United States Nuclear Regulatory Commission

Protecting People and the Environment

NUREG-1520, Rev. 2

Standard Review Plan for Fuel Cycle Facilities License Applications

Final Report

Office of Nuclear Material Safety and Safeguards

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Standard Review Plan for Fuel Cycle Facilities License Applications

Final Report

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ABSTRACT

NUREG-1520, “Standard Review Plan (SRP) for Fuel Cycle Facilities License Applications” (hereinafter referred to as the SRP), provides guidance to the staff reviewers in the U.S. Nuclear Regulatory Commission’s (NRC’s) Office of Nuclear Material Safety and Safeguards who perform safety and environmental impact reviews of applications to construct or modify and operate nuclear fuel cycle facilities. This SRP addresses the longstanding health, safety, and environmental-protection requirements of Title 10, “Energy,” of the *Code of Federal Regulations* (10 CFR) Part 20, “Standards for Protection against Radiation,” and 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” as well as the accident-safety requirements reflected in Subpart H, “Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material,” of 10 CFR Part 70.

The SRP is intended to be a comprehensive and integrated document that provides the reviewer with guidance that describes methods or approaches that the staff has found acceptable for meeting NRC requirements. Separate chapters of this SRP discuss the major topics addressed within the safety program description of a facility license application, including general information, organization and administration, ISA and ISA summary, radiation protection, nuclear criticality safety, chemical process safety, fire safety, emergency management, environmental protection, decommissioning, management measures, material control and accounting, and physical protection. This SRP also makes information about licensing acceptance criteria widely available to interested members of the public and the regulated industry and is intended to improve industry and public stakeholder understanding of the staff review process. Each SRP section addresses the responsibilities of the staff reviewers, the matters that they review, the Commission's regulations pertinent to specific technical matters, the acceptance criteria used by the staff, the process and procedures used to accomplish the review, and the conclusions that are appropriate to summarize the review.

The draft SRP was made publicly available for public comment on June 5, 2014, with a comment period ending on November 3, 2014 (79 FR 32579 and 79 FR 45849). A comment resolution table listing all comments and the NRC staff’s responses was made publicly available on March 23, 2015 (Agency Wide Documents Access and Management System Accession No. ML15065A339). This SRP is not a substitute for NRC regulations and compliance is not required. The approaches and methods in this report are provided for information only. Methods and solutions different from those described in this report will be acceptable if they provide a basis for the staff to make the determination needed to issue or continue a license.

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ACRONYMS AND ABBREVIATIONS

ACGIH	American Conference of Governmental Industrial Hygienists
AEC	active engineered control
AEGL	Acute Exposure Guideline Level
ALARA	as low as is reasonably achievable
ANS	American Nuclear Society
ANSI	American National Standards Institute
ASME	(formerly the American Society of Mechanical Engineers)
ASTM	(formerly the American Society for Testing and Materials)
B.A.	Bachelor of Arts [degree]
B.S.	Bachelor of Science [degree]
BDC	baseline design criterion/criteria
CAAS	criticality accident alarm system
CD	chemical dose
CFR	*Code of Federal Regulations*
Ci	curie(s)
CM	configuration management
DFP	decommissioning funding plan
DOE	U.S. Department of Energy
DP	decommissioning plan
EA	environmental assessment
EAL	emergency action level
EIS	environmental impact statement
ERDA	Energy Research and Development Administration
ERPG	Emergency Response Planning Guidelines

FCSE	Division of Fuel Cycle Safety, Safeguards, and Environmental Review [in the Office of Nuclear Material Safety and Safeguards]
FHA	fire-hazards analysis/analyses
FONSI	finding(s) of “no significant impact”
FR	*Federal Register*
GBq	gigabecquerel(s)
HFE	human-factors engineering
HPS	Health Physics Society
HS&E	health, safety, and environment
HSI	human/systems interface
ICRP	International Commission on Radiological Protection
IEF	initiating-event frequency
IROFS	item(s) relied on for safety
ISA	integrated safety analysis/analyses
ISO	International Organization for Standardization
kg	kilogram(s)
km	kilometer(s)
MDC	minimum detectable concentration
mg	milligram(s)
mi	mile(s)
MTTF	mean time to failure
MTTR	mean time to repair
NCRP	National Council on Radiation Protection and Measurements
NCS	nuclear criticality safety
NFPA	National Fire Protection Association
NMSS	Office of Nuclear Material Safety and Safeguards [in the U.S. Nuclear Regulatory Commission]

NRC	U.S. Nuclear Regulatory Commission
OCB	oxide-conversion building
OER	operating-experience review
ORR	operational readiness review
OSHA	Occupational Safety and Health Administration
PEC	passive engineered control
PFOD	probability of failure on demand
PHA	process hazard analysis/analyses
PM	preventive maintenance
PMF	probable maximum flood
QA	quality assurance
RAI	request(s) for additional information
RD	radiological dose
RWP	radiation work permits
SBC	Standard Building Code
SER	safety-evaluation report
SNM	special nuclear material
SRP	standard review plan
SSE	safe-shutdown earthquake
Sv	sievert
TEDE	total effective dose equivalent(s)
UF_6	uranium hexafluoride
UO_2	uranium dioxide
V&V	verification and validation
yr	year(s)

INTRODUCTION

NUREG-1520, "Standard Review Plan (SRP) for Fuel Cycle Facilities License Applications" (hereinafter referred to as the SRP), provides U.S. Nuclear Regulatory Commission (NRC) guidance for reviewing and evaluating the health, safety, and environmental protection aspects of applications for licenses to possess and use special nuclear material (SNM) to produce nuclear reactor fuel. This guidance is specific to fuel cycle facilities regulated under Title 10, "Energy," of the *Code of Federal Regulations* (10 CFR) Part 70, "Domestic Licensing of Special Nuclear Material"; that is, facilities that are authorized for or are seeking a license to possess and use more than a critical mass of SNM. This guidance also applies to the review and evaluation of proposed amendments and license renewal applications for nuclear fuel cycle facilities. This guidance does not apply to conversion facilities,[1] reprocessing facilities, or plutonium processing facilities.[2]

The principal purpose of this SRP is to ensure the quality and uniformity of reviews conducted by the staff of the NRC's Office of Nuclear Material Safety and Safeguards (NMSS). This SRP also provides a well-defined foundation from which to evaluate proposed changes in the scope, level of detail, and acceptance criteria of reviews. It also provides information and guidance to assist the licensing staff and the applicant in understanding the underlying objectives of the regulatory requirements, the relationships among NRC requirements, the licensing process, the major guidance documents that the NRC staff has prepared for licensing fuel cycle facilities, and information about aspects of the staff review process set out in individual SRP sections. Another important purpose of this SRP is to make information about regulatory reviews widely available and to improve communication and understanding of the staff review process. In addition, because this SRP describes the scope, level of detail, and acceptance criteria for reviews, it contains regulatory guidance for applicants who need to determine what information to present in a license application and related documents. This SRP does not preclude licensees or applicants from suggesting alternative approaches to those specified in the SRP to demonstrate compliance with applicable regulations.

This SRP addresses the longstanding health, safety, and environmental-protection requirements of 10 CFR Part 20, "Standards for Protection against Radiation," and 10 CFR Part 70, as well as the accident safety requirements reflected in Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material," of 10 CFR Part 70.

Subpart H of 10 CFR Part 70 identifies risk-informed performance requirements and requires applicants and existing licensees to conduct an integrated safety analysis (ISA) and submit an ISA Summary, as well as other information. Specific requirements for ISA Summaries are described in 10 CFR 70.65, "Additional Contents of Applications." For new facilities that have not already been designed, built, licensed and operated, Subpart H also requires adherence to baseline design criteria, as specified in 10 CFR 70.64, "Requirements for New Facilities or New Processes at Existing Facilities."

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[1] The NRC regulates conversion facilities under the provisions of 10 CFR Part 40, "Domestic Licensing of Source Material."

[2] Guidance for the review of a license application for a Mixed Oxide (MOX) Fuel Fabrication Facility is provided in NUREG-1718, "Standard Review Plan for the Review of a License Application for a MOX Fuel Fabrication Facility," issued August 2000.

In reviewing a license application, renewal application, or license amendment for a fuel cycle facility, the staff must determine whether 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 adequately protect the health and safety of workers, the public, and the environment. The staff uses a "reasonable assurance" paradigm and focuses on the programmatic provisions of the applicant's proposed activities. To carry out this responsibility, the staff focuses on the descriptive commitments of the safety program in the license application and the description of processes, hazards, controls, and management measures in its ISA Summary and onsite ISA documentation. The staff evaluates the information that the applicant provides and, through independent assessments, determines whether the applicant has proposed an adequate safety program that is compliant with regulatory requirements. To assist the staff in carrying out this responsibility, this SRP clearly states and identifies those standards, criteria, and bases that the staff will use in reaching licensing decisions.

An application for a 10 CFR Part 70 license must satisfy the requirements described in 10 CFR 70.22, "Contents of Application," including specific information on the proposed equipment and facility in accordance with 10 CFR 70.22(a)(7), which states that each application shall contain the following:

A description of equipment and facilities which will be used by the applicant to protect health and minimize danger to life or property (such 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.).

Consequently, the licensing decision is ultimately based on information with a sufficient level of detail that permits reviewers to understand process system functions and, functionally, how items relied on for safety (IROFS) can perform as intended and be reliable. This staff review method is intended to ensure that the staff decision is based on a reasonable assurance that the submitted ISA Summary is complete, that the licensee will comply with the ISA and maintain it consistent with the regulations, and that the applicant's programs will be adequate to design and operate a facility that complies with all applicable regulations and provides for adequate protection of public health and safety. For new facilities or new processes at existing facilities, there may not be complete detail or a final design available at the time of licensing. However, sufficient information must be available to permit the staff to understand the theory of operation and function of each IROFS, to have reasonable assurance that all credible accident sequences have been identified, that a sufficient set of IROFS has been defined, and that management measures will be sufficient to ensure IROFS will be available and reliable to perform their intended functions in the context of 10 CFR 70.61, "Performance Requirements."
For uranium enrichment facilities, to ensure that the applicant's programs have been sufficiently implemented and commitments have been properly applied in the final facility design and in the constructed facility, 10 CFR 70.32(k) states:

No person may commence operation of a uranium enrichment facility until the Commission verifies through inspection that the facility has been constructed in accordance with the requirements of the license.

This requirement applied through inspections, and not by licensing reviews, will ensure that the programmatic commitments made by licensee are properly applied in the as built facility. This inspection is intended to inspect the final design of the facility and the procedures that have

been prepared to implement the licensee's commitments that are reflected in the license. Furthermore, for significant modifications to existing fuel cycle facilities, such as the licensing and construction of new processes, the staff may impose a license condition that specifies that an operational readiness review (ORR) inspection be conducted before operation to verify that the new part of the facility has been constructed in accordance with the requirements of the license. To facilitate the planning and accomplishment of a risk-informed ORR, the staff relies upon the licensee to provide a complete set of information. This complete set of information has been referred to in some projects as IROFS boundary packages.[3] For simplicity they will be referred to hereinafter in this document as IROFS boundary packages. Regardless of what they are called in a license application, the key point is that they provide information to the reviewers and inspectors about supporting systems that directly affect the effectiveness of the IROFS and the reliability and availability of the IROFS as required by 10 CFR 70.62(d). Inspectors use this information during the ORR inspection to determine if the licensee meets the requirements in 10 CFR 70.23(a)(3)–(4) and in 10 CFR 70.61(e).

In developing the performance requirements in 10 CFR Part 70, the NRC anticipated that, in the future, changes would be made to the facility design and processes and, therefore, described a process for addressing these changes is described in 10 CFR 70.72, "Facility Changes and Change Processes." For a uranium enrichment facility, the licensee may make changes to its design, after receiving its license, during the construction phase, and after operations begin. These changes, therefore, need to be submitted and reviewed in accordance with 10 CFR 70.72.

The requirements in 10 CFR 70.22; 10 CFR 70.23, "Requirements for the Approval of Applications"; and Subpart H to 10 CFR Part 70 specify, in general terms, the information to be supplied in a safety program description. As such, this SRP identifies the specific information that an applicant should submit for staff evaluation. Prospective applicants should study the topic areas treated in this SRP and the sections within each chapter (particularly those regarding areas of review and acceptance criteria). To facilitate the staff's review, a license application should contain a safety program description that addresses the contents of this SRP

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[3] IROFS boundary packages are documents that contain the physical descriptions and parameters of structures, systems, and components that are used to meet the performance requirements of 10 CFR 70.61. IROFS boundary definition packages are also prepared for administrative procedures or worker actions that are defined as IROFS. The boundary packages identify the specific functions to be performed by an IROFS and identify any items that may affect the function of the IROFS. The boundary packages also identify the facility areas in which the IROFS is used, its design and functional attributes, management measures related to it, any open items about it, and its supporting documentation (e.g., piping and instrumentation diagrams and schematics).

Design and functional attributes should include safety functions such as separation from other IROFS, redundancy and diversity, fail-safe design, set points, environmental qualification, seismic qualification, and fire protection. System interfaces such as instrumentation, electrical, cooling, and lubrication requirements should also be included under design and functional attributes.

Management measures should address all of the management measures required to be applied to IROFS under 10 CFR 70.4, "Definitions," and should include summary descriptions; references to maintenance, training, and procedures documents; or both, as appropriate for the IROFS. The references should be adequate to identify the actual working-level training or procedures document.

Open items that affect the reliability, the effectiveness, or both of the IROFS should be closed by the time of the ORR. The open items section should identify open items associated with the IROFS during the review and describe how the open items were resolved.

in the same order as presented in this document. Applicants may reference material submitted in one location in a license application at another location to avoid unnecessary duplication. In addition, 10 CFR 70.61 requires each applicant to evaluate, in an ISA performed in accordance with 10 CFR 70.62, “Safety Program and Integrated Safety Analysis,” its compliance with the performance requirements in 10 CFR 70.61(b), 10 CFR 70.61(c), and 10 CFR 70.61(d).

Based on the information in the ISA Summary provided in accordance with 10 CFR 70.65, the NRC makes licensing decisions as required under 10 CFR 70.21, “Filing”; 10 CFR 70.22; 10 CFR 70.23; and 10 CFR 70.60, “Applicability,” through 10 CFR 70.66, “Additional Requirements for Approval of License Application.” These decisions include compliance with the performance requirements, the baseline design criteria, defense in depth, and the adequacy of management measures. Staff analyses 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. If the staff determines that an application contains inadequate descriptions or commitments, the staff will inform the applicant of what is needed and the basis on which the determination was made.

The acceptance criteria delineated in this SRP are intended to communicate the underlying objectives, but they do not represent the only means of satisfying those objectives. An applicant should tailor its safety program to the particular features of its facility. If an applicant chooses approaches other than those presented in this SRP, the applicant should identify the portions of its license application that differ from the design approaches and acceptance criteria of the SRP and should document 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 concerning the adequacy of the applicant’s proposed approaches.

Each SRP chapter is structured as follows:

Purpose of Review

This section presents a brief statement of the purpose and objectives of reviewing the subject areas. It emphasizes the staff’s evaluation of the ways in which the applicant will achieve identified performance objectives and ensures (through the review) that the applicant has used a multidisciplinary, systems-oriented approach to establish designs, controls, and procedures within individual technical areas.

Responsibility for Review

This section identifies the NRC organization and individuals (by function) who are responsible for evaluating the specific subject or functional area. In general, the licensing project manager has responsibility for the total review product, which is referred to as a safety evaluation report (SER). However, an identified technical specialist will have primary responsibility for a particular review topic (usually an SRP chapter) and one or more specialists may have supporting responsibility.

Areas of Review

This section describes the topics, functions, systems, components, analyses, applicant commitments, data, or other information that should be reviewed as part of the given subject area of the license application. Because this 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 topics identified in this section also set the content of the next two sections of the SRP, covering the acceptance criteria and review procedures. Applications should address, in the same order, the topics set forth as areas of review.

Acceptance Criteria

This section defines a set of applicable NRC acceptance criteria on the basis of regulatory requirements, and these collectively establish the basis for assessing 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, and industry codes and standards. As such, the acceptance criteria present positions and approaches that are acceptable to the staff. As noted above, other than the regulations, the NRC does not consider these criteria to be the only acceptable positions or approaches, and the applicant may propose others.

The requirements for approval of an application are listed in 10 CFR 70.23(a)(1) through (12) and 10 CFR 70.66. As a technical matter, NMSS will determine how final the design must be to make this finding. The NRC staff will interpret applicant commitments to follow an industry standard as a commitment to adhere to all "shall" statements in the standard. The staff will not consider suggestions and recommendations in the standards (so-called "should" statements) as binding commitments by the applicant, unless the applicant specifically states an intent to treat the "should" statements as binding commitments (i.e., to treat them as if they are "shall" statements). The applicant may make such commitments as part of its description of the safety program basis. If the staff finds that a definitive commitment to a "should" statement is necessary to provide adequate protection, the reviewer will raise this as an issue in any request for additional information on specific licensing actions. However, applicants should note that some industry or consensus standards specifically direct users to provide justifications for not abiding by recommendations contained in the standards. For example, American National Standards Institute/American Nuclear Society Standard 8.1, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors," states that "when recommendations are not implemented, justification shall be provided," thus effectively mixing "should" and "shall" statements. In such instances, applicants should be prepared to justify any decisions not to abide by recommendations contained in the standards.

Review Procedures

This section 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 could include identifying which licensee commitments the reviewer needs to verify, and could include directing the reviewer to coordinate with others having review responsibilities for other portions of the application than those 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.

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, the staff SER publishing the results of the review will include a conclusion of this type. The SER will also contain a description of the review, including aspects that received special emphasis, matters that the applicant modified during the review, matters that require additional information or will be resolved in the future, aspects where the facility'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.

In the SER, the staff may recommend license conditions to address any issues that were not previously resolved by an applicant's commitments. Such conditions are discussed with an applicant before issuing the license (or license amendment) and become commitments to performance in addition to those commitments that the applicant presented in the application.

References

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

1. GENERAL INFORMATION

1.1 Facility and Process Overview

1.1.1 Purpose of Review

The purpose of this review is to ascertain whether an application for a new, renewed, or amended license includes an overview of the facility layout and a summary description of its manufacturing processes. All reviewers, U.S. Nuclear Regulatory Commission (NRC) managers, and the public may use this overview to gain a general understanding of the purpose of the facility and an overview of the design of its processes. The integrated safety analysis (ISA) summary describes the facility and its manufacturing processes in more detail.

1.1.2 Responsibility for Review

Primary: Licensing Project Manager

Secondary: ISA Reviewer, Environmental Reviewer, Emergency Protection Reviewer, other Technical Reviewers

Supporting: None

1.1.3 Areas of Review

The staff should review the general facility and process descriptions provided in the license application. The areas of review should include the following:

1. Facility Layout Description—This area includes a description of the purpose of each feature and the interrelationships between features.

2. Process Overview—The process description should be a narrative description of the different processes at the facility involving licensed material.

3. Site Overview—The description includes the proximity of facility buildings to the site boundary and nearby populations, including the most recent census data available when the license application was submitted.

4. Descriptive Summary of Licensed Material—The summary should include the name, amount, and specification (including chemical and physical forms) of the special nuclear material (SNM). The license application also should include a list of raw materials, byproducts, wastes, moderators, and finished products of the facility.

The facility and process description in the license application must be consistent with the information presented in the ISA summary and in Chapter 8, which addresses emergency management, of this standard review plan (SRP).

Review Interfaces

In addition to the general information in the application, the reviewer should examine information in the following areas to ensure that it is consistent with the general information section in the license application:

- information about the facility and site and the different processes that will involve SNM in Chapter 3 of this SRP
- the facility and process descriptions in Chapter 8 of this SRP

1.1.4 Acceptance Criteria

1.1.4.1 Regulatory Requirements

The regulations applicable to the areas of review in this SRP are Title 10, "Energy," of the *Code of Federal Regulations* (10 CFR) 70.22, "Contents of Applications," and 10 CFR 70.65(b)(1) and (2).

1.1.4.2 Regulatory Guidance

No regulatory guides apply to a general facility description for a fuel cycle facility.

*1.1.4.3 Regul*atory Acceptance Criteria

The reviewer should find the applicant's general information acceptable if it provides reasonable assurance that the acceptance criteria presented below are adequately addressed and satisfied.

1.1.4.3.1 Facility Layout Description

The applicant's overview of the facility is acceptable if it meets the following conditions:

1. The application presents information at a level of detail that is appropriate for general familiarization with and understanding of the proposed facility. This information should be consistent with that presented in the ISA summary but may be less detailed.

2. The overview should describe the relationship of specific facility features to the major processes that will be ongoing at the facility.

3. This description should include the building locations of major process components; drawings illustrating the layout of the buildings and structures within the controlled area boundary should be used to support the description.

4. If applicable, the applicant has marked portions of the application to identify any proprietary or sensitive information related to the facility (e.g., the location of certain enrichment processes).

1.1.4.3.2 Process Overview

The process overview is acceptable if it summarizes the major chemical or mechanical processes involving licensable quantities of radioactive material based, in part, on information presented in the ISA summary. This description should include the building locations of major process components and brief accounts of the process steps.

1.1.4.3.3 Site Overview

The license application summarizes the site information contained in the ISA summary. This includes descriptions of the overall facility layout and the drawings to support such descriptions. The license application describes the site's geographical characteristics and facility structural features (such as buildings, towers, and tanks), transportation rights of way, and proximity to nearby populations. The license application fully describes the facility location. These descriptions are consistent with the information in Chapter 8 of this SRP.

If applicable, the applicant has portion-marked the application to identify any proprietary or sensitive information (e.g., the location of the controlled area boundary).

1.1.4.3.4 Descriptive Summary of Licensed Material

The summary is acceptable if it includes the following:

1. The summary should describe chemical and physical 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.

2. The application presents a summary identification of the raw materials byproducts, wastes, and finished products of the facility. This information should include data on expected levels of trace impurities or contaminants (particularly fission products or transuranic elements) characterized by identity and concentration. In addition, this summary should identify the proposed possession at the facility of any moderator or reflector with special characteristics, such as beryllium or graphite.

