify the concentrations at which an investigation would be performed and levels at which process operations would be shut down.

6. MDCs are specified for sample analyses, and are at least as low as those selected for effluent monitoring in air and water. MDCs for sediment, soil, and vegetation are selected based upon the action levels to ensure sampling and analytical methods are sensitive and reliable enough to support application of the action levels.

7. Data analysis methods and criteria to be used for evaluating and reporting the environmental sampling results are appropriate and will indicate when an action level is being approached in time to take corrective actions.

8. The description of the status of all licenses, permits, and other approvals of plant operations required by Federal, State and local authorities is complete and accurate.

9) Environmental monitoring is adequate to assess impacts to the environment from potential radioactive and nonradioactive releases as identified in the ISA.

9.4.2.3 Integrated Safety Analysis

In accordance with 10 CFR 70.60, applicant's requesting a critical mass of special nuclear material are required to perform an ISA. The applicant's treatment of environmental protection in the ISA is acceptable if it fulfills the following criteria:

- The ISA provides a complete list of accident sequences which result in radiological and nonradiological releases to the environment.

- The ISA provides a reasonable estimate for the likelihood and consequences of each accident sequence identified.

- Adequate controls are identified for each accident sequence of environmental significance. The controls (engineering or administrative) will prevent of mitigate potential accidents to an acceptable level.

- Adequate levels of assurance are afforded to the controls to ensure that items relied on for safety will satisfactorily perform their safety functions. This may be accomplished through configuration management, training, and maintenance activities.

- The ISA uses acceptable methods for estimating environmental effects from accident sequences.

9.5 REVIEW PROCEDURES

The staff will review the environmental report and the environmental protection measures to verify that each meets the acceptance criteria in Section 9.4. If the applicant has not provided sufficient information to make these determinations, then a request for additional information (RAI) should be made in coordination with the facility project manager. The format for an RAI is specified in Chapter 4 of the Fuel Cycle Licensing Branch "Materials Licensing Procedures Manual." Additional review procedures are provided in Sections 9.5.1 - 9.5.3.

9.5.1 Environmental Report

Review of the environmental report or information presented to support a categorical exclusion includes review of occupational exposure information. This review should be coordinated with the radiation safety reviewer to assess the adequacy of the information provided by the applicant.

9.5.2 Environmental Protection

For renewal and amendment applications, review of environmental protection by the environmental specialist will include coordination with the fuel cycle facility inspector responsible for environmental protection. Any comments or concerns that the inspector identifies will be addressed and resolved, and the Safety Evaluation Report (SER) (described in Section 9.6.1) for the licensing action will contain a statement indicating if the inspection staff has any objections to approval of the proposed licensing action. In addition, the review of applications will include review of inspection reports and semi-annual effluent reports submitted in accordance with 10 CFR 70.59 to assure licensee performance in environmental protection.

As part of the environmental protection review, the environmental specialist will review the ISA summary and other ISA documents as needed. All accident sequences identified in the ISA that can have significant environmental consequences will be reviewed to determine that the list of potential accidents is complete and properly identified. This review will be coordinated with the ISA reviewer.

Evaluation of the ISA summary requires coordination with other technical reviewers. The environmental review of the controls will be coordinated with the reviewers for the specific assurance functions, such as training and maintenance. These assurance functions are usually reviewed by the Project Manager for the facility.

Finally, review of the complete ISA findings and conclusions may require examination of detailed supporting documents that have not been submitted for the public record and are instead located at the facility. The reviewer should decide, as a result of these reviews, what supporting documents need to be forwarded to the NRC for inclusion in the public record of the application. As a general rule, material that directly supports a licensing decision of reasonable assurance of safety should be a matter of public record. Whether the material is placed in the public record or only available at the facility, the reviewer will clearly cite in the SER what materials were examined, and what descriptions and commitments were considered and relied upon or the basis for the staff's safety decision.

9.6 EVALUATION FINDINGS

Documentation of the evaluation findings for the environmental protection review is contained in two types of products. A Safety Evaluation Report (SER) documents the review of the environmental protection program and the ISA summary or related documents. The EA or EIS documents the staff's independent assessment of the environmental impacts of the proposed action.

9.6.1 Safety Evaluation Report

In the SER, the staff will document the findings of the adequacy of the application, will describe the bases for the findings, and will recommend additional license conditions in areas where the license application is not adequate. The documentation will include the bases for the conclusions, including a discussion of the areas of review and how the information demonstrates that the acceptance criteria have been met.

Often, environmental protection is reviewed and evaluated in conjunction with the environmental report, and the environmental protection function is summarized in the EA or EIS. However, the EA or EIS does not become part of the license. Issues identified during the review should be discussed briefly in the SER, and any recommended license conditions based on the analysis in the EA or EIS should be added to the license.

If an EA and EIS were prepared for the licensing action, the date the documents were issued should be reported in the environmental safety section of the SER. If the EA resulted in a FONSI, the FONSI's publication date in the Federal Register should be included in the SER. If an EIS is prepared, the SER would include the Federal Register publication date for the Record of Decision. When applicable, the SER also documents the determination that an action meets a categorical exclusion.

9.6.2 Environmental Assessment, Finding of No Significant Impact, Environmental Impact Statement

Before taking a licensing action, including issuance, renewal, or amendment, the appropriate NRC Branch Chief will determine whether the proposed action qualifies for a categorical exclusion under 10 CFR 51.22 or whether an EA or EIS should be prepared:

- An EA will be prepared if the action meets the criteria in 10 CFR Part 51.21. On completion of the EA, the NRC determines whether to prepare an EIS or a FONSI.

- An EIS will be prepared if the action meets the criteria in 10 CFR Part 51.20. An EA is not necessary if it is determined that an EIS will be prepared.

- A categorical exclusion will suffice if the action meets the criteria for categorical exclusions as defined in 10 CFR Part 51.22(c). (An action that qualifies for a categorical exclusion is usually identified at the start of the licensing review, and an ER is not required.)

Requirements for the preparation of an EIS, EA, or FONSI are described in detail in 10 CFR Part 51. Documents prepared in accordance with NEPA will follow pertinent NMSS procedures, including consultation with states (Policy & Procedures Letter 1-48), evaluation of environmental justice (Policy & Procedures Letter 1-50), and Chapter 6 of the NRC Division of Fuel Cycle Safety and Safeguards, Fuel Cycle Licensing Branch Manual. Sections 9.6.2.1 and 9.6.2.2 contain an overview of the regulatory requirements for an EA, FONSI, EIS and Record of Decision specified in 10 CFR Part 51**.** However, this discussion is not intended to be all-inclusive.

9.6.2.1. Environmental Assessment (EA)

The staff will prepare an EA that identifies the proposed action and includes the following, in accordance with 10 CFR 51.30:

1. A brief discussion of:

    a. The need for the proposed action
    b. Alternatives to the proposed action as required by Section 102(2)(E) of NEPA
    c. The environmental impacts of the proposed action and alternatives, as appropriate
    d. As required by NMSS Policy and Procedures letter 1-50, April 21, 1995, disproportionately high and adverse human health or environmental effects on low income and minority populations

2. A list of agencies and persons consulted and identification of sources used. During preparation of an EA, the staff will consult with affected States on environmental issues and will document such contact in the EA. This documentation will include the following information identified in NMSS Policy and Procedures Letter 1-48, January 1995:

    a. The name of each State, agency (including contacted individual's name), or person consulted
    b. date of consultation(s)
    c. purpose for the consultation
    d. brief summary of the views or comments expressed by the consulted party and the staff's resolution
    e. reference to publicly available documents containing additional information, if applicable

    Much of the information used to prepare the EA is provided by the applicant in the environmental report. However, the staff will perform independent analyses of the environmental impacts of the proposed action and will discuss the conclusions of these analyses in the EA. The EA should focus on the impacts of the proposed action and should be no more than 15 pages, unless necessary to explain any complicated environmental issues associated with the proposed action.

    On completion of the EA, the appropriate NRC Branch Chief will determine whether to prepare an EIS or a FONSI on the proposed action. As discussed in Section 9.6.2.2

and provided in 10 CFR 51.33, a determination to prepare a draft FONSI may be made. As provided in 10 CFR 51.25, an EA is not necessary if it is determined that an EIS will be prepared.

9.6.2.2. Finding of No Significant Impact (FONSI)

When the staff makes a final finding that there are no significant environmental impacts for the proposed action, a final FONSI will be published in the Federal Register. The Commission will not take the proposed action, including license issuance, renewal, or amendment, until after the FONSI has been published. Requirements for the preparation of a FONSI for materials licensing actions are contained in 10 CFR 51.32-51.35. A FONSI will include the following:

a. Identification of the proposed action
b. Statement that the Commission has determined not to prepare an EIS for the proposed action
c. Brief presentation of the reasons why the proposed action will not have a significant impact on the quality of the human environment
d. The EA or a summary of the EA
e. A note of any other related environmental documents
f. A statement that the finding and any related environmental documents are available for public inspection and where the documents may be inspected

NRC may make a determination to prepare and issue a draft FONSI for public review and comment before making a final determination whether to prepare an EIS or a final FONSI on the proposed action. A draft FONSI may be prepared if a FONSI appears warranted, but the proposed action is similar to one that normally requires an EIS or is without precedent.

The draft FONSI will be identified as a "draft" and will contain the information specified above for a final FONSI. The draft FONSI will be accompanied by or will include a request for comments on the proposed action and the draft findings within 30 days, or a longer period as may be specified in the notice of the draft findings. This draft FONSI will be published in the Federal Register, distributed as provided in 10 CFR 51.74(a), and made available in accordance with 10 CFR 51.123.

When a draft FONSI is issued, a final determination to prepare an EIS or final FONSI will not be made until the last day of the public comment period has expired.

9.6.2.3 Environmental Impact Statement (EIS)

When the appropriate NRC Branch Chief determines that an EIS will be prepared for the licensing action, a Notice of Intent to prepare an EIS will be published in the Federal Register in accordance with 10 CFR 51.27, and a scoping process will be conducted in accordance with 10 CFR 51.28 and 51.29. The scoping process may include a public scoping meeting.

A draft EIS is prepared as soon as practicable after publication of the Notice of Intent and completion of the scoping process. The general requirements, the requirements on content, and the requirements on supplements to a Draft EIS are found in 10 CFR 51.70-51.72. Public comments will be solicited on the draft in accordance with 10 CFR 51.73, and the draft will be distributed according to 10 CFR 51.74. After receipt and consideration of comments, the staff will prepare a Final EIS in accordance with 10 CFR 51.90 and 51.91, which will be distributed in accordance with 10 CFR 51.93.

The scoping process for the EIS will begin after the notice of intent is published. The purposes of the process are set forth in 10 CFR 51.29(a). At the conclusion of the scoping process, the staff will prepare a concise summary of the determinations and conclusions reached during the scoping process, including the significant issues identified, and will send a copy of the summary to each participant in the scoping process. This summary will be signed by an NRC staff director. At any time before issuance of the draft EIS, the staff may revise the determinations if substantial changes are made in the proposed action, or if significant new circumstances or information arises that bears on the proposed action or its impacts.

3. Draft Environmental Impact Statement

General requirements for the preparation of a Draft EIS are contained in 10 CFR 51.70-51.74. The draft must include the following:

a. An analysis of major points of view concerning the proposed action and alternatives including significant problems and objections raised by other Federal, State, and local agencies, by any affected Indian tribes, and other interested persons
b. A Discussion of the status of compliance with all Federal, State, and local permits, licenses, approvals, and other entitlements obtained in implementing the proposed action
c. An analysis which considers and weighs the environmental effects of the proposed action and alternatives
d. A preliminary recommendation by the NRC staff concerning the proposed action

4. Final Environmental Impact Statement

The format of the final EIS is set forth in Section 1(a) of Appendix A to 10 CFR Part 51, and the content is specified in 10 CFR 51.91. The final EIS must include any comments on the draft EIS or on any supplement to the draft, which may include modification of alternatives, development of new alternatives, and modification of analyses. All substantive comments received on the draft will be attached to the final EIS and any relevant responsible opposing view not adequately discussed in the draft will be presented. The final EIS will include:

a. A summary of the final EIS
b. A discussion of the purpose and need for the proposed action
c. A discussion of alternatives including the proposed action
d. A description of the affected environment
e. A discussion of the environmental consequences and mitigating actions

f. A list of preparers
g. Final recommendation on the action to be taken

9.6.2.4 Record of Decision

A Record of Decision (ROD) will be published after preparation of the final EIS and may be integrated into any other record prepared by the NRC in connection with the action. Requirements for the preparation of a ROD for materials licensing actions are contained in 10 CFR 51.102- 51.103. A ROD will include the following:

a. A statement of the decision
b. Identification of the alternatives considered
c. Identification of the environmentally preferable alternative
d. Discussion of the preferences among the alternatives, based on economic and technical considerations, the NRC's statutory mission, and any essential considerations of national policy, which were balanced by the NRC in making the decision
e. Statement of whether the NRC has taken all practical measures within its jurisdiction to avoid or minimize environmental harm, and if not, to explain why those measures were not adopted
f. Summary of any license conditions and monitoring programs adopted in connection with mitigation measures

9.7 REFERENCES

American National Standards Institute, N13.1-1982, "Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities".

American National Standards Institute, N42.18-1980, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents".

National Council on Radiation Protection and Measurements, NCRP Report No. 123 I & II, *"Screening Models for Releases of Radionuclides to Atmosphere, Surface Water, and Ground,"* January 1996.

NRC Information Notice No. 94-23: "Guidance to Hazardous, Radioactive and Mixed Waste Generators on the Elements of a Waste Minimization Program," March 25, 1994.

NRC Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20," January 28, 1994.

U.S. Nuclear Regulatory Commission, NMSS/FCSS/Fuel Cycle Licensing Branch, Rev. 5, *"Materials Licensing Procedures Manual,"* September 1996.

U.S. Nuclear Regulatory Commission, Regulatory Guide 4.15, Rev. 2, *"Quality Assurance for Radiological Monitoring Programs (Normal Operations) ! Effluent Streams and the Environment,"* February 1979.

U.S. Nuclear Regulatory Commission, Regulatory Guide 4.16, Rev. 2, *"Monitoring and Reporting Radioactivity in Releases of Radioactive Materials in Liquid and Gaseous Effluents from Nuclear Fuel Processing and Fabrication Plants and Uranium Hexafluoride Production Plants,"* December 1985.

U.S. Nuclear Regulatory Commission, Regulatory Guide 4.20, *"Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees other Than Power Reactors,"* December 1996.

U.S. Nuclear Regulatory Commission, Regulatory Guide 8.37, *"ALARA Levels for Effluents from Materials Facilities"*, July 1993.

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U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

10.0 DECOMMISSIONING

10.1 PURPOSE OF REVIEW

The purpose of the review of the applicant's plans for decommissioning is to ensure that these plans provide reasonable assurance that the applicant will be able to decommission the facility safely and in accordance with NRC requirements.

At the time of the initial license application, and upon license renewal, the applicant/licensee may be required to submit a decommissioning funding plan (DFP). The purpose of NRC review of the DFP is to determine that the applicant/licensee has considered decommissioning actions which may be needed in the future, has performed a credible site-specific cost estimate for those actions, and has presented NRC with financial assurance to cover the cost of these actions in the future. The DFP, therefore, should contain an overview of the proposed decommissioning actions, the methods used to determine the cost estimate and the financial assurance mechanism. These must be in sufficient detail to allow the reviewer to determine that the decommissioning cost used in the DFP is reasonably accurate.

In general, decommissioning plans (DP) are submitted through license amendments prior to the initiation of decommissioning activities, for the entire site or some portion of the site. The review for a DP is more rigorous than the review of the DFP. A DP must contain a detailed description of the specific decommissioning activities to be performed and must be sufficient to allow the reviewer to assess the appropriateness of the decommissioning activities, the potential impacts on health and safety of the public, workers, and the environment and the adequacy of the actions to protect health and safety and the environment. The reviewer must ascertain that the applicant understands decommissioning requirements and procedures, and commits to health and safety during decommissioning.

10.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: Environmental Reviewer
Technical and financial specialists in the Division of Waste Management

Supporting: Fuel facility inspection staff

10.3 AREAS OF REVIEW

The reviewer will evaluate the applicant's decommissioning funding plan or decommissioning plan in accordance with "NMSS Decommissioning Program Standard Review Plan" currently under development in the Division of Waste Management.

10.4 ACCEPTANCE CRITERIA

10.4.1 Regulatory Requirements

Decommissioning planning, financial assurance for decommissioning, recordkeeping for decommissioning, and waste and contamination minimization are required by the following NRC regulations:

10 CFR 70.22(a)(9)	Decommissioning Funding Plan
10 CFR 70.25	Financial Assurance and Recordkeeping for Decommissioning
10 CFR 70.38	Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas
10 CFR 20.1401-1406 (Subpart E)	Radiological Criteria for License Termination

10.4.2 Regulatory Guidance

Relevant regulatory guidance for decommissioning in license applications and amendment requests is included in the "NMSS Decommissioning Program Standard Review Plan" currently under development.

10.5 REVIEW PROCEDURES

Upon acceptance of the application/amendment for review, the primary reviewer will review the application against NRC requirements and acceptance criteria identified in "NMSS Decommissioning Program SRP". This review will be supplemented as appropriate by detailed review of any contamination and waste minimization plans submitted by the applicant in response to 10 CFR 20.1406. The reviewer will also coordinate with the principal reviewers for environmental protection under SRP 9.0 to confirm review of a new applicant's descriptions of plans for waste minimization, as well as plans for existing licensees to minimize contamination and reduce exposures and effluents as part of radiation protection established under 10 CFR Part 20. The purpose of this coordination is to ensure that any issues that are relevant to the environmental review are properly conveyed to the lead reviewers for these sections for consideration and resolution. Similarly, any decommissioning issues that arise in the

environmental review that are most suited for review under SRP 10.0 are conveyed to the primary reviewer for consideration and resolution.