3. If applicable, the applicant has marked portions of the application to identify any proprietary or sensitive information (e.g., possession limits).

1.1.5 Review Procedures

1.1.5.1 Acceptance Review

During the NRC staff's acceptance review, the staff should screen the submittals to identify major deficiencies in the information provided in each review area in Section 1.1.3. Reviewers must decide whether they have enough information to proceed with a detailed technical review. Less significant errors or deficiencies that can be addressed in a request for additional information should be accepted. However, before the NRC performs a detailed review, the applicant should correct major deficiencies that would require several requests for additional information to resolve.

Reviewers should record whether each area of review is adequately addressed in the application, is adequately addressed in a referenced document, is not applicable to the application, or has a major deficiency.

1.1.5.2 Safety Evaluation

The information submitted by the applicant in this section is informational in nature and no technical analysis is required. In addition, the reviewers use the information in this section only as background for the more detailed descriptions in later sections of the application. Therefore, the primary reviewer ascertains whether the descriptive information presented is consistent with the information presented in the ISA summary and the emergency management plan. During the initial review, the reviewer should draft the safety evaluation report (SER) described below. A request for additional information (RAI) will be prepared when clarification and additional information are needed to determine whether the licensee's submittals comply with the regulations. The primary reviewer should coordinate with the licensing project manager in preparing RAIs. Additional information submitted by the applicant will be evaluated and a final SER will be provided to the licensing project manager.

1.1.6 Evaluation Findings

The regulations in 10 CFR 70.23, "Requirements for the Approval of Applications," and 10 CFR 70.66, "Additional Requirements for Approval of License Application," state that an application for a license will be approved if the Commission can make the general findings listed in those sections. The basis for the general findings is an evaluation of whether the application adequately addresses all of the applicable regulatory requirements. More specifically, the staff's evaluation should determine whether the licensing submittals provide sufficient information to satisfy the regulatory requirements listed in Section 1.1.4.1 of this SRP and whether the applicant has appropriately addressed the regulatory acceptance criteria in SRP Section 1.1.4.3. The SER should state how the applicable regulatory requirements have or have not been met based on the acceptance criteria described in this chapter of the SRP. If the applicant chooses to use an alternative approach, the reviewer should discuss in the SER whether the proposed approach satisfies the applicable regulatory requirements. The reviewers should use the following approach to document their evaluation:

1. State a specific regulatory requirement that applies to the application. Detailed acceptance criteria may be included where appropriate or necessary.

2. Identify the areas where the regulatory requirement is addressed in the application, including the areas where the specific acceptance criteria described in this SRP are addressed.

3. Describe your evaluation of the application, the basis for your conclusion, and whether regulatory requirements are met.

4. Repeat these steps for every regulatory requirement that applies to the application.

There are three possible outcomes to the staff's licensing review: (1) approval of the applicant's application or amendment request, (2) denial of the application or request, or (3) approval with conditions. If the reviewer cannot make a finding of a reasonable assurance of safety, the reviewer may consider proposing a license condition. Absent an NRC Order, license conditions

must be agreed upon with the licensee or applicant before becoming part of the license. A license condition should only be proposed if there is reasonable assurance that, if the licensee meets the condition, all regulatory requirements will be satisfied. Thus, license conditions should not be used to cover major deficiencies in an application. License conditions should be unambiguous, inspectable, and enforceable. They should only require those actions necessary to ensure compliance with applicable regulations. The basis for license conditions must be documented in the SER.

The report should include a statement, summarizing what was reviewed and why the reviewer finds the submittal acceptable, such as the following:

> The staff has reviewed the general facility description for [name of facility] according to Section 1.1 of the Standard Review Plan. [Name of facility] has adequately described (1) the facility and its processes so that the staff has an overall understanding of the relationships of the facility features and (2) the function of each feature. [Name of facility] has cross-referenced its general description with the more detailed descriptions elsewhere in the application. The staff also confirmed that the information provided in the license application is consistent with the ISA summary and the emergency management plan. Therefore, the NRC staff concludes that [name of facility] has complied with the general requirements of 10 CFR 70.22, “Contents of Applications,” and 10 CFR 70.65(b)(1) and (2), as applicable to this section.

1.2 Institutional Information

1.2.1 Purpose of Review

The purpose of this review is to establish whether 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 Federal and State Materials and Environmental Management Programs/Division of Waste Management and Environmental Protection
Office of Nuclear Reactor Regulation/Division of Policy and Rulemaking

1.2.3 Areas of Review

The staff should review the institutional information provided by the applicant or licensee in the license application. Information provided for review should include the following:

1. Corporate Identity and Ownership—This section should include the identity and physical address of the applicant's facility and corporate headquarters, corporate information sufficient to show the relationship of the applicant's organization to other corporate entities, and the existence and extent of foreign ownership or influence.

2. Financial Qualifications—Information provided for review in this section should include the applicant's financial qualifications to pursue the activities for which the license is sought.

3. Characteristics of the Material—This information should include the type, quantity, and form(s) of material(s) proposed for use at the licensed facility.

4. Authorized Uses—The application should clearly describe each proposed licensed activity in the form of requested authorized uses and the type of license the applicant is requesting.

5. Special Exemptions or Special Authorizations—The application should clearly describe any special exemptions and authorizations the applicant is requesting and the regulatory requirements for which the applicant is seeking approval or exemption.

6. Protection of Safeguard Information— The application should describe how safeguards information will be protected against unauthorized disclosure.

7. Security of Classified Information—The license application will include this section only if the applicant or licensee has requested and received a facility security clearance in accordance with 10 CFR Part 95, "Facility Security Clearance and Safeguarding of National Security Information and Restricted Data."

8. Period of Time for Which the License Is Requested—The license application should specify the period of time for which the applicant is seeking approval.

Review Interfaces

None

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; 10 CFR 70.23, "Requirements for the Approval of Applications"; 10 CFR 70.33, "Renewal of Licenses"; and 10 CFR Part 95.

1.2.4.2 Regulatory Guidance

No regulatory guides apply to institutional information for a fuel cycle facility.

1.2.4.3 Regulatory Acceptance Criteria

The application is acceptable if it meets the criteria below.

1.2.4.3.1 Corporate Identity

The applicant has furnished its full name and physical address and the address of the fuel cycle facility if it is different from that of the applicant. If the application is for license renewal, the applicant has identified the number of the license to be renewed. The application indicates the State where the applicant is incorporated or organized and the location of the principal office. The application should include any information known to the applicant concerning the control or ownership, if any, exercised over the applicant by any alien, foreign corporation, or foreign government. 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.

1.2.4.3.2 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 10 CFR 70.22(a)(8) and 10 CFR 70.23(a)(5). The information should provide a basis for the NRC staff to find that projected revenue and expenses are within reasonable expectations given past performance. Such information could include income statements for three or more of the most recent fiscal years. In addition, the information could include balance sheet forecasts for 3 or more years into the future.

A license application that involves the use of special nuclear material in a uranium enrichment facility must include the applicant's provisions for liability insurance in accordance with 10 CFR 70.22(n). Under 10 CFR 140.13b, uranium enrichment facilities must have, and maintain, offsite liability insurance. Proof of insurance must be provided prior to the issuance of the license. The methods and instruments where applicants and licensees prove that they have the necessary financial protection are provided in 10 CFR 140.15. For new facilities, the description includes sufficient details demonstrating that the applicant has adequate financial resources to support the safe siting, construction, operation, maintenance, and eventual decommissioning of the proposed facility.

1.2.4.3.3 Characteristics of the Material

The application identifies the elemental name, maximum quantity, and specifications, including the chemical and physical form(s), of the licensable material that the applicant proposes to acquire, deliver, receive, possess, produce, use, transfer, or store. For such material, the specifications include the isotopic content and amount of enrichment by weight percent.

1.2.4.3.4 Authorized Uses

The application includes a summary, nontechnical narrative description for each activity or process in which the applicant proposes to acquire, deliver, receive, possess, produce, use, process, transfer, or store SNM. The authorized uses of SNM proposed for the facility are described and are consistent with the Atomic Energy Act of 1954, as amended. The description is consistent with more detailed process descriptions submitted as part of the ISA summary reviewed in Chapter 3 of this SRP.

If the application is for a license renewal, the applicant has clearly stated the time period for which renewal is sought.

Applicants seeking authorization to possess and use byproduct material or source material are subject to additional regulations and guidance that is not provided in this SRP. For byproduct materials, regulations in 10 CFR Part 30, “Rules of General Applicability to Domestic Licensing of Byproduct Material,” through 10 CFR Part 39, “Licenses and Radiation Safety Requirements for Well Logging,” would apply; guidance is provided in NUREG-1556, “Consolidated Guidance About Materials Licenses.” Additional requirements described in 10 CFR Part 40, “Domestic Licensing of Source Material,” would apply if applicants are seeking to receive, possess, use, transfer, or deliver source materials.

1.2.4.3.5 Special Exemptions or Special Authorizations

The license application clearly describes any proposed exemptions, and authorizations of an unusual nature and adequately justifies them for the NRC’s consideration. The applicant has explained any cross-reference to other sections in the license application supporting such justifications. The license application clearly discusses special authorizations and/or exemptions already granted by the NRC.

1.2.4.3.6 Protection of Safeguards and Classified Information

The license application describes how the requirements to protect safeguards information from unauthorized disclosure have been satisfied in accordance with 10 CFR 70.22(l), and how the requirements to protect classified information have been met in accordance with 10 CFR Part 25, "Access Authorization," and 10 CFR Part 95.

1.2.4.3.7 Information Security at Uranium Enrichment Facilities

For license applications regarding authorization to enrich uranium, the application describes how the requirements in 10 CFR 70.22(m) have been satisfied as well as the applicable regulations described in 10 CFR Part 25 and Part 95.

The applicant has requested and received a facility security clearance in accordance with 10 CFR Part 95, if this is applicable.

1.2.5 Review Procedures

1.2.5.1 Acceptance Review

The primary reviewer should determine whether the license application is complete and addresses each issue in Section 1.2.3. Reviewers must decide whether they have enough information to proceed with a detailed review. Less significant errors or deficiencies that can be addressed in a request for additional information should be accepted. However, before the NRC performs a detailed review, the applicant should correct major deficiencies that would require several requests for additional information to resolve.

Reviewers should record whether each area of review is adequately addressed in the application, is adequately addressed in a cited document, is not applicable to the application, or has a major deficiency.

1.2.5.2 Safety Evaluation

The information submitted by the applicant in this section is, for the most part, informational in nature, and detailed technical analysis is generally not required beyond the acceptance criteria. For new facilities, the reviewer requests review assistance, as needed, from the Office of the General Counsel, the Office of Federal and State Materials and Environmental Management Programs/Division of Waste Management and Environmental Protection, and the Office of Nuclear Reactor Regulation/Division of Policy and Rulemaking in the review of corporate and financial information. During the initial review, the reviewer should draft the SER described below. A request for additional information (RAI) will be prepared when clarification and additional information are needed to determine whether the licensee's submittals comply with the regulations. The primary reviewer should coordinate with the licensing project manager in preparing RAIs. Additional information submitted by the applicant will be evaluated and a final SER will be provided to the licensing project manager.

1.2.6 Evaluation Findings

The regulations in 10 CFR 70.23 and 70.66 state that an application for a license will be approved if the Commission can make the general findings listed in those sections. The basis for the general findings is an evaluation of whether the application adequately addresses all of the applicable regulatory requirements. More specifically, the staff's evaluation should determine whether the licensing submittals provide sufficient information to satisfy the regulatory requirements listed in Section 1.2.4.1 of this SRP and whether the applicant has appropriately addressed the regulatory acceptance criteria in SRP Section 1.2.5.4.3. The SER should state how the applicable regulatory requirements have or have not been met based on the acceptance criteria described in this chapter of the SRP. If the applicant chooses to use an alternative approach, the reviewer should discuss in the SER whether the proposed approach satisfies the applicable regulatory requirements. The reviewers should use the following approach to document their evaluation:

1. State a specific regulatory requirement that applies to the application. Detailed acceptance criteria may be included where appropriate or necessary.

2. Identify the areas where the regulatory requirement is addressed in the application, including the areas where the specific acceptance criteria described in this SRP are addressed.

3. Describe your evaluation of the application, the basis for your conclusion, and whether regulatory requirements are met.

4. Repeat these steps for every regulatory requirement that applies to the application.

There are three possible outcomes to the staff's licensing review: (1) approval of the applicant's application or amendment request, (2) denial of the application or request, or (3) approval with conditions. If the reviewer cannot make a finding of a reasonable assurance of safety, the reviewer may consider proposing a license condition. Absent an NRC Order, license conditions must be agreed on with the licensee or applicant before becoming part of the license. A license condition should only be proposed if there is reasonable assurance that, if the licensee meets the condition, all regulatory requirements will be satisfied. Thus, license conditions should not be used to cover major deficiencies in an application. License conditions should be unambiguous, inspectable, and enforceable. They should only require those actions necessary to ensure compliance with applicable regulations. The basis for license conditions must be documented in the SER.

If the submittal is acceptable, the final SER input should conclude with a statement similar to the following:

> The staff has reviewed the institutional information for [name of facility] according to Section 1.2.of the Standard Review Plan. On the basis of the review, the NRC staff has determined that [name of facility] has adequately described and documented its corporate structure and financial information, and is in compliance with those requirements in 10 CFR 70.22 and 10 CFR 70.65 related to other institutional information. In addition, in accordance with 10 CFR 70.22(a)(2), (3), and (4), [name of facility] has adequately described:

(1) the period of time for which the license is requested and the (2) types, (3) forms, (4) quantities, and (5) proposed authorized uses of licensed materials to be permitted at this facility as follows:

Material Form Quantity Authorized Use(s)

[name of facility]'s proposed activities are consistent with the Atomic Energy Act of 1954, as amended. [Name of facility] has provided all institutional information necessary to understand the ownership, financial qualifications, and location of the facility to be licensed, as well as the planned activities at the facility and the nuclear materials to be handled in connection with the requested license.

1.3 Site Description

1.3.1 Purpose of Review

The purpose of this review is to determine whether the information provided by an applicant adequately describes the geographic, demographic, meteorological, hydrologic, geologic, and seismologic characteristics of the site and the surrounding area. The site description is a summary of the information that the applicant used in preparing the environmental report, emergency plan, and ISA summary.

1.3.2 Responsibility for Review

Primary: Licensing Project Manager

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

Supporting: None

1.3.3 Areas of Review

The information in this section of the application is summarized from the information presented in more detail in the applicant's environmental report, emergency-management plan, and ISA summary. The information that the NRC staff will review includes the following (as appropriate for the facility being reviewed):

1. Site geography

    a. Site location: State, county, municipality, topographic quadrangle (in eight 7-1/2-minute quadrants), site boundary, and controlled-area boundary

    b. Major nearby highways

    c. Nearby bodies of water

    d. Any other significant geographic feature that may affect accident analysis within 1.6 kilometers (1 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 of and distance and direction to nearby public facilities (e.g., schools, hospitals, and 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 the licensed facility or its proposed boundaries (i.e., residential, industrial, commercial, or agricultural)

f. Description of nearby bodies of water and their uses

3. Meteorology

a. Primary wind directions and average windspeeds

b. Annual amount and forms of precipitation, as well as the design-basis values for accident analysis of maximum snow or ice load and probable maximum precipitation

c. Type, frequency, and magnitude of severe weather (e.g., lightning, tornado, and hurricane) and design-basis event summary descriptions for accident analysis

4. Hydrology

a. Characteristics of nearby rivers, streams, and bodies of water as appropriate

b. Depth to the water table and potentiometric surface map

c. Groundwater flow direction and velocity for the site

d. Characteristics of the uppermost aquifer and any hydrogeological connections to other aquifers in the region

e. Design-basis flood events used for accident analysis

5. Geology

a. Onsite characteristics of soil types and bedrock

b. Design-basis earthquake magnitudes and return periods used for accident analysis

c. Description of other geologic hazards (e.g., mass wasting)

Review Interfaces

To ensure consistency, the listed SRP sections and documents interface with this section as follows:

- Review information about the facility and site and the different processes that will involve licensable material in Chapter 3 of the SRP.
- Review the facility and process descriptions in Chapter 8 of the SRP.

- Review information in the applicant's environmental report about the site's geography, demographics, meteorology, hydrology, and geology.

1.3.4 Acceptance Criteria

1.3.4.1 Regulatory Requirements

The regulations applicable to the areas of review in this SRP are 10 CFR 70.22 and 10 CFR 70.65(b)(1) and (2).

1.3.4.2 Regulatory Guidance

No regulatory guides apply to site descriptions for a fuel cycle facility.

1.3.4.3 Regulatory Acceptance Criteria

The reviewer should find the site description—including the site geography, demographics, meteorology, hydrology, and geology (see Section 1.3.3) —acceptable if it meets the following acceptance criteria:

1. The summary briefly describes site geography, including its location relative to prominent natural and manmade features (such as mountains, rivers, airports, population centers, schools, and commercial and manufacturing facilities). The summary also describes the site boundary and the controlled area.

2. The summary provides population information on the basis of the most current available census data. To the extent possible, data reflect observations and measurements made over a period of years, especially for conditions that are expected to vary seasonally (e.g., precipitation, windspeed, wind direction, and groundwater levels).

3. The application addresses appropriate meteorological data, including a summary of design-basis values for accident analysis of maximum snow or ice load and probable maximum precipitation, as may be developed by the applicant and presented in the ISA summary. 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. The application includes a summary description of the hydrology and geology (including seismicity) for the area and cites the design-basis flood event for which the facility may be safely shut down.

5. The applicant's descriptions are consistent with the more detailed information presented in the ISA summary, the environmental report, and the emergency plan, if these are applicable.

1.3.5 Review Procedures

1.3.5.1 Acceptance Review

The staff will initially determine whether the application is complete and addresses all topics discussed in Section 1.3.3. Reviewers must decide whether they have enough information to proceed with a detailed review. Less significant errors or deficiencies that can be addressed in a request for additional information should be accepted. However, before the NRC performs a detailed review, the applicant should correct major deficiencies that would require several requests for additional information to resolve.

Reviewers should record whether each area of review is adequately addressed in the application, is adequately addressed in a cited document, is not applicable to the application, or has a major deficiency.

1.3.5.2 Safety Evaluation

The material in this section of the SRP is informational, because it summarizes material in the ISA summary, environmental report, emergency plan, and other documents cited by the applicant. No technical analysis is required because the primary reference for the information is the ISA summary. The applicant may also need to update this section to verify any information changes made in response to the staff's environmental, emergency-management, and ISA summary reviews. During the initial review, the reviewer should draft the SER described below. A request for additional information (RAI) will be prepared when clarification and additional information are needed to determine whether the licensee's submittals comply with the regulations. The primary reviewer should coordinate with the licensing project manager in preparing RAIs. Additional information submitted by the applicant will be evaluated and a final SER will be provided to the licensing project manager.

1.3.6 Evaluation Findings

The regulations in 10 CFR 70.23 and 70.66 state that an application for a license will be approved if the Commission can make the general findings listed in those sections. The basis for the general findings is an evaluation of whether the application adequately addresses all of the applicable regulatory requirements. More specifically, the staff's evaluation should determine whether the licensing submittals provide sufficient information to satisfy the regulatory requirements listed in Section 1.3.4.1 of this SRP and whether the applicant has appropriately addressed the regulatory acceptance criteria in SRP Section 1.3.4.3. The SER should state how the applicable regulatory requirements have or have not been met based on the acceptance criteria described in this chapter of the SRP. If the applicant chooses to use an alternative approach, the reviewer should discuss in the SER whether the proposed approach satisfies the applicable regulatory requirements. The reviewers should use the following approach to document their evaluation:

1. State a specific regulatory requirement that applies to the application. Detailed acceptance criteria may be included where appropriate or necessary.

2. Identify the areas where the regulatory requirement is addressed in the application, including the areas where the specific acceptance criteria described in this SRP are addressed.

3. Describe your evaluation of the application, the basis for your conclusion, and whether regulatory requirements are met.

4. Repeat these steps for every regulatory requirement that applies to the application.

There are three possible outcomes to the staff's licensing review: (1) approval of the applicant's application or amendment request, (2) denial of the application or request, or (3) approval with conditions. If the reviewer cannot make a finding of a reasonable assurance of safety, the reviewer may consider proposing a license condition. Absent an NRC order, license conditions must be agreed on with the licensee or applicant before becoming part of the license. A license condition should only be proposed if there is reasonable assurance that, if the licensee meets the condition, all regulatory requirements will be satisfied. Thus, license conditions should not be used to cover major deficiencies in an application. License conditions should be unambiguous, inspectable, and enforceable. They should only require those actions necessary to ensure compliance with applicable regulations. The basis for license conditions must be documented in the SER.

If the license application provides sufficient information and is consistent with the guidance in this SRP, the staff will conclude that this evaluation is complete and that the applicant's site description is acceptable with statements similar to the following:

> The staff has reviewed the site description for [name of facility] in accordance with Section 1.3 of the Standard Review Plan. [Name of facility] has adequately described and summarized general information pertaining to (1) the site geography, including its location relative to prominent natural and manmade features such as mountains, rivers, airports, population centers, schools, and commercial and manufacturing facilities; (2) population information using the most current available census data; (3) meteorology, hydrology, and geology for the site; and (4) applicable design-basis events. The review verified that the site description is consistent with the information used as a basis for the environmental report, emergency-management plan, and ISA Summary.

1.4 References

U.S. Code of Federal Regulations, "Domestic Licensing of Special Nuclear Material," Part 70, Chapter I, Title 10, "Energy."

U.S. Code of Federal Regulations, "Facility Security Clearance and Safeguarding of National Security Information and Restricted Data," Part 95, Chapter I, Title 10, "Energy."

2. ORGANIZATION AND ADMINISTRATION

2.1 Purpose of Review

The purpose of the review of the applicant's organization and administration is to ensure that the proposed management hierarchy and policies will 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 applicant has identified and provided adequate qualification descriptions for key management positions.

2.2 Responsibility for Review

Primary: Licensing Project Manager

Secondary: None

Supporting: Primary Reviewers for Other Standard Review Plan (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 policies, and qualifications of key management positions and describe how these will provide reasonable assurance that the health, safety, and environmental (HS&E) protection functions will be effective.

For new facilities, or currently licensed facilities undergoing major modifications, the applicant should describe the comprehensive management policies and procedures that will be used to manage and closely monitor the facility design, engineering, construction, and modifications.

The application should address how the management policies ensure the establishment and maintenance of design and operations. The administrative and management policies should describe the relationships among major facility safety functions and programs, such as the integrated safety analysis, management measures for items relied on for safety (IROFS), radiation safety, nuclear criticality safety, fire safety, chemical safety, environmental monitoring, and emergency planning. The applicant should also describe its qualification criteria with regard to education (i.e., degree and field), training, and experience for key management positions. Management positions for which such criteria should be described include the facility manager, operations manager, shift supervisor, and managers for various safety and environmental disciplines. Alternative named management positions could be proposed. 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 of experience managing the operations of a nuclear fuel manufacturing facility."

Review Interfaces

None

2.4 Acceptance Criteria

2.4.1 Regulatory Requirements

The regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) 70.22(a)(6), 70.23(a)(2), and 70.62(d) require a management system and administrative procedures for the effective implementation of HS&E functions concerning the applicant's corporate organization, qualifications of the staff, and 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 description of the organization and administration of fuel cycle facilities.

2.4.3 Regulatory Acceptance Criteria

The application is acceptable if it meets the criteria identified below. The applicant's safety program description should include appropriate commitments relevant to these criteria.

A. The following criteria apply to 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 that are responsible for managing the design, construction, operations, and modifications of the facility or licensed activities. The application also includes organizational charts.

2. Clear, unambiguous management controls and communications exist among the organizational units responsible for managing the design, construction, operations, and modifications of the facility or licensed activities.

3. The personnel responsible for managing the design, construction, operation, and modifications of the facility or licensed activities 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 are clearly defined in position descriptions that are accessible to all affected personnel and to the U.S. Nuclear Regulatory Commission (NRC), upon request.

4. The applicant has described specific plans to commission the facility's startup and operation, including the transition from the startup phase to operations, under the direct supervision of the applicant's personnel responsible for safe operations. The application clearly describes the roles and responsibilities of the different functions engaged in these commissioning activities.

B. The following criteria apply to existing facilities:

1. The applicant has identified and functionally described the specific organizational groups responsible for operating the facility and managing the development of design changes to the facility. The application also includes organizational charts.

2. The qualifications, responsibilities, and authorities of key supervisory and management positions with HS&E responsibilities are clearly defined in position descriptions that are accessible to affected persons and to the NRC, upon request.

3. 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. (However, both may report to a common manager.) Lines of responsibility and authority are clearly drawn.

4. The individual delegated overall responsibility for the HS&E functions has the authority to shut down operations if they appear to be unsafe and, in that case, must approve restart of shutdown operations or licensed activities.

5. 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.

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

7. The application clearly defines effective lines of communication and authority among the organizational units involved in the engineering, HS&E, and operations functions of the facility.

8. The applicant has committed to establishing the formal management measures required to ensure the availability and reliability of IROFS. Chapter 11 of this SRP discusses management measures.

9. Written agreements exist with offsite emergency resources such as fire, police, ambulance and rescue units, and medical services. Chapters 7 and 8 of this SRP address these agreements in more detail.

The applicant's safety program description includes commitments relevant to meeting the acceptance criteria described above.

2.5 Review Procedures

2.5.1 Acceptance Review

During the acceptance review of a license application, the reviewer should examine the submittals to identify major deficiencies in the information provided for each area of review specified in SRP Section 2.3. Reviewers must decide whether they have enough information to proceed with a detailed review. Less significant errors or deficiencies that can be addressed in a request for additional information should be accepted. However, before the NRC performs a detailed review, the applicant should correct major deficiencies that would require several requests for additional information to resolve.

Reviewers should record whether each area of review is adequately addressed in the application, is adequately addressed in a referenced document, is not applicable to the application, or has a major deficiency.

2.5.2 Safety Evaluation

The primary reviewer should perform a safety evaluation with respect to 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, is clear with respect to assignments of primary responsibility. If necessary, 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. If necessary, the reviewer may visit the site to discuss and verify implementation of the acceptance criteria with facility management.

On the basis of the foregoing, the supporting staff reviewers determine the overall acceptability of the applicant's management system, management qualifications, organizational structure, and administrative procedures. The reviewers should determine whether the application satisfies the acceptance criteria of Section 2.4 and then prepare a safety evaluation report (SER) in accordance with Section 2.6. During the initial review, the reviewer should draft the safety evaluation report (SER) described below. A request for additional information (RAI) will be prepared when clarification and additional information are needed to determine if the licensee's submittals comply with the regulations. The primary reviewer should coordinate with the licensing project manager in preparing RAIs. Additional information submitted by the applicant will be evaluated and a final SER will be provided to the licensing project manager.

2.6 Evaluation Findings

The regulations in 10 CFR 70.23, "Requirements for the Approvals of Applications," and 70.66, "Additional Requirements for Approval of License Application," state that an application for a license will be approved if the Commission can make the general findings listed in those sections. The basis for the general findings is an evaluation of whether the application adequately addresses all of the applicable regulatory requirements. More specifically, the staff's evaluation should determine whether the licensing submittals provide sufficient information to satisfy the regulatory requirements listed in SRP Section 2.4.1 and whether the applicant has appropriately addressed the regulatory acceptance criteria in SRP Section 2.4.3. The SER

should state how the applicable regulatory requirements have or have not been met based on the acceptance criteria described in this chapter of the SRP. If the applicant chooses to use an alternative approach, the reviewer should discuss in the SER whether the proposed approach satisfies the applicable regulatory requirements. The reviewers should use the following approach to document their evaluation:

1. State a specific regulatory requirement that applies to the application. Detailed acceptance criteria may be included where appropriate or necessary to clarify the requirement.

2. Identify the areas where the regulatory requirement is addressed in the application, including the areas where the specific acceptance criteria described in this SRP are addressed.

3. Describe your evaluation of the application, the basis for your conclusion, and whether regulatory requirements are met.

4. Repeat these steps for every regulatory requirement that applies to the application.

There are three possible outcomes to the staff's licensing review: (1) approval of the applicant's application or amendment request, (2) denial of the application or request, or (3) approval with conditions. If the reviewer cannot make a finding of a reasonable assurance of safety, the reviewer may consider proposing a license condition. Absent an NRC Order, license conditions must be agreed upon with the licensee or applicant before becoming part of the license. A license condition should only be proposed if there is reasonable assurance that, if the licensee meets the condition, all regulatory requirements will be satisfied. Thus, license conditions should not be used to cover major deficiencies in an application. License conditions should be unambiguous, inspectable, and enforceable. They should only require those actions necessary to ensure compliance with applicable regulations. The basis for license conditions must be documented in the SER.

If the submittal is acceptable, the final SER input should conclude with a statement similar to the following:

> The staff has reviewed the organization and administration for [name of facility] according to Chapter 2 of the Standard Review Plan.
>
> (a) <u>For new facilities</u>
>
> [Name of facility] described: (1) clear responsibilities and associated resources for the design, construction, operations, and modifications of the facility, and (2) its plans for managing 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 qualified resources have been established or are committed to satisfy [name of facility]'s commitments for the design, construction, operations, and modifications of the facility.

(b) For operating and new facilities

[Name of facility] 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 this information and concluded that [name of facility] has an acceptable organization, administrative policies, and sufficient qualified resources to provide for the safe operation of the facility under both normal and abnormal conditions.

2.7 References

U.S. Code of Federal Regulations, "Domestic Licensing of Special Nuclear Material," Part 70, Chapter I, Title 10, "Energy."

U.S. Nuclear Regulatory Commission, "Proposed Methods for Regulating Major Materials Licensees," NUREG-1324, Sections 3.1, "Organization Plan," and 3.2, "Managerial Controls and Oversight," February 1992
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3. INTEGRATED SAFETY ANALYSIS AND INTEGRATED SAFETY ANALYSIS SUMMARY

3.1 Purpose of Review

An integrated safety analysis (ISA) identifies potential accident sequences in the facility's operations, designates items relied on for safety (IROFS) to either prevent such accidents or mitigate their consequences to an acceptable level, and describes management measures to provide reasonable assurance of the availability and reliability of IROFS. Applicants for new licenses and persons holding licenses under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, "Domestic Licensing of Special Nuclear Material," on September 18, 2000, must perform an ISA and submit a summary (referred to as an "ISA Summary") to the U.S. Nuclear Regulatory Commission (NRC) for approval. The ISA Summary focuses on higher risk accident sequences with consequences that could exceed the criteria of 10 CFR 70.61, "Performance Requirements." The ISA Summary is a synopsis of the results of the ISA and contains information specified in 10 CFR 70.65(b).

The ISA and supporting documentation (such as piping and instrumentation diagrams, criticality safety analyses, dose calculations, process safety information, and ISA worksheets) would be maintained on site at an existing facility. For an applicant seeking a license before commencing construction of a facility, full details concerning hardware, procedures, and programs usually would not exist. However, at the time of the operational readiness review[1] for a new facility, or major modifications to an existing facility, such details must exist to comply with the safety program requirements of 10 CFR Part 70, Subpart H, "Additional Requirements for Certain Licensees Authorized to Possess a Critical Mass of Special Nuclear Material." The level of detail that is acceptable in a license application and ISA Summary does not differ between existing and new facilities.

The NRC determines the acceptability of the applicant's ISA by reviewing a portion of the ISA documentation and any supporting documentation maintained on site and by reviewing and approving the applicant's ISA Summary which, although not part of the license application, is placed on the public docket. Neither the ISA nor the ISA Summary is incorporated as part of the license.

Reviewers must confirm that an ISA Summary meets the regulatory requirements of 10 CFR 70.65, "Additional Content of Applications," and, specifically, that suitable IROFS and management measures have been designated for high-risk accident sequences and that programmatic commitments to maintain the ISA and ISA Summary are acceptable. The term "programmatic" is used here to refer to the organization, criteria, methods, and practices for conducting activities important to safety, such as the ISA program, criticality and other safety discipline programs, and the management measures programs addressed in Chapter 11 of this Standard Review Plan (SRP). In fact, the primary purpose of the review conducted under the guidance of this chapter is to attain reasonable assurance that the applicant has established an

[1] The operational readiness review is an assessment review inspection performed by a multidisciplinary inspection team to ensure that a plutonium or enrichment facility has been completed in accordance with the application or license, and so can be operated safely within the intended safety basis. For new facilities other than plutonium or enrichment facilities regulated under 10 CFR Part 70, Subpart H, or major modifications to existing ones, such reviews, though not strictly required, are normally conducted.

ISA *program* that is, and will continue to be, in compliance with 10 CFR Part 70, Subpart H. Other chapters of this SRP offer guidance for review of management measures and other safety programs. This reasonable assurance of ISA program compliance is attained in part by a selective review of some of the ISA results, as described in Section 3.5 of this chapter under the subjects of "horizontal slice" and "vertical slice" reviews. However, it is not normally necessary to review the full details of all processes and IROFS in order to attain such reasonable assurance. An applicant may submit, for NRC approval, one ISA Summary for the entire facility, or multiple ISA Summaries for individual processes (or groups of processes) in the facility as they are completed. Reviewers of ISA Summaries for new and existing facilities may find it useful to examine the ISA and its supporting documentation to confirm the underpinnings of calculations, conclusions, and components of safety programs.

This chapter provides guidance for the NRC's review of two types of information submitted by applicants:

(1) commitments regarding the applicant's safety program including the ISA, pursuant to the requirements of 10 CFR 70.62, "Safety Program and Integrated Safety Analysis"

(2) ISA summaries submitted in accordance with 10 CFR 70.62(c)(3)(ii) and 10 CFR 70.65

In the case of license applications (either initial or renewal), applicants would submit both types of information. In the case of a license amendment, an applicant may submit either or both types of information, as needed, to address the areas amended.

The purpose of the review of the ISA Summary is to establish reasonable assurance that the applicant has performed the following tasks:

- Conducted an ISA of appropriate detail for each applicable process, using methods and staff adequate to achieve the requirements of 10 CFR 70.62(c)(1) and (2).

- Identified and evaluated, in the ISA, all credible events (accident sequences) involving process deviations or other events internal to the facility (e.g., explosions, spills, and fires) and credible external events that could result in facility-induced consequences to workers, the public, or the environment, that could exceed the performance requirements of 10 CFR 70.61. As a minimum, external events normally include the following:

  – natural phenomena such as floods, high winds, tornadoes, and earthquakes
  – fires external to the facility
  – transportation accidents and accidents at nearby industrial facilities

- Designated engineered and administrative IROFS and correctly evaluated the set of IROFS addressing each accident sequence, as providing reasonable assurance, through preventive or mitigative measures and through application of supporting management measures (discussed in Chapter 11 of this SRP) that the performance requirements of 10 CFR 70.61 are met.

3.2 Responsibility for Review

Primary: Assigned Licensing Reviewer

Secondary: Technical Specialists in Specific Areas
Licensing Project Manager

Supporting: Fuel Facility Inspectors

3.3 Areas of Review

This chapter addresses two types of submittals: (1) those containing descriptive commitments regarding the safety program, including the ISA; and (2) ISA summaries. The descriptive commitments for the safety program should be found in license applications, renewals, and amendments. ISA summaries may be submitted for an entire existing facility, a new facility, a new process, or altered processes requiring revision of the ISA.

The safety program and ISA commitments and descriptions to be reviewed consist of (1) process safety information (10 CFR 70.62(b)), (2) methods used to perform the ISA, (3) qualifications of the team performing the ISA (10 CFR 70.62(c)(2)), (4) methods of documenting and implementing the results of the ISA, (5) procedures to maintain the ISA current when changes are made to the facility, and (6) management measures (10 CFR 70.62(d)). An ISA chapter in the license application will usually contain appropriate documentation of these commitments and descriptions. However, pursuant to Chapter 11 of this SRP, a separate chapter of an application may address the commitments to and descriptions of management measures.

An ISA Summary presents the results of ISA analyses performed for compliance with Subpart H of 10 CFR Part 70. This ISA Summary may be submitted with an application for a new license, a license renewal, or a license amendment, but in accordance with 10 CFR 70.65(b) is not incorporated as part of the license.

The staff will review the ISA Summary submitted to the NRC and the portions of the ISA and ISA documentation maintained on site to determine the adequacy of the applicant's ISA. The contents of the ISA Summary, specified in 10 CFR 70.65, include the following nine topics:

(1) general description of the site
(2) general description of the facility
(3) description of facility processes, hazards, and types of accident sequences
(4) demonstration of compliance with 10 CFR 70.61 performance requirements
(5) description of the ISA team qualifications and ISA methods
(6) descriptive list of IROFS
(7) description of acute chemical exposure standards used
(8) descriptive list of sole IROFS
(9) definition of the terms "credible," "unlikely," and "highly unlikely"

The documentation supporting the ISA (e.g., piping and instrumentation drawings, engineered IROFS boundary descriptions, criticality safety analyses, dose calculations, process hazards analysis, process safety information, ISA worksheets) will normally be maintained at the facility

site. The reviewer may find it efficient to consult the ISA supporting documentation at the facility site to establish the completeness and acceptability of the ISA or, in the case of an existing facility, to visit the site to fully understand a process operation. For example, the reviewer could confirm that accident sequences that were not reported in the ISA Summary because they were not credible were correctly identified and analyzed in the ISA.

3.3.1 Safety Program and Integrated Safety Analysis Commitments

The NRC reviews the application to determine whether the applicant's commitments to establish a safety program and to perform and maintain an ISA are adequate. In the following, the phrase "process node" or "process" refers to a single, reasonably compact piece of equipment or workstation where a single unit process or processing step is conducted. A typical fuel cycle facility is divided into several major process lines or areas, each consisting of many process nodes. The areas of review for ISA commitments are as follows:

- The applicant's description of, and commitments to, a method for maintaining a current and accurate set of process safety information, 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).

- The applicant's description of, and commitments to, requirements for ISA team training and qualifications (Section 11.4) for those individuals who will conduct and maintain the ISA and ISA Summary.

- The applicant's description of, and commitments to, ISA methods, method selection criteria, or specific methods to be used for particular classes of process nodes (usually process workstations). The review of the ISA method includes evaluating the applicant's methods in the following specific areas:

  – hazard identification
  – process hazard analysis (accident identification)
  – accident sequence construction and evaluation
  – consequence determination and comparability to 10 CFR 70.61
  – likelihood categorization for determining compliance with 10 CFR 70.61

- The applicant's description of, and commitments to, management procedures for conducting and maintaining the ISA. Specific review areas include the following applicant procedures:

  – performance of, and updates to, the ISA
  – review responsibility
  – ISA documentation
  – reporting of ISA Summary changes per 10 CFR 70.72(d)(1) and (3)
  – maintenance of ISA records per 10 CFR 70.62(a)(2)

3.3.2 Integrated Safety Analysis Summary and Documentation

The NRC reviews the ISA Summary and, if necessary, the ISA and supporting ISA documentation to determine whether there is reasonable assurance that the applicant has performed a systematic evaluation of the hazards and has identified credible accident sequences, IROFS, and management measures that satisfy the performance requirements of 10 CFR 70.61. The NRC confirms that credible accidents that result in a release of radioactive material, a nuclear criticality event, or any other exposure to radiation resulting from use of licensed material that exceeds the exposure limits stated in 10 CFR 70.61 are "highly unlikely" or "unlikely," as appropriate. In addition, the NRC reviews accidents involving hazardous chemicals produced from licensed materials. Hazardous chemical include chemicals that are licensed materials or have licensed materials as precursor compounds, or substances that physically or chemically interact with licensed materials and that are toxic, explosive, flammable, corrosive, or reactive to the extent that they endanger life or health. These include substances that are commingled with licensed material or are produced by a reaction with licensed material. If a chemical accident has the potential to cause, or reduce protection from, a radiation exposure accident, then it also must be addressed (see Chapter 6 for more information on chemical process safety). On the other hand, accident sequences having unmitigated consequences that will not exceed the performance requirements of 10 CFR 70.61(c), once identified as such, do not require reporting in the ISA Summary.

The areas of review for the ISA Summary are as follows:

- Site: The site description in the ISA Summary (see Section 1.3) focuses on those factors that could affect safety, such as geography, meteorology (e.g., high winds and flood potential), seismology, demography, and nearby industrial facilities and transportation routes.

- Facility: The facility description in the ISA Summary focuses on 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.

- Processes, Hazards, and Accident Sequences: The process description in the ISA Summary addresses each process that was analyzed as part of the ISA. Specific areas reviewed include basic process function and theory, functions of major components and their operation, process design and equipment, and process operating ranges and limits. This description must also include a list of the hazards (and interactions of hazards) for each process and the accident sequences that could result from such hazards and for which unmitigated consequences could exceed the performance requirements of 10 CFR 70.61.

- Demonstration of Compliance with 10 CFR 70.61: For each applicable process, this section presents the following information that should be developed in the ISA to demonstrate compliance with the performance criteria of 10 CFR 70.61:

  – postulated consequences and comparison to the consequence levels identified in 10 CFR 70.61, as well as information, such as inventory and release path factors supporting the results of the consequence evaluation

- information showing how the applicant established the likelihoods of accident sequences that could exceed the performance requirements of 10 CFR 70.61
- information describing how designated IROFS protect against accident sequences that could exceed the performance requirements of 10 CFR 70.61
- information on management measures applied to the IROFS (addressed in greater detail in Chapter 11)
- information on how the criticality monitoring requirements of 10 CFR 70.24, "Criticality Accident Requirements," are met
- if applicable, ways that the baseline design criteria of 10 CFR 70.64, "Requirements for New Facilities or New Processes at Existing Facilities," are addressed

- Team Qualifications and ISA Methods: This section should discuss the applicant's ISA team qualifications and ISA methods, as described in the ISA Summary. (If methods are adequately described in the license application, the applicant will not need to duplicate this information in the ISA Summary. The ISA Summary should include specific examples of the application of ISA methods to enable the reviewer to understand their selection and use.)

- List of IROFS: This list describes the IROFS for all intermediate- and high-consequence accidents in sufficient detail to permit an understanding of their safety function.

- Chemical Consequence Standards: This discussion identifies the applicant's quantitative standards for assessing the chemical consequence levels specified in 10 CFR 70.61, as described in the ISA Summary.

- List of Sole IROFS: This list identifies those IROFS that are the sole item preventing or mitigating an accident for which the consequences could exceed the performance requirements of 10 CFR 70.61.

- Definitions of "Unlikely," "Highly Unlikely," and "Credible": The applicant must define the terms "unlikely," "highly unlikely," and "credible," as used in the ISA Summary.

The regulations in 10 CFR 70.65(b) list the types of information required to be submitted in an ISA Summary. This includes generic information, such as site description, ISA methods, and ISA team qualifications. This also includes process-specific information, such as a list of IROFS, general descriptions of types of accident sequences, and "information demonstrating compliance with 10 CFR 70.61." To meet the latter requirement, an applicant would have to provide, at a minimum, likelihood and consequence information for each type of process accident sequence identified in the ISA Summary. To evaluate the effectiveness of the applicant's likelihood and consequence evaluation methods, the reviewer should also examine the analyses of some accident sequences that are not reported in the ISA Summary for which the applicant established that consequences will not exceed the performance requirements of 10 CFR 70.61.

In some simple cases, the information normally contained in the ISA Summary process descriptions and list of IROFS might be sufficient to enable the reviewer to understand how compliance is achieved when considered with the description of ISA likelihood evaluation methods and criteria. However, in general, the applicant should describe how its ISA team evaluated a credible accident likelihood to be "highly unlikely" or "unlikely."

The reviewer should evaluate the efficacy of the applicant's ISA methods. To do this, in addition to reviewing the description of the ISA methods, the reviewer will need to understand how these methods have been applied in practice to the wide diversity of process safety designs in the facility. Examples in the ISA Summary of how the methods are applied to a representative sample of processes would help the reviewer to understand the applicant's ISA methods. However, if the ISA Summary does not include examples providing details of how the methods were applied, such information may be available at the applicant's site, as part of the overall safety information records.