If the review identifies the need for the applicant to submit information that has not already been included in the application, the reviewer will document these additional information needs in a Request for Additional Information (RAI). The RAI will be transmitted to the applicant with a request for the information in a reasonable amount of time (e.g., 30 to 60 days). Failure of the applicant to provide the information by the requested date, or on an alternative schedule that is mutually agreeable, could be grounds to terminating or suspending the application review.

In accordance with the FCLB licensing manual, the lead reviewer will coordinate with the Division of Waste Management for appropriate technical assistance reviewing proposed decommissioning plans and financial assurance. The lead reviewer will coordinate the evaluation of the application with reviewers assigned by the Division of Waste Management and will incorporate, as appropriate, RIAs and review findings in licensing correspondence and safety evaluation reports related to decommissioning.

10.6 EVALUATION FINDINGS

If the staff's review verifies that sufficient information has been provided in the application to satisfy the acceptance criteria and requirements identified in SRP 10.4, the staff will document its review as follows:

> The NRC staff has reviewed the applicant/licensee's plans for financial assurance for decommissioning in accordance with SRP 10.0 Based upon this review, the NRC staff has determined that the applicant's plans for decommissioning and decommissioning financial assurance provide reasonable assurance of protection for members of the public and the environment and comply with NCR's regulations.

10.7 REFERENCES

Code of Federal Regulations, Title 10, Part 70, Domestic Licensing of Special Nuclear Material, U.S. Government Printing Office, Washington, DC.

Orlando, D. A., *et al*. 1997. *NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees*, U.S. Nuclear Regulatory Commission, NUREG/BR-0241.

U.S. Nuclear Regulatory Commission, date to de determined, *NMSS Decommissioning Program Standard Review Plan*, NUREG-XXX,

U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

11.0 MANAGEMENT MEASURES

Management measures are functions that are performed by a licensee, generally on a continuing basis, that are applied to items relied on for safety, to ensure the items are available and reliable to perform their functions when needed. The phrase "available and reliable" as used in this rule means that, based upon the analyzed, credible conditions in the integrated safety analysis, items relied on for safety will perform their intended safety function when needed and management measures will be implemented that ensure continuous compliance with the performance requirements, considering factors such as necessary maintenance, operating limits, common cause failures, and the likelihood and consequences of failure or degradation of the items and the measures. Management measures include configuration management, maintenance, training and qualifications, procedures, audits and assessments, and other quality assurance elements. The degree to which measures are to be applied to the items is a function of the item's importance in terms of meeting the performance requirements. In the Chapter 11 discussions that follow, aspects of configuration management, maintenance, training and qualifications, procedures, and audits and assessments are briefly discussed under the overall umbrella of quality assurance in section 11.8; however, these areas are discussed in more depth in individual sections in Section 11 (i.e., sections 11.1 - 11.7) because of their importance and because they are broader in scope than discussed in section 11.8.

11.1 CONFIGURATION MANAGEMENT

11.1.1 PURPOSE OF REVIEW

This review should ensure that the applicant has a plan for or has implemented an acceptable configuration management (CM) function. The reviewer should determine, with reasonable assurance, that the applicant has described and committed to a CM function that assures consistency among the facility design and operational requirements, the physical configuration, and the facility documentation. The reviewer should also determine that the applicant's CM function captures formal documentation governing the design and continued maintenance of those facility structures, systems, and components (SSC) and supporting management measures, as identified and described in the ISA. The review should assure that the CM function is adequately coordinated and integrated with the other management measures.

11.1.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: Primary ISA Reviewer, Quality Assurance Reviewer, Records Management Reviewer

Supporting: Fuel Cycle Facility Inspector

11.1.3 AREAS OF REVIEW

The NRC staff should review the applicant's descriptions and commitments for CM, focusing on the processes for documenting an established baseline configuration and controlling changes to it to preclude inadvertent degradation of safety. The reviewers should examine descriptions of the organizational structure responsible for CM activities and the process, procedures, and documentation required by the applicant for modifying the site; items relied on for safety and the supporting management measures. The staff review should focus on the applicant's management measures that ensure the disciplined documentation of engineering, installation, and operation of modifications; the training and qualification of affected staff; revision and distribution of operating, test, calibration, surveillance, and maintenance procedures and drawings; post-modification testing; and readiness review.

The NRC staff should review the following topics:

1. CM Policy

The review should cover the applicant's description of overall CM functions, including at least the following topics: (a) the scope of the SSCs to be included in the CM function (b) objectives of each CM activity, (c) a description of each CM activity, and (d) the organizational structure and staffing interfaces.

The review should examine the applicant's establishment of a baseline CM policy applicable to all operations, initially independent of the ISA. The review should also examine the applicant's proposed reduced level of CM that the applicant may propose for certain SSCs based on the ISA.

2. Design Requirements

The review should cover the applicant's demonstration that design requirements and associated design bases have been established and are maintained by an appropriate organizational unit. The applicant's CM controls on the design requirements and the ISA should be evaluated.

3. Document Control

The review should include the applicant's methods used to establish and control documents within the CM function.

4. Change Control

The review should examine the applicant's commitments to ensure that the CM function maintains strict consistency among the design requirements, the physical configuration, and the facility documentation. An important component of this review is the applicant's process, within the CM function, for ensuring that the ISA will be systematically reviewed and modified to reflect design or operational changes from an established safety basis, and that all documents outside the ISA that are affected by safety basis changes will be properly modified, authoritatively approved, and made available to personnel.

5. Assessments

The review should examine the applicant's commitments to conduct assessments, including initial and periodic examinations of the CM system, to determine the function's effectiveness, and to correct deficiencies, consistent with the acceptance criteria in SRP Section 11.7, "Audits and Assessments."

6. Design Reconstitution

The review will examine the applicant's discussion of design reconstitution of the current design basis that has been done for the purpose of the application, and how that reconstitution was/is translated into a fixed baseline design basis from which subsequent changes are measured.

11.1.4 ACCEPTANCE CRITERIA

11.1.4.1 Regulatory Requirements

The requirement for configuration management is explicitly addressed in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," as revised (e.g., Part 70 definitions; 70.72).

11.1.4.2 Regulatory Guidance

There are no regulatory guides that apply to configuration management for a facility licensed under 10 CFR Part 70.

11.1.4.3 Regulatory Acceptance Criteria

The reviewers should determine that an applicant's CM function is acceptable if it satisfies the following criteria.

1. CM Policy

The applicant's description of overall CM functions describes at least the following topics: (a) the scope of the items relied on for safety (SSCs and management measures) to be included in the CM function (coordinate with the Section 3, ISA, reviewer for the application), (b) the objectives of each CM function activity, (c) a description of each CM function activity, and (d) the organizational structure and staffing interfaces. The functional interfaces with maintenance, and training and qualification are of particular importance and should be addressed individually. The scope of SSCs should include all those items relied on for safety as defined by the ISA summary.

An important element of an applicant's overall CM policy is the establishment of a baseline CM policy applicable to all applicant operations, independent of ISA. That baseline initially includes all the CM functions described in this SRP Chapter. After an ISA is completed and SSCs are identified that may not be associated with high risk accident sequences, as defined by the ISA summary or the ISA, the applicant may choose to reduce or eliminate certain features of the CM function as applied to those lesser risk design or operational features. In that case, the applicant then, in its description of CM policy, defines the specific attributes of a reduced level or levels of CM that would be applied to selected items relied on for safety, and in the ISA identifies those items that will be assigned the lesser category of CM.

2. Design Requirements

The applicant demonstrates that design requirements and associated design bases have been established and are maintained by an appropriate organizational unit. The applicant demonstrates that the design requirements and the ISA are kept current and that suitable hazard/accident analysis methods, including controlled computer codes, if used, are available and are properly used to evaluate safety margins of proposed changes. Technical management review and approval procedures are described. The specific items relied on for safety included in the CM function are identified within the ISA summary report.

3. Document Control

The applicant describes an acceptable method to establish and control documents within the CM function, including cataloging the document data base, the information content of the document data base, maintenance and distribution of documents, document retention policies, and document retrieval policies. A list of the types of documents controlled is established and includes key

documents, such as drawings, procurement specifications, engineering analyses, operating procedures, training/qualification records, and preventive and corrective maintenance procedures, and maintenance completion records.

4. Change Control

The applicant demonstrates that the CM function maintains strict consistency among the design requirements, the physical configuration, and the facility documentation. The applicant describes an acceptable process for identifying and authorizing proposed changes, performing appropriate technical and safety reviews of proposed changes, approving changes, implementing changes, and documenting changes. The applicant describes an acceptable process, within the CM function, for ensuring that the ISA is systematically reviewed and modified to reflect design or operational changes from an established safety basis, and that all documents outside the ISA that are affected by safety basis changes are properly modified, authoritatively approved, and made available to personnel.

5. Assessments

The applicant confirms that assessments, including initial and periodic examinations of the CM system, are conducted to determine the program's effectiveness and to correct deficiencies. The applicant indicates that such assessments are systematically planned and conducted in accordance with an overall facility audit and assessment function as described by the applicant and reviewed by NRC in accordance with Section 11.7 of this SRP.

6. Design Reconstitution [Existing Facilities Only]

The applicant describes the design reconstitution that has been done for the purpose of the application. Because this information may duplicate the plant design bases information described elsewhere to support the ISA, this information may be included by reference to other parts of the application. The applicant has reconstituted the current design bases, supporting analyses, requirements, and documentation that support items important to safety. The reconstitution process, including walk-downs, is complete and verifies that the configuration is consistent with as-built facility documentation.

11.1.5 REVIEW PROCEDURES

11.1.5.1 Acceptance Review

The primary reviewer should evaluate the application to determine whether it addresses the "Areas of Review" discussed in Section 11.1.3, above. If significant

deficiencies are identified, the applicant should be requested to submit additional material before the start of the safety evaluation.

The reviewer should also determine that the applicant has committed to a formal CM function for establishing design bases and reviewing proposed changes to items, procedures, and processes that may impact SSCs relied on for safety.

11.1.5.2 Safety Evaluation

After determining that the application is acceptable for review in accordance with Section 11.1.1, above, the primary reviewer should perform a safety evaluation against the acceptance criteria described in Section 11.1.4. Review procedures for each criterion are discussed in the following:

1. CM Policy Management

The primary reviewer should consider the CM plan that states management commitments, gives the policy directive, and defines key responsibilities, terminology, and equipment scope. The method for initiating immediate corrective actions is examined. The secondary reviewers should examine the ISA summary and the ISA as needed for the identification of dependence on CM of items relied on for safety. Appropriate interfaces both within the CM function and with external organizations and functions should be examined. In particular, the functional interfaces with QA, maintenance, and training (including qualification) should be examined. The reviewers look for the applicant's identification of required databases and the rules for their maintenance. The reviewers examine implementing procedures for the CM function.

2. Design Requirements

The primary reviewer should confirm that the design process leading to drawings and other statements of requirements proceeds logically from the design basis. The design basis is a set of facts, about the systems covered by CM, that has been reviewed and approved by appropriate authority within the organization. The reviewers should verify that specific personnel are assigned the responsibility for maintaining the design bases and requirements. These may be the same personnel that maintain the ISA and controlled computer codes. The reviewers should verify that the items relied on for safety to be listed under CM are clearly defined in the requirements documents, along with the assignment of any grades or quality levels. The grades or quality levels, if specified, are based on the qualitative risk associated with postulated accident sequences in which the items relied on for safety are required to function. This part of the review should be coordinated with the ISA primary reviewer. The ISA summary specifies all items relied on for safety, and the applicant should have indicated in the ISA what level of CM attributes are applied to a particular item. However, in the ISA this indication may consist of only an index or category designation. The

definition of the individual content of multiple CM levels, if used, should be in the CM Chapter of the application. The primary reviewer for the CM Chapter is responsible to determine if the reduced levels the applicant would apply to safety items for lesser risk accident sequences are adequate.

3. Document Control

The primary reviewer should evaluate the applicant's material showing that the CM system will capture documents that are relevant and important to safety. This includes design requirements, the ISA, as-built drawings, specifications, all safety-important operating procedures, procedures involving training (note that general training is also discussed in SRP Section 11.3) , QA, maintenance, audits and assessments, emergency operating procedures, emergency response plans, system modification documents, assessment reports, and others, as necessary, that the applicant may deem part of the CM function. The primary reviewer should determine whether a controlled document database is used to control documents and track document change status. Rules of storage for originals or master copies of documents within the CM function follow the guidance of "Records Management" discussed in SRP Section 11.7.

4. Change Control

The primary reviewer should ensure that the description of change control within the CM function commits to acceptable methods in place for: (a) the identification of changes in configurations relied on for safety; (b) technical and management review of changes, and (c) tracking and implementing changes, including placement of documentation in a document control center and dissemination to affected functions such as training, engineering, operations, maintenance, and QA. Post-modification testing of hardware (or procedure drills or walk-throughs) may be done in conjunction with periodic equipment performance monitoring and normal maintenance functions.

5. Assessments

The primary reviewer should ensure that both document assessments and physical assessments (system walkdowns) will be conducted periodically to check the adequacy of the CM function. The primary reviewer should ensure that all assessments and follow-ups are documented. These reports can provide a supporting basis for future changes. The primary reviewer should assure that assessments will include at least a sampling level of reviews of safety systems from design requirements through implementation.

6. Design Reconstitution [Existing Facilities Only]

Design reconstitution may be necessary for older plants if existing design information is not adequate. The primary reviewer examines the applicant's description of work to establish, organize, and document design requirements

and design bases for items for which design information was not available before the application was submitted. Of particular importance are the methods used to evaluate, verify, and validate reconstituted design data for SSCs. For older plants, the design requirements and physical configuration may have greatly changed according to the demands of a changed mission. If documentation has not kept pace, it will be necessary for the applicant to walk down systems, update drawings and specifications, perform new calculations and analyses, and otherwise rebuild the design bases. The reviewer looks for evidence that the applicant has considered system interactions, such as heavy overhead equipment falling on sensitive equipment below, the effect of leaks and electrical problems on nearby equipment, and difficulties of inspection and maintenance. The reviewer will seek evidence that the need for design bases reconstitution was investigated, that reconstitution was accomplished as necessary, and that new or revised documentation was properly incorporated into the CM function. On the basis of its review, the staff may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria in Section 11.1.4 of this SRP.

11.1.6 EVALUATION FINDINGS

The staff's evaluation should verify that the license application provides sufficient information to satisfy the regulatory requirements of Section 11.1.4.1 and that the regulatory acceptance criteria in Section 11.1.4.3 have been appropriately considered in satisfying the requirements. On the basis of this information, the staff should conclude that this evaluation is complete. The reviewers should write material suitable for inclusion in the SER prepared for the entire application. The SER should include a summary statement of what was evaluated and the basis for the reviewers' conclusions.

The staff can document the evaluation as follows:

The staff has reviewed the Configuration Management (CM) function for (name of facility) according to Section 11.1 of the Standard Review Plan. **[Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.]**

The applicant has suitably and acceptably described its commitment to a proposed CM system, including the method for managing changes in procedures, facilities, activities, and equipment for systems important to safety. Management level policies and procedures, including an analysis and independent safety review of any proposed activity involving systems important to safety, are described that will ensure that the relationship between design requirements, physical configuration, and facility documentation is maintained as part of a new activity or change in an existing activity involving licensed material. The management measures will include (or do include) the following elements of CM.

1. <u>CM Management</u>

The organizational structure, procedures, and responsibilities necessary to implement configuration management are in place or committed to.

2. Design Requirements

The design requirements and bases are documented and supported by analyses and the documentation is maintained current.

3. Document Control

Documents, including drawings, are appropriately stored and accessible. Drawings and related documents adequately describe systems important to safety.

4. Change Control

Responsibilities and procedures adequately describe how the applicant will achieve and maintain strict consistency among the design requirements, the physical configuration, and the facility documentation. Methods are in place for suitable analysis, review, approval, and implementation of identified changes to systems important to safety. This includes appropriate CM controls to assure configuration verification, functional tests, and accurate documentation for equipment or procedures that have been modified.

5. Assessments

Methods or plans are in place to perform initial and periodic examination of the effectiveness of the CM system itself. In the case of existing facilities, assessments and follow-up reports of corrective actions are documented.

6. Design Reconstitution **[Existing Facilities Only]**

For older plants whose design documentation was not adequate, the applicant has committed to reconstructing the current design bases, supporting analyses, requirements, and documentation that support items important to safety. The reconstitution process, including walk-downs, is complete and verifies that the configuration is consistent with as-built facility documentation.

In situations where the applicant proposes a graded CM function based on risk significance the following can be added*: the applicant has described its approach to applying at least two levels of CM attributes to items relied on for safety, and has identified which safety items involve lower risk and may receive the reduced level of CM requirements. The applicant's proposed reduced CM features are found adequate to contribute to the reliability and availability of the lesser risk items relied on for safety identified in the application.*

11.1.7 REFERENCES

Code of Federal Regulations, Title 10, Part 70, *Domestic Licensing of Special Nuclear Material,* U.S. Government Printing Office, Washington, DC.

Proposed Revision to Code of Federal Regulations, Title 10, Part 70, *Domestic Licensing of Special Nuclear Material,* as revised.

NUREG-1324, *Proposed Method for Regulating Major Materials Licensees*, Section 3.2.6, Configuration Management, U.S. Nuclear Regulatory Commission, 1992.

DOE-STD-1073-93, *DOE Standard: Guide for Operational Configuration Management Function,* Parts I and II, Department of Energy, 1993.

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STANDARD REVIEW PLAN

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11.2 MAINTENANCE

11.2.1 PURPOSE OF REVIEW

The purpose of this review is to determine with reasonable assurance that the applicant has committed to provide an adequate graded approach for the maintenance and surveillance of items that they identified "as items relied on for safety". The objective for the maintenance function is make sure that the graded approach utilized by the applicant will provide the availability and reliability that is necessary, according to the ISA, for items relied on for safety to perform their function when needed.

11.2.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: Criticality, chemical, fire, radiation protection and environmental reviewers

Supporting: Fuel Cycle Facility Inspection Staff
Region Inspection Staff and Resident Inspector

11.2.3 AREAS OF REVIEW

The NRC staff will evaluate the applicant's description of their maintenance function. The applicant should demonstrate that items relied on for safety (safety controls) are inspected, calibrated, tested and maintained, to the level commensurate with the risk, to ensure their ability to perform their safety functions when called upon. These safety controls are identified by the applicant in either the ISA summary. The staff will review the applicant's description of how each of the following functions is implemented within the site organization. *Note that not every aspect of the four maintenance functions is necessarily required, the applicant is expected to identify the items relied on for safety in the ISA Summary and would justify assigning differing degrees of maintenance to safety components based on the item's contribution to the reduction of risk.*

1. Corrective maintenance

2. Preventive maintenance

3. Surveillance/monitoring

4. Functional testing

11.2.4 ACCEPTANCE CRITERIA

11.2.4.1 Regulatory Requirements

10 CFR 70.62(d), *Safety Program and Integrated Safety Assessment,* requires that the applicant's management measures shall ensure that engineered and administrative controls and control systems that are identified as items relied on for safety pursuant to §70.61(e) are maintained to ensure they are available and reliable to perform their function when needed.

11.2.4.2 Regulatory Guidance

Regulatory guidance applicable to this area of the SRP is listed below.

U.S. Nuclear Regulatory Commission, *Guidance on Management Controls/Quality Assurance, Requirements for Operation, Chemical Safety, and Fire Protection for Fuel Cycle Facilities*, Federal Register 54 (No. 53), 11590 ! 11598, March 21, 1989.

11.2.4.3. Regulatory Acceptance Criteria

NRC will find the applicant's submittal acceptable if the application includes the following:

1. Surveillance/monitoring

   For items relied on for safety identified in the ISA summary. The applicant describes the surveillance function and its commitment to the organization and conduct of surveillance at a specified frequency, to measure the degree to which engineered safety functions meet performance specifications. This activity is used in setting preventive maintenance frequencies for items relied on for safety and the determination of performance trends for safety items. Applicant describes how results from incident investigations (described in SRP Section 11.6) and identified root causes are used to modify the affected maintenance function and eliminate or minimize the root cause from recurring. Records showing the current surveillance schedule, performance criteria, and test results for all safety features subject to this maintenance component are maintained by the applicant. For surveillance tests that can only be done while equipment is out of service, proper compensatory measures are prescribed for the continued normal operation of a process.

2. Corrective maintenance

   Applicant provides the documented approach used to perform corrective actions or repairs on items that are relied on for safety (safety controls). These safety controls are provided in the ISA summary . The maintenance function provides a planned,

systematic, integrated and controlled approach for the repair and replacement activities associated with identified failures to safety controls. After conducting corrective maintenance and prior to returning a safety control to operational status, if necessary, a functional test is conducted to ensure that a safety control performs as designed and provides the safety action expected. Applicant describes how results from incident investigations and identified root causes are used to modify the affected maintenance function and eliminate or minimize the root cause from recurring. Contractors that work on or near safety controls identified in the ISA summary receive the same level of training and follow the same work control activities as listed above. Note that general training guidance is discussed in SRP Section 11.3.

3. Preventive maintenance

Applicant provides a description of the preventive maintenance (PM) function that demonstrates a commitment to conduct preplanned and scheduled periodic refurbishing, partial or complete overhaul, for the purpose of ensuring that unplanned outages of selected safety functions do not occur. This activity includes using the results of the surveillance component of maintenance. Instrumentation calibration and testing is addressed by the applicant as part of this component. The applicant describes how the function will be designed to ensure that the objective of preventing failures through maintenance is appropriately balanced against the objective of minimizing unavailability of safety features because of monitoring or preventive maintenance. After conducting PM and prior to returning a safety control to operational status, if necessary, a functional test is conducted to ensure that a safety control performs as designed and provides the safety action expected. The methodology or basis used to determine PM frequency is described. Applicant describes how results from incident investigations and identified root causes are used to modify the affected maintenance function and eliminate or minimize the root cause from recurring. Feedback from the PM and corrective maintenance function is used to change frequency or scope of the maintenance activity. A rationale for deviation from industry standards or vendor recommendations is provided. Records showing the PM schedule, and results, for all safety features subject to this maintenance component are maintained by the applicant.

4. Functional testing

Applicant includes a description of and commitment to the functional testing of safety controls for surveillance purposes or if needed after corrective/ preventive maintenance or calibration. These tests are conducted using approved procedures and include compensatory measures while the test is being conducted. The description includes the methods used, the frequency, and the basis for each. Applicant ensures that the functional tests cover all aspects of the safety control. As an example, if a level controller is used to actuate a three-way valve and divert flow to an alternate tank, then the level monitor sending unit and the valve, power supplies, utility services, and any corresponding local or control room displays are tested at the same time during the functional test. The intent is to simulate actual upset conditions and demonstrate that the safety control is available and reliable and will function in the field as intended. Applying a

milliamp signal across the leads of the level monitor and watching the valve cycle open or close, is not considered an adequate functional test. During startup of new process equipment these functional tests are conducted, documented and maintained for NRC review. Records showing the functional test schedule for all safety features subject to this maintenance component, and results, are maintained by the applicant.

If any Administrative Controls are identified as being an item relied on for safety, the applicant should provide a discussion in SRP Section 11.3, Training and Qualification, on how this type of item relied on for safety is kept available and reliable to perform it's intended safety function.

The work control methods listed below are applied to the corrective, preventive and functional testing maintenance elements and include (as applicable): a) authorized work instructions with detailed steps and a reminder on the importance of the safety controls identified in the ISA summary; b) parts lists; c) as built or redlined drawings; d) a notification step to the operations function prior to conducting repairs and removing a safety control from service; e) work permits for welding and cutting, confined space or radiation related work; f) replacement with like/kind parts and the control of new or replacement parts to ensure compliance with 10 CFR Part 21; g) compensatory measures while performing work on safety controls; h) procedural control of removal of components from service for maintenance and for return to service; i) ensuring safe operations during the removal of safety controls from service; j) and, notification to operations personnel that repairs have been completed. Written procedures for the performance of maintenance includes these steps (a through j) and the elements discussed in SRP Section 11.4, "Procedures". All approved documents, work requests and maintenance procedures include technical, safety discipline reviews and approval as well as approval by responsible management.

The four maintenance elements described above are covered by elements of the management measures discussed in SRP Section 11.0. The applicant includes a discussion or provides references, of how the maintenance function utilizes, interfaces with, or is linked to the various management measures. As an example, maintenance workers are trained and qualified to perform their duties and a description of the link between maintenance and the training and qualification function is described.

11.2.5 REVIEW PROCEDURES

The reviewer should review the Regulatory Guidance: references in this chapter; the applicant's 91-01, 7050, and 70.74 reports and 10 CFR 70 Appendix A reporting requirements.

11.2.5.1 Acceptance Review

The Primary Reviewer should review the applicant's maintenance function for completeness against requirements in 10 CFR 70.61, 70.62, 70.64 and Acceptance Criteria in 11.2.4. Using guidance in the "Materials Licensing Procedures Manual", if deficiencies are identified, the

applicant should be requested to submit additional material, or the application should be denied for further safety evaluation under section 11.2.5.2.

11.2.5.2 Safety Evaluation

If the applicant's submittal is acceptable, the reviewer conducts the review of the applicant's maintenance function with respect to the acceptance criteria. The SER forms the basis for NRC staff's findings and supports the reviewers' conclusions based on the "Acceptance Criteria" in Section 11.2.4. The reviewer will evaluate the applicant's description of how the maintenance function will coordinate and utilize the other management measures listed in this chapter. The Primary Reviewer should consult with the Supporting Reviewers to identify any common weaknesses in the applicant's approach and consider these during the review.

An acceptable maintenance function includes descriptions and demonstrates applicant's adequate commitments to the following: corrective maintenance, preventive maintenance, surveillance/monitoring, and functional testing.

11.2.6 EVALUATION FINDINGS

The applicant's commitments regarding ability to maintain the availability and reliability of items relied on for safety (as identified by the ISA sumary) should be deemed acceptable if they satisfy the acceptance criteria. Based on a positive finding the staff will include a statement in the SER using the following language:

> The applicant has committed to maintenance of items relied on for safety. The applicant's maintenance commitments contain the basic elements to ensure availability and reliability: corrective maintenance, preventive maintenance, functional testing, equipment calibration, work control, and management measures for safety controls. The applicant's maintenance function is proactive, using maintenance records, preventive maintenance records, and surveillance tests to analyze equipment performance and to seek the root causes of repetitive failures.
>
> The surveillance activities described in this section of the application ensure the validity of the ISA by examination and calibration and testing of equipment that monitors process safety parameters and acts to prevent or mitigate accident consequences.
>
> The maintenance function: (1) is based on approved procedures; (2) employs work control methods that properly consider personnel safety, awareness of facility operating groups, quality assurance, and the rules of configuration management; (3) links items relied on for safety requiring maintenance to the ISA summary; (4) justifies the preventive maintenance intervals in the terms of equipment reliability goals; (5) provides for training that emphasizes importance of ISA or ISA summary identified controls, regulations, codes, and personal safety; and (6) creates documentation that includes detailed records of all surveillance, inspections, equipment failures, repairs, and replacements.

The staff concludes that the applicant's maintenance functions meet the requirements of 10 CFR Part 70, and provide reasonable assurance that the health and safety of the public are protected.

In cases where the SER is drafted in advance of resolving all outstanding maintenance issues, the reviewer documents the review as described above and includes a list of open issues that require resolution prior to the staff's position finding of reasonable assurance.
For partial reviews, revisions, and process changes, the reviewer will use applicable sections of the acceptance criteria and the SER will be written to reflect what portions were not reviewed and the maintenance significance, if any. Upon completion of the review, NRC staff may impose temporary or one-time license conditions to authorize short duration activities. For certain functions and requirements that concern safety or regulatory issues, a license condition may be imposed and remain in effect until removed by an amendment or license renewal.

11.2.7 REFERENCES

Code of Federal Regulations, Title 10, Part 21, *Reporting of Defects and Noncompliance*, U.S. Government Printing Office, Washington D.C., as revised.

Code of Federal Regulations, Title 29, Part 1910.119, *Process Safety Management of Highly Hazardous Chemicals*, U.S. Government Printing Office, Washington D.C., as revised.

Code of Federal Regulations, Title 40, Part 68, *Risk Management Program for Chemical Accidental Release Prevention*, U.S. Government Printing Office, Washington D.C., as revised.

U.S. Nuclear Regulatory Commission, *Guidance on Management Controls/Quality Assurance, Requirements for Operation, Chemical Safety, and Fire Protection for Fuel Cycle Facilities*, Federal Register 54 (No. 53), 11590 ! 11598, March 21, 1989.

U.S. Nuclear Regulatory Commission, Inspection Procedure 88062, *Maintenance and Inspection*, dated January 16, 1996.

U.S. Nuclear Regulatory Commission, Inspection Procedure 88025, *Maintenance and Surveillance Testing*, dated May 23, 1984.

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OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

11.3 TRAINING AND QUALIFICATION

11.3.1 PURPOSE OF REVIEW

Training and qualification is a management measure to be applied to items relied on for safety (in this case, activities of personnel identified as an item relied on for safety), commensurate with their contribution to risk, to ensure that personnel will perform their safety functions when needed. The purpose of this review is to establish that the applicant's proposed training and qualifications provide reasonable assurance that personnel will understand, recognize the importance of, and be qualified to perform their activities that are relied on for safety as required by 10 CFR Part 70 in a manner that adequately protects (1) the health and safety of the public and workers and (2) the environment.

11.3.2 RESPONSIBILITY FOR REVIEW

Primary: Training Specialist, Quality Assurance Specialist, or Human Factors Specialist

Secondary: Licensing Project Manager

Supporting: Site Representative/Fuel Cycle Facility Inspector

11.3.3 AREAS OF REVIEW

Part 70 of Title 10 of the Code of Federal Regulations requires that personnel who perform activities relied on for safety be trained, tested, and retested as necessary to ensure that they understand, recognize the importance of, and are qualified to perform these activities in a manner that adequately protects (1) the health and safety of the public and workers and (2) the environment. As appropriate for their authority and responsibilities, these personnel should have the knowledge and skills necessary to design, construct, start-up, operate, maintain, modify, and decommission the facility in a safe manner. Therefore, the training, testing, retesting, and qualification of these personnel should be described in the application and should be reviewed by the staff. This should include the training, testing, retesting, and qualification of managers, supervisors, designers, technical staff, construction personnel, plant operators, technicians, maintenance personnel and other personnel who perform activities relied on for safety. The review of the training and qualification should address the following training objectives:

1. Organization and management of the training system
2. Trainee selection
3. Conduct of needs/job analysis and identification of tasks for training

4. Development of learning objectives as the basis for training
5. Organization of instruction using lesson plans and other training guides
6. Evaluation of trainee mastery of learning objectives
7. Conduct of on-the-job training
8. Systematic evaluation of training effectiveness
9. Personnel qualification
10. Applicant's provisions for continuing assurance

11.3.4 ACCEPTANCE CRITERIA

The regulatory requirements, regulatory guidance, and regulatory review criteria applicable to personnel training and qualification are listed in the following sections.

11.3.4.1 Regulatory Requirements

Regulatory requirements applicable to personnel training and qualification are:

1. Code of Federal Regulations, Title 10 (10 CFR), Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," specifically Section 19.12, "Instructions to Workers."

2. 10 CFR Part 70, "Requirements for the Domestic Licensing of Special Nuclear Material."

11.3.4.2 Regulatory Guidance

NRC guidance that may be applied to personnel training and qualification is given in NUREG-1220, "Training Review Criteria and Procedures," Revision 1, January 1993.

11.3.4.3 Regulatory Acceptance Criteria

The NRC reviewers should find the applicant's submittal regarding personnel training and qualification provides reasonable assurance that the regulatory review criteria below are adequately addressed and satisfied. In addition to the regulatory review criteria given below, SRP Subsections 4.1.5.4 and 4.1.5.6 provide criteria for personnel training and qualification for radiation safety functions. Thus, some of the information specified below may be found in other sections of the SRP and incorporated by reference.

1. Organization and Management of Training - The organization and management of training are acceptable if the design, construction, start-up, operation, maintenance, modification, and decommissioning of the facility are organized, staffed, and managed to facilitate planning, directing, evaluating, and controlling a systematic training process that fulfills job-related training needs. Formal training should be provided for each position or activity for which the required performance is relied on for safety. The application should state what training will be conducted and which personnel will be provided this training.

The following commitments should be in the application regarding organization and management of training:

1. Line management is responsible for the content and effective conduct of the training.
2. The job function, responsibility, authority, and accountability of personnel involved in managing, supervising, and implementing training is clearly defined.
3. Performance-based training is used as the primary management tool for analyzing, designing, developing, conducting, and evaluating training.
4. Procedures are documented and implemented to ensure that all phases of training are conducted reliably and consistently.
5. Training documents are linked to the configuration management system to ensure that design changes are accounted for in the training.
6. Exemptions from training are granted to trainees and incumbents only when justified, documented, and approved by management.
7. Both programmatic and individual training records are maintained. These records, support management information needs and provide required data on each individual's training, job performance, and fitness for intended duty. (Refer to SRP Section 11.9 for detailed guidance on records management.)

2. Trainee Selection - Trainee selection is acceptable if minimum requirements for trainees are specified for candidates whose activities are relied on for safety or who perform actions that prevent/mitigate accident sequences described in the Integrated Safety Analysis summary (ISA - See SRP Section 3). Trainees should meet entry-level criteria defined for the position including minimum educational, technical, experience, and physical fitness (if necessary) requirements.

3. Conduct of Needs/Job Analysis and Identification of Tasks for Training - The conduct of needs/job analysis and identification of tasks for training are acceptable if the tasks required for competent and safe job performance are identified, documented, and included in the training.

Construction personnel, operations personnel, training staff, and other subject matter experts, as appropriate, should have conducted or should conduct a needs/job analysis to develop a valid task list for specific jobs. The jobs treated in this manner should include - as a minimum - those responsible for managing, supervising, performing, and verifying the activities specified in the ISA summary as preventing or mitigating accident sequences. Each task selected for training (initial or continuing) from the facility-specific task list should be matrixed to supporting procedures and training materials. The facility-specific list of tasks selected for training and the comparison to training materials should be reviewed on an established schedule and updated as necessitated by changes in procedures, facility systems/equipment, or job scope.

4. Development of Learning Objectives as the Basis for Training - The development of learning objectives as the basis for training is acceptable if learning objectives that identify training content and define satisfactory trainee performance are derived from job performance requirements. Learning objectives should state the knowledge, skills, and abilities the trainee should demonstrate; the conditions under which required actions will take place; and the standards of performance the trainee should achieve upon completion of the training activity. Learning objectives should be sequenced based on their relationship to each other.

5. Organization of Instruction Using Lesson Plans and Other Training Guides - The organization of instruction using lesson plans and other training guides is acceptable if the plans/guides are based on the required learning objectives derived from specific job performance requirements.

Plans/guides should be used for in-class training and on-the-job training and should include standards for evaluating proper trainee performance. Review and approval requirements should be established for all plans/guides and other training materials before their issue and use.