The NRC review of the applicant's example accident sequence evaluations included in the ISA Summary is not a substitute for the "vertical slice" and "horizontal" reviews that should be performed using detailed information at the site. The NRC must select this onsite evaluation of ISA documentation and processes to confirm that the ISA was actually performed as described in the ISA Summary.

3.4 Acceptance Criteria

3.4.1 Regulatory Requirements

The regulation in 10 CFR 70.62 specifies the requirement to establish and maintain a safety program, including performance of an ISA. Paragraph (c) of 10 CFR 70.62 specifies requirements for conducting an ISA, which include a demonstration that credible high-consequence and intermediate-consequence events meet the safety performance requirements of 10 CFR 70.61. The requirement to prepare and submit an ISA Summary for NRC approval, stated in 10 CFR 70.65(b), also describes the contents of an ISA Summary. The regulation in 10 CFR 70.72, "Facility Changes and Change Process," set forth requirements for maintaining a current ISA and other safety program documentation when changes are made to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel; however, the ISA Summary need be updated only annually.

The information to be included in the ISA Summary can be divided into four categories: (1) site and facility characteristics, (2) ISA methods, (3) hazards and accident analysis, and (4) IROFS. Table 3.1 summarizes the information requirements of each category, the corresponding regulatory citation, and the section of this chapter that describes the expectations for such information.

Table 3.1 Information Requirements for the ISA Summary

Information Category and Requirement	10 CFR Part 70 Regulatory Citation	NUREG-1520, Chapter 3 Section Reference
Site and Facility Characteristics: Site description	70.65(b)(1)	3.4.3.2(1)
Facility description	70.65(b)(2)	3.4.3.2(2)
Criticality monitoring and alarms	70.65(b)(4)	3.4.3.2(4c)
Compliance with baseline design criteria, criticality monitoring, and alarms	70.64 (if applicable) 70.65(b)(4)	3.4.3.2(4d)
ISA Methods		
ISA method(s) description	70.65(b)(5)	3.4.3.2(5)
ISA team description	70.65(b)(5)	3.4.3.2(5)
Quantitative standards for acute chemical exposures	70.65(b)(7)	3.4.3.2(7)
Definition of “unlikely,” “highly unlikely,” and “credible”	70.65(b)(9)	3.4.3.2(9)
Hazards and Accident Analysis		
Description of processes analyzed	70.65(b)(3)	3.4.3.2(3a)
Identification of hazards	70.65(b)(3)	3.4.3.2(3b)
Description of accident sequences	70.65(b)(3)	3.4.3.2(3c)
Characterization of high- and intermediate-consequence accident sequences	70.65(b)(3)	3.4.3.2(3c)
Items Relied on for Safety		
List and description of IROFS	70.65(b)(6)	3.4.3.2(6)
Description of IROFS’ link to accident sequences to show 10 CFR 70.61 compliance	70.65(b)(6)	3.4.3.2(4) and (6)
IROFS management measures	70.65(b)(4)	3.4.3.2(4b) and (6)
List of sole IROFS	70.65(b)(8)	3.4.3.2(8)

3.4.2 Regulatory Guidance

NUREG-1513, “Integrated Safety Analysis Guidance Document,” issued May 2001, contains guidance applicable to performing an ISA and documenting the results. NUREG/CR-6410, “Nuclear Fuel Cycle Facility Accident Analysis Handbook,” issued March 1998, provides

guidance on acceptable methods for evaluating the chemical and radiological consequences of potential accidents. NUREG-1601, "Chemical Process Safety at Fuel Cycle Facilities," issued August 1997, provides guidance on chemical safety practices acceptable for compliance with the regulations.

3.4.3 Regulatory Acceptance Criteria

The acceptance criteria for an ISA are derived from and support compliance with the relevant requirements of 10 CFR Part 70. The ISA will form the basis for the safety program by identifying potential accidents, designating IROFS and management measures, and evaluating the likelihood and consequences of each accident sequence for compliance with the performance requirements of 10 CFR 70.61. Some of the acceptance criteria address the programmatic commitments made by the applicant to perform and maintain an ISA. The remainder of the criteria address the ISA results, as documented in the ISA Summary, and whether those documented results demonstrate that the applicant's IROFS and management measures can reasonably be expected to ensure that the relevant accident sequences will meet the performance requirements of 10 CFR 70.61. The acceptance criteria are thus intended to support the ultimate finding of the license review that, based on the information submitted and reviewed, there is reasonable assurance that the proposed facility, IROFS, safety programs, and management measures conforming to the commitments in the application comply with the regulations and provide adequate protection of public health and safety.

A high level of detail describing the process designs and IROFS might not be submitted with the license application or ISA Summary. In other words, the applicant might not provide information about all the components in a system, because not every component would be a safety-related component. In particular, for proposed new facilities, the level of detail may be limited since the hardware has not actually been fabricated. However, the applicant must describe the IROFS in enough detail to permit an understanding of the intended safety function and to permit an assessment that it is capable of the reliability expected of it in the evaluation of likelihoods of accident sequences. The NRC staff may obtain additional details for processes selected for the vertical slice review by visiting the applicant's site. While there may be an *actual* difference in the level of detail known about processes and IROFS, as documented at the applicant's site, for existing and proposed new facilities, the minimum level of detail that is sufficient in descriptions of processes and IROFS, as documented in the ISA Summary, does not differ between existing and proposed new facilities.

The purpose of the review, and its acceptance criteria, for most facilities, is primarily to permit a finding that the applicant's safety program, including the ISA program as described, provides reasonable assurance that compliance will be achieved. However, to generate the ISA Summary, which is a required submission, the applicant must first perform an ISA. This in turn requires that the applicant identify process designs, accident sequences, and IROFS. These latter items are not programmatic, but are elements of design and analysis of design. Attainment of reasonable assurance that the ISA program is and will be effective does not usually require that all safety elements and IROFS be reviewed in full detail, nor is it required that the applicant's description of IROFS and process designs be at the level of detail that will eventually exist at the time of operations (see the discussion of vertical slice review in Section 3.5). The requisite level of detail to achieve reasonable assurance may vary among processes, depending on factors such as use of established technology, commitment to standards, applicant expertise, industry experience, safety margins, and inherent difficulty in achieving the safety function. However, the underlying requirements for the descriptions are

exactly the same for each process and IROFS; namely, "…a description of each process…in sufficient detail to understand the theory of operation…" (10 CFR 70.65(3)); and "a description of IROFS…in sufficient detail to understand their functions in relation to the performance requirements…" (10 CFR 70.65(8)). Thus, the requirements for new technology are no different than those for old technology, but more explanatory detail may be necessary to meet the requirements related to "sufficient detail to understand."

3.4.3.1 Safety Program and Integrated Safety Analysis Commitments

This section discusses the acceptance criteria for license commitments pertaining to the facility's safety program including the performance of an ISA. A number of specific safety program requirements related to the ISA appear in 10 CFR Part 70. Section 3.4.3.2 presents the acceptance criteria for the content of the ISA Summary. These include the primary requirements that an ISA be conducted and that, based on the ISA Summary submitted, there is reasonable assurance that the applicant's facility and safety program complies with the ISA requirements of 10 CFR Part 70, Subpart H, including the performance requirements of 10 CFR 70.61. For each component of the safety program, several elements may be necessary, including organization, assignment of responsibilities, management policies, required activities, written procedures for activities, use of industry consensus standards, and technical safety practices, among others.

Procedures and industry standards for hardware safety controls vary according to the type of equipment and by the degree of reliability and performance required in specific applications. For this reason, blanket commitments to apply all standards in all cases may not appear in the license application. However, some standards for engineering practices and hardware and software design or analysis are generic. Hence, an applicant may specify a general commitment to such a generic standard or may make conditional commitments to standards, subject to specified applicability criteria. The purpose of such commitments is to support likelihood or other performance evaluations for compliance with the regulations. NRC guidance has endorsed some standards, possibly with exceptions. Such commitments to standards are acceptable if they are consistent with their use in demonstrating compliance and with specific NRC guidance.

Among those engineering practices and standards that are generically applicable to IROFS and safety controls are those that apply to personnel activities relevant to administrative controls, management measures, or human-machine interfaces. This area is called human factors engineering. Human factors engineering should generally be part of the safety program. Human factors practices should be incorporated into the applicant's safety program sufficiently to ensure that IROFS and management measures perform their functions in meeting the requirements of 10 CFR Part 70. Appendix E to this chapter describes areas of review and acceptance criteria for human factors engineering in the context of 10 CFR Part 70 for fuel cycle facilities.

The applicant's commitments for each of the three elements of the safety program defined in 10 CFR 70.62(a) should be acceptable if the applicant does the following:

(1) Process Safety Information

a. The applicant commits to compiling and maintaining an up-to-date database of process safety information. Written process safety information will be used in

updating the ISA and in identifying and understanding the hazards associated with the processes. The compilation of written process safety information should include information pertaining to the following:

i. The description of hazards of all materials used or produced in the process, which should include information on chemical and physical properties (such as toxicity, acute exposure limits, reactivity, and chemical and thermal stability) such as are included on Material Safety Data Sheets (meeting the requirements of 29 CFR 1910.1200(g)).

ii. The discussion of the technology of the process should include a block flow diagram or simplified process flow diagram, a brief outline of the process chemistry, safe upper and lower limits for controlled parameters (e.g., temperature, pressure, flow, and concentration), and evaluation of the health and safety consequences of process deviations.

iii. The description of the equipment used in the process should include general information on topics such as the materials of construction, piping and instrumentation diagrams, ventilation, design codes and standards employed, material and energy balances, IROFS (e.g., interlocks, detection, or suppression systems), electrical classification, and relief system design and design basis.

b. The applicant includes procedures and criteria for changing the ISA, along with a commitment to design and implement a facility change mechanism that meets the requirements of 10 CFR 70.72. The applicant should discuss the evaluation of the change within the ISA framework, as well as procedures and responsibilities for updating the facility's ISA.

c. The applicant commits to engage personnel with appropriate experience and expertise in engineering and process operations to maintain the ISA. The ISA team for a process should consist of individuals who are knowledgeable in the facility's ISA methods and the operation, hazards, and safety design criteria of the particular process.

(2) ISA

a. The applicant conducts and commits to maintaining an ISA of appropriate complexity for each process, such that it identifies (i) radiological hazards, (ii) chemical hazards that could increase radiological risk, (iii) facility hazards that could increase radiological risk, (iv) potential accident sequences, (v) consequences and likelihood of each accident sequence, and (vi) IROFS including the assumptions and conditions under which they support compliance with the performance requirements of 10 CFR 70.61. The application is acceptable if it describes sufficiently specific methods and criteria that would be effective in accomplishing each of these tasks. Such effective methods and criteria are described in NUREG-1513, NUREG/CR-6410, item (5) of Section 3.4.3.2 of this SRP, and Appendix A to this chapter.

b. The applicant commits to keeping the ISA and its supporting documentation accurate and up to date by means of a suitable configuration management system and to submitting changes to the ISA Summary to the NRC, in accordance with 10 CFR 70.72(d)(1) and (3). The ISA must account for any changes made to the facility or its processes (e.g., changes to the site, operating procedures, or control systems). Management policies, organizational responsibilities, revision timeframe, and procedures to perform and approve revisions to the ISA should be outlined succinctly. The applicant commits to evaluating any facility changes or changes in the process safety information that may alter the parameters of an accident sequence by means of the facility's ISA methods. For any revisions to the ISA, the applicant commits to using personnel with qualifications similar to those of ISA team members who conducted the original ISA.

c. The applicant commits to training personnel in the facility's ISA methods and/or using suitably qualified personnel to update and maintain the ISA and ISA Summary.

d. The applicant commits to evaluating proposed changes to the facility or its operations by means of the ISA methods and to designating new or additional IROFS and appropriate management measures as required. The applicant also agrees to promptly evaluate the adequacy of existing IROFS and associated management measures and to make any required changes that may be affected by changes to the facility and/or its processes. If a proposed change results in a revised accident sequence in the ISA Summary or increases the consequences and/or likelihood of a previously analyzed accident sequence within the context of 10 CFR 70.61, the applicant commits to promptly evaluating the adequacy of existing IROFS and associated management measures and to making necessary changes, if required.

e. The applicant commits to addressing any unacceptable performance deficiencies in the IROFS that are identified through updates to the ISA.

f. The applicant commits to maintaining written procedures on site.

g. The applicant commits to establishing all IROFS (if not already established) and to maintaining them so that they are available and reliable when needed.

In citing industry consensus standards, the applicant should delineate specific commitments in the standards that will be adopted. The applicant should provide justification if it has not adopted all of the required elements of a standard.

(3) Management Measures

The applicant commits to establishing management measures (which are evaluated using SRP Chapter 11) that constitute the principal mechanism for ensuring the reliability and availability of each IROFS.

3.4.3.2 Integrated Safety Analysis Summary and Documentation

Information in the ISA Summary should provide the basis for the reviewer to conclude that there is reasonable assurance that the identified IROFS will satisfy the performance requirements of 10 CFR 70.61. To do this, the reviewer must conclude that the applicant's ISA program has the capability to identify appropriate IROFS and that IROFS identified in the ISA Summary are adequate to control the potential accidents of concern at the facility. The accidents of concern are those that would have consequences at the high and intermediate levels, absent any preventive or mitigative controls. In this context, adequacy means the capability of the IROFS to prevent the related accidents with sufficient reliability, or to sufficiently mitigate their consequences, so that the performance requirements of 10 CFR 70.61 can be met. To support such a review, the ISA Summary must include sufficient information about an accident sequence and the proposed IROFS to allow the reviewer to assess the contributions of the IROFS to prevention or mitigation. The ISA Summary must contain enough information concerning the ISA methods and the qualifications of the team that performed the ISA and any other resources employed to give the reviewer confidence that the list of potential accidents identified is reasonably complete.

In addition, the reviewer needs to determine that appropriate management measures will be in place to ensure the availability and reliability of the identified IROFS, when needed. Chapter 11 of this SRP addresses the review of designated management measures

The following acceptance criteria address each of the content elements of the ISA Summary required by 10 CFR 70.65(b). For new facilities, the reviewer should also evaluate those aspects of the design that address the baseline design criteria of 10 CFR 70.64 applicable to individual processes. Thus, the following nine content elements have defined acceptance criteria:

(1) general description of the site
(2) general description of the facility
(3) description of facility processes, hazards, and types of accident sequences
(4) demonstration of compliance with 10 CFR 70.61 performance requirements
(5) description of the ISA team qualifications and ISA methods
(6) descriptive list of IROFS
(7) description of acute chemical exposure standards used
(8) descriptive list of sole IROFS
(9) definitions of "credible," "unlikely," and "highly unlikely"

Detailed acceptance criteria for each element of the ISA Summary follow:

(1) Site. The description in the ISA Summary of the site for processing nuclear material is considered acceptable if the applicant includes, or references, the following safety-related information, with emphasis on those factors that could affect safety:

a. A description of the site geography, including its location, taking into account prominent natural and manmade features such as mountains, rivers, airports, population centers, possibly hazardous commercial and manufacturing facilities, transportation routes, etc., adequate to permit evaluation of (i) the likelihoods of accidents caused by external factors and (ii) the consequences of potential accidents.

b. Population information, based on the most 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, floods, and earthquakes) and other external events sufficient to allow assessment of their impact on facility safety and their likelihood of occurrence. At a minimum, the 100-year flood should be postulated, consistent with U.S. Army Corps of Engineers flood plain maps. The applicant should also provide earthquake accelerations for the site associated with a 250-year and 500-year earthquake. The discussion should identify all design-basis natural events for the facility, indicate which events are considered incredible, and describe the basis for that determination. The assessment should also indicate which events could occur without adversely impacting safety.

(2) Facility. The description of the facility is considered acceptable if the applicant identifies and describes the general features that affect the reliability or availability of IROFS. 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 a minimum, the applicant should adequately identify and describe the following:

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. restricted area and controlled area boundaries

c. design information regarding the resistance of the facility to failures caused by credible external events, when those failures may produce consequences exceeding those identified in 10 CFR 70.61

d. the location and arrangement of buildings on the facility site

(3) Processes, Hazards, and Accident Sequences

a. Processes. The descriptions of processes in the ISA Summary must include all processes in which upset conditions could credibly lead to accidents with high or intermediate consequences. No areas or processes can be omitted, unless screened out because the accidents are non-credible. The description in the ISA Summary of the processes analyzed as part of the ISA (10 CFR 70.62(c)(1)(i–vi)) is considered acceptable if it describes the following features in sufficient detail to permit an understanding of the theory of operation and to assess compliance with the performance requirements of 10 CFR 70.61. A description at a systems level is acceptable, provided that it permits the NRC reviewer to adequately evaluate (1) the completeness of the hazard and accident identification tasks and (2) the likelihood and consequences of the accidents identified. If the information is available elsewhere in the application and is adequate to support the purposes

of the ISA Summary, reference to the appropriate sections is considered acceptable. The descriptions of processes must permit an understanding of how the set of IROFS in that process could reliably perform their safety function for each high- and intermediate-consequence accident sequence. Hence, all process designs must be described in sufficient detail to reasonably permit identification of all accident sequences and IROFS to prevent or mitigate them.

The level of detail in process safety documentation held at the site would normally be greater than the descriptions in the ISA Summary and may include some or all of the information listed as items i through iv below, as needed.

a. Basic process function and theory includes a general discussion of the basic theory of the process. Normally, this would include the following:

- parameters to be controlled and strategy for complying with 10 CFR 70.61
- chemical or mechanical theory principles, materials, and quantities needed to understand the hazards and safety functions
- normal and potential transport and changes in materials in the process

b. Major components include the general arrangement, function, and operation of major components in the process. If appropriate, it could also include arrangement drawings and process schematics showing the major components and instrumentation, and flowsheets showing compositions of the various process streams.

iii. Process design and equipment include a discussion of process design, equipment, and instrumentation that is sufficiently detailed to permit an adequate understanding of the results of the ISA. As appropriate, it includes schematics indicating safety interrelationships of parts of the process. In particular, it is usually necessary for criticality safety to diagram the location and geometry of the fissile and other materials in the process, for both normal and bounding abnormal conditions. This can be done using either schematic drawings or textual descriptions indicating the location and geometry of fissile materials, moderators, etc., sufficient to permit an understanding of how the IROFS limit the mass, geometry, moderation, reflection, and other factors.

iv. Process safety limits and margins on variables (e.g., temperatures, pressures, flows, fissile mass, enrichment, and composition) that are controlled by IROFS to ensure safe operations of the process, should be specified, because these limits and margins would be needed to understand the likelihood of failure assigned by the applicant to the IROFS. For example, if a process is designed, and an IROFS procedure specified, to ensure critical mass control by double-batching proof, the

margin from a single batch to the subcritical limit should be specified. Traditionally, the single batch is 45 percent of the subcritical limit.

b. Hazards. The description of process hazards provided in the ISA Summary is acceptable if it identifies, for each process, all types of hazards that are relevant to determining compliance with the performance criteria of 10 CFR 70.61. That is, the acceptance criterion is completeness. All hazards that could result in an accident sequence in which the consequences could exceed the performance requirements of 10 CFR 70.61 should be listed, even if later analysis of a particular hazard shows that resulting accident sequences do not exceed these limits. Otherwise, the reviewer cannot determine completeness. General exclusion from consideration of certain hazards for an entire facility can be justified by bounding case analyses showing that, for the conditions or credible inventories on site, the performance requirements of 10 CFR 70.61 cannot be exceeded. In this case, the bounding inventories or conditions, if under the control of the applicant, become IROFS.

Any locations where hazardous regulated material, including fissile material, could accidentally be located should also be considered. Improper screening out of locations and processes that are not normally hazardous, but that could become so in upset conditions, can lead to a failure to apply IROFS to prevent such upsets and potential accidents arising from them.

The list of process hazards is acceptable if the ISA Summary provides the following information:

i. 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), including the maximum intended inventory amounts and locations of the hazardous materials at the facility

ii. potential interactions among materials or conditions that could result in hazardous situations

c. Accident Sequences. The general description of types of accident sequences in the ISA Summary is acceptable if the reviewer can determine the following:

The applicant has identified all types of accidents for which the consequences could exceed the performance requirements of 10 CFR 70.61. The level of detail required in describing accidents is closely related to the level of detail in describing IROFS, as many events leading to consequences of concern in 10 CFR 70.61 are failures of IROFS. It is not usually necessary to specify all modes and mechanisms by which the IROFS failure could occur in order to understand the role that the IROFS plays in preventing or mitigating the accident.

The applicant has identified how the IROFS listed in the ISA Summary protect against each such type of accident.

To satisfy the requirement that all accidents be identified, the applicant should describe the process design in sufficient detail. In particular, all IROFS need to be specified. The level of detail in specifying the process and IROFS should be sufficient to permit a reasonable understanding as to how the safety function will be performed so as to meet the performance requirements of 10 CFR 70.61.

General types of accident sequences differ if they consist of a different set of IROFS failures. Thus, several processes, each using a set of IROFS that is functionally of the same type (e.g., having the same mechanical, physical, and/or electrical principle of operation), can be summarized as a single type of accident sequence and listed only once. However, the individual processes covered by this system should be individually identified in a way that the reviewer can determine the application's completeness in addressing all processes.

For this reason, it is not generally acceptable as a description of an accident to merely list the type of hazard, or the controlled parameters, without referencing the items relied on to control the parameters or hazard. The description of general types of accident sequences is acceptable if it covers all types of sequences, initiating events, and IROFS failures. Initiating events can be (1) an external event such as a hurricane or earthquake, (2) a facility event external to the process being analyzed (e.g., fires, explosions, failures of other equipment, flooding from facility water sources), (3) deviations from normal operations of the process (credible abnormal events), or (4) failures of an IROFS in the process. Human errors that are initiating events would generally be administrative IROFS failures. The description of a general type of accident sequence is acceptable if it permits the reviewer to determine how each accident sequence for which the consequences could exceed the performance requirements of 10 CFR 70.61 is protected against by IROFS or a system of IROFS.

One acceptable way to do this is to show a fault tree on which the basic events are IROFS failures. Another acceptable method is to provide a table in which each row displays the events in an accident sequence, such as in Appendix A to this chapter, Table A-7, where, in general, each event is a failure of an IROFS. Another acceptable way is to provide a narrative summary for each process describing the sequence of events in each type of accident.