6. Evaluation of Trainee Mastery of Learning Objectives - The evaluation of trainee mastery of learning objectives is acceptable if trainees are evaluated periodically during training to determine their progress toward mastery of job performance requirements and at the completion of training to determine their mastery of job performance requirements.

7. Conduct of On-the-Job Training - The conduct of on-the-job training is acceptable if on-the-job training used for activities required by the ISA are fully described. On-the-job training should be conducted using well-organized and current performance-based training materials. On-the-job training should be conducted by designated personnel who are competent in the program standards and methods of conducting the training. Completion of on-the-job training should be by actual task performance. When the actual task cannot be performed and is therefore "walked-down," the conditions of task performance, references, tools, and equipment should reflect the actual task to the extent possible.

8. Systematic Evaluation of Training Effectiveness - A systematic evaluation of training effectiveness and its relation to on-the-job performance is acceptable if it ensures that the training program conveys all required skills and knowledge and is used to revise the training, where necessary, based on the performance of trained personnel in the job setting. A comprehensive evaluation of individual training programs should be conducted periodically by qualified individuals to identify program strengths and weaknesses. Feedback from trainee performance during training and from former trainees and their supervisors should be used to evaluate and refine the training. Change actions (for example procedure changes, equipment changes, facility modifications) should be monitored and evaluated for their impact on the development or modification of initial and continuing training and should be incorporated in a timely manner. This should be accomplished through the configuration management system (See SRP Section 11.1). Improvements and changes to initial and continuing training should be systematically initiated, evaluated, tracked, and incorporated to correct training deficiencies and performance problems.

9. Personnel Qualification - The following commitments should be in the application regarding personnel qualification for managers, supervisors, designers, technical staff, construction personnel, plant operators, technicians, maintenance personnel and other staff required to meet NRC regulations:

a. Managers should have a minimum of a B.S./B.A. or equivalent. Each manager should have either management experience or technical experience in facilities similar to the facility identified in the application.

b. Supervisors should have at least the qualifications required of personnel being supervised with either one additional year experience supervising the technical area at a similar facility or should have completed the supervisor training.

c. Technical staff identified in the ISA summary whose actions or judgments are critical to satisfy the performance requirements identified in 10 CFR Part 70 (i.e. item relied on for safety) should have a B.S. in the appropriate technical field and three years

experience. Other technical staff should have a B.S. in the appropriate technical field and one year experience.

d. Construction personnel, plant operators, technicians, maintenance personnel, and other staff whose actions are required to comply with NRC regulations should have completed the applicant's training process or have equivalent experience or training.

e. Candidates for process operators should be required to meet minimum qualifications described in the application. Candidates for job functions other than process operators should also be required to meet minimum qualifications, but these minimum qualifications need not be described in the application.

10. Applicant's Provisions for Continuing Assurance - The applicant's provisions for continuing assurance of personnel training and qualification are acceptable if the submittal addresses periodic retesting of personnel as necessary to ensure that they continue to understand, recognize the importance of, and are qualified to perform their activities that are relied on for safety.

11.3.5 REVIEW PROCEDURES

11.3.5.1 Acceptance Review

The primary reviewer evaluates the application to determine whether it addresses the "Areas of Review" discussed in Section 11.3.3, above. If significant deficiencies are identified, the applicant should be requested to submit additional material before the start of the safety evaluation.

11.3.5.2 Safety Evaluation

After determining that the application is acceptable for review in accordance with Section 11.3.5.1, above, the primary reviewer should perform a safety evaluation against the acceptance criteria described in Section 11.3.4, recognizing that the rigor and formality of a systematic approach to training and the required personnel qualification may be graded to correspond to the hazard potential of the facility and to the complexity of the training needed. The review should determine whether the applicant has adequately planned for the training and personnel qualification to be accomplished and whether necessary policies, procedures, and instructions will be in place and appropriate training and qualification will be accomplished before personnel begin activities relied on for safety. The reviewers should focus on the training and qualification of personnel who will perform activities relied on for safety.

The secondary reviewer should confirm that the applicant's personnel training and qualification commitments are consistent with other sections of the submittal. The secondary reviewer should also integrate the personnel training and qualification input into the Safety Evaluation Report (SER).

The supporting reviewer should become familiar with the applicant's personnel training and qualification commitments and determine whether ongoing activities are in agreement with them.

On the basis of its review, the staff may request that the applicant provide additional information or modify the application to meet the acceptance criteria in SRP Section 11.3.4. The staff or applicant may also propose license conditions to ensure that the personnel training and qualification meet the acceptance criteria. The review should result in a determination that there is reasonable assurance that the applicant's personnel training and qualification will ensure that only properly trained and qualified personnel will perform activities relied on for safety.

When the safety evaluation is complete, the primary staff reviewer, with assistance from the other reviewers, should prepare the personnel training and qualification input for the SER as described in Section 11.3.6 using the acceptance criteria from Section 11.3.4.

11.3.6 EVALUATION FINDINGS

The staff's evaluation should verify that the license application provides sufficient information to satisfy the regulatory requirements of Section 11.3.4.1 and that the regulatory acceptance criteria in Section 11.3.4.3 have been appropriately considered in satisfying the requirements. The primary reviewer should also describe the applicant's approach to ensuring the quality and reliability of the controls required for personnel training and qualification. On the basis of this

information, the staff should conclude that this evaluation is complete. The reviewers write material suitable for inclusion in the SER prepared for the entire application. The SER should include a summary statement of what was evaluated and the basis for the reviewers' conclusions.

The staff can document the evaluation as follows:

> *"Based on its review of the license application,* [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] *the NRC staff has concluded that the applicant has adequately described and assessed its personnel training and qualification that (1) satisfy regulatory requirements, (2) are consistent with the guidance in this SRP, and (3) are acceptable.*
>
> *"There is reasonable assurance that implementation of the described training and qualification will result in personnel who are qualified and competent to design, construct, start-up, operate, maintain, modify, and decommission the facility safely. The staff concludes that the applicant's plan for personnel training and qualification meet the requirements of 10 CFR Part 70."*

11.3.7 REFERENCES

1. Proposed Revision to Code of Federal Regulations, Title 10, Part 70, *Domestic Licensing of Special Nuclear Material,* as revised.

2. NUREG-1220, Rev.1*, Training Review Criteria and Procedures*, U.S. Nuclear Regulatory Commission, January 1993.

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11.4 PROCEDURES

11.4.1 PURPOSE OF REVIEW

The purpose of this review is to determine if the applicant is capable and committed to providing operational control through development, review, control, and implementation of written procedures, which will protect the workers, the public and the environment.

11.4.2 RESPONSIBILITY FOR REVIEW

Primary: Radiation Protection, Criticality, Chemical, and Fire Safety Reviewers

Secondary: Fuel Cycle Facility Inspection Staff

Supporting: ISA Reviewer, Region staff and Resident Inspector

11.4.3 AREAS OF REVIEW

The NRC staff will review the process the applicant has developed for the production, use and management control of written procedures. This will include the basic elements of identification, development, verification, review and comment resolution, approval, validation, issuance, change control, and periodic review. The review includes two general types of procedures: 1) Procedures used to directly control process operations, commonly called "operating procedures". These are procedures for workstation operators and should include directions for normal operations as well as off-normal events caused by human error or failure of an item relied on for safety. Procedures of this type include required actions to ensure nuclear criticality safety, chemical safety, fire protection, emergency planning, and environmental protection; and, 2) Procedures used to effect activities that support the process operations, that are commonly referred to as "management control procedures". These are procedures used to manage the conduct of activities such as configuration management, radiation safety, maintenance, human-systems interface, quality assurance, training and qualification, audits and assessments, incident investigations, record-keeping and, reporting.

The applicant describes the following:

1. The method for identification of the procedures that are needed plant-wide. The ISA summary identifies items relied on for safety where human actions are important. Procedures exist for all necessary steps or operations that are conducted at the facility.

Procedures are provided for every element of management control that is discussed in the SRP sections.

2. Essential elements that are generic to all procedures including: criticality, chemical process and fire safety; warning notes; reminders or pertinent information regarding specific hazards or concerns which include station limits, MSDS availability, special precautions, radiation and explosive hazards; and, special personal protective equipment.

3. The method for creating and controlling procedures within plant management control systems. Includes how procedures are managed within the plant configuration management function.

4. Method for verifying and validating procedures before use. During procedure development, workers and operators review procedures to ensure they are usable and accurate.

5. The method for periodically reverifying and revalidating procedures.

6. The method for ensuring that current procedures are available to personnel and that personnel are qualified to use the latest procedures.

11.4.4 ACCEPTANCE CRITERIA

11.4.4.1 Regulatory Requirements

The regulation requirement for procedures that protect health and minimize danger to life is specified in 10 CFR 70.22(a)(8).

11.4.4.2 Regulatory Guidance

The Branch Technical Position on Management Controls/Quality Assurance for Fuel Cycle Facilities contained in the guidance listed below provides the regulatory guidance applicable to the areas of review in this SRP:

U.S. Nuclear Regulatory Commission, *Guidance on Management Controls/Quality Assurance, Requirements for Operations, Chemical Safety, and Fire Protection for Fuel Cycle Facilities*, Federal Register 54 (No. 53), 11590 ! 11598, March 21, 1989.

11.4.4.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's process for developing and implementing procedures is acceptable if it satisfies the following:

1. Procedures are written or planned for the conduct of all operations involving controls identified in the ISA summary as items relied on for safety and for all management control systems supporting those controls.

2. Operating procedures contain the following elements: (a) purpose of the activity; (b) regulations, polices, and guidelines governing the procedure; (c) type of procedure; (d) steps for each operating process phase; (e) initial startup; (f) normal operations; (g) temporary operations; (h) emergency shutdown; (I) emergency operations; (j) normal shutdown; (k) startup following an emergency or extended downtime; (l) hazards and safety considerations; (m) operating limits (n) precautions necessary to prevent exposure of hazardous chemicals or licensed special nuclear material; (o) measures to be taken if contact or exposure occurs; (p) safety controls associated with the process and their functions; (q) time frame for which the procedure is valid.

3. Management control procedures contain elements reflecting the important elements of the functions described in the applicable chapters of this SRP. Procedures exist to manage the following activities: a) configuration management; b) radiation safety; c) maintenance; d) human-systems interface; e) quality assurance; f) training and qualification; g) audits and assessments; h) incident investigations; i) records management; j) criticality safety; k) fire safety; l) chemical process safety; and, m) reporting requirements.

4. The applicant's method for identifying the procedures includes using ISA findings and conclusions to identify needed procedures. Process operating procedures provide specific direction regarding administrative controls to ensure process operational safety.

5. The applicant describes the method for identifying, developing, approving, implementing, and controlling procedures. This method includes, as a minimum, that (a) operating limits and controls are specified in the procedure; (b) procedures include required actions for off-normal conditions of operation as well as normal operations; (c) if needed, safety checkpoints are identified at appropriate steps in the procedure; (d) procedures are validated through field tests; (e) procedures are approved by management personnel responsible and accountable for the operation; (f) a mechanism is specified for revising and reissuing procedures in a controlled manner; (g) the quality assurance and configuration management programs at the plant ensure that current procedures are available and used at all work locations; and (h) the plant training program ensures that the required persons are trained in the use of the latest procedures available.

6. The applicant includes the following statement regarding procedure adherence: “Activities involving special licensed nuclear material will be conducted in accordance approved procedures”.

7. The applicant describes the types of procedures used by the facility. These will typically include management control, operating, maintenance, and emergency procedures. The applicant provides information regarding the procedure categories used at the facility. The applicant develops procedures for site wide safe work practices to provide for the control of processes and operations with licensed special nuclear material and hazardous chemicals. These safe work practices apply to workers, visitors and

contractors or vendors. An acceptable identification discussion clearly states areas for which a procedure is required. Procedures are required for operator actions that are necessary to prevent or mitigate accidents identified in the ISA and ISA summary. The applicant provides a listing (in an appendix) of the types of activities that are covered by written procedures. The listing includes the topics of administrative procedures; system procedures that address startup, operation, and shutdown; abnormal operation/alarm response; maintenance activities that address system repair, calibration, inspection and testing; and emergency procedures. Appendix A provides an acceptable listing of the items to be included under each topic.

8. Applicant reviews procedures following unusual incidents, such as an accident, unexpected transient, significant operator error, or equipment malfunction, or following any modification to a system and revises procedures as needed.

9. Applicant ensures technical accuracy of procedures and that they can be performed as written. The discussion identifies who is responsible for verification. The verification process ensures that the technical information is included and correct, including formulas, set points, acceptance criteria and includes either a walk-down of the procedure in the field or a table-top walk through. The review process includes technical, cross-discipline reviews by affected organizations. This process includes both new procedures and procedure changes. The review ensures that the operating limits and controls identified in the ISA are specified in the procedures and that quality assurance requirements are identified and included in operating procedures. The applicant describes who can approve procedures and includes the approval level for each procedure type. At a minimum, responsible management along with the safety disciplines approve new procedures and changes to existing procedures.

10. Documents are distributed in accordance with current distribution lists. A process is used to limit the use of outdated procedures. Copies are available to appropriate members of plant staff. Issuance and distribution of procedures is documented and refers to the Records Management function.

11. The applicant has formal requirements governing temporary changes. Temporary changes do not involve a change to the ISA or involve an item relied on for safety. The review and approval process is documented. Temporary procedures may be issued only when permanent procedures do not exist to: a) direct operations during testing, maintenance, and modifications; b) provide guidance in unusual situations not within the scope of permanent procedures; and, c) ensure orderly and uniform operations for short periods when the plant, a system, or component of a system is performing in a manner not covered by existing permanent procedures, or has been modified or extended in such a manner that portions of existing procedures do not apply. The discussion includes establishment of a time frame for use of the temporary procedure and includes the same level of review and approval as that for permanent procedures.

12. Maintenance procedures involving safety controls commit to the topics listed below for corrective, preventive, functional testing after maintenance, and surveillance maintenance activities:

a. Pre-maintenance activity requires reviews of the work to be performed, including procedure reviews for accuracy and completeness.

b. Steps that require notification of all affected parties (operators and supervisors) prior to performing work and upon completion of maintenance work. The discussion includes potential degradation of safety controls during the planned maintenance.

c. Control of work by comprehensive procedures to be followed by maintenance technicians. Maintenance procedures are reviewed by the various safety disciplines including criticality, fire, radiation, industrial, and chemical process safety. The procedures describe, as a minimum the following:

   i. Qualifications of personnel authorized to perform the maintenance or surveillance.

   ii. Controls on and specification of any replacement components or materials to be used (this should be controlled by the configuration management function to ensure like/kind replacement and adherence to 10 CFR Part 21.

   iii. Post-maintenance testing to verify operability of the equipment.

   iv. Tracking and records management of maintenance activities.

   v. Safe work practices (e.g., lockout/tagout, confined space entry, moderation control or exclusion area, radiation or hot work permits, criticality, fire, chemical, environmental or human-systems interface issues).

13. Applicant conducts periodic reviews of procedures to ensure their continued accuracy and usefulness and establishes the time frame for reviews of the various types of procedures. At a minimum all procedures are reviewed every 5 years and emergency procedures are reviewed every year. The applicant describes the use and control of procedures. Provisions allow for operations to stop and place the process in a safe condition if a step of a procedure cannot be performed as written. Guidance identifies the manner in which procedures are to be implemented. Routine procedural actions that are frequently repeated might not require the procedure to be present. Procedures for complex jobs or dealing with numerous sequences where memory cannot be trusted may require valve alignment check sheets, approved operator aids or in-hand procedures that are referenced directly when the job is conducted.

11.4.5 REVIEW PROCEDURES

11.4.5.1 Acceptance Review

The staff will review the application portions related to the procedures program by comparing them to the acceptance criteria contained in section 11.4.4. The purpose of these reviews is to ensure completeness against NRC requirements and topics. If deficiencies are identified, the applicant is requested to submit additional information to correct these deficiencies before NRC acceptance of the application and the start of the evaluation.

11.4.5.2 Safety Evaluation

Upon acceptance of the application for review, the primary reviewer will evaluate whether the applicant has adequately addressed the acceptance criteria listed in section 11.4.4. The reviewer will document in a safety evaluation report that the applicant has committed to the following:

1. Controls identified in the ISA summary are highlighted in safety procedures (i.e., procedures that constitute administrative controls for safety). There may be several levels of requirements within procedures for diagnosing and correcting process upsets, dealing with abnormal situations, or other matters. There is a clear hierarchy of requirements within procedures. Cautions and notes appearing in procedures precede the steps to which they apply. Rules for entering and leaving a procedure are clear.

2. Procedures important to safety are independently verified and validated before use and this is documented in a policy on procedures.

3. Policy and administrative procedures, non-crucial operating procedures, and other non-operational procedures that do not impact items relied on for safety or other environmental, safety, and health concerns need not be controlled with the stringency applied to operating procedures or management control procedures associated with controls specified by the ISA summary. The applicability of less stringent procedure control should be specified to avoid misunderstandings in implementation.

4. Changes to operating, management control, or maintenance procedures are reviewed and approved by an independent multi-disciplinary safety review team and controlled by the configuration management function.

5. The applicant includes a statement to follow approved procedures while processing licensed special nuclear material.

6. Procedures exist for the notification of operations personnel before and after maintenance is performed on safety controls and activities are controlled by procedures.

11.4.6 EVALUATION FINDINGS

The review should establish that the applicant's process for developing and implementing procedures will provide adequate protection for workers, the public and the environment during the processing of licensed material and hazardous chemicals. Based on the review of the applicant's process for development, approval, and implementation of procedures against the

acceptance criteria, the staff will determine the acceptability of the program. If deemed adequate, a statement similar to the following can be placed in the SER:

> The application has described suitably detailed process for the development, approval, and implementation of procedures. Special attention has been paid to items relied on for safety, as well as to systems important to the health of plant workers and the public and to the protection of the environment.

11.4.7 REFERENCES

Code of Federal Regulations, Title 10, Part 70, Domestic Licensing of Special Nuclear Material, U.S. Government Printing Office, Washington, DC.

U.S. Nuclear Regulatory Commission, "Guidance on Management Controls/Quality Assurance, Requirements for Operations, Chemical Safety, and Fire Protection for Fuel Cycle Facilities," *Federal Register* 54 (No. 53), 11590 ! 11598, March 21, 1989.

Appendix A: CHECKLIST FOR PROCEDURES

All activities listed below are covered by written procedures. The list is not intended to be all inclusive nor is it intended to imply that procedures be developed with the same titles as those on the list. This listing is divided into four categories and provides guidance on topics to be covered.

1. Management Control Procedures:

   Training
   Audits and Assessments
   Incident Investigation
   Records Management
   Configuration Management
   Quality Assurance
   Equipment control (lockout/tagout)
   Shift turnover
   Work Control
   Management control
   Procedure management
   Nuclear criticality safety
   Fire protection
   Radiation protection
   Radioactive waste management
   Maintenance
   Environmental protection
   Chemical process safety
   Operations
   Calibration control
   Preventive maintenance

2. Operating Procedures

   a. System Procedures that Address Startup, Operation, Shutdown Control of Process Operations and Recovery After a Process Upset

      Ventilation
      Criticality alarms
      Shift routines, shift turnover and operating practices
      Decontamination operations
      Uranium recovery
      Plant Utilities (air, other gases, cooling water, fire water, steam)
      Temporary changes in operating procedures

b. Abnormal Operation/Alarm Response:

Loss of cooling water
Loss of instrument air
Loss of electrical power
Loss of criticality alarm system
Fires
Chemical process releases

3. Maintenance Activities that Address System Repair, Calibration, Surveillance, and Functional Testing

Repairs and preventive repairs of items relied on for safety
Testing of criticality alarm units
Calibration of items relied on for safety
HEPA filter maintenance
Functional testing of items relied on for safety
Relief valve replacement/testing
Surveillance/monitoring
Pressure vessel testing
Non-fired pressure vessel testing
Piping integrity testing
Containment device testing

4. Emergency Procedures:

Response to a criticality
Hazardous process chemical releases (including UF_6)

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11.5 AUDITS AND ASSESSMENTS

11.5.1 PURPOSE OF REVIEW

The purpose of this review is to confirm that the applicant has implemented a system of audits and assessments to ensure that safety controls are in accordance with regulatory requirements and to ensure that the system is adequate and effective.

11.5.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: Fuel Cycle Facility Inspector

Supporting: Reviewers for other applicable discipline areas

11.5.3 AREAS OF REVIEW

The applicant describes a system of audits and assessments which consists of two distinct levels of activities: an audit activity structured to monitor compliance with regulatory requirements and license commitments, and an assessment activity oriented to determining the effectiveness of the activities in achieving applicant-specified objectives that ensure continued availability and reliability of safety controls.

The reviewer will examine the applicant's presentation with respect to:

1. The commitments to audit and assessment activities;

2. The use of qualified and independent audit and assessment personnel;

3. The general structure of typical audits and assessments;

4. The facility procedures to be used to direct and control the audit and assessment activities; and

5. The planned use of the results of the audit and assessment activities, and the documentation to record and distribute the findings and recommendations of these audits and assessments, and take necessary corrective actions.

11.5.4 ACCEPTANCE CRITERIA

11.5.4.1 Regulatory Requirements

The requirements specified in 10 CFR 70.65(b) require organization and management controls to provide reasonable assurance that management systems and structures are in place and effective in planning, implementing, performing audits and assessments, and controlling site operations in a fashion that ensures comprehensive management control and oversight function of the health, safety, and environment.

11.5.4.2 Regulatory Guidance

Regulatory guides applicable to the areas of review in this SRP is:

U.S. Nuclear Regulatory Commission, "Guidance on Management Controls/Quality Assurance, Requirements for Operation, Chemical Safety, and Fire Protection for Fuel Cycle Facilities,"*Federal Register* **54** (No. 53), 11590–11598, March 21, 1989.

11.5.4.3 Regulatory Acceptance Criteria

Acceptable commitments to audits and assessments satisfy the following criteria: audits measure the applicant's compliance with regulatory requirements; assessments measure the effectiveness of existing applicant activities in achieving worker and public safety, and environmental protection. Audits and assessments are conducted by qualified personnel who are independent of the activities being audited or assessed. Such personnel could be either the applicant's employees or contractors. The results of their work are reviewed and acted upon by the applicant's management.

The determination of the adequacy of the applicant's commitments relative to the establishment and maintenance of effective audit and assessment activities will be based on the following acceptance criteria:

1. The applicant commits to and justifies a frequency and a described scope of the audit and assessment function which includes reviews of major safety and environmental activities. This includes all activities listed as chapter or subchapter headings in this SRP, Chapters 3 through 11. Policy directives are established for the applicant's requirements for conducting the audits and assessments. The policy directives cover, for each activity to be reviewed, schedules, guidance for conducting the audit or assessment, assigned responsibilities for each phase of the work, and procedures for recording the results of the audit or assessment activity and for ensuring that identified deficiencies are corrected in a timely and effective manner.

2. The applicant identifies the qualifications and responsibilities of a specific manager responsible for the overall success of the audit and assessment activity pertaining to the license. Other organizational responsibilities are identified if established by the applicant. Qualification requirements for audit and assessment personnel are described.

   The applicant's organizational structure and management provide the independence of individual audit or assessment members from the area responsibilities and activities they are reviewing and assessing. The audit or assessment team has authority to investigate any aspect of the review program and has access to all relevant information.

3. With respect to both audits and assessments, the applicant considers risk significance in establishing technical and administrative attributes of the facility operations and audit and assessment frequencies. For audits, compliance with regulatory requirements and license commitments, including selected operating limits, is directly measured and tracked. Further, performance indicators are established to facilitate scheduled assessments of the degree to which selected operations important to safety are meeting the applicant's objectives to ensure safety and environmental protection.

4. Audits or assessments are conducted according to written procedures and checklists. Both audits and assessments include detailed walk-downs of the area, including out-of-the-way and limited-access areas, with accurate, documented descriptions of deficiencies. On-the-spot corrective actions are provided for, as appropriate. Daily inspections of a focus area are conducted by operating staff with assignments in the area. Deficiencies noted in these inspections are communicated to appropriate management for prompt attention and resolution. [Note: Inspection and surveillance by the operations organization should be addressed by the applicant in standard maintenance procedures.]

5. Reports of findings and recommendations are documented and distributed to appropriate management for review and response. A management corrective action program is administered to ensure proper control of corrective actions as defined in Section 11.8 of the Quality Assurance function.

11.5.5 REVIEW PROCEDURES

The reviewer determines whether the applicant has in place or has committed to establishing:

1. A comprehensive system of audits and assessments including elements, responsibilities, requirements, scheduling, action plan, performance, reporting, records, response, and follow-up actions.

2. Audit and assessment teams that are composed of independent, qualified, and competent personnel.

3. Procedures that ensure that the scope of audits and assessments is well defined and is adequate.

4. Procedures that ensures that the areas to be reviewed encompass its entireties and the level of details of the review are sufficient to ensure that the audit or assessment team has adequate information to make reasoned judgments of the system effectiveness.

5. Procedures that ensure that the documentation of findings, the distribution of reports, and the assignment of follow-up responsibilities are defined and that appropriate remedial or corrective actions are taken.

On the basis of its review, the staff may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria in Section 11.5.4 of this section.

11.5.6 EVALUATION FINDINGS

The applicant's commitments for audits and assessments will be deemed to be adequate if, based on the NRC staff's review, the reviewer makes the following conclusions:

1. The applicant has committed to conduct internal audits and independent assessments of activities significant to plant safety and environmental protection in accordance with the acceptance criteria in SRP Section 11.5.4.

2. Audits will be conducted to verify that operations are being conducted in accordance with regulatory requirements and commitments in the license application.

3. Independent assessments will be conducted by off-site groups or individuals not involved in the licensed activity to verify that the health, safety, and environmental compliance functions are effectively achieving their designed purposes.

4. Audits and assessments will be conducted for the areas of radiation safety, nuclear criticality safety, chemical safety, fire safety, environmental protection, emergency management, quality assurance, configuration management, maintenance, training and qualification, procedures, human factors, incident investigation, and records management. These audits and assessments will be conducted according to a written plan.

5. Qualified personnel without direct responsibility for the function and area being audited or assessed will be used. The staff positions and committees responsible for audits and assessments are specified. The levels of management to which results are reported and the systems to ensure that corrective actions are taken, are also described.

11.5.7 REFERENCES

Code of Federal Regulations, Title 10, Part 70, "Domestic Licensing of Special Nuclear Material," U.S. Government Printing Office, Washington, D.C.

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11.6 INCIDENT INVESTIGATIONS

11.6.1 PURPOSE OF REVIEW

Abnormal events should be investigated and corrective action taken to prevent (or minimize) their recurrence or their leading to more serious consequences. The purpose of this review is to determine that the applicant has a system in place for the systematic investigation of abnormal events, assignment and acceptance of corrective actions, and follow-up to ensure completion of the actions.

11.6.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: None

Supporting: Fuel Cycle Facility Inspector or on-site Resident Inspector

11.6.3 AREAS OF REVIEW

The NRC staff will review the applicant's policy, procedures, and management structure for investigating abnormal events and completing appropriate corrective actions. The review will include the provisions for establishing investigating teams, the methods for determining root causes, and procedures for tracking and completing corrective actions and for documenting the process for the purpose of applying the "lessons learned" to other operations.

11.6.4 ACCEPTANCE CRITERIA

11.6.4.1 Regulatory Requirements

Incident investigation and reporting required by 10 CFR 70.74(a) and (b).

11.6.4.2 Regulatory Guidance

There is no specific regulatory guidance for the overall conduct of incident investigation. See the References at the end of this section for guidance on specific aspects of incident management such as corrective action and root cause analysis.

11.6.4.3 Regulatory Acceptance Criteria

The applicant's description and commitments in the application will be acceptable if the reviewer finds reasonable assurance of the following:

1. The applicant will establish teams to investigate abnormal events that may occur during operation of the facility, to determine the root cause(s) of the event, and to recommend corrective actions. These teams will be independent from the line function(s) involved with the incident under investigation. Investigations will begin within 48 hours of the abnormal event, or sooner, depending on the safety significance of the event.

2. The applicant will monitor and document corrective actions through completion.

3. The applicant will maintain documentation so that "lessons learned" may be applied to future operations of the facility. Details of the event sequence will be compared to accident sequences already considered in the ISA, and actions will be taken to ensure that the ISA includes the evaluation of the risk associated with accidents of the type actually experienced.

The applicant has a formal policy or procedure in place for conducting an incident ivestigation, and that policy or procedure contains the following elements:

1. A documented plan for investigating an abnormal event. This plan is separate from any required Emergency Plan. The investigation of an abnormal event should commence as soon as possible, commensurate with the safety of the investigative team, after the event has been brought under control.

2. A description of the functions, qualifications, and responsibilities of the management person who would lead the investigative team and those of the other team members, the scope of the team's authority and responsibilities, and assurance of cooperation of management.

3. Assurance of the team's authority to obtain all the information considered necessary and independence from responsibility for or to the functional area involved in the incident under investigation.

4. Procedures requiring maintenance of all documentation relating to abnormal events for 2 years or for the life of the operation, whichever is longer.

5. Guidance for the team conducting the investigation on how to apply a reasonable, systematic, structured approach to determine the root cause(s) of the problem. The level of investigation should be based on a graded approach relative to the severity of the incident.

6. Requirements to make available to NRC original reports of investigative teams, on request.

7. A system for monitoring to ensure completion of any corrective measures specified.

The assessment of the adequacy of the applicant's commitments to establish and use a plan for the investigation of abnormal events will also be based upon the following acceptance criteria:

1. The licensee has described the overall plan and method for investigating abnormal events.

2. The functions, responsibilities, and scope of authority of investigating teams are documented in the plan.

3. Qualified internal or external investigators are appointed to serve on investigating teams. The teams will include at least one process expert and at least one team member will be trained in root cause analysis.

4. The applicant commits to prompt investigation of any abnormal events, and precursors to abnormal events (such as undetected failure of controls).

5. The investigation process and investigating team are independent of the line management and participants are assured of no retribution from participating in investigations.

6. A reasonable, systematic, structured approach is used to determine the root cause(s) of unusual or abnormal events.

7. Auditable records and documentation related to abnormal events, investigations, and root cause analysis are maintained. For each incident, the incident report should include a description, contributing factors, root-cause analysis, and findings and recommendations. Relevant findings are reviewed with all affected personnel.

8. Documented corrective actions are taken within a reasonable period to resolve findings from abnormal event investigations.

11.6.5 REVIEW PROCEDURES

11.6.5.1 Acceptance Review

The primary reviewer will first evaluate whether the content of the application as required by 10 CFR Part 70 regarding incident investigations for fuel cycle facilities has been included -- see Section 11.6.4.1 “Regulatory Requirements”. The reviewer will also evaluate whether the application contains enough information to review with respect to the acceptance criteria.

If significant deficiencies are identified in the application, the applicant should be requested to submit additional material before the start of the safety evaluation.

11.6.5.2 Safety Evaluation

The primary reviewer will verify that the applicant has described a comprehensive incident investigation function based on the areas of review in Section 11.6.3 and the acceptance criteria presented in Section 11.6.4 of this SRP.

During the review, the reviewer will consult with the NRC inspection staff and review any historical information regarding the adequacy of the applicant's incident investigation process. On the basis of its review, the staff may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria in Section 3.7.4 of this SRP.

11.6.6 EVALUATION FINDINGS

The staff's review will verify that sufficient information has been provided in the license application to satisfy 10 CFR Part 70 requirements relating to incident investigations. On the basis of this review, the staff should be able to conclude this evaluation as follows:

1. The applicant has committed to and established an organization responsible for performing incident investigations of abnormal events that may occur during operation of the facility, determining the root cause(s) of the event, and recommending corrective actions for ensuring a safe facility and safe facility operations in accordance with the acceptance criteria of Subsection 11.6.4 of the SRP.

2. The applicant has committed to monitoring and documenting of corrective actions, through completion.

3. The applicant has committed to the maintenance of documentation so that "lessons learned" may be applied to future operations of the facility.

Accordingly, the staff concludes that the applicant's description of the incident investigation process complies with applicable NRC regulations and is adequate.

11.6.7 REFERENCES

Code of Federal Regulations, Title 10, Part 70, "Domestic Licensing of Special Nuclear Material", U.S. Government Printing Office, Washington, DC.

U.S. Nuclear Regulatory Commission, NUREG/CR-4616, *Root Causes of Component Failures Program: Methods and Applications*, December 1986.

U.S. Nuclear Regulatory Commission, NUREG/CR-5665, *A Systematic Approach to Repetitive Failures*, February 1991.

U.S. Nuclear Regulatory Commission, Information Notice 96-28, *Suggested Guidance Relating to Development and Implementation of Corrective Action*, May 1966.

U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

11.7 RECORDS MANAGEMENT

11.7.1 PURPOSE OF REVIEW

The staff will review the enrichment facility records management system for health and safety (H&S) records to ensure that the applicant has committed to a system adequate to comply with NRC requirements and to help ensure protection of the H&S of the public, workers, and the protection of the environment over the life span of the enrichment facility.

11.7.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: Primary Staff Reviewers

Supporting: Fuel Cycle Facility Inspector
Designated Configuration Management Reviewer

11.7.3 AREAS OF REVIEW

The requirements for the management of H&S records vary according to the nature of the facility and the hazards and risks posed by it. The staff will review areas related to the handling and storing of H&S records and the records generated or needed in the design, construction, operation, and decommissioning phases of the facility. The staff will review the following:

1. The process whereby H&S records, including training, dosimetry, effluents, classified, facility structures, systems, or components having safety-significance are created, selected, verified, categorized, indexed, inventoried, protected, stored, maintained, distributed, deleted, or preserved. The process(es) may be linked with or be a part of the facility configuration management (CM) function.

2. The handling and control of various kinds of records and the methods of recording media that comprise the records (including contaminated and classified records).

3. The physical characteristics of the records storage area(s) with respect to the preservation and protection of the records for their designated lifetimes.

11.7.4 ACCEPTANCE CRITERIA

11.7.4.1 Regulatory Requirements

Records management is required by 10 CFR Parts 19, 20, 21, 25, and 70.

11.7.4.2 Regulatory Guidance

Regulatory guidance applicable to the areas of records management is:

U.S. Nuclear Regulatory Commission, NUREG-1460, Rev. 1, *Guide to NRC Reporting and Recordkeeping Requirements*, July 1994

11.7.4.3 Regulatory Acceptance Criteria

The reviewer will find the applicant's records management system for H&S records acceptable if it satisfies the following criteria:

1. H&S records are specified, prepared, verified, characterized, and maintained.

2. H&S records are legible, identifiable, and retrievable for their designated lifetimes.

3. H&S records are protected against tampering, theft, loss, unauthorized access, damage, or deterioration for the time they are in storage.

4. Procedures are established and documented specifying the requirements and responsibilities for H&S record selection, verification, protection, transmittal, distribution, retention, maintenance, and disposition.

5. The organization and procedures are in place to promptly detect and correct any deficiencies in the H&S records management system or its implementation.

Examples of records that should be included in the system are listed in Appendix A: Health and Safety Records. Records are categorized by relative safety importance to identify record protection and storage needs and to designate the retention period for individual kinds of records. The procedures should assign responsibilities for records management, specify the authority needed for records retention or disposal, specify which records must have controlled access and provide the controls needed, provide for the protection of records from loss, damage, tampering, or theft or during an emergency, and specify procedures for ensuring that the records management system remains effective.