To demonstrate completeness, the process hazard analysis identifying general types of accident sequences must use systematic methods and consistent references. Therefore, each description of a general type of accident sequence is acceptable if it meets the following criteria:

i. An acceptable method of hazard identification and process hazard analysis is used in accordance with the criteria of NUREG-1513.

ii. The selected method is correctly applied.

iii. The applicant does not overlook any type of accident sequence for which the consequences could exceed the performance requirements of 10 CFR 70.61. A key test of whether a type of accident has been

overlooked is whether IROFS have been identified to meet the performance requirements.

iv. The applicant uses a method of identifying facility processes that ensures identification of all processes.

During the early phases of an ISA, accidents will be identified for which the consequences may initially be unknown. These accidents will later be analyzed and may be shown to have consequences that are less than the levels identified in 10 CFR 70.61.

The ISA Summary need not list as a separate type of accident sequence, every conceivable permutation of an accident. Accidents having characteristics that all fall in the same categories can be grouped as a single type of accident in the ISA Summary provided that the following conditions are met:

i. The initiating IROFS failures or events have the same effect on the system.

ii. They all consist of failures of the same IROFS or system of IROFS.

iii. They all result in violation of the safety limit on the same parameter.

iv. They all result in the same type and severity categories of consequences.

(4) Information Demonstrating Compliance with the Performance Requirements of 10 CFR 70.61

a. Accident Sequence Evaluation and IROFS Designation. The regulation in 10 CFR 70.65(b)(4) requires that the ISA Summary contain "information that demonstrates the licensee's compliance with the performance criteria of 10 CFR 70.61…" Since the requirements of 10 CFR 70.61 are expressed in terms of consequences and likelihoods of events, the ISA Summary should provide sufficient information to demonstrate the following:

i. Credible high-consequence events are highly unlikely.

ii. Credible intermediate-consequence events are unlikely.

iii. Under normal and credible abnormal conditions, all nuclear processes are subcritical.

The performance requirements of 10 CFR 70.61 have three elements, including completeness, consequences, and likelihood.

"Completeness" refers to the requirement that the ISA address *each* credible event. "Consequence" refers to the magnitude of the chemical and radiological doses of the accident and is the basis for classification of an accident as a high- or intermediate-consequence event as described in 10 CFR 70.61. "Likelihood" refers to the requirement in 10 CFR 70.61 that intermediate-consequence events

be “unlikely” and high-consequence events be “highly unlikely.” Thus, the information provided must address each of these three elements.

To be acceptable, the information provided must correspond to the ISA methods, consequence, and likelihood definitions described in the submittal. The information must also show the basis for and results of applying these methods to each process. In addition, the information must show that the methods have been properly applied in each case.

The information showing completeness, consequences, and likelihood for accident sequences can be presented in various formats, including logic diagrams, fault trees, or tabular summaries. Appendix A to this chapter shows one example of how an application can present this information.

Each of these performance requirements (completeness, consequences, and likelihood) is discussed below.

i. Completeness is demonstrated by correctly applying an appropriate accident identification method, as described in NUREG-1513. Completeness can be effectively displayed by using an appropriate diagram or description of the identified accidents.

ii. Consequence information in the ISA Summary is acceptable for showing compliance with 10 CFR 70.61 provided that the following conditions are met:

- For each accident for which the consequences could exceed the performance requirements of 10 CFR 70.61, the ISA Summary includes an estimate of its quantitative consequences (doses, chemical exposures, criticality) in a form that can be directly compared with the consequence levels in 10 CFR 70.61 or includes a reference to a value documented elsewhere in the ISA Summary that applies to or bounds that accident.

- The consequences were calculated using a method and data consistent with NUREG/CR-6410, or another method described and justified in the methods description section of the ISA Summary.

- All consequences that could result from the accident sequence have been evaluated. That is, if an accident can result in a range of consequences, all possibilities must be considered, including the maximum source term and most adverse weather that could occur. In other words, because of possible variations in weather or other conditions, the consequences of a type of potential accident may vary. If, for some such conditions, the consequences will be high, then the subset of such accidents resulting in high consequences are a “high consequence accident

sequence" in the ISA, even though for average conditions, such high consequences would not result. If such conditions are *unlikely* to occur, credit can be taken for this in the evaluation of likelihood.

- The ISA Summary correctly assigns each type of accident to one of the consequence categories of 10 CFR 70.61 (namely, high or intermediate).

  Unshielded nuclear criticality accidents are considered to be high-consequence events, because the radiation exposure that an individual could receive exceeds the acute 1-sievert (Sv) (100-rem) dose established by 10 CFR 70.61(b)(1). For processes with effective engineered shielding, criticalities may actually produce doses below the intermediate consequences of 10 CFR 70.61. As stated in 10 CFR 70.61(d), such processes must nevertheless be subcritical for all normal and credible abnormal conditions, and primary reliance must be on prevention. This applies notwithstanding shielding or other mitigative features. If needed, NUREG/CR-6410 provides methods for estimating the magnitudes of criticality events that can be applied for workers or members of the public at varying distances from the event.

c. Likelihood information in the ISA Summary is acceptable to show compliance with 10 CFR 70.61, provided that the following conditions are met:

- The ISA Summary specifies the likelihood of each general type of accident sequence that could exceed the performance requirements of 10 CFR 70.61.

- The likelihoods are derived using an acceptable method described in the ISA Summary's section on methods.

- The likelihoods comply with acceptable definitions of the terms "unlikely" and "highly unlikely," as described in this SRP chapter. When interpreted as required accident frequencies, these terms refer to long-run average frequencies, not instantaneous values. That is, a system complies with the performance requirements of 10 CFR 70.61 as a long-run average. Otherwise, failure of any IROFS, even for a very short period, would violate the requirement, which is not the intent.

b. Management Measures. According to 10 CFR 70.65(b)(4), the ISA Summary must include a description of the management measures to be applied to IROFS, as well as information necessary to demonstrate compliance with the performance requirements of 10 CFR 70.61. Chapter 11 of this SRP provides detailed criteria for use in evaluating the adequacy of such management measures.

c. Criticality Monitoring. The regulation in 10 CFR 70.24 defines specific sensitivity and coverage requirements for criticality monitors. Chapter 5 of this SRP describes the acceptance criteria and review of information supporting a demonstration of compliance with 10 CFR 70.24.

Specific emergency preparations are also required by 10 CFR 70.24. Specifically, the application should provide information to demonstrate that the applicant's equipment and procedures are adequate to meet these requirements.

d. Requirements for New Facilities or New Processes at Existing Facilities. The baseline design criteria specified in 10 CFR 70.64 must be used, as applicable, for new facilities and new processes at existing facilities. If the application involves such new facilities or processes, the ISA Summary should explain how the design of the facility addresses each baseline design criterion. For deterministic design criteria such as double contingency, the process-specific information may be provided, along with the other process information in the ISA Summary. The application should also describe the design-basis events and safety parameter limits. In addition, the application should provide methods, data, and results of analysis showing compliance with these design bases for individual processes and facilities.

10 CFR 70.64(b) states that facility and system design must be founded on defense-in-depth practices and must incorporate, to the extent practicable: (1) preference for engineered controls over administrative controls and (2) reduction of challenges to IROFS. Thus, facility and system designs relying only on administrative controls, or relying on IROFS that are frequently or continuously challenged, are not acceptable, unless the application provides a justification showing that alternatives to achieve the design criteria are not practicable.

(5) ISA Team Qualifications and ISA Methods. The ISA teams (10 CFR 70.62(c)(2)) and their qualifications as stated in the ISA Summary are acceptable if the following criteria are met:

a. The ISA team has a leader who is formally trained and knowledgeable in the ISA methods chosen for the hazard and accident evaluations. In addition, the team leader should have an adequate understanding of all process operations and hazards under evaluation but should not be the responsible, cognizant engineer or expert for that process.

b. At least one member of the ISA team has thorough, specific, and detailed experience in the type of process design under evaluation.

c. The team has a variety of process design and safety experience in the particular safety disciplines relevant to hazards that could credibly be present in the process, including, if applicable, radiation safety, nuclear criticality safety, fire protection, and chemical safety disciplines.

d. A manager provides overall administrative and technical direction for the ISA.

The description of the ISA methods is acceptable if the following criteria are met:

a. Hazard Identification Method. The hazard identification method selected is considered acceptable if it meets the following criteria:

   i. The description includes a list of materials (radioactive, fissile, flammable, and toxic) and conditions that could result in hazardous situations (e.g., loss of containment of licensed nuclear material). The list should include maximum intended inventory amounts and the location of the hazardous materials at the facility.[1]

   ii. The method has determined potential interactions between materials or upset conditions that could result in hazardous situations where not normally present.

b. Process Hazard Analysis Method. The process hazard analysis method is acceptable if it involves selecting one of the methods described in NUREG-1513 in accordance with the selection criteria established in that document. Methods not described in NUREG-1513 may be acceptable provided that they fulfill the following conditions:

   i. Criteria are provided for their use for an individual process and are consistent with the principles of the selection criteria in NUREG-1513.

   ii. The method adequately addresses all the hazards identified in the hazard identification task. If an identified hazard is eliminated from further consideration, such action is justified.

   iii. The method provides reasonable assurance that the applicant can identify all significant accident sequences (including the IROFS used to prevent or mitigate the accidents) that could exceed the performance requirements of 10 CFR 70.61.[2]

   iv. The method considers the interactions of identified hazards and proposed IROFS, including system interactions that could result in an accident sequence for which the consequences could exceed the performance requirements of 10 CFR 70.61.

   v. The method addresses all modes of operation, including startup, normal operation, shutdown, and maintenance.

   vi. The method addresses hazards resulting from process deviations (e.g., high temperature and high pressure), initiating events internal to the

[1] At a minimum, the inventory list should include the following hazardous materials if present on site: ammonia, fines (uranium oxide dust, beryllium), flammable liquids and gases, fluorine, hydrofluoric acid, hydrogen, nitric acid, organic solvents, propane, uranium hexafluoride, and Zircaloy.

[2] The release of hazardous chemicals is of regulatory concern to the NRC only to the extent that such hazardous releases result from the processing of licensed nuclear material or have the potential to adversely affect radiological safety.

facility (e.g., fires or explosions), and hazardous credible external events (e.g., floods, high winds, earthquakes, and airplane crashes). The applicant provides justification for determinations that certain events are not credible and, therefore, not subject to the likelihood requirements of 10 CFR 70.61.

vii. The method adequately considers initiation of or contribution to accident sequences by human error through the use of human-systems interface analysis or other appropriate methods.

viii. The method adequately considers common mode failures and system interactions in evaluating systems that rely on redundant controls.

ix. The ISA Summary provides justification that the individual method would comply with conditions (ii) through (viii), above.

c. Consequence Analysis Method. The methods used for ISA consequence evaluation, as described in the ISA Summary, are acceptable, provided that the following conditions are met:

i. The methods are consistent with the approaches described in NUREG/CR-6410.

ii. The use of generic assumptions and data is reasonably conservative for the types of accidents analyzed.

d. Likelihood Evaluation Method. The method for evaluating the likelihood of accident sequences, as described in the ISA Summary, is considered acceptable, provided that it meets the following conditions:

i. The method clearly shows how each designated IROFS acts to prevent or mitigate the consequences (to an acceptable level) of the accident sequence being evaluated.

ii. When multiple IROFS are designated for an accident sequence, the method considers the interaction of all such IROFS, as in a logic diagram or tabulation that accounts for the impact of redundancy, independence, and surveillance on the likelihood of occurrence of the accident.

iii. The method has objective criteria for evaluating, at least qualitatively, the likelihood of failure of individual IROFS. When applicable, such likelihood criteria should include the means to limit potential failure modes, the magnitude of safety margins, the type of engineered equipment (active or passive) or human action that constitutes the IROFS, and the types and safety grading (if any) of the management measures applied to the IROFS.

iv. The method evaluates the likelihood of each accident sequence as “unlikely,” “highly unlikely,” or neither, as defined by the applicant, in accordance with Section 3.4.3.2, item (9), of this chapter.

v. For nuclear criticality accident sequences, the method evaluates compliance with 10 CFR 70.61(d). That is, even in a facility with engineered shielding to limit the consequences of nuclear criticalities, *preventive* controls must be in place that are sufficient to ensure that the process is subcritical for all credible abnormal conditions. Compared to unshielded processes, a moderately higher likelihood may be permitted in preventing such events, consistent with American National Standards Institute/American Nuclear Society (ANSI/ANS) Standard 8.10, "Criteria for Nuclear Criticality Safety Controls in Operations with Shielding and Confinement," reaffirmed in 2005. In particular, criticality cannot result from any credible failure of a single IROFS. In addition, potential criticality accidents must meet an approved margin of subcriticality for safety. Acceptance criteria for such margins are reviewed as programmatic commitments, but the ISA methods must consider, and the ISA Summary must document, the actual magnitude of those margins when they are part of the reason that the postulated accident sequence resulting in criticality is deemed highly unlikely.

Appendix A to this chapter provides an example of one acceptable method for evaluating likelihood that is based on a likelihood index. Appendix B offers additional guidance on acceptable methods for qualitative evaluation of likelihood. Appendix C discusses issues relating to the use of initiating event frequencies in demonstrating compliance with the likelihood requirements. Appendix D discusses acceptable ways for the ISA to address natural phenomena.

(6) Descriptive List of All IROFS. The "list describing items relied on for safety" required by 10 CFR 70.62(c)(1)(vi) is acceptable, provided that it meets the following conditions:

a. The list includes all IROFS in the identified high- and intermediate-consequence accident sequences.

b. The description of the IROFS may include management measures applied to the IROFS (including the safety grading); should include the characteristics of its preventive, mitigative, or other safety function; and may include assumptions and conditions, such as safety limits or margins, if these are needed to understand how the item is capable of achieving compliance with 10 CFR Part 70, Subpart H.

The above acceptance criteria are explained in greater detail below.

a. The primary function of the list describing each IROFS is to document the safety basis of all processes in the facility. This list assists in ensuring that the items (IROFS) are not degraded without a justifying safety review. Thus, the key feature of this list is that it includes *all* IROFS. To be acceptable, no item, control, or control system of a process that is needed to show compliance with the safety performance requirements of the regulation may be omitted from this list (see 10 CFR 70.61(e)). However, sets of hardware or procedures that perform the same safety function may be referred to as a single set of IROFS and do not need to be individually identified. The list of IROFS may erroneously

be incomplete in a number of ways: (1) an ineffective method of identifying accident sequences may have been used, (2) in applying the method to identify accidents something was overlooked, (3) a whole area or process subject to accidents was improperly screened out or simply omitted from the ISA, (4) IROFS were not applied to an identified accident, or (5) the list of accidents was incomplete because of incompleteness in the process design itself. The reviewer should attempt, in the horizontal slice review, to determine if any of these errors has occurred.

b. IROFS may be hardware with a dedicated safety function or hardware with a property that is relied on for safety. Thus, IROFS may be the dimension, shape, capacity, or composition of hardware. The ISA Summary need not provide a breakdown of hardware IROFS by component or identify all support systems. However, the ISA documentation maintained on site, such as system schematics and/or descriptive lists, should contain sufficient detail about items within a hardware IROFS, that it is clear to the reviewer and the applicant what structure, system, equipment, or component is included within the hardware IROFS' boundary and would, therefore, be subject to management measures specified by the applicant. Some examples of items within a hardware IROFS are detectors, sensors, electronics, cables, valves, piping, tanks, and dikes. In addition, ISA documentation should also identify essential utilities and support systems on which the IROFS depends to perform its intended function. Some examples of these are backup batteries, air supply, and steam supply. In some processes, the frequency of demands made on IROFS must be controlled or limited to comply with 10 CFR 70.61. In such processes, whatever features are needed to limit the frequency of demands are themselves IROFS.

c. The essential features of each IROFS should be described. Sufficient information should be provided about engineered hardware controls to permit an evaluation that, in principle, controls of this type will have adequate reliability. Because the likelihood of failure of items often depends on safety margins, descriptions of the safety parameter controlled by the item, the safety limit on the parameter, and the margin to true failure may be needed. For IROFS that are administrative controls, 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. Features of the IROFS that affect its independence from other IROFS, such as reliance on the same power supplies, should be indicated.

The description of each IROFS should identify its expected function, conditions needed for the IROFS to reliably perform its function, and the effects of its failure. The description of each IROFS within an ISA Summary should identify the management measures, such as maintenance, training, and configuration management that are applied to it. If a system of graded management measures is used, the grade applied to each control should be determinable from information in the ISA Summary. The reliability required for an IROFS is proportionate to the amount of risk reduction it is expected to supply. Thus, the quality of the management measures applied to an IROFS may be graded commensurate with the required reliability. The management measures should ensure that IROFS are designed, implemented, and maintained, as necessary, to be available and reliable to perform their function when needed. The degree of

reliability and availability of IROFS ensured by these measures should be consistent with the evaluations of accident likelihoods. In particular, for redundant IROFS, all information necessary to establish the average vulnerable outage time is required in order to maintain acceptable availability. Otherwise, failures must be assumed to persist for the life of the facility. In particular, for IROFS whose availability is to be relied on, the time interval between surveillance observations or tests of the item should be stated, since restoration of a safe state cannot occur until the failure is discovered.

Table A-13 in Appendix A to this chapter is one example of a tabular description of IROFS meeting these criteria.

(7) Quantitative Standards for Chemical Consequences. The applicant's description in the ISA Summary of proposed quantitative standards used to assess consequences from acute chemical exposure to licensed material or chemicals incident to the processing of licensed material is acceptable, provided that the following criteria are met:

a. Unambiguous quantitative standards exist for each of the applicable hazardous chemicals that meet the criteria of 10 CFR 70.65(b)(7) on site, corresponding to, and consistent with, the quantitative standards in 10 CFR 70.61(b)(4)(i), 70.61(b)(4)(ii), 70.61(c)(4)(i), and 70.61(c)(4)(ii).

b. The quantitative standard of 10 CFR 70.61(b)(4)(i) addresses exposures that could endanger the life of a worker. The applicant is appropriately conservative in applying the language "could endanger," so as to include exposures that could result in death for some workers, consistent with the methods used in the U.S. Environmental Protection Agency's acute exposure guidelines in Appendix A, "Table of Toxic Endpoints," to 40 CFR Part 68, "Chemical Accident Prevention Provisions."

c. The quantitative standards for 10 CFR 70.61(b)(4)(ii) and 10 CFR 70.61(c)(4)(i) will correctly categorize all exposures that could lead to irreversible or other serious, long-lasting health effects to individuals. As with criterion (b) above, the standard selected should have appropriate conservatism.

d. The quantitative standard for 10 CFR 70.61(c)(4)(ii) will correctly categorize all exposures that could cause mild transient health effects to an individual.

The NRC finds the use of the Emergency Response Planning Guidelines (ERPGs) established by the American Industrial Hygiene Association, the Acute Exposure Guideline Levels (AEGLs) established by the National Advisory Committee for Acute Guideline Levels for Hazardous Substances, and exposure limits established by the Occupational Safety and Health Administration or contained in International Organization for Standardization (ISO) standards to be acceptable. If the applicant does not use a published exposure standard, or if a chemical has an unknown exposure standard, the ISA Summary must describe how an alternative exposure standard was established for use in the ISA. The ISA Summary must list the actual exposure values for each chemical, specify the source of the data (e.g., ERPG, AEGL, ISO), and provide information or a reference supporting the claim that they meet the acceptance criteria stated above. (See also Section 6.4.3.1 of this SRP.)

(8) List of Sole IROFS. The descriptive list in the ISA Summary that identifies all IROFS that are the sole item credited as such for demonstrating compliance with 10 CFR 70.61 is acceptable if it includes the following:

a. descriptive title of the IROFS

b. an unambiguous and clear reference to the process to which the item applies

c. clear and traceable references to the description of the item as it appears in the full list of all IROFS and the list of accident sequences

(9) Definitions of "Unlikely," "Highly Unlikely," and "Credible." The regulation in 10 CFR 70.65 requires that the applicant's ISA Summary must define the terms "unlikely," "highly unlikely," and "credible." The applicant's definitions of these terms are acceptable if, when used with the applicant's method of assessing likelihoods, they provide reasonable assurance that the performance requirements of 10 CFR 70.61 can be met. The applicant's *method* of likelihood evaluation and the *definitions* of the likelihood terms are closely related. Qualitative methods require qualitative definitions. Such a qualitative definition would identify the qualities of IROFS controlling an accident sequence that would qualify that sequence as "unlikely" or "highly unlikely."

An applicant may use quantitative methods and definitions for evaluating compliance with 10 CFR 70.61, but nothing in this SRP should be construed as an interpretation that such methods are required. The reviewer should focus on objective qualities and information provided concerning accident likelihoods.

As stated in 10 CFR 70.61, credible high-consequence events must be "highly unlikely." Thus, the meaning of the phrase "highly unlikely" is on a per-event basis. The same is true for the terms "unlikely" and "credible." Hence, applicant definitions should be on a per-event basis. The events referred to are occurrences of consequences, which are synonymous with the phrase "accident sequence" in this context. This is important to recognize, since an ISA may identify hundreds of potential accident sequences. Thus, the likelihood of each individual sequence must be quite low.

Acceptance Criteria for the Definition of "Credible"

The regulation in 10 CFR 70.65 requires that the applicant define the term "credible." This term is used in 10 CFR 70.61, which requires that all credible accident sequences for which the consequences could exceed the performance requirements of 10 CFR 70.61 must be controlled to be unlikely or highly unlikely, as appropriate. If an event is not credible, IROFS are not required to prevent or mitigate the event. Thus, to be "not credible" could be used as a criterion for exemption from use of IROFS. This raises a danger of circular reasoning. In the safety program embodied in Subpart H to 10 CFR Part 70, the "not credible" nature of an event must not depend on any facility feature that could credibly fail to function or be rendered ineffective as a result of a change to the system. Each facility feature that is needed to ensure that accident events are sufficiently unlikely is an IROFS. Management measures must offer high assurance, that such features are not removed or rendered ineffective during system changes. One

cannot claim that a process does not need IROFS because it is “not credible” due to characteristics provided by some other controls or features of the plant that are not IROFS. Such an evaluation would be inconsistent with 10 CFR 70.61. However, although an accident sequence may not meet a definition of “not credible,” it may meet the standards for “highly unlikely” or “unlikely” because of an infrequent external initiating event, without the use of IROFS. In such a case, IROFS are not necessary, but information is needed to show that the event does qualify as “highly unlikely” or “unlikely.”