For H&S-related computer codes/computerized data, the applicant establishes procedure(s) for maintaining readability and usability of older codes/data as computing technology changes. This could include transcribing the older forms of H&S information (e.g., punched cards or paper tapes) and H&S codes for older computing equipment to contemporary computing media and equipment.

11.7.5 REVIEW PROCEDURES

The reviewer will review the applicant's records management system to determine the adequacy of the policies, procedures, and practices. The reviewer should coordinate this review with the person reviewing the CM function, SRP Section 11.1.

For fuel cycle facilities that are parts of larger organizations, certain documents may be retained or stored at a site other than the plant site. For example, master drawings for structures might

be kept in the engineering department of the headquarters of the parent company. The reviewer may choose to review the physical characteristics of these offsite record storage areas, as well, particularly for records for controls or high risk accidents sequences.

On the basis of the review, the reviewer may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria presented in Section 11.7.4 of this SRP.

11.7.6 EVALUATION FINDINGS

The reviewer verifies that sufficient information has been submitted and the appropriate commitments have been made to conclude that the actual or proposed records management system will be adequate to meet the requirements to keep and maintain H&S-related records. The review should be sufficiently complete to support conclusions similar to the following in the SER:

> The staff has reviewed the applicant's records management system against the SRP's acceptance criteria and concluded that the system: (1) will be effective in collecting, verifying, protecting, and storing information about the health and safety (H&S) aspects of the facility and its operations and will be able to retrieve the information in readable form for the designated lifetimes of the records; (2) will provide a records storage area(s) with the capability to protect and preserve H&S records that are stored there during the mandated periods, including protection of the stored records against loss, theft, tampering or damage during and after emergencies; and (3) will ensure that any deficiencies in the H&S records management system or its implementation will be detected and corrected in a timely manner.

11.7.7 REFERENCES

Code of Federal Regulations, Title 10, Part 70, Domestic Licensing of Special Nuclear Material, U.S. Government Printing Office, Washington, DC.

U.S. Nuclear Regulatory Commission, NUREG-1460, Rev. 1, *Guide to NRC Reporting and Recordkeeping Requirements,* July 1994

APPENDIX A: HEALTH AND SAFETY RECORDS

The requirements for records management vary according to the nature of the facility and the hazards and risks posed by it. Examples of the records required by 10 CFR Parts 19, 20, 21, 25, and 70 are presented in Table 11.7-1. These listings are organized under the chapter headings of the SRP. Although they indicate the kinds of records to be found in these chapters of the SRP, the listing is not intended to be exhaustive or prescriptive in format. For example, in particular instances, different or additional records might fall within these groupings. Furthermore, the applicant may choose to organize the records in ways other than shown here.

Table 11.7-1. Examples of Records

SRP Chapter	
1.0 General Information	
	Construction records
	Facility and equipment descriptions and drawings
	Design criteria, requirements, and bases for safety-related structures, systems, or components, as specified by the facility configuration management system
	Records of facility changes and associated integrated safety analyses, as specified by the facility configuration management system
	Safety analyses, reports, and assessments
	Records of site characterization measurements and data
	Records pertaining to onsite disposal of radioactive or mixed wastes in surface landfills
	Specifications for safety-related procedurement items
2.0 Organization and Administration	
	Administrative procedures with safety implications
	Change control records for material control and accounting program
	Organization charts, position descriptions, and qualifications records
	Safety and health compliance records, medical records, personnel exposure records, etc.
	Quality Assurance records

2.0 Organization and Administration (continued)

Safety inspections, audits, assessments, and investigations

Safety Statistics and trends

3.0 Integrated Safety Analysis

4.0 Radiation Safety

Bioassay data

Exposure records

Radiation protection (and contamination control) records

Radiation training records

Radiation work permits

5.0 Nuclear Criticality Safety

Nuclear criticality control written procedures and statistics

Nuclear criticality safety analyses

Records pertaining to nuclear criticality inspections, audits, investigations, and assessments

Records pertaining to nuclear criticality incidents, unusual occurrences, or accidents

Records pertaining to nuclear criticality safety analyses

6.0 Chemical Safety

Chemical process safety procedures and plans

Records pertaining to chemical process inspections, audits, investigations, and assessments

Diagrams, charts, and drawings

Records pertaining to chemical process incidents, unusual occurrences, or accidents

6.0 Chemical Safety (continued)

Chemical process safety reports and analyses

Chemical process safety training

7.0 Fire Safety

Fire Hazard Analysis

Fire prevention measures, including hot-work permits and fire-watch records

Records pertaining to inspection, maintenance, and testing of fire protection equipment

Records pertaining to fire protection training and retraining of response teams

Pre-fire emergency plans

8.0 Emergency Management

Emergency plan(s) and procedures

Comments on emergency plan from outside emergency response organizations

Emergency drill records

Memorandum of understanding with outside emergency response organizations

Records of actual events

Records pertaining to the training and retraining of personnel involved in emergency preparedness functions

Records pertaining to the inspection and maintenance of emergency response equipment and supplies

9.0 Environmental Protection

Environmental release and monitoring records

Environmental Report and Supplements to the Environmental Report, as applicable

10. 0 Decommissioning

10. 0 Decommissioning (continued)

Decommissioning records

Financial assurance documents

Decommissioning cost estimates

Site characterization data

Final survey data

Decommissioning procedures

11.0 Management Control Systems

11.1 Configuration Management

- safety analyses, reports, and assessments that support the physical configuration of process designs, and changes to those designs
- validation records for computer software used for safety analysis or MC&A
- ISA documents, including process descriptions, plant drawings and specifications, purchase specifications for items relied on for safety
- approved, current operating procedures and emergency operating procedures

11.2 Maintenance

- preventive maintenance records, including trending and root cause analysis
- calibration and testing data for items relied on for safety
- corrective maintenance records

11.3 Training and Qualification

- personnel training and qualification records
- procedures

11.4 Procedures

- standard operating procedures
- functional test procedures

11.5 Audits and Assessments

- audits and assessments of safety and environmental activities

11.6 Incident Investigations

- investigation reports
- changes recommended by investigation reports, how and when implemented
- summary of reportable events for the term of the license
- incident investigation policy

11.7 Records Management

- policy
- material storage records
- records of receipt, transfer and disposal of radioactive material

11.8 Quality Assurance

- audit records

11.8 QUALITY ASSURANCE

11.8.1 PURPOSE OF REVIEW

The purpose of this review is to determine if the quality assurance (QA) elements applied to items relied on for safety provide reasonable assurance that they will be available and reliable to perform their function when needed. Items relied on for safety should be documented in the applicant's Integrated Safety Analysis (ISA) summary. The application may be for a new facility, a new process at an existing facility, facility modification, or license renewal. The review should also determine whether the measures are applied to the items relied on for safety in proportion to their importance to safety (graded approach).

11.8.2 RESPONSIBILITY FOR REVIEW

Primary: QA Engineer/Specialist

Secondary: Licensing Project Manager

Supporting: Site Representative/Fuel Cycle Facility Inspector
Staff Reviewers of applicable SRP Chapters 3 through 15

11.8.3 AREAS OF REVIEW

The application must address the 10 CFR Part 70 requirements with respect to management measures, that include quality assurance elements, that must be established to provide continuing assurance with the performance requirements. Management measures are defined as functions performed by the licensee, generally on a continuing basis, that are applied to items relied on for safety, to ensure the items are available and reliable to perform their functions when needed. Management measures include configuration management (section 11.1), maintenance (section 11.2), training and qualifications (section 11.3), procedures (section 11.4), audits and assessments (section 11.5), incident investigations (section 11.6), records management (section 11.7) and other quality assurance elements (section 11.8). The applicant may grade the application of the QA elements commensurate with the item’s importance in terms of meeting the performance requirements as analyzed in the ISA.

The reviewer should determine that a complete description of the applicant’s application of QA elements to items relied on for safety is included in the application and should examine it in terms of the Acceptance Criteria of this section. The review objective is to obtain reasonable assurance of the implementation of accepted QA principles in the design, construction, operation, maintenance, and modification phases of a facility's life. Fundamental to this effort is the applicant's application of QA to both the hazards analysis process in the applicant’s ISA and

to the identified items relied on for safety resulting from the ISA and identified in the ISA summary.

The application defines the levels of QA to be applied to items relied on for safety identified by the ISA (SRP Sectionin 3.0). Further, the relationship between QA and other management measures should be described. The application assigns QA levels to each item relied on for safety. The applicant addresses, in either Section 11.2 or this section, its approach to determining the relative risk, or relative safety importance, of the various items relied on for safety to be treated by both maintenance and QA. This safety importance ranking will determine the levels of QA to be applied to individual items relied on for safety.

The reviewer should recognize that facility safety may not be the only criterion for QA at a fuel cycle facility. The applicant's customers and the NRC, under 10 CFR Part 50, may impose product-related QA criteria. NRC concern is generally limited to ensuring the safety (nuclear safety, chemical safety, fire safety, etc.) of workers, the public, and the environment.

Since many QA elements may be described in other sections of the application, the reviewer should determine the applicant's commitment to overall QA, the selection of quality criteria and quality level, and the proposed method for implementation. The applicant may reference other areas of the application that present information relevant to QA. The reviewer will focus on the management controls applied to criticality, containment of licensed materials, personnel protection, and environmental safety. With the application of graded QA, quality levels commensurate with the risk involved should parallel the same risk levels established for maintenance addressed in SRP Section 11.2.

11.8.4 ACCEPTANCE CRITERIA

11.8.4.1 Regulatory Requirements

The requirements for fuel cycle facility management measures, including QA elements, are specified in 10 CFR Part 70 (section 70.62(d)).

11.8.4.2 Regulatory Guidance

In its discussion of management measures, specifically, QA elements applied to items relied on for safety, the applicant should commit to meet, in a graded fashion, the applicable requirements of American National Standard Institute/American Society of Mechanical Engineers standard, ANSI/ASME NQA-1-1994, “Quality Assurance Requirements for Nuclear Facility Applications;” an appropriate ISO 9000 quality management standard; an appropriate ANSI/ISO/ASQ 9000 quality systems standard; International Atomic Energy Agency 1995 Safety Guide 50-SG-Q1, “Establishing and implementing a Quality Assurance Program;” DOE’s September 1997 draft “Implementation Guide for use with 10 CFR Part 830.120 and DOE Order 5700.6C;” or a document that provides equivalent QA for such facilities.

11.8.4.3 Regulatory Acceptance Criteria

To be acceptable, the applicant's QA program should be structured to apply appropriate QA measures and controls to the site design features and items relied on for safety. QA measures may be applied in proportion to the importance of the item to the achievement of safety (graded approach). QA programs are expected to differ based on the purpose and complexity of the facility and processes to be controlled.

The ISA summary should identify the items relied on for safety, the degree of their importance to safety, and the related controls that are required for safety. An applicant may choose to apply the highest level of QA and control to all items relied on for safety or may grade its QA in proportion to the importance of the item to the achievement of safety.

When used, the graded approach for the application of QA should be described and should parallel the maintenance defined and applied by the applicant as described in the application. At a minimum, the same items relied on for safety that are included in the maintenance program should have QA controls. When the applicant implements a graded QA program, the relative risk importance ranking of items relied on for safety, as established within the maintenance program, should be the same as those used in QA. For each of the items relied on for safety as identified in the ISA summary, but commensurate with the feature's risk level, the applicant identifies and defines the applicable level of QA. From that point on, the assignment of QA levels to be used may be based on the graded QA application.

A checklist for evaluating QA is given below. When QA is graded, the attributes listed below are applied collectively only for accident sequences that run the highest level of risk. QA requirements may be reduced by modifying or eliminating some attributes.

) charts of the

1. lines, interrelationships, and areas of responsibility and authority for all organizations performing quality-related safety activities including the organization of the applicant and, as applicable, its principal contractors (architect/engineer, constructor, construction manager, and operator). Persons or organizations responsible for ensuring that appropriate QA has been established and verifying that activities affecting quality have been correctly performed have sufficient authority, access to work areas, and organizational independence to carry out their responsibilities.

nents listed in

2. Section 11.8.4.2 above or equivalent. The commitment may describe the applicants graded approach to QA, describing controls implemented consistent with an item's importance to safety. The QA function is well-documented, planned, implemented, and maintained to ensure the availability and reliability of items important to safety. It should be functional prior to performing the ISA required by Part 70.

s, verification,

3. interfaces, changes, and design documentation and records.

re included or

4. referenced in documents for procurement of items or services relied on for safety. To the extent necessary, suppliers are required to have QA consistent with the quality level of the item or service to be procured.

d instructions,

5. procedures, or drawings of a type appropriate for the circumstances.

s or prescribe

6. activities affecting quality are controlled to ensure that the appropriate documents are in use. Document changes are reviewed for adequacy and approved for implementation by authorized personnel.

with specified

7. requirements.

at incorrect or

8. defective items are not used.

the course of

9. maintenance, modifications, and testing activities, such as welding, heat treating, nondestructive testing, and chemical cleaning and that they are performed by qualified personnel using qualified procedures and equipment.

10. Inspection required to verify conformance of items relied on for safety is planned and executed. Inspection requirements are specified in written procedures with provisions included for documenting and evaluating inspection results. Personnel qualification programs are established for Inspection test personnel.

11. Tests are conducted to verify that items relied on for safety conform to specified requirements and will perform satisfactorily in service. Test requirements are specified in written procedures with provisions included for documenting and evaluating test results. Personnel qualification programs are established for test personnel.

12. Provisions are made to ensure that tools, gauges, instruments, and other measuring and testing devices are properly identified, controlled, calibrated, and adjusted at specified intervals to maintain performance within required limits.

13. Provisions are made to control the handling, storage, shipping, cleaning, and preservation of items relied on for safety in accordance with work and inspection instructions to prevent damage, loss, and deterioration caused by environmental conditions such as temperature or humidity.

14. Provisions are made to control the inspection, test, and operating status of items relied on for safety to prevent inadvertent use of nonconforming items or bypassing of inspections and tests.

15. Provisions are made to control the identification, segregation, disposition, and prevention of installation or use of nonconforming items relied on for safety.

16. Provisions are made to ensure that conditions adverse to safety are promptly identified and corrected and that measures are taken to preclude repetition. These actions should be documented and reported to appropriate levels of management.

17. Provisions are made for the identification, retention, retrieval, and maintenance of records that furnish evidence of the control of quality for items relied on for safety.

18. Provisions are made for planning and scheduling assessments and audits to verify compliance with and to determine the effectiveness of QA; responsibilities and procedures are identified for assessing, auditing, documenting, and reviewing results and for designating management levels to review assessment and audit results; and provisions are made for incorporating the status of recommendations in management reports.

19. The applicant's provisions for continuing QA address reviews and updates QA documents based on reorganizations, revised activities, lessons learned, changes to applicable regulations, and other QA program changes.

11.8.5 REVIEW PROCEDURES

11.8.5.1 Acceptance Review

The primary reviewer evaluates the application to determine whether it addresses the "Areas of Review" discussed in Section 11.8.3 above regarding the applicant's (and its principal contractors') QA. If significant deficiencies are identified, the applicant should be requested to submit additional material before the start of the safety evaluation. Note that the applicant's commitment to implement and maintain its QA program in conformance with the applicable requirements of one of the references listed in Section 11.8.4.2 above or equivalent should satisfy the acceptance review criteria.

11.8.5.2 Safety Evaluation

After determining that the application is acceptable for review in accordance with Section 11.8.5.1, above, the primary staff reviewer should review the QA information with respect to the acceptance criteria in Section 11.8.4. The primary staff reviewer should determine whether the applicant has adequately planned the work to be accomplished and whether necessary policies, procedures, and instructions either are in place or will be in place before work starts. The review is based on an assessment of the material presented. It should provide reasonable assurance that the applicant's QA, maintenance, and configuration management are coordinated and that QA is an integral part of everyday work activities. The review should provide reasonable assurance that the applicant will be able to monitor the effectiveness of the implementation of QA and will make needed adjustments on a timely basis. The staff is to look for and measure the effectiveness of QA design, not just the existence of appropriate elements.

The primary reviewer should also determine that the applicant has specified the QA criteria and the basis on which the criteria were selected and how they are apportioned within the sections of the application as well as the proposed method for implementation. If the applicant references other sections of the application when describing its QA, the primary reviewer should review these other sections of the application to determine the applicant's commitment to QA and the proposed method for implementation.

The secondary reviewer (Licensing Project Manager) should confirm that the applicant (and the applicant's principal contractors') QA commitments are consistent with other sections of the

submittal. The secondary reviewer is also responsible for integrating the QA input into the Safety Evaluation Report (SER).

The supporting reviewer (Site Representative/Fuel Cycle Facility Inspector) should become familiar with the applicant's (and principal contractors') QA commitments and determine whether ongoing activities (at an existing facility) are in agreement with them.

The other supporting reviewers (Staff Reviewers of SRP Chapters 3 through 15) should determine whether items within their areas of review that are relied on for safety are specified to be within the appropriate level of the applicant's QA program.

On the basis of its review, the staff may request that the applicant provide additional information or modify the application to meet the acceptance criteria. The staff or applicant may also propose license conditions to ensure QA meets the acceptance criteria. The review should result in a determination that there is reasonable assurance that the applicant's (and the applicant's principal contractors') QA will provide reasonable assurance that items relied on for safety will perform their safety function in a satisfactory manner.

When the safety evaluation is complete, the primary staff reviewer, with assistance from the other reviewers, should prepare the QA input for the SER as described in SER Section 11.8.6 using the acceptance criteria from SER Section 11.8.4.