Any one of the following three independent acceptable sets of qualities could define an event as not credible:

(1) An external event has a frequency of occurrence that can conservatively be estimated as less than once in a million years.

(2) A process deviation consists of a sequence of many unlikely events or errors for which there is no reason or motive. In determining that there is no reason for such errors, a wide range of possible motives, short of intent to cause harm, must be considered. Complete ignorance of safe procedures is possible for untrained personnel, which should be considered a credible possibility. Obviously, no sequence of events should be categorized as not credible if it has actually occurred in any fuel cycle facility.

(3) A convincing argument exists that, given physical laws, process deviations are not possible, or are extremely unlikely. The validity of the argument must not depend on any feature of the design or materials controlled by the facility’s system of IROFS or management measures.

Such a demonstration of “not credible” must be convincing despite the absence of designated IROFS. Typically, this can be achieved only for external events known to be extremely unlikely.

Acceptance Criteria for Qualitative Definitions of Likelihood

If the applicant’s definitions are qualitative, they are acceptable if they meet all of the following criteria:

- They are reasonably clear and based on objective criteria.
- They can reasonably be expected to consistently distinguish accidents that are “highly unlikely” from those that are merely “unlikely.”
- Their categorization of events as “highly unlikely” or “unlikely” yields results reasonably consistent with quantitative information and quantitative criteria such as those given in the example here.

The phrase “objective criteria” means the extent to which the method relies on specific identifiable characteristics of a process design, rather than subjective judgments of

adequacy. Objective criteria are needed to achieve consistency. "Consistency" means the degree to which different analysts obtain the same results when they apply the method. This is important in maintaining an adequate standard of safety because the ISAs of future facility modifications may be performed by individuals not involved in conducting the initial ISA. An acceptable qualitative method of likelihood evaluation should yield results comparable to the examples of evaluation methods given in the appendices to this chapter.

Reliability and Availability Qualities

Qualitative methods of evaluating the likelihood of an accident sequence involve identifying the reliability and availability qualities of each of the events that constitute the sequence. The following lists of qualities are not necessarily complete, but they do contain many of the factors most commonly encountered. Some of these qualities relate to the characteristics of individual IROFS, such as the following examples:

- safety margin in the controlled parameter, compared with process variation and uncertainty
- whether the IROFS is an active engineered control, a passive engineered control, an administrative control, or an enhanced administrative control
- the type and safety grading, if any, of management measures applied to the control
- fail-safe, self-announcing, or surveillance measures to limit downtime
- failure modes
- demand rate
- failure rate

Other reliability qualities relate to characteristics of the IROFS or system of IROFS that protect against the following accident sequences as a whole, among others:

- defense in depth
- degree of redundancy
- degree of independence
- diversity
- vulnerability to common-cause failure

Methods of likelihood evaluation and definitions of the likelihood terms "unlikely" and "highly unlikely" may mix qualitative and quantitative information. Certain types of

objective quantitative information may be available concerning specific processes in a facility. Examples of such objective quantitative information include the following:

- reports of failure modes of equipment or violations of procedures recorded in maintenance records or corrective action programs
- the time intervals at which surveillance is conducted to detect failed conditions
- the time intervals at which functional tests or configuration audits are held
- for a fail-safe, monitored, or self-announcing IROFS, the time it takes to render the system safe
- demand rates (i.e., the frequency of the demands on an IROFS to perform) (some situations amount to effectively continuous demand)

Such items of quantitative information should be considered in evaluating the likelihood of accident sequences, even in purely qualitative evaluations. For example, knowing the value to which downtime is limited by surveillance can indicate that a system's availability is extremely high. For redundant systems, such high availability can virtually preclude concurrent independent failures of multiple IROFS.

Acceptance Criteria for Likelihood Indexing Methods

One acceptable definition for the likelihood terms "unlikely" and "highly unlikely" could be based on a risk-indexing method. The example in Appendix A to this chapter shows the use of such a method, which primarily relies on a qualitative evaluation of reliability and availability factors. In such methods, qualitative characteristics of the system of IROFS, such as those listed above, are used to estimate a quantitative likelihood index for each accident sequence. Then, the definitions of "highly unlikely" and "unlikely" would be acceptable limiting values of this likelihood index. For example, "highly unlikely" could be defined as "having a risk index value less than or equal to minus 5," and "unlikely" could be defined as "having a risk index value less than or equal to minus 4."

Acceptance Criteria for Purely Qualitative Methods

A purely qualitative method of defining "unlikely" and "highly unlikely" is acceptable if it incorporates all of the applicable reliability and availability qualities to an appropriate degree. For example, one statement of applicable qualities is double-contingency protection, the quality of 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 explicitly addresses several reliability and availability qualities:

- factors of safety: safety margins
- at least two: redundancy

- unlikely: low failure rate, low downtime of one of two controls
- concurrent: low downtime
- independent: independence
- process conditions: physical events, not virtual human errors

One acceptable definition of "highly unlikely" is a system of IROFS that possesses double-contingency protection, where each of the applicable qualities is present to an appropriate degree. For example, as implied by the modifier "at least" in the phrase "at least two unlikely, independent and concurrent changes," sometimes more than two-fold redundancy may be appropriate.

A qualitative method may also be proposed for defining "unlikely." Such a qualitative method might simply list various combinations of reliability qualities for a system of IROFS that would qualify as "unlikely." For example, a single high-reliability IROFS, such as an engineered hardware control with a high grade of applicable management measures, might qualify to be considered "unlikely to fail." Systems relying on administrative controls would normally have to use enhancing qualities, such as large safety margins and redundancy, to qualify as "unlikely to fail." A single simple administrative control, regularly challenged, and without any special safety margin or enhancement, where a single simple error would lead to an accident, would not qualify as "unlikely to fail." Likewise, two simple administrative controls without special margins or enhancements, particularly of their independence, would not normally qualify as "highly unlikely to fail."

Acceptance Criteria for Quantitative Definitions of Likelihood

An applicant may choose to provide quantitative definitions of the terms "unlikely" and "highly unlikely." One example of acceptable quantitative guidelines is given in the next paragraph. These guidelines serve two purposes. Specifically, these guidelines can be used as acceptance criteria for quantitative definitions of "highly unlikely" and "unlikely," if provided by an applicant.

Quantitative Guidelines

A discussion of quantitative guidelines here does not imply that quantitative demonstration of compliance with 10 CFR 70.61 is required. The NRC has provided various guidance documents, including a strategic plan pertinent to ensuring that exposures of individuals to NRC-regulated hazards, such as radiation, are acceptably infrequent. For example, the NRC Strategic Plan has a performance goal of "no inadvertent nuclear criticalities." The quantitative guidelines given below for definitions of "highly unlikely" and "unlikely", as used in 10 CFR 70.61, were developed so as to be reasonably consistent with other relevant NRC guidance.

Highly Unlikely

Among other considerations, the guideline for acceptance of the definition of "highly unlikely" considers the highest acceptable frequency that is consistent with the performance goal of having no inadvertent nuclear criticality accidents. This guideline is thus applied in considering the 10 CFR 70.61 requirement that high-consequence events be highly unlikely, because such events may involve high radiation doses, as is often true for criticality accidents. To within an order of magnitude, this is taken to mean a definition that translates to a frequency limit of less than one such accident in the industry every 100 years. This results in a guideline limiting the frequency of any individual accident to 10^{-5} per event, per year. As the goal is to have no such accidents, the expectation is that most accidents would have frequencies substantially below this guideline when feasible.

Unlikely

Intermediate-consequence events include significant radiation exposures to workers (those exceeding 0.25 Sv or 25 rem). The NRC has a strategic goal that there be no increase in the rate of such significant exposures. This guideline has been interpreted here to correspond to a range between 10^{-4} and 10^{-5} per event, per year.

Quantitative Guidelines for Use with Acceptance Criteria

The applicant's quantitative definitions of the terms "unlikely" and "highly unlikely," as applied to individual accident sequences identified in the ISA, are acceptable to show compliance with 10 CFR 70.61 if they are reasonably consistent with the following quantitative guidelines:

Likelihood Term of 10 CFR 70.61	Guideline
Unlikely	Less than 10^{-4} per event, per year
Highly Unlikely	Less than 10^{-5} per event, per year

The stated quantitative guidelines are used to define the *largest* likelihood values that would be acceptable limits. Definitions based on lower limits are also acceptable. Note that the word "unlikely" as it appears in 10 CFR 70.61(c) does not have the same meaning as it does in the definition of double contingency. (See Chapter 5 of this SRP.)

3.5 Review Procedures

Organization of the reviews addressed by this chapter of the SRP will differ depending on the scope of the documents submitted. For a license application, renewal, or amendment application containing a new or revised chapter addressing the applicant's safety program and ISA commitments, there may be only a primary ISA reviewer. However, for an initial ISA Summary submittal, specialists in the various safety disciplines and management measures will assist the primary ISA reviewer. An ISA Summary update submitted as part of an amendment for a process that has hazards in multiple disciplines would also require a team approach. In general, a primary ISA reviewer will evaluate generic methods, risk, and reliability criteria used

in the ISA and generic information about individual processes. Assisting this primary reviewer will be secondary reviewers, who will evaluate selected individual accidents and advise on the completeness of the accident list for specific safety disciplines.

3.5.1 Acceptance Review

During the acceptance review of a license application, the reviewer should examine the submittals to identify major deficiencies in the information provided for each area of review specified in SRP Section 3.3. Reviewers must decide whether they have enough information to proceed with a detailed review. Less significant errors or deficiencies that can be addressed in a request for additional information should be accepted. However, before the NRC performs a detailed review, the applicant should correct major deficiencies that would require several requests for additional information to resolve.

Reviewers should record whether each area of review is adequately addressed in the application, is adequately addressed in a referenced document, is not applicable to the application, or has a major deficiency.

For an ISA Summary, the primary ISA reviewer will also conduct an acceptance review to determine whether the document submitted contains sufficient information addressing the areas of review noted in Section 3.3.2, including specifically each of the elements required by 10 CFR 70.65(b), to permit an evaluation of safety for compliance with the regulations. If sufficient information is not present, the ISA Summary will not be accepted for review.

3.5.2 Safety Evaluation

The primary reviewer will perform a safety evaluation with respect to the acceptance criteria in Section 3.4. During the initial review, the reviewer should draft the safety evaluation report (SER) described below. A request for additional information (RAI) will be prepared when clarification and additional information are needed to determine if the licensee's submittals comply with the regulations. The primary reviewer should coordinate with the licensing project manager in preparing RAIs. Additional information submitted by the applicant will be evaluated and a final SER will be provided to the licensing project manager.

3.5.2.1 Evaluation of Safety Program and Integrated Safety Analysis Commitments

The reviewer examines the descriptions and commitments to program elements in the application or other documents for the areas of review described in Section 3.3.1 to ascertain whether the program elements are sufficient to meet the acceptance criteria of Section 3.4.3.1. The ISA reviewer must coordinate his or her review with reviews being conducted under other chapters of this SRP.

3.5.2.2 Evaluation of ISA Summary

A team consisting of a primary reviewer together with specialists in each category of accidents would normally perform an evaluation of the ISA Summary to determine if it meets the acceptance criteria of Section 3.4.3.2. These categories of accidents depend on the facility, but in general, they are nuclear criticality, fires, chemical accidents, and radiological accidents. If external event analysis is complex, specialists may be employed to review these separately, as well. The primary ISA reviewer would normally evaluate the acceptability of the generic

elements of the ISA Summary as described in 10 CFR 70.65, such as site and facility descriptions, ISA methods, criteria, and consequence and likelihood definitions. However, each specialist should also review these elements to obtain information in support of his or her own evaluations.

In contrast to these generic ISA elements, process-specific information is needed by, and must be acceptable to, all of the specialists. Thus, all team members should evaluate the process descriptions in the ISA Summary.

Separate specialists for each category of accidents (i.e., nuclear criticalities, fires, radiological releases, and chemical accidents) should undertake the reviews of accident sequence descriptions and the likelihood and consequence information showing compliance with 10 CFR 70.61. As indicated in Appendix A to this chapter, one acceptable format for the ISA Summary is to separately tabulate or give logic diagrams for accident sequences in each accident category.

After a preliminary team review of the ISA Summary, the team should visit the facility to become familiar with the three-dimensional geometry of process equipment, to review components of the ISA, and to address any issues that arose during review of the ISA Summary.

To select a subset of the accident sequences reported in the ISA Summary for more detailed review, the reviewer should look at the applicant's tabulation of high- and intermediate-consequence accident sequences and the types of IROFS designated for each. High-consequence accident sequences protected by administrative controls should be examined very carefully, whereas intermediate consequence accident sequences protected by redundant passive engineered controls warrant less scrutiny.

To select specific accident sequences and IROFS for more detailed evaluation, the reviewer should evaluate potential accidents using information supplied in the ISA Summary. The applicant's method for identifying and establishing the consequences and likelihood of an accident sequence may provide information sufficient for this purpose. The NRC reviewer may evaluate the accidents using qualitative screening criteria analogous to those in Table A-6 in Appendix A to this chapter. Other, more rigorous reliability or consequence analyses may be performed as deemed necessary. On the basis of this analysis, accidents will be categorized. The reviewer may elect to examine in greater detail the engineered and administrative controls for accidents in the category of highest consequences. While onsite, the reviewer should also select for specific evaluation a small sample of accident sequences determined by the applicant either to result in less than intermediate consequences or to be not credible.

From the list of the IROFS, the reviewer should categorize IROFS so that similar items are grouped together. The reviewer should then ensure that he or she has fully understood one or more prototype IROFS selected from each category. For these selected prototypes, the reviewer may, if necessary, request additional information needed to completely understand a particular IROFS. For complex processes, the reviewer may need to visit the facility to reach an adequate understanding of how the IROFS work for the process.

3.5.2.3 Onsite Integrated Safety Analysis Review

The reviewer should plan on visiting the applicant's facility at least once as part of the application review process. This visit should be scheduled after the applicant's ISA Summary

has received a preliminary review. The visits will enable the reviewer to confirm through detailed examination of the ISA and ISA documentation that the ISA methods were selected and applied in a reasonable and thorough manner to all facility processes, that all credible high- and intermediate-consequence accident sequences were correctly identified, that accident sequence consequences and likelihoods were reasonably determined, and that appropriate IROFS and supporting management measures have been proposed. By means of a "horizontal" review and several "vertical" slice reviews (defined below) of processes selected by the reviewer, the NRC staff can establish the completeness and adequacy of the applicant's ISA method. The reviewer may use the ISA documentation to perform independent evaluations of process hazards and accident sequences using methods selected from NUREG-1513, Appendix A to this SRP chapter, or other NRC guidance.

The reviewer should not attempt a comprehensive, all-encompassing review of every facility process and every accident sequence on the site visit. Rather, the reviewer should use the site visit to confirm the appropriateness and adequacy of the applicant's ISA method and the completeness of the ISA and accuracy of analysis of accident sequences by means of a horizontal review and several vertical slice reviews of selected processes. The site visit will also afford the reviewer an opportunity to seek answers to questions from the applicant (or possibly the ISA team) that may have arisen in the preliminary review of the ISA Summary.

<u>The following discusses each of the three facets of the onsite ISA review:</u>

(1) ISA Methods Review

The purpose of the ISA methods review is two-fold: (a) to ensure that the applicant selected appropriate ISA methods for each facility process and (b) to ensure that the methods were correctly applied in conducting the ISA. The ISA Summary should describe the ISA methods and give a few examples of the application of the ISA methods. The ISA methods review should answer any questions that a reviewer may have concerning ISA methods and procedures after completion of the preliminary review of the ISA Summary. In reviewing process-specific information in the ISA Summary and ISA documentation maintained on site, the reviewer should select a few processes and accident sequences to examine the adequacy of the selected ISA methods and their application. The reviewer should examine any procedures, checklists, or guidance documents that the applicant may have onsite as guidance to ISA team members to ensure a complete understanding of the applicant's ISA methods. The reviewer should then examine the ISA documentation, including the selected processes and accident sequences, showing how the ISA methods were applied as part of the horizontal and vertical slice reviews discussed below.

(2) Horizontal Review

The basic purpose of the horizontal review is to ensure completeness of the ISA of facility processes. This does not require an absolute checkoff of ISA documentation against the full list of processes to be covered, but it does mean that a substantial fraction of the processes should receive a brief examination.

The reviewer should consult the ISA and ISA documentation to answer questions or to resolve outstanding issues resulting from the preliminary review of the ISA summary. In particular, the reviewer should examine safety information that is not included in the

ISA summary. For example, ISA documentation related to hardware IROFS, such as system schematics and/or descriptive lists, should contain sufficient detail about hardware IROFS so that it is clear to the reviewer what components (such as cables, detectors, alarms, valves, and piping) are included within the boundary of the hardware IROFS system and would therefore be subject to management measures specified by the applicant. In addition, such documentation should also identify support systems (such as backup batteries, air supply, and steam supply) on which the IROFS depends to perform its intended function. The reviewer should also examine a few processes to confirm that all accident sequences were considered and that the ISA summary includes those having potential consequences exceeding the performance requirements of 10 CFR 70.61.

(3) Vertical Slice Review

The purpose of the vertical slice review is to examine the application of the ISA methods to a selected subset of facility processes. For this subset of facility processes, the reviewer should examine the underpinnings of calculations, conclusions, and the design of safety programs that result from the ISA, as well as safety information that is not identified in the ISA summary. The reviewer should examine accident sequences for this subset of processes to determine the adequacy of the applicant's consequence and likelihood determinations. In addition, the reviewer should examine the appropriateness and robustness of designated IROFS and the suitability of proposed management measures.

The ISA Summary will have categorized accidents according to their consequences, likelihoods, and IROFS. The reviewer should select a subset of processes for vertical slice review of these categories. The subset should include accident sequences with relatively high levels of consequence and likelihood and accident sequences for which IROFS of different types and relatively low robustness are designated. For ISAs where the index method of Appendix A is used, and where the index scoring for all accident sequences is readily available to the reviewer, in principle, these index scores could be used to establish sequences of relatively higher risk. However, if the ISA declares as IROFS only a set of controls that are minimally necessary to demonstrate compliance with 10 CFR 70.61 likelihood requirements, then such index scores would be misleading. Instead, in selecting processes or sequences for the vertical slice reviews, one may need to use other objective qualities of the processes. For example, the selection might be based on experience or potential consequences as in (1) criticality accidents in solution systems, solvent extraction process upsets, or using plutonium or high-enriched uranium or (2) chemical processes involving large quantities of toxic chemicals that are highly reactive, flammable, or volatile, or are exceptionally toxic. Vertical slice reviews should examine processes for which less robust IROFS are designated (e.g., those with greater reliance on administrative rather than engineered controls). Again, if only a minimal set of IROFS is declared, it may be supported by more robust controls that are not IROFS and hence are not documented in the ISA Summary. Still, a review of sets of IROFS that are purely administrative, or are otherwise known from experience to be unreliable, may be advisable.

While on site, the reviewer may confirm the adequacy of sample accident analyses that the applicant included in the ISA Summary. However, the reviewer should focus on

processes and/or accident sequences that were not included as sample accident analyses in the ISA Summary to ensure the completeness of the ISA.

The vertical slice review should address any specific questions the reviewer may have related to the ISA methods. If the applicant's methods are evaluated as effective in these selected cases, there is greater assurance that they will be effective for other processes. If questions or weaknesses are discovered that may be generic, the reviewer may have to perform vertical slice analyses on several additional processes. However, a specific question on the ISA of one process may not imply that there is a generic question requiring further examination. The purpose of the vertical slice reviews is not complete verification of ISA implementation.

The total number of vertical slice reviews to be conducted will depend on the facility's total number of accident sequences for which the consequences could exceed the performance requirements of 10 CFR 70.61, the diversity of the types of processes and types of IROFS at the facility, and the results of initial reviews of the ISA Summary and the horizontal and vertical slice reviews. For most fuel fabrication facilities, the reviewer should plan on conducting vertical slice reviews for 5 to 10 processes significant to nuclear criticality safety, 1 to 3 fire-significant processes, and 1 to 3 chemical/radiological/environmental-significant processes. However, if the initial reviews of the ISA Summary and the horizontal and vertical slice reviews identify significant issues, then additional vertical slice reviews may be warranted. Ultimately, to approve the ISA and ISA program, the reviewer must attain reasonable assurance that the applicant has implemented them in compliance with the regulations.

Each vertical slice review should include (1) familiarization of the reviewer with the safety design of the selected process and (2) examination of all onsite documentation related to the ISA of that process. If the content of the documentation leaves certain issues unclear, interviews with facility personnel may be necessary. The review should focus on the onsite information that is not provided in the ISA Summary but is key to determining compliance with 10 CFR 70.61 requirements.

Following the horizontal and vertical slice reviews, if outstanding questions remain about compliance with the performance requirements of 10 CFR 70.61, the reviewer may conduct an independent evaluation using appropriate methods selected from NUREG-1513, Appendix A to this chapter, or other agency guidance. The purpose of such an independent review is to identify strengths and weaknesses in the applicant's ISA methods or implementation practices, not simply to check compliance in this one case.

The reviewer should take care to document findings and evaluations made during this process.