11.8.6 EVALUATION FINDINGS

The staff's evaluation verifies that the license application provides sufficient information to satisfy the regulatory requirements of Section 11.8.4.1 and that the regulatory acceptance criteria in Section 11.8.4.3 have been appropriately considered in satisfying the requirements. The review record should demonstrate that the adequacy of the applicant's QA program for the design, construction, operations, and/or decommissioning phase for a fuel cycle facility according to this section of the SRP. On the basis of this information, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the SER prepared for the entire application. The report includes a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.

The staff can document the evaluation as follows:

Based on its review of the license application, [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] *the NRC staff has concluded that the applicant has adequately described its QA program (and the QA program of its principal contractors). The staff concludes further that:*

1. The applicant has established and documented a commitment for an organization responsible for developing, implementing, and assessing the management controls for ensuring safe facility operations in accordance with the criteria in Section 11.8.4 of this SRP.

2. The applicant has established and documented a commitment for QA, and the administrative controls for staffing, performance, assessing findings, and implementing corrective actions are in place.

3. The applicant has developed a process for preparation and control of written administrative plant procedures, including procedures for evaluating changes to procedures, items, tests, and processes relied on for safety. A process for review, approval, and documentation of procedures will be implemented and maintained.

4. The applicant has established and documented a surveillance, test, and inspection program to ensure satisfactory in-service performance of items relied on for safety. Specified standards or criteria and testing steps have been provided.

5. Periodic independent audits are conducted to determine the effectiveness of the management controls. Management controls will provide for documentation of audit findings and implementation of corrective actions.

6. Training requirements have been established and documented to provide employees with the skills to perform their jobs safely. Management controls have been provided for evaluation of the effectiveness of training against predetermined objectives and criteria.

7. The organizations and persons performing QA functions have the required independence and authority to effectively carry out their QA functions without undue influence from those directly responsible for process operations.

8. QA covers the items relied on for safety, as identified in the ISA summary, and controls are established to prevent hazards from becoming pathways to higher risks and accidents.

Accordingly, the staff concludes that the applicant's QA program (and the QA program of its principal contractors) meets the requirements of 10 CFR Part 70 and provide reasonable assurance of protection of public health and safety and of the environment.

11.8.7 REFERENCES

Code of Federal Regulations, Title 10, Part 70, "Domestic Licensing of Special Nuclear Material," U.S. Government Printing Office, Washington, DC.

U.S. Nuclear Regulatory Commission NUREG-1324, "Proposed Method for Regulating Major Material Licensees," February 1992.

American National Standard Institute/American Society of Mechanical Engineers Standard, ANSI/ASME NQA-1-1994, “Quality Assurance Requirements for Nuclear Facility Applications.”

ISO 9000 quality management standard.

ANSI/ISO/ASQ 9000 quality systems standard.

International Atomic Energy Agency 1995 Safety Guide 50-SG-Q1, “Establishing and implementing a Quality Assurance Program;”

DOE,“Implementation Guide for use with 10 CFR Part 830.120 and DOE Order 5700.6C,” September 1997 draft.

ACRONYMS AND ABBREVIATIONS

AEGL	Acute Exposure Guideline Level
ALARA	As Low As Reasonably Achievable
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
BDC	Baseline Design Criteria
CAM	Continuous Air Monitor
CFR	Code of Federal Regulations
CM	Configuration Management
EA	Environmental Assessment
EIS	Environmental Impact Statement
ERPG	Emergency Response Planning Guidelines
FLIB	Fuel Cycle Licensing & International Safeguards Branch
FHA	Fire Hazards Analysis
FONSI	Finding of No Significant Impact
HS&E	Health, Safety and Environmental
ISA	Integrated Safety Assessment
ISO	International Organization for Standardization
MOU	Memorandum of Understanding
NCS	Nuclear Criticality Safety
NEPA	National Environmental Policy Act
NFPA	National Fire Protection Association
NRC	Nuclear Regulatory Commission
OSHA	Occupational Safety and Health Administration
RWP	Radiation Work Permits
SECY	Office of the Secretary of the Commission
SER	Safety Evaluation Report

SNM	Special Nuclear Material
TWA	Time-weighted Average
QA	Quality Assurance

GLOSSARY

The following terms are defined here by the staff for the purposes of this SRP. Many of the terms are taken from 10 CFR70.4. The definitions from this CFR section have not been changed in the list below, but are repeated for convenience. Terms listed in this glossary represent the definition of the word in any chapter of this SRP. Words for which the definitions change between chapters are listed in the individual chapters.

Active-engineered controls	Controls that use active sensors to determine values of Controlled Parameters and automatically provide a response. Operation of these controls require no human intervention.
Accident sequence	In general, an unintended sequence of events or process failures that would result in adverse consequences. In the context of this SRP, an unintended sequence of events which results in environmental contamination, a radiation exposure, a release of radioactive material, an inadvertent nuclear criticality, or an exposure to hazardous chemicals, provided the chemicals are produced from licensed radioactive material; or if the accident has the potential to jeopardize the safety of regulated activities. The term “accident” may be used interchangeably with accident sequence.
Acute	As used in section 70.61of this Part means a single radiation dose or chemical exposure event or multiple radiation dose or chemical exposure events occurring within a short time (24 hours or less).
Augmented-administrative controls	Controls that use warning device(s) to notify humans that intervention is necessary to implement the controls. Operation of these controls require human intervention for implementation
Available and reliable to perform their function when needed	As used in Subpart H of the Part means that, based upon the analyzed, credible conditions in the integrated safety analysis, items relied on for safety will perform their intended safety function and management measures will be implemented that ensure continuous compliance with the performance requirements of §70.61 of this Part, considering factors such as necessary maintenance, operating limits, common cause failures, and the likelihood and consequences of failure or degradation of the items and measures.
Baseline Design Criteria	A set of criteria specifying design features and assurance measures that are required and acceptable under certain conditions for new processes or facilities specified in 10 CFR 70.64. These criteria are, in general, the acceptance criteria applicable to safety design described in the chapters of this SRP.
Configuration management (CM)	Ensuring, as part of the safety program, oversight and control of all design information, safety information, and modifications (both temporary and permanent) that might impact the ability of items relied on for safety to perform their function when needed.

Control	A system or device intended to regulate a device or process.
Controlled Parameter	A measurable parameter for which the value is maintained within a specified range by specific controls to ensure the safety of an operation.
Consequence	Any result of interest caused by an event or sequence of events. In this context, adverse consequences refers to the adverse health or safety effects on workers or the public, and to adverse environmental impacts of accidents.
Consequence of concern	Adverse radiological, chemical, or environmental effects exceeding any of the levels specified in 10 CFR 70.61.
Credible event	An initiating (or secondary) event that is not an incredible event (e.g., an event with a likelihood of occurrence greater than one in a million in any year). Any accident sequence identified in the ISA as initiated by a credible event must have its consequences assessed, and controls applied so as to comply with 10 CFR 70.61.
Critical mass of special nuclear material (SNM)	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; 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	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	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.
Double contingency principle	A licensed processes should, in general, incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.
Double contingency protection	A licensed process possesses double contingency protection if it has incorporated the double contingency principle. Double contingency protection is the standard; exceptions should be made only when it is not practicable and then redundancy and diversity of controls is expected to be present in the process.
Event	An occurrence; a change of conditions from a prior state.
External event	An event for which the likelihood cannot be altered by changes to the regulated facility or its operation. This would include all

natural phenomena events plus airplane crashes, explosions, toxic releases, fires, etc. occurring near or on the plant site that cannot be controlled by actions of plant personnel.	
Hazardous chemicals produced from licensed materials	Substances having licensed material as precursor compound(s) or substances that physically or chemically interact with licensed materials; that are toxic, explosive, flammable, corrosive, or reactive to the extent that they can endanger life or health if not adequately controlled. These include substances commingled with licensed material, and include substances such as hydrogen fluoride that is produced by the reaction of uranium hexafluoride and water, but do not include substances prior to process addition to licensed material or after process separation from licensed material.
Integrated safety analysis (ISA)	A systematic analysis to identify plant and external hazards and their potential for initiating accident sequences, the potential accident sequences, their likelihood and consequences, and the site, structures, systems, equipment, components, and activities of personnel that are relied on for safety. As used here, *integrated* means joint consideration of, and protection from, all relevant hazards, including radiological, nuclear criticality, fire, and chemical. However, with respect to compliance with the regulations of this Part, the focus of the integrated safety analysis is limited to the effects of all relevant hazards on radiological safety, prevention of nuclear criticality accidents, or chemical hazards directly associated with NRC licensed radioactive material.
Integrated safety analysis summary	The document submitted in conjunction with the license application, license amendment application, or license renewal application that provides a synopsis of the results of the integrated safety information specified in §70.65(b).
Items relied on for safety	Structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in §70.61 or to mitigate their potential consequences. However, the does not limit the licensee from identifying additional structures, systems, equipment, components, and activities of personnel(i.e, beyond those in the minimum set necessary for compliance with the performance requirements) as items relied on for safety.
Management measures	The functions performed by the licensee, generally on a continuing basis, that are applied to items relied upon for safety, identified in the integrated safety analysis, to ensure

they are available and reliable to perform their functions when needed. Management measures include configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance systems.	Mitigative cControl
A control intended to reduce the consequences of an accident sequence, not to prevent it entirely. When a mitigative control works as intended, the results of the sequence are called the mitigated consequences.	Natural phenomena event
Earthquakes, floods, tornadoes, tsunamis, hurricanes, and other events that occur in the natural environment and could adversely affect safety. Natural phenomena events, depending on their likelihood of occurrence, may be credible or incredible.	
New processes at existing facilities	Systems-level or facility-level design changes to process equipment, process technology, facility layout, or types of licensed material possessed or used. This definition does not, generally, include component-level design changes or equipment replacement.
Passive-engineered Controls	Controls that use only fixed design features to control a Controlled Parameter. Operation of these controls require no human intervention.
Preliminary process hazards analysis (PHA)	An analysis undertaken during the early design or development phases of a process to identify the principal hazards and to enable them to be eliminated, minimized or controlled with minimal cost or disruption. The analysis also assists in identification and optimization of potential corrective, mitigative or preventive safety controls and management measures.

Preventive control	A control intended to prevent an accident entirely, i.e., to prevent any of the types of radiological or chemical consequences in 10 CFR 70.61 of any magnitude.
Safety control	A system, device, or procedure intended to regulate a device, process, or human activity, so as to maintain a safe state. Effectively synonymous with "item relied on for safety". In the context of this SRP, use of the unmodified term "control" normally means safety control. Other controls will be referred to as "process controls". The function of safety controls is the avoidance of consequences of concern defined in 10 CFR Part 70.61. Controls may be active or passive engineered controls or administrative (procedural) controls. Controls may be preventive or mitigative. A process control may or may not be "an item relied on for safety" depending on whether the control of the process is required to assure safety.
Simple-administrative controls	Controls that requires only human intervention for implementation
Unacceptable performance deficiencies	Deficiencies in the items relied on for safety or the measures used to assure the items are available and reliable to perform their function when needed, that need to be corrected to ensure an adequate level of protection as defined in 10 CFR 70.61(b), (c), or (d).
Uncontrolled outcome	The sequence of events and consequences that result if no controls or barriers are available to prevent or mitigate an accident sequence. Thus the consequences of an uncontrolled outcome are, by definition, unmitigated. These consequences may also be referred to as uncontrolled consequences.
Unmitigated consequences	The consequences that result from an accident sequence when mitigative control fails or does not exist.
Worker	An individual whose assigned duties in the course of employment involve exposure to radiation and/or radioactive material from licensed and unlicenced sources of radiation (i.e., an individual who is subject to an occupational dose as in 20 CFR 20.1003).

Integrated Safety Analysis Guidance Document

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

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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)[10], American Petroleum Institute (1990), and Chemical Manufacturing Association (1992)) as well as recent State (New Jersey (1986), California (1986), Delaware (1988), and Nevada (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

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

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.[11] 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 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,

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

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.[12] 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 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

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

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

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

Biodegradability

Aquatic toxicity

Persistence in the environment

Odor threshold

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

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

Abbreviations:

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

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[13]. 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.

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[13]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).

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 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.

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

What-If Analysis of Pelletizing Step

Subject: Criticality

What-If/Cause	Consequence/Hazard	Safeguards
Moderation Control Fails Because:		
Hydraulic fluid leaks.	Moderator reaches powder/criticality.	All hydraulic fluid systems are shielded from powder.
Powder is not dry enough.	Moderator reaches powder/criticality.	Multiple quality control steps for analytical results.
Room floods.	Moderator reaches powder/criticality.	No piped water systems in bulk powder handling areas.
Bulk powder storage container collects and holds liquid.	Moderator reaches powder/criticality.	Bulk containers are moved with sealed opening facing down.
Geometry Control Fails Because:		Passive stops welded to bottom of carts.
Cart tips over.	Safe geometry exceeded/criticality.	Buildup prevention devises within equipment.
Powder builds up in pelletizing equipment.	Safe geometry exceeded/ criticality.	Containers are of rugged construction, containers are administratively protected.
Small powder storage container breaks.	Safe geometry exceeded/ criticality.	Training, administrative controls
Sintering boats are stacked too high.	Safe geometry exceeded/ criticality.	

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

Subject: Criticality

What-If/Cause	Consequence/Hazard	Safeguards
Moderation Control Fails Because:		
Assembly shroud collects moderator.	Moderator reaches rods/criticality.	Shrouds are split to prevent accumulation.
Room floods.	Moderator reaches rods/criticality.	No piped water systems in bulk powder handling areas.
Geometry Control Fails Because:		
Stored fuel rods are stacked.	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.
Assemblies are stored too close.	Safe geometry exceeded/ criticality.	Storage racks control spacing.
Assemblies are spaced too closely during cleaning.	Safe geometry exceeded/ criticality.	Wash tanks have spacers to control distance.
Rods dissolve during cleaning step.	Safe geometry exceeded/ criticality.	Wash tank contents are strictly controlled.
Poison inserted to supplement geometry is removed.	Safe geometry exceeded/ criticality.	Boral shelves are fixed inside carts.

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

Figure B.3

UF_6 Dry Conversion Process

Hydrolysis Operation

Item Number	Deviation	Causes	Consequences	Safeguards
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

Item Number	Deviation	Causes	Consequences	Safeguards
5.2	Low level		No consequence of interest (NCI)	
5.3	High temperature	High flow in the 120-psig plant steam to vaporizer (raw steam) (Item 2.1) Low/no flow in the emergency cooling water line when needed (Item 4.2)	Potential loss of containment if the temperature exceeds the temperature rating of the cylinder vessel (Item 5.11)	High-temperature alarm Temperature indication
5.4	Low temperature	Low/no flow in the 120-psig plant steam line to the vaporizer (Item 2.2)	Potential loss of production form solid UF_6 plug in the pigtail; also unable to maintain the cylinder pressure	Temperature indication
5.5	High pressure in the vaporizer steam chest	Valve in vent line closed 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 6.2)	Release of steam with the potential for injury to personnel (e.g., burn hazard) Potential leak (Item 5.11) Potential rupture (Item 5.12)	Conservation vent valve on vaporizer vent line (relieves at 2 inches (WC) pressure)
5.6	Low pressure in the vaporizer steam chest	Rapid cooling of the steam chest or steam condensation	Potential process upset	Conservation vent valve on vaporizer vent line (draws air in at 1-inch WC vacuum)

Item Number	Deviation	Causes	Consequences	Safeguards
5.7	High pressure in the UF_6 cylinder	Low/no flow in the emergency cooling water (Item 4.2) Heat overfilled cylinder	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)	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
5.8	Low pressure in the UF_6 cylinder	Empty UF_6 cylinder	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)	
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	NCI - Conductivity false alarm Potential for plugging drain lines	Conductivity monitor Administrative control to check for debris (foreign material) after maintenance and before each cylinder installation
5.10	High concentration of UF_6	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	Potential release or personnel exposure to UF_6 and/or HF acid Potential criticality concern	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

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

Set No.	Event Name	Description	C	B.E. Prob	Calc Result	Cutset Prob
	GT					0.00E+00
1.	[illegible]	Leak [illegible]				1.00E+00
2.	[illegible]	[illegible]				1.00E+00
3.	[illegible]	[illegible]				1.00E+00
4.	[illegible]	[illegible]				1.00E+00
5.	[illegible]	[illegible]				1.00E+00
6.	[illegible]	[illegible]				1.00E+00
7.	[illegible]	[illegible]				1.00E+00
8.	[illegible]	[illegible]				1.00E+00
9.	[illegible]	[illegible]				1.0(

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. Emits toxic fumes of NO_x when heated.	1177
2	Ammonium Hydroxide	Incompatable with HF, HNO_3, and UF	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 100EC	1302
7	Steam		
8	Water		

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

Chemical reactions:

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

   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. $UF_6 + HNO_3 + water \rightarrow UO_2F_2 + 4HF + HNO_3 + heat$

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

4. $UF_6 + Steam \rightarrow UO_2F_2 + 4HF$

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 = 169.6EC and decomposes above 210EC, 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.

PART 70 AMENDMENT

DRAFT REGULATORY ANALYSIS

May 17, 1999

ATTACHMENT 7

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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 risk 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 available and reliable when needed. In addition, to ensure confidence in the margin of safety, the Commission believes that the safety basis for the facility should be docketed with 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 applicants or licensees who are authorized to possess greater than a critical mass of SNM and who are or plan to be engaged in enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, fabrication of mixed-oxide fuel or fuel assemblies, scrap recovery, decommissioning of facilities used for these activities, or any other activity that the Commission determines could significantly affect public health and safety.

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.[14] 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.[15]

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

[15] Ibid., page 7-16.

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.¢[16] 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.¢[17] The evaluation also found that ¡... hazards analyses or engineering safety analyses of plant systems and components are not routinely performed¢[18] 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 10 CFR Parts 50 and 72, 10 CFR Part 70 contains no ¡general design criteria.¢[19] 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;[20] does not require management review or audits of changes of procedures and methods; and does not mention managerial controls, including elements of 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. This delay can allow changes accomplished without a license amendment (see above) to accumulate without NRC licensing review.

- 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

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

[17] Ibid., page 18.

[18] Ibid., page 27.

[19] Ibid., pages 17 and 30.

[20] 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 fix the weaknesses of the current safety regulations in 10 CFR Part 70 in order to regulate major SNM licensees, without undue burden, 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.[21]

4.0. Background

On January 4, 1986, a worker lost his life during an accidental release of uranium hexafluoride (UF_6) at a facility regulated under 10 CFR Part 40. A Congressional inquiry[22] 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

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

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

specifically into the licensing requirements of Part 70. The same is true of branch technical positions on fire safety,[23] management controls,[24] and requirements for operation.[25]

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, the NRC reviewed the causes of a number of what it considers serious incidents and precursor events at fuel cycle facilities reported between 1992 and 1998.[26] 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.

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[23] *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.

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

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

[26] 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.

o) September, 1996: Second instance of a fire at the same facility in local ventilation duct 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,[27] 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 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[28] 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. On July 30, 1998, staff submitted a proposed rule to the Commission in SECY-98-185[29]. In a December 1, 1998 SRM, the Commission disapproved publication of the staff's submittal as a proposed rule. The Commission directed the staff to continue to discuss all relevant documents with stakeholders (Nuclear Energy Institute, Department of Energy, and others) in public, including use of the Internet, and submit a revised proposed rulemaking

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

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

[29] SECY-98-185, *"Proposed Rulemaking - Revised Requirements for the Domestic Licensing of Special Nuclear Material".*

package to the Commission for approval six months from December 1, 1998. The current proposed rule has been modified from that of SECY-98-185 as a result of that additional public interaction between the staff and the stakeholders. Staff's recommended approach to rulemaking includes the basic elements of the PRM-70-7, with some modifications.

As previously stated, the purpose of the present proposed rulemaking is to establish a risk-informed framework for regulating major[30] 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.

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

5.0 Alternatives

The alternatives considered are:

- Option 1 -- no action;
- Option 2 -- the proposed rule and standard review plan (SRP); and
- Option 3 -- a quantitative probabilistic risk analyses (PRA) type requirement.

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 ISA, is needed because the existing regulations in Part 70 do not require establishment of a safety program based on 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.

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¢[31] 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

[31] 10 Section CFR 70.22(I)(1)(ii).

more reliable than procedural means, and are preferred for nuclear criticality safety, are not addressed in the regulation.

For 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, 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.[32]

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 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.[33]

[32]Regulatory Guide 3.52, Revision 1, November, 1986, page vii.
[33]Ibid., page viii.

> 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.[34]
>
> The types of accidents considered and their potential impact on occupational safety and the environment should be summarized.[35]

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.[36]

5.1.2 Option 1b

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 applicants to dispute 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 measures 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.)

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[34] Ibid., page 29 (Section 15.2).
[35] Ibid., page 30 (Chapter 16).
[36] NUREG-1450

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, as refined and modified by additional stakeholder interaction and by the Dec. 1, 1998 SRM on SECY-98-185. This new subpart includes requirements aimed at increasing NRC's confidence in the margin of safety at certain licensed facilities authorized to possess greater than a critical mass of special nuclear material. Option 2 is a risk-informed, performance-based regulatory approach that includes: (1) the identification of appropriate performance 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 available and reliable when needed. In addition, in order to ensure confidence in the margin of safety, a licensee would be required to maintain its safety basis by using its ISA in evaluation of changes and periodically updating its ISA. Also, the summary of the ISA would be docketed with the license application, and revisions to the ISA summary would be required to be provided to NRC.

In brief, staff proposes 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 greater than 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 applicants or licensees who are authorized to possess greater than a critical mass of SNM and who are or plan to be engaged in enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, fabrication of mixed-oxide fuel or fuel assemblies, scrap recovery, decommissioning of facilities used for these activities, or any other activity that the Commission determines could significantly affect public health and safety. .

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

c) Inclusion of the safety basis, as reflected in the ISA summary, with 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 availability and reliability of these items when needed).

d) Ability of licensees, based on the results of an ISA, to make certain changes without NRC pre-approval.

Also included in Option 2 are new reporting requirements, which are based on consideration of the consequences or 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 summary, 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 and elsewhere in the regulations (e.g., 10 CFR Part 20).

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 revised 10 CFR Part 70 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 or mitigate the consequences of potential accidents to levels specified in the proposed §70.6, 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 quantitatively. 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 quantitative PRA would be difficult and expensive to assemble and evaluate.

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.¢[37]
- 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 an area that is moderator-controlled for nuclear criticality safety. 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 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) those items will be reliable and available when needed; and, (d) future changes will not significantly 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 70.61 would provide explicit safety performance requirements as well as, in §70.64, baseline design criteria for new facilities. The risk-informed regulation specifies protection must be provided to limit risk of credible high-consequence and intermediate-consequence events. 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. The rule would require a safety program that includes management measures, such as configuration management and quality assurance. It also requires

[37] 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.

personnel to be trained to ensure they understand the safety features that are relied on to prevent accidents. The required ISA would have to address criticality hazards, and those chemical and fire hazards that affect radiological hazards, as well as direct 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. Any changes to the safety basis documentation will be handled by a structured change control process.

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 relative immaturity of 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 greater than 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 produced from licensed material.

6.1.2.1 Onsite Consequences

Deaths of two workers are directly attributable to accidents involving licensed nuclear material.[38] (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 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

[38] 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.

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 and focus 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 ($1,000)			
	Costs for average licensee preparing ISA under Option 1b		Costs for average licensee not preparing ISA under Option 1b	
	Low average	High average	Low average	High average
Incremental Sunk Cost of Option 1b Compared to 1a				
Average licensee one time cost ($[39]/licensee)	$700	$2,200	$80	$110
Average licensee recurring costs ($/licensee- year)	$170	$240	$40	$40
Average NRC one time cost ($/licensee)	$60	$140	$0	$140
Average NRC recurring costs ($/licensee- year)	($24)[40]	($23)	$0.7	$1.7
Incremental Cost of Option 2 Compared to Option 1b				
Average licensee one time cost ($/licensee)	$140	$400	$700	$2,200
Average licensee recurring costs ($/licensee- year)	$20	$40	$150	$230
Average NRC one time cost ($/licensee)	($9)	$10	$50	$120
Average NRC recurring costs ($/licensee- year)	($19)	($16)	($11)	($8)
Incremental Cost of Option 3 Compared to Option 1b[41]				
Average licensee one time cost ($/licensee)	$350	$1,400	$800	$3,200
Average licensee recurring costs ($/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

[39] 1997 dollars.
[40] Savings are indicated as negative values, shown in parentheses.
[41] No difference in NRC cost was estimated for Option 3 versus Option 2.

relied on for safety, are estimated to have license conditions costing on average[42] 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.

- 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.

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

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 $150,000[43].

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 $60,000 to $140,000 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 $24,000 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 $8,000 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 $4,800 and $12,000 per year, or between $700 and $1,700 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 $33,000 per year per each of the four licensees.

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

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:

- 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 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[44], 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 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

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

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 summaries and on-site review of selected ISA details 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 ISA summaries that would contain the information specified in the rule, in contrast to the very brief or no submittals that are expected under Option 1b. The summaries are expected to reduce NRC staff expenditures of time and effort associated with reviewing ISAs. License reviewers, however, still will need to spend some 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 $13,000 to $40,000 less than the comparable costs would have been under Option 1b, or an average cost of $47,000 to $100,000 per licensee.[45] 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 $8,500 to $26,000 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 $6,000 to $9,000 per licensee for licensees required to perform an ISA under Option 1b and on the order of $27,000 to $40,000 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 summaries as their ISAs are modified to reflect changes to systems and processes. NRC review of ISA updates for the three licensees not required to provide updates to the demonstration part of their license applications

[45] 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 $5,000 to $13,000 for each of the licensees preparing ISAs under Option 1b.

under Option 1b is estimated to cost the NRC about $4,900 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 summaries 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 $2,700 per licensee per year. With a savings of $10,800 per year for four licensees and an additional cost of $14,700 per year for three licensees, the net cost to the NRC is $3,900 per year, or an average of $600 per year per licensee.

The increased number of licensee event reports expected with Option 2 are estimated to increase NRC operational costs by $13,300 to $33,200 annually compared to the cost of reviews under Option 1b, or $1,900 to $4,700 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 periodically update safety basis 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[46] 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.[47]

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

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46 The Center for Chemical Process Safety states: "The term 'Chemical Process Quantitative Risk Analysis' (CPQRA)

47 *Guidelines for Chemical Process Quantitative Risk Analysis*,

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.

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.

8.0 Implementation

The action evaluated in this regulatory analysis would be enacted through publication in the *Federal Register*, and on the NRC Rulemaking Forum web site (http://ruleforum.llnl.gov), of a Notice of Proposed Rulemaking. Then staff will consider comments received during a formal public comment period, which is expected to be of 75 days duration.

The NRC staff has developed a draft Standard Review Plan, which will be used by NRC staff for evaluating submittals from applicants and licensees for assurance of adequate safety and compliance with the regulation, in parallel with development of the rule. This SRP is also being made available for public review and comment.

Several comments have already been received and considered by NRC staff during the development of the draft proposed rule and draft Standard Review Plan via the NRC Technical Conferences Forum web site (http://techconf.llnl.gov). Following a period of staff consideration of the comments received during the formal public comment period, and revision to the proposed rule and Standard Review Plan, as deemed appropriate, staff will then publish a Final Rule and SRP.

The rule will become effective 30 days after its publication as a Final Rule.

The proposed rule states:

> Individuals holding an NRC license on the effective date of this rule shall, with regard to existing licensed activities:
>
> (i) within six months of the effective date of this rule, submit, for NRC approval, a plan that describes the integrated safety analysis approach that will be used, the processes that will be analyzed, and the schedule for completing the analysis of each process. Pending the correction of unacceptable performance deficiencies identified by the integrated safety analysis, the licensee shall implement appropriate compensatory measures to ensure adequate protection.
>
> (ii) within four years of the effective date of this rule, unless otherwise specified by the conditions of a license held on the effective date of this rule, complete an integrated safety analysis, correct all unacceptable performance deficiencies, and submit an integrated safety analysis summary in accordance with §70.65 or the approved plan submitted under paragraph (c)(3)(i) of this section.

Regulatory Analysis - Appendix

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[48] 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[49] was used to estimate the range in the labor requirements for HAZOP and What-if analyses. The estimate is based on the following assumptions:

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

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48 Center for Chemical Process Safety of the American Institute of Chemical Engineers (AIChE) 1992. *Guidelines for Hazard Evaluation Procedures, Second Edition with Worked Examples*. This is one of ... Occupational Safety and Health Administration in its rulemaking on Process Safety Management (29 CFR 1910.119) ... 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

49 Ibid.

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/BR-0184, "Regulatory Analysis Technical Evaluation Handbook", which gives $67.50 as the NRC labor rate for 1996. . The resulting NRC labor rate was taken to be $71 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 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).[50]

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 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.

[50] 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.

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[51]		
	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	-
Cost per Licensee (in 1997 dollars)	$540,000 - $840,000		

[51] 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.

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[52], 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

[52] 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										
Update design basis documents to as-built conditions (re changes)	6	$4	11	1	0	$0	$24	$66	$0	$0

Table G - Incremental Cost Impacts (cont.)

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**
Recurring Costs per Year										

Table G - Incremental Cost Impacts (cont.)

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**

D R A F T

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 requirements.

The proposed changes are an outgrowth of an NRC review conducted after a fuel fabrication facility had a near criticality incident (i.e., a nuclear chain reaction) in May of 1991. As a result of this review, NRC took a number of steps to improve licensee safety programs, event reporting to NRC, and regulatory guidance. In addition, NRC concluded that, in order to increase confidence in the safety margin, the regulations should be amended to require similar licensees to 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, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, fabrication of mixed-oxide fuel or fuel assemblies, scrap recovery of special nuclear material, or any other activity involving a critical mass of 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 supplement 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 on December 3, 1998, and again on January 13 and March 23 of this year. NRC has also maintained an Internet website through which the agency has obtained public comments.

The proposed new regulations would require licensees to perform an integrated safety analysis, as described above, which would include identification of the radiological and related 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. A summary of the analysis would have to be submitted at the time of license application. All related documentation on-site and at the NRC would have to be maintained on a regular basis.

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 certain related 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 that they will perform their safety function. Licensee personnel would have to be trained and tested to confirm their qualifications to perform their safety duties. Appropriate management measures would have to be established to ensure that items relied on for safety are available and reliable to perform their function when needed.

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: Rulemakings 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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Draft May 3, 1999

The Honorable James M. Inhofe, Chairman
Subcommittee on Clean Air, Wetlands, Private
Property and Nuclear Safety
Committee on Environment 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 available and reliable to perform their function when needed; 4) require the submission of a

summary of the ISA, with the 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

Draft May 3, 1999

The Honorable Joe L. Barton, 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.

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summary of the ISA, with the 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 M. Hall

UNITED STATES NUCLEAR REGULATORY COMMISSION

Environmental Assessment and Finding of No Significant Impact

(PRE-DECISIONAL DRAFT)

For

Proposed Amendments to 10 CFR Part 70

June 1999

Division of Fuel Cycle Safety and Safeguards

Office of Nuclear Material Safety and Safeguards

ATTACHMENT 10

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 enriched uranium processing, fabrication of uranium fuel or fuel assemblies, uranium enrichment, enriched uranium hexafluoride conversion, plutonium processing, fabrication of mixed-oxide fuel or fuel assemblies, scrap recovery of special nuclear material, or any other activity involving a critical mass of special nuclear material that the Commission determines could significantly affect public health and safety. This action is being taken in response to a Petition for Rulemaking (PRM 70-7) filed by the Nuclear Energy Institute (NEI). NEI explained, to the Commission, industry's position on the need for revision of NRC regulations, in Part 70, at a July 2, 1996, meeting, and in a subsequent filing, in September 1996, of a Petition for Rulemaking (PRM 70-7). 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 Commission, in an SRM dated August 22, 1997, approved the staff's proposal to revise Part 70 and directed the staff to submit a draft proposed rule by July 31, 1998. The amendments to 10 CFR Part 70 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 are available and reliable to perform their function when needed. 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. Performance of an Integrated Safety Analysis (ISA) to identify potential accidents at the facility and the items relied on for safety;

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

3. Measures to ensure that items relied on for safety are available and reliable to perform their function when needed;

4. Submission of an ISA summary, with the license application; and

5. Flexibility for licensees to make certain changes to their facilities, without prior NRC approval.

The Commission's approach, outlined above, agrees in principle with the NEI's petition, with the modifications described in SECY-XX-XXX. 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 availability and reliability to perform their function when needed. 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 availability and reliability of the items relied on for safety to perform their function when needed. 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) Alternative 1-no-action, and 2) Alternative 2- the proposed rule revision and development of a standard review plan (SRP).

Alternative 1

Alternative 1 is the status-quo, no action alternative that reflects the current Part 70 requirements including the current license conditions requiring ISAs in most, but not all, of the licenses which have been renewed. Prior to the addition of the ISA license conditions, NRC was criticized in House Report 100-167 for concentrating on radiological hazards and largely for ignoring other hazards. Under Alternative 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 Alternative 1, there are other licensees that are not performing ISAs at all. Therefore, even with a revised SRP, there would continue to be inconsistencies between the individual licensees.

Alternative 2

Alternative 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

Alternative 2

The potential environmental impacts of Alternative 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[53], and the benefits to the public health 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

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

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.

Alternative 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:

1. Provide protection against accidents with the following consequences so that their occurrence would be highly unlikely:
   (a) an acute worker dose of 1 Sv (100 rem) or greater total effective dose equivalent;
   (b) an acute dose of 0.25 Sv (25 rem) or greater total effective dose equivalent to any individual located outside the controlled area; or
   (c) an intake of 30 mg or greater of uranium in a soluble form by any individual located outside the controlled area
   (d) an acute chemical exposure to an individual form licensed material or hazardous chemicals produced from licensed material that:
      (i) could endanger the life of a worker, or
      (ii) could lead to irreversible or other serious, long-lasting health effects to any individual located outside the controlled area.
2. Provide protection against accidents with the following consequences so that their occurrence would be unlikely:
   (a) an acute worker dose of 0.25 Sv (25 rem) or greater total effective dose equivalent;
   (b) an acute dose of 0.05 Sv (5 rem) or greater total effective dose equivalent to any individual located outside the controlled area;
   (c) a 24-hour averaged release of radioactive material outside the restricted area in concentrations exceeding 5000 times the values in Table 2 of Appendix B to 10 CFR Part;
   (d) an acute chemical exposure to an individual form licensed material or hazardous chemicals produced from licensed material that:
      (i) could lead to irreversible or other serious, long-lasting health effects to a worker, or

(ii) could cause mild transient health effects to any individual located outside the controlled area.

3. Limit by assuring that under normal and credible abnormal conditions, all nuclear processes are subcritical.
4. Submit, with the license application a summary of the ISA and keep the summary and other ISA documentation updated.
5) Identify and maintain items relied on for safety to ensure that they are available and reliable to perform their function when needed.
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.
7) Apply for NRC pre-approval only for certain changes to its safety program and facility.

The benefits of the proposed action in reducing the likelihood of potential accidents and mitigating their 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.

Alternative 1

The first alternative, Alternative 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 Alternative, 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
Alternative 1-no action	less than Alternative 2	less than Alternative 2	less than Alternative 2
Alternative 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*, US NRC, February 1992.

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

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

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

Principal Contributors:

FCSS staff