3.6 Evaluation Findings

The regulations in 10 CFR 70.23, "Requirements for the Approval of Applications," and 10 CFR 70.66, "Additional Requirements for Approval of License Application," state that an application for a license will be approved if the Commission can make the general findings listed in those sections. The basis for the general findings is an evaluation of whether the application adequately addresses all of the applicable regulatory requirements. More specifically, the staff's evaluation should determine whether the licensing submittals provide sufficient information to

satisfy the regulatory requirements listed in Section 3.4.1 of this SRP and whether the applicant has appropriately addressed the regulatory acceptance criteria in SRP Section 3.4.3. On the basis of this information, the reviewers should write material for inclusion in the SER. In general, the review findings should state that the requirements of 10 CFR 70.64 for a new facility, 10 CFR 70.65 for content, and 10 CFR 70.66 have been met, and provide the basis for each finding. A finding statement should follow the evaluation of each specific area of review, stating how and why the information submitted in that area complies with the related regulatory requirement, if it does so. The SER should state how the applicable regulatory requirements have been met based on the acceptance criteria described in this chapter of the SRP. If the applicant chooses to use an alternative approach, the reviewer should discuss in the SER whether the proposed approach satisfies the applicable regulatory requirements. The reviewers should use the following approach to document their evaluation findings:

5. State a specific regulatory requirement that applies to the finding. Detailed acceptance criteria may be included where appropriate or necessary to clarify the requirement.

6. Identify the areas where the regulatory requirement is addressed in the application, including the areas where the specific acceptance criteria described in this SRP are addressed.

7. Describe your evaluation of the application, the basis for your conclusion, and whether regulatory requirements are met.

8. Repeat these steps for every regulatory requirement that applies to the application.

There are three possible outcomes to the staff's licensing review: (1) approval of the applicant's application or amendment request, (2) denial of the application or request, or (3) approval with conditions. If the reviewer cannot make a finding of a reasonable assurance of safety, the reviewer may consider proposing a license condition. Absent an NRC order, license conditions must be agreed upon with the licensee or applicant before becoming part of the license. A license condition should only be proposed if there is reasonable assurance that, if the licensee meets the condition, all regulatory requirements will be satisfied. Thus, license conditions should not be used to cover major deficiencies in an application. License conditions should be unambiguous, inspectable, and enforceable. They should only require those actions necessary to ensure compliance with applicable regulations. The basis for license conditions must be documented in the SER.

If the submittal is acceptable, the final SER input should conclude with statements similar to the following:

- general conclusion resulting from the reviewer's evaluation of safety program commitments:

  > The NRC staff concludes that the applicant's safety program, if established and maintained pursuant to 10 CFR 70.62, is adequate to provide reasonable assurance that IROFS will be available and reliable to perform their intended safety function when needed and in the context of the performance requirements of 10 CFR 70.61.

General findings for each of the areas of review should state how the applicant's information demonstrates compliance with the acceptance criteria of Section 3.4.3.1. If the reviewer finds that the acceptance criteria are not met and the applicant is not in compliance with the regulations, then the situation must be rectified before approval can be given. If the applicant has submitted an adequate explanation of an alternative way of complying with the regulations, the NRC's safety evaluation report should contain a finding that the alternative is acceptable to meet the basic regulatory requirement addressed.

- general conclusions resulting from the staff's evaluation of an ISA Summary:

Many hazards and potential accidents can result in unintended exposure of persons to radiation, radioactive materials, or toxic chemicals incident to the processing of licensed materials. The NRC staff finds that the applicant has performed an ISA to identify and evaluate those hazards and potential accidents as required by the regulations. The NRC staff has reviewed the ISA Summary and other information and finds that it provides reasonable assurance that the applicant has identified IROFS and established engineered and administrative controls to ensure compliance with the performance requirements of 10 CFR 70.61. Specifically, the NRC staff finds that the ISA results, as documented in the ISA Summary, provide reasonable assurance that the IROFS, the management measures, and the applicant's programmatic commitments will, if properly implemented, make all credible intermediate-consequence accidents unlikely, and all credible high-consequence accidents highly unlikely.

Findings should be made concerning any specific requirement in 10 CFR Part 70 that addresses the nine elements in the ISA Summary. In particular, these findings should include statements concerning compliance with the requirements of 10 CFR 70.64 (regarding new facilities and new processes at existing facilities).

The review should result in findings concerning the compliance of specific processes with the requirements of 10 CFR 70.61, or other parts of the regulation, for those processes that receive specific detailed review. However, such findings should be limited to a finding of reasonable assurance that a process having the IROFS described in the ISA Summary is capable of meeting the requirements if properly implemented, operated, and maintained.

3.7 References

U.S. Code of Federal Regulations, "Domestic Licensing of Special Nuclear Material," Part 70, Chapter I, Title 10, "Energy."

U.S. Code of Federal Regulations, "Air Contaminants," Section 1910.100, Chapter XVII, Title 29, "Labor."

U.S. Code of Federal Regulations, "Table of Toxic Endpoints," Appendix A to "Chemical Accident Prevention Provisions," Part 68, Chapter I, Title 40, "Protection of Environment."

American Institute of Chemical Engineers, "Guidelines for Hazard Evaluation Procedures, Second Edition with Worked Examples," New York, NY, September 1992.

American National Standards Institute/American Nuclear Society, “Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors,” ANSI/ANS-8.1-1983, La Grange Park, IL, 1983.

U.S. Department of Commerce, Bureau of the Census, “Statistical Abstract of the United States,” Table No. 688, Washington, DC, 1995.

U.S. Nuclear Regulatory Commission, “Integrated Safety Analysis Guidance Document,” NUREG-1513, May 2001.

U.S. Nuclear Regulatory Commission, “Chemical Process Safety at Fuel Cycle Facilities,” NUREG-1601, August 1997.

U.S. Nuclear Regulatory Commission, “Nuclear Fuel Cycle Facility Accident Analysis Handbook,” NUREG/CR-6410, March 1998.

APPENDIX A

EXAMPLE PROCEDURE FOR ACCIDENT SEQUENCE EVALUATION

This appendix provides the U.S. Nuclear Regulatory Commission (NRC) reviewer with an example of one method of evaluating accident sequences for compliance with the likelihood requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 70.61, "Performance Requirements." It employs a semiquantitative risk index method for categorizing accident sequences in terms of their likelihood of occurrence and their consequences of concern. The risk index method framework will enable the applicant to identify, and the NRC reviewer to confirm, which accident sequences have consequences that exceed the performance requirements of 10 CFR 70.61 and, therefore, require designation of items relied on for safety (IROFS) and supporting management measures. The integrated safety analysis (ISA) summary should include descriptions of these general types of higher consequence accident sequences.

This appendix presents an example of how the risk index method can be applied to a uranium powder blender. It describes one method of evaluating compliance with the consequence and likelihood performance requirements of 10 CFR 70.61. The method is intended to permit any available quantitative information to be considered. For consistency, the NRC reviewer's approach could also include assigning quantitative values to any qualitative likelihood assessments made by an applicant, since likelihoods are inherently quantitative. This method should not be interpreted as a requirement that an applicant use quantitative evaluation. However, evaluation of a particular accident should be consistent with any facts available, which may include quantitative information concerning the availability and reliability of IROFS involved.

This appendix is not a "format and content guide" for either the ISA or the ISA summary. It simply presents one method of analysis and categorization of credible accident sequences for facility processes. The method described in this appendix uses both qualitative and quantitative criteria for evaluating frequency indices of safety controls. These criteria for assigning indices, particularly the descriptive criteria provided in some tables of this appendix, are intended to be examples, not universal criteria. It is preferable that each applicant develop such criteria based on particular types of IROFS and management measure programs. The applicant should modify and improve such criteria as insights are gained during performance of the ISA.

If the applicant evaluates accidents using a different method, the method should produce similar results in terms of how accidents are categorized. The method should be regarded as a screening method, not as a definitive method of proving the adequacy or inadequacy of the IROFS for any particular accident. Because methods can rarely be universally valid, an evaluation using other methods may be justified for individual accidents for which this method does not appear applicable. The method does have the benefit that it evaluates, in a consistent manner, the characteristics of IROFS used to limit accident sequences. This will permit identification of accident sequences with defects in the combination of IROFS used. Such IROFS can then be further evaluated or improved to establish adequacy. The procedure also ensures the consistent evaluation of similar IROFS by different ISA teams. Sequences or IROFS that are risk significant and are evaluated as marginally acceptable are good candidates for more detailed evaluation by the applicant and the reviewer.

For each sequence, the tabular accident summary resulting from the ISA should identify the engineered or administrative IROFS that must fail to allow the occurrence of consequences that exceed the levels identified in 10 CFR 70.61. Chapter 3 of this Standard Review Plan (SRP)

specifies acceptance criteria for these IROFS and for meeting the performance requirements of 10 CFR 70.61. These criteria require that IROFS be sufficiently unlikely to fail. However, the acceptance criteria do not explicitly mandate any particular method for assessing likelihood. The purpose of this appendix is to provide an example of an acceptable method to perform this evaluation of likelihood.

A.1 Risk Matrix Development

Consequences

The regulation in 10 CFR 70.61 specifies two categories for accident sequence consequences: "high consequences" and "intermediate consequences." Implicitly, there is a third category for accidents that produce consequences less than "intermediate." This category will be referred to as "low-consequence" accident sequences. The primary purpose of process hazard analysis (PHA) is to identify all uncontrolled and unmitigated accident sequences. These accident sequences can then be categorized into one of these three consequence categories (high, intermediate, or low) based on their predicted radiological, chemical, and/or environmental impacts. Although the subsequent ISA analysis focuses only on those accident sequences having high or intermediate consequences, by examining low-consequence events identified and tabulated in the ISA, the reviewer can evaluate the completeness of the PHA and ISA analyses. Table A-1 presents the radiological and chemical consequence severity limits of 10 CFR 70.61 for each of the three accident consequence categories.

Table A-1 Consequence Severity Categories Based on 10 CFR 70.61

	Workers	**Offsite Public**	**Environment**
Category 3 High Consequence	*RD > 1 sievert (Sv) (100 rem) **CD = endanger life	RD > 0.25 Sv (25 rem) 30 milligrams (mg) sol U intake CD = long-lasting health effects	
Category 2 Intermediate Consequence	0.25 Sv (25 rem) < RD ≤ 1 Sv (100 rem) CD = long-lasting health effects	0.05 Sv (5 rem) < RD ≤ 0.25 Sv (25 rem) CD = mild transient health effects	Radioactive release > 5,000 x Table 2 of 10 CFR Part 20, Appendix B
Category 1 Low Consequence	Accidents with lower radiological and chemical exposures than those above in this column	Accidents with lower radiological and chemical exposures than those above in this column	Radioactive releases producing lower effects than those referenced above in this column

* RD = Radiological Dose
** CD = Chemical Dose

Likelihood

The regulation in 10 CFR 70.61 also specifies the permissible likelihood of occurrence of accident sequences of different consequences. High-consequence accident sequences must be "highly unlikely" and intermediate-consequence accident sequences must be "unlikely." Implicitly, accidents in the low-consequence category can have a likelihood of occurrence less than "unlikely" or simply "not unlikely." Table A-2 shows the likelihood of occurrence limits of 10 CFR 70.61 for each of the three likelihood categories.

Table A-2 Likelihood Categories Based on 10 CFR 70.61

	Qualitative Description
Likelihood Category 1	Consequence Category 3 accidents must be "highly unlikely."
Likelihood Category 2	Consequence Category 2 accidents must be "unlikely."
Likelihood Category 3	Consequence Category 1 accidents may be "not unlikely."

Risk Matrix

The three categories of consequence and likelihood can be displayed as a 3x3 risk index matrix. By assigning a number to each category of consequence and likelihood, a qualitative risk index can be calculated for each combination of consequence and likelihood. The risk index equals the product of the integers assigned to the respective consequence and likelihood categories. Table A-3 illustrates the risk index matrix, along with computed risk index values. The shaded blocks identify accidents for which the consequences and likelihoods yield an unacceptable risk index and to which IROFS must be applied.

Table A-3 Risk Matrix with Risk Index Values

Severity of Consequences	**Likelihood of Occurrence**		
	Likelihood Category 1 Highly Unlikely (1)	Likelihood Category 2 Unlikely (2)	Likelihood Category 3 Not Unlikely (3)
Consequence Category 3 High (3)	Acceptable Risk 3	Unacceptable Risk 6	Unacceptable Risk 9
Consequence Category 2 Intermediate (2)	Acceptable Risk 2	Acceptable Risk 4	Unacceptable Risk 6
Consequence Category 1 Low (1)	Acceptable Risk 1	Acceptable Risk 2	Acceptable Risk 3

The risk indices can initially be used to examine whether the consequences of an uncontrolled and unmitigated accident sequence (i.e., without any IROFS) could exceed the performance requirements of 10 CFR 70.61. If the performance requirements could be exceeded, the applicant must designate IROFS to prevent the accident or to mitigate its consequences to an acceptable level. A risk index value less than or equal to 4 means that the accident sequence is acceptably protected against and/or mitigated. If the applicant provides this risk index in the ISA and ISA summary, the reviewer can quickly scan these data to confirm that each accident sequence meets the performance requirements of 10 CFR 70.61.

If the risk index of an uncontrolled and unmitigated accident sequence exceeds 4, the likelihood of the accident must be reduced through designation of IROFS. In this risk index method, the likelihood index for the uncontrolled and unmitigated accident sequence is adjusted by subtracting a score corresponding to the type and number of IROFS that have been designated. Table A-4 lists the qualitative scores assigned to the four types of IROFS.

Reviewers should note that the qualitative scores assigned in Table A-4 are for illustrative purposes only. IROFS meeting the criteria for a particular score in Table A-4 could have a wide range of availability or reliability. Such coarse criteria are useful for screening purposes, but when the total evaluated likelihood score for an accident sequence lies near the acceptance guideline value, a more careful evaluation should be done. Such evaluations should consider the management measures applied to all the reliability and availability qualities of the IROFS, or system of IROFS, protecting against the accident, as explained in the likelihood acceptance criteria of Section 3.4.3.2 of this SRP.

Table A-4 Qualitative Categorization of IROFS

Numeric Value	Description of IROFS
1	Protection by a single trained operator with adequate response time **(Administrative IROFS)**
2	Protection by a single, active engineered IROFS, functionally tested on a regular basis **(Active Engineered IROFS)**
3	Protection by a single, passive engineered IROFS, functionally tested on a regular basis, or by an active engineered IROFS with a trained operator for backup **(Passive Engineered IROFS or Combined Engineered and Administrative IROFS)**
4	Protection by two independent and redundant engineered IROFS, as appropriate, functionally tested on a regular basis **(Combination of Two Active or Passive Engineered IROFS)**

To demonstrate compliance with the performance requirements of 10 CFR 70.61, the ISA should assign a consequence category to each identified accident sequence. The likelihood of occurrence of those accident sequences identified as high- or intermediate-consequence events must then be assigned to one of the three likelihood categories. To be acceptable, the

controlled and/or mitigated accident consequences and likelihoods must have valid bases, and the applicant must include the bases for all general types of high- and intermediate-consequence accident sequences in the ISA summary.

A.2 Consequence Category Assignment

Categorization of an accident sequence as a high-consequence event or an intermediate-consequence event, or neither, is based on the estimated consequences of prototype accidents. Although accident consequences can be determined by actual calculations, calculations need not be performed for each individual accident sequence listed for a process. Accident consequences may also be estimated by comparison to similar events for which reasonably bounding conservative calculations have been made. Categorization also requires consideration of acute chemical exposures that an individual could receive from licensed material or hazardous chemicals incident to the processing of licensed material. The applicant must select appropriate acute chemical exposure data and relate these data to the performance requirements of 10 CFR 70.61(b)(4) and (c)(4). This appendix uses the Acute Exposure Guideline Level (AEGL) and Emergency Response Planning Guideline (ERPG). AEGL-3 and ERPG-3 exposure levels are life threatening.

Consequence Category 3 (High Consequences) includes accidents resulting in any consequence specified in 10 CFR 70.61(b). These include (1) acute worker exposures of (a) radiation doses greater than 1 Sv (100 rem) total effective dose equivalent (TEDE), and (b) chemical exposures that could endanger life (above AEGL-3 or ERPG-3), and (2) acute exposures to members of the public outside the controlled area to (a) radiation doses greater than 0.25 Sv (25 rem) TEDE, (b) soluble uranium intakes greater than 30 mg, and (c) chemical exposures that could lead to irreversible or other serious long-lasting health effects (exceeding AEGL-2 or ERPG-2). An unshielded nuclear criticality would normally be considered a high-consequence event because of the potential for producing a high radiation dose to a worker.

Consequence Category 2 (Intermediate Consequences) includes accidents resulting in any consequence specified in 10 CFR 70.61(c). These include (1) acute exposures of workers to (a) radiation doses between 0.25 Sv (25 rem) and 1 Sv (100 rem) TEDE, and (b) chemical exposures that could lead to irreversible or other serious long-lasting health effects above AEGL-2 or ERPG-2), and (2) acute exposures of members of the public outside the controlled area to (a) radiation doses between 0.05 Sv (5 rem) and 0.25 Sv (25 rem) TEDE, (b) chemical exposures that could cause mild transient health effects (exceeding AEGL-1 or ERPG-1), and (3) release of radioactive material outside the restricted area that would, if averaged over a 24-hour period, exceed 5,000 times the values specified in Table 2 of Appendix B, “Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage,” to 10 CFR Part 20, “Standards for Protection against Radiation.”

Consequence Category 1 (Low Consequences) includes accidents with potential adverse radiological or chemical consequences but at exposures less than Categories 3 and 2.

Table A-5 shows this system of consequence categories.

Table A-5 Consequence Severity Categories Based on 10 CFR 70.61

	Workers	Offsite Public	Environment
Category 3 High Consequence	*RD > 1 Sv (100 rem) **CD > AEGL-3, ERPG-3	RD > 0.25 Sv (25 rem) 30 mg sol U intake CD > AEGL-2, ERPG-2	
Category 2 Intermediate Consequence	0.25 Sv (25 rem) < RD ≤ 1 Sv (100 rem) AEGL-2, ERGP-2 < CD ≤ AEGL-3, ERPG-3	0.05 Sv (5 rem) < RD ≤ 0.25 Sv (25 rem) AEGL-1, ERGP-1 < CD ≤ AEGL-2, ERPG-2	Radioactive release > 5,000 x Table 2 in Appendix B to 10 CFR Part 20
Category 1 Low Consequence	Accidents with lower radiological and chemical exposures than those above in this column	Accidents with lower radiological and chemical exposures than those above in this column	Radioactive releases with lower effects than those referenced above in this column

* RD = Radiological Dose
**CD = Chemical Dose

The applicant should document the bases for bounding calculations of the consequence assignment in the ISA summary submittal. NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook," issued March 1998, describes valid methods and data that the applicant or staff may use for confirmatory evaluations.

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 occurrences at the facility, the record of failures of IROFS at the facility, applicable event data for similar systems, objective qualitative criteria governing system failure rates and availability, or other methods that have objective validity. Because sequences leading to accidents often involve multiple failures, the likelihood of the whole sequence will depend on the frequencies of initiating events and failure likelihoods of engineered and administrative IROFS. The method of likelihood assignment used in this appendix relies on the expert engineering judgment of the analyst and includes assessment of the number, type, independence, and observed failure history of designated IROFS. Engineered and administrative IROFS, even those of the same types, have a wide range of reliability. By requiring explicit consideration of most of the underlying events and factors that significantly affect the likelihood of the accident and explicit criteria for assigning likelihood, greater consistency in assigning likelihood to accident sequences across different systems within a facility and among different applicants should be possible.

This section provides one example of a set of acceptable semiquantitative risk guidelines for determining compliance with the likelihood requirements of 10 CFR 70.61 when using methods of evaluation that are either quantitative or use the risk index method outlined in this appendix.

The performance criteria of 10 CFR 70.61 are formulated in terms of likelihood limits on each separate event sequence. The example guidelines given in Table A-6 are based on the acceptance criteria guidance on likelihood definitions given in Section 3.4.3.2 of this SRP.

Table A-6 Example Likelihood Index Limit Guidelines

	Likelihood Category	Event Frequency Limits*	Risk Index Limits
Not Unlikely	3	more than 10^{-4} per event, per year	> -4
Unlikely	2	between 10^{-4} and 10^{-5} per event, per year	-4 to -5
Highly Unlikely	1	less than 10^{-5} per event, per year	≤ -5

Any risk or risk index method of likelihood evaluation using criteria as simple as those provided in the example method in this appendix should not be relied on exclusively in deciding the acceptability of the likelihood of a given event sequence. Consideration of qualitative criteria, such as degree of defense in depth or independence of controls, may be used to alter decisions based on the example of simple semiquantitative criteria presented here.

A.4 Assessing Effectiveness of Items Relied on for Safety

The risk of an accident sequence is reduced through application of different numbers and types of IROFS. By either reducing the likelihood of occurrence or by mitigating the consequences, IROFS can reduce the overall resulting risk. The designation of IROFS should generally be made to reduce the likelihood (i.e., prevent an accident), but the consequences may also be reduced by minimizing the potential hazards (e.g., quantity), if practical. Based on hazards identification and accident sequence analyses for which the resulting unmitigated or uncontrolled risks are unacceptable, key safety controls (administrative and/or engineered IROFS) may be designated as IROFS to reduce the likelihood of occurrence and/or mitigate the consequence severity.

The accident evaluation method described below does not preclude the need to comply with the double-contingency principle for sequences leading to criticality (see Chapter 5 of this SRP).

A.5 Example Risk Index Evaluation Method

As previously mentioned, one acceptable way for the applicant to present the results of the ISA is a tabular summary of the identified accident sequences. Table A-7 shows an acceptable format for such a table. This table lists several example accident sequences for a powder blender at a typical facility. Table A-7 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. This risk index is a representation of the frequency of the accident sequence in accordance with the mathematics underlying accidents resulting from sequences of events. The next section describes the underlying mathematics of this approach.

A.5.1 Mathematics of Accident Sequence Frequencies and the Risk Index Method

According to 10 CFR 70.61, controls must be applied so that high-consequence events are highly unlikely and intermediate-consequence events are unlikely. This means that each accident sequence, consisting of initiating events and subsequent events, that leads to high consequences must be highly unlikely. In quantitative terms, "highly unlikely" will be treated here in terms of annual frequency of occurrence. The purpose of this section is to explain the concepts and mathematical formulas underlying the risk index method of likelihood evaluation, which is cited in this appendix as one example of an acceptable method for such evaluations in ISAs.

Since high-consequence events are, for workers, potentially life threatening or fatal, "highly unlikely" must be taken to mean of quite low frequency. Generally, achieving such low frequency requires either redundancy, robust passive control with large safety margin, or rare external events. Redundancy of safety controls is a method for limiting the occurrence rate of accidents by applying controls such that two coincident failure conditions must exist for a high-consequence event to occur. Use of redundant controls is common in criticality safety, where the double-contingency principle is standard. There are different types of redundant control systems. The effectiveness of each of these systems depends not just on having controls with low failure rates, but also on limiting downtime after failure occurs. Downtime, or the period of vulnerability resulting from an event, may be limited by the inherent fail-safe or failure-evident nature of the event. For events lacking these properties, failure should be detected either by hardware monitoring or by surveillance testing, which is usually part of the plant preventive maintenance program. Definition of the following symbols will aid in understanding how accident frequencies depend on frequency of failure events and downtime:

λ_i = rate of failure of control i or of occurrence of initiating event i (in units of per year)
t = mean time to failure (MTTF) = $1/\lambda_i$ = mean uptime
T_i = mean downtime of control i = $1/\mu_i$
u_i = unavailability of control i
sfr = system failure rate (accident rate)

Mean downtime is often not the same as mean time to actually repair the affected safety system (MTTR), but rather indicates the mean time that the system is vulnerable to the second failure. This may be considerably shorter than the MTTR, if there is an alternative means of placing the system in a state as safe as it was with the unfailed control.

Unavailability, u, is defined as the probability that a control or system is not available to perform its function at a particular time. Unavailability is usually the predominant component of probability of failure of a system on demand. The normal model is that a control or system is either in an unavailable ("down") state or an available ("up") state. The system randomly changes from one state to the other over time, governed by the failure rate λ and the repair rate $\mu = 1/T$. As a long-run average, the unavailability of a control is thus the fraction of the time that it is down, which is the ratio of downtime to downtime plus uptime:

$$u = T/(t+T)$$

For any reasonably available system, uptime is much greater than downtime, $t >> T$.

Thus, approximately, $u \approx T/t$ and $t = 1/\lambda$, so that $u \approx \lambda T$.

The three most common types of redundant control systems have the following equations for their system failure rate (accident rate):

two continuous parallel controls: $sfr = \lambda_1 u_2(1 - u_1) + \lambda_2 u_1(1 - u_2)$
usually approximated as: $sfr \approx \lambda_1 u_2 + \lambda_2 u_1 \approx \lambda_1(\lambda_2 T_2) + \lambda_2(\lambda_1 T_1)$

Equation (1)

three continuous parallel controls: $sfr = \lambda_1 u_2 u_3(1 - u_1) + \lambda_2 u_1 u_3(1 - u_2) + \lambda_3 u_1 u_2(1 - u_3)$
usually approximated as: $sfr \approx \lambda_1 u_2 u_3 + \lambda_2 u_1 u_3 + \lambda_3 u_1 u_2$

Equation (2)

challenging initiating event of frequency λ_1 with one control: $sfr = \lambda_1 u_2$

Equation (3)

initiating event i with two redundant standby identical controls: $sfr = \lambda_i u_1 u_2$

Equation (4)

The system of frequency and probability (of failure on demand) described in this appendix is based on taking the logarithm of each of the terms in the above equations. Thus, for Equation (1), in log space, two terms would correspond to the two accident sequences by which the system could fail, namely control 1 first or control 2 first:

sequence 1: $\log(\lambda_2) + \log(u_1)$
sequence 2: $\log(\lambda_1) + \log(u_2)$

If only failure rates λ and downtimes T are used, then, with the approximation $u \approx \lambda T$, the formulas corresponding to Equation (1) become the following:

$sfr = \lambda_1(\lambda_2 T_2) + \lambda_2(\lambda_1 T_1)$

sequence 1: $\log(\lambda_2) + \log(\lambda_1) + \log(T_1)$
sequence 2: $\log(\lambda_1) + \log(\lambda_2) + \log(T_2)$

Thus, for two continuous redundant controls, two accident sequences are typically scored for likelihood. One of the two will usually have a larger frequency, so it is important to evaluate both. For situations modeled by Equation (3), there would be just one term.

Table A-9 below provides one example of criteria that might be used to assign frequency index numbers (log(frequency) = log(λ)). Table A-10 provides one example of criteria that might be used to assign index numbers for probabilities of failure on demand (log(unavailability) = log(u)). Table A-11 provides one example of criteria for assigning index numbers for downtime, that is, logarithms of durations of vulnerability, log(T). Note that when MTTF >> MTTR, $u = \lambda T$ approximately, so that the values λ from Table A-9 and the values T from Table A-11 can be combined to obtain u for a given control if λ and T are the known quantities.

The “average” downtime, when determined by surveillance, depends on the interval of time between scheduled system surveillance tests. If a surveillance test is done weekly, then, when the system is found to be in a failed state, the time that it could have been in this state is between zero and 1 week. Thus, the average time that the system will have been down, when

discovered by the test, is half this, or 3.5 days. In units of per year, this is 3.5/365 = 0.01 year, and log(.01) = -2. Thus, a short surveillance interval can considerably reduce the system failure rate.

A.5.2 An Example Application of a Risk Index Method of Likelihood Evaluation

Accident sequences result from initiating events, followed by failure of one or more IROFS. Thus, Table A-7 has columns for the initiating event and for IROFS. The initiating event may be failure of one of the IROFS, which may be mitigative or preventive. Mitigative IROFS are measures that reduce the consequences of an accident. In accordance with Tables A-9 through A-11, index numbers are assigned to initiating events, IROFS failure events, and mitigation failure events, based on the reliability characteristics of these items.

As an example, with two redundant IROFS, there is an accident sequence in which an initiating failure of one IROFS places the system in a vulnerable state. While the system is in this vulnerable state, the second IROFS may fail, which would result in an accident with consequences exceeding the criteria in 10 CFR 70.61. For such sequences, the frequency of the accident depends on three quantities: the frequency of the first event, the duration of vulnerability, and the frequency of the second IROFS failure. For this reason, the duration of the vulnerable state should be considered, and a duration index should be assigned. The values of all index numbers for a sequence are added to obtain a total likelihood index, T. In this risk index method of evaluation, accident 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-8.

The values of index numbers in accident sequences are assigned considering the criteria in Tables A-9 through A-11. Each table applies to a different type of event. Table A-9 applies to events that have frequencies of occurrence, such as initiating events, which may be IROFS failures or external events. When failure probabilities are required for an event subsequent to the initiating event, Table A-10 provides the index values. Table A-11 provides index numbers for durations of failure. These are used in cases where information on probability of failure on demand is not available for the IROFS failures subsequent to the initiating event. Note the third row in Table A-7; it evaluates the reverse sequence to that in the first row. That is, the second IROFS fails first. This should be considered as a separate accident sequence, because, as shown, it may have a different frequency.

Table A-7 Example Accident Sequence Summary and Risk Index Assignment

Process: uranium dioxide (UO_2) powder preparation (PP)
Unit Process: additive blending
Node: blender hopper node (PPB2)

Accident Identifier A	Initiating Event or IROFS 1 Failure B	Preventive Safety Parameter 2 or IROFS 2 Failure/Success C	Mitigation IROFS Failure/ Success D	Likelihood* Index T E=B+C+D	Likelihood Category F	Consequence Category G	Risk Index H=F+G	Comments and Recommendations
PPB2-1A (**Criticality from blender leak of UO_2**)	PPB2-C1: Mass Control Failure: Blender leaks UO_2 onto floor; critical mass exceeded Frq1 = -1 Dur1 = -4	PPB2-C2: Moderation Failure: Sufficient water for criticality introduced while UO_2 on floor: Frq2 = -2	N/A	T = -7	1	3	4	Criticality, consequences = 3, IROFS 2 fails while IROFS 1 is in failed state. T = -1-4-2 = -7
PPB2-1B (**Radiation release from blender leak of UO_2**)	PPB2-C1: Mass Control Failure: Mass control fails but critical mass not exceeded Frq1=-1 Dur1 N/A	PPB2-C2: N/A	Ventilation Failure: Ventilated blender enclosure Prf = -3	T = -4	1	2	3	Rad consequences, no criticality unmitigated sequence: IROFS 1 and mitigation fail. T= -1-3 = -4
PPB2-1C (**Criticality from presence of water under blender**)	PPB2-C2: Moderation Failure: Sufficient 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	T = -6	1	3	4	Criticality by reverse sequence of PPB2-1A. Moderation fails first. Note different likelihood. T = -6

Table A-8 Likelihood Category Assignment

Likelihood Category	Likelihood Index T* (= sum of index numbers)
1	T ≤ -5
2	-5 < T ≤ -4
3	-4 < T

Table A-9 Failure Frequency Index Numbers

Frequency Index No.	Based on Evidence	Based on Type of IROFS**	Comments
-6*	External event with frequency < 10^{-6}/yr		If initiating event, no IROFS needed.
-4*	No failures in 30 years for hundreds of similar IROFS in industry	Exceptionally robust passive engineered IROFS (PEC), or an inherently safe process, or two independent active engineered IROFS (AECs), PECs, or enhanced administrative IROFS	Rarely justified by evidence. Further, most types of single IROFS have been observed to fail.
-3*	No failures in 30 years for tens of similar IROFS in industry	A single IROFS with redundant parts, each a PEC or AEC	
-2*	No failure of this type in this facility in 30 years	A single PEC	
-1	A few failures may occur during facility lifetime	A single AEC, an enhanced administrative IROFS, an administrative IROFS with large margin, or a redundant administrative IROFS	
0	Failures occur every 1 to 3 years	A single administrative IROFS	
1	Several occurrences per year	Frequent event, inadequate IROFS	Not for IROFS, just initiating events.
2	Occurs every week or more often	Very frequent event, inadequate IROFS	Not for IROFS, just initiating events.

* Indices less than (more negative than) -1 should not be assigned to IROFS unless the configuration management, auditing, and other management measures are of high quality, because without these measures, the IROFS may be changed or not maintained.

** Failure frequencies based on experience for a particular type of IROFS, as described in this column, may differ from values in column 1; in this case, data from experience take precedence.

Table A-10 Failure Probability Index Numbers

Probability Index No.	Probability of Failure on Demand	Based on Type of IROFS	Comments
-6*	10^{-6}		If initiating event, no IROFS needed.
-4 or -5*	10^{-4}–10^{-5}	Exceptionally robust passive engineered IROFS (PEC), or an inherently safe process, or two redundant IROFS more robust than simple administrative IROFS (AEC, PEC, or enhanced administrative)	Rarely justified by evidence. Most types of single IROFS have been observed to fail.
-3 or -4*	10^{-3}–10^{-4}	A single passive engineered IROFS (PEC) or an active engineered IROFS (AEC) with high availability	
-2 or -3*	10^{-2}–10^{-3}	A single active engineered IROFS, or an enhanced administrative IROFS, or an administrative IROFS for routine planned operations	
-1 or -2	10^{-1}–10^{-2}	An administrative IROFS that must be performed in response to a rare unplanned demand	

* Indices less than (more negative than) -1 should not be assigned to IROFS unless the configuration management, auditing, and other management measures are of high quality, because without these measures, the IROFS may be changed or not maintained.

Table A-11 Failure Duration Index Numbers

Duration Index No.	Average Failure Duration	Duration in Years	Comments
1	More than 3 years	10	
0	1 year	1	
-1	1 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}	

As shown in Table A-11, the duration of failure, and thus the period that the system is in a state of heightened vulnerability, is accounted for in establishing the overall frequency of the accident sequence. The period of vulnerability will normally be terminated by discovery of the vulnerable condition or failure; the system will then be rendered safe, either by removing the hazardous material, or by repairing or substituting for the safety function of the failed IROFS. The duration of this period of vulnerability determines the index value to be assigned from Table A-11.

For all these index numbers, the more negative the number, the lower the frequency of the event. 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, except the initiating event, for which only the occurrence frequency index should be used. For example, a three-event sequence would correspond to an event sequence frequency of the form $\lambda_1(\lambda_2 T_2)\ (\lambda_3 T_3)$, or five index values, three being frequencies, and two durations.

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 consequence categories are based on the levels identified in 10 CFR 70.61. Multiple types of consequences can result from the same event. If there are multiple types of consequence, the consequence category is the most severe. Similarly, if a range of consequences could occur, then the highest consequence event of this range could occur, and if it falls in the high-consequence range, it should be evaluated as such.

Table A-12 provides a more detailed description of the accident sequences used in the example of Table A-7. Such descriptive information may be necessary for the reviewer to understand the nature of the accident sequences listed in Table A-7.

Table A-13 is an example of one format for the descriptive list of IROFS required by the regulation. It should also include external initiating events that appear in the accident sequences and whose frequencies are relied on in demonstrating that the overall accident sequence frequency complies with the likelihood requirements. The information on IROFS in Table A-13 should have sufficient detail to permit the reviewer to understand why the initiating events and IROFS listed in Table A-7 have the frequency, unavailability, or duration indices assigned. Thus, Table A-13 may also contain such information as (1) the margins to safety limits, (2) the redundancy of an IROFS, and (3) the measures taken to ensure adequate reliability of an IROFS, if this information is necessary to understand the reliability and safety function of the IROFS with respect to the likelihood performance requirements.

Table A-12 Accident Sequence Descriptions

Process: UO_2 powder preparation (PP)
Unit: additive blending
Node: blender hopper node (PPB2)

Accident (see Table A-6)	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 the UO_2 can be removed, moderator sufficient to cause criticality is introduced. Duration of critical mass UO_2 on floor is estimated to be 1 hour.
PPB2-1B Blender UO_2 leak, radiological release	The initial failure is a blender leak of UO_2 that results in a mass insufficient for criticality on the floor or a 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, the blender leaks a critical mass of UO_2 onto the floor. Criticality occurs.

Table A-13 Descriptive List of IROFS

Process: UO_2 powder preparation (PP)
Unit: additive blending
Node: blender hopper node (PPB2)

IROFS Identifier	Safety Parameter and Limits	IROFS Description	Max. Value of Other Parameters	Reliability Management Measures	Quality Assurance 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 UO_2 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 under safety-grade maintenance	A

Note: In addition to IROFS, which are facility hardware and procedures, this table should describe external initiating events, the low likelihood of which is relied on to achieve acceptable risk, especially those that 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.

A.6 Determination of Likelihood Category in Table A-8

The likelihood category is determined by calculating the likelihood index, T, which equals the sum of the indices for the events in the accident sequence. Based on the calculated value of T, the likelihood category of each accident sequence can be determined from Table A-8.

A.7 Failure Probability Index Numbers in Table A-10

Occasionally, information concerning the reliability of an IROFS may be available as a probability on demand. That is, there may be a history of tests or incidents where the system in question is demanded to function. To quantify such accident sequences, the demand frequency, the initiating event, and the demand failure probability of the IROFS must be known. This table provides an assignment of index numbers for such IROFS in a way that is consistent with Table A-9. 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 function.

A.8 Management Measures for Items Relied on for Safety

Table A-13 is an acceptable way of listing IROFS in all the general types of accident sequences having consequences exceeding those identified in 10 CFR 70.61. The items listed should include all IROFS and all external events whose low likelihood of occurrence is relied on to meet the performance requirements of 10 CFR 70.61. For certain IROFS or accident sequences included in this list, information on management measures that is specific to that sequence or IROFS should be presented to permit the reviewer to understand how the IROFS perform. The reviewer examines this list to determine whether adequate management measures have been applied to each IROFS to ensure its continual availability and reliability, in conformance with 10 CFR 70.62(d). Management measures include such activities as maintenance, training, configuration management, audits and assessments, and quality assurance. The baseline design criteria indicate criteria for management measures; SRP Chapters 4 through 7 and Chapter 11 describe other criteria in greater detail. IROFS may have management measures applied in varying ways or to varying degrees, depending on the nature of the IROFS, and the degree of reliability assumed in demonstrating compliance with the likelihood requirements. This is the meaning of “graded management measures.”

A.9 Risk-Informed Review of Items Relied on for Safety

Column (H) in Table A-7 gives the risk indices for each accident sequence identified in the ISA. There are two indices, uncontrolled and controlled. The controlled index is a measure of risk without credit for the IROFS. If the uncontrolled risk index is a 6 or 9, while the controlled index is an acceptable value (4 or less), the set of IROFS involved are significant in achieving acceptable risk. That is, these IROFS have high risk significance. Reviewers will use the uncontrolled risk index to identify all risk-significant systems of IROFS. These systems of IROFS will be reviewed more closely than IROFS established to prevent or mitigate accident sequences of low risk.

REFERENCES

U.S. Code of Federal Regulations, Chapter I, Title 10, “Energy,” Part 20, “Standards for Protection Against Radiation.”

U.S. Code of Federal Regulations, Chapter I, Title 10, “Energy,” Part 70, “Domestic Licensing of Special Nuclear Material.”

U.S. Nuclear Regulatory Commission, “Nuclear Fuel Cycle Facility Accident Analysis Handbook,” NUREG/CR-6410, March 1998.

ANNEX TO APPENDIX A

USE OF APPENDIX A RISK INDEX METHODOLOGY

Introduction

The purpose of this annex is to clarify the proper use of the semiquantitative index method as described in Appendix A to Chapter 3 of this Standard Review Plan. Several licensees and applicants have used the index method of Appendix A (or a variation thereof) in performing their integrated safety analyses (ISAs). The U.S. Nuclear Regulatory Commission (NRC) reviews of these ISA Summaries have discovered a need for additional guidance on the use of this method. Because of the method's widespread use and a lack of common understanding about its use, guidance on the index method is appropriate.

As stated in the introduction to Appendix A, the index method is but one method of likelihood evaluation. The index method is not strictly a qualitative method; rather, it is a semiquantitative method that considers both qualitative and quantitative information (if it is available and applicable). In this method, the definition of likelihood terms (i.e., "not unlikely," "unlikely," and "highly unlikely") is expressed quantitatively (more than 10^{-4} per event, per year; between 10^{-4} and 10^{-5} per event, per year; and less than 10^{-5} per event, per year, respectively). As a purely qualitative method would use purely qualitative definitions of likelihood and qualitative methods of evaluating likelihood, much of the quantitative discussion in this appendix would not apply. However, this method illustrates the logic that should be used in even a purely qualitative method.

The index method is one acceptable method of demonstrating compliance with the performance requirements. However, taking credit for using this method requires that the applicant follow all of the guidance contained in Appendix A. Otherwise, the applicant should provide additional justification.

Likelihood Definitions

The likelihood definitions in Table A-6 of Appendix A are, as stated above, given in quantitative terms (e.g., "highly unlikely" is defined as less than 10^{-5} per event, per year). The footnote to Table A-6 indicates, however, that these are based on approximate order-of-magnitude ranges. Therefore, these values should not be regarded as strict numerical limits but as indicative of the approximate order of magnitude of likelihood. Any definition of likelihood should be stated on a per-event basis.

Likelihood Evaluation Method

The likelihood evaluation method used should be consistent with the likelihood definitions, such that the qualitative score assigned can be compared to the likelihood definitions. In the index method, the likelihood index for the accident sequence must be no greater than -5 to meet the definition of "highly unlikely" and must be no greater than -4 to meet the definition of "unlikely." The likelihood index for the accident sequence is determined by summing likelihood indices for the initiating event and subsequent failures of items relied on for safety (IROFS). Tables A-9, A-10, and A-11 of Appendix A present criteria for the assignment of the likelihood indices.

Appendix A distinguishes between two different kinds of events that can be combined to form the accident sequences in the ISA summary. The two basic kinds of events are (1) events that are characterized by a frequency of occurrence, and (2) events that are characterized by a probability of failure on demand (PFOD). In the index method of Appendix A, the category to which an event belongs determines how it is scored by means of either Table A-9 or A-10, as explained below.

Events characterized by a frequency of occurrence (f-type events) can include external events, internal events that are not IROFS failures, or IROFS failures. IROFS failures characterized by a frequency of occurrence are those that are required to be continuously present, rather than those that are required to perform a safety function only when certain conditions are present. Examples may include favorable geometry equipment or an active engineered device monitoring a continuous process.

Events characterized by a PFOD (p-type events) typically include IROFS that are not required to be continuously present but that must perform a safety function on demand (subsequent to some process deviation or failure). Examples include active interlocks that perform some protective function when system parameters exceed preset limits, administrative controls required in response to process deviations, or certain administrative controls in batch processes. These are usually part of the subsequent failures following the initiating event but may sometimes be part of the initiating event.

In general, accident sequences may comprise many individual events. In general, accident sequences consist of an initiating event followed by the failure of one or more IROFS. Because the overall accident sequence likelihood must be consistent with the likelihood categories, it must have the same dimensional units as those of the likelihood definitions (i.e., probability per event, per year). Even though qualitative indices are used instead of quantitative probabilities, this requirement imposes constraints on the ways in which individual indices may be combined.

For simplicity, the following considers only two-event sequences (in which the events are independent). The two basic kinds of events result in four basic types of two-event accident sequences, as described in the following sections.

F-Type Initiating Event with Subsequent P-Type IROFS Failure

In the index method of Appendix A, a failure frequency index may be applied to the initiating event using the criteria in Table A-9, and a failure probability index may be applied to the subsequent IROFS failure using the criteria in Table A-10. The overall likelihood index for the accident sequence is the sum of the likelihood indices for the two events. This is because the IROFS is assumed to be demanded every time the initiating event occurs.

Mathematically, this results in an accident sequence likelihood index corresponding to an accident sequence likelihood with the correct dimensional units:

- accident sequence likelihood (yr^{-1}) = initiating event frequency (yr^{-1}) × PFOD
  accident sequence index = initiating event index + subsequent failure index

An example of this type of accident sequence is a criticality sequence consisting of a loss of concentration control in a continuous solution processing operation, followed by failure of an

inline concentration monitor that closes an isolation valve on a transfer line upon detection of highly concentrated solution.

F-Type Initiating Event with Subsequent F-Type IROFS Failure

Using the index method of Appendix A, a failure frequency index may be applied to both the initiating event and the subsequent IROFS failure using the criteria in Table A-9. The overall likelihood index for the accident sequence is the sum of the individual likelihood indices for the two events and a duration index for the initiating event. This is because the probability of the second event occurring concurrently with the first event is dependent on the time during which the conditions caused by the first event persist. For the accident sequence likelihood to have the correct units (yr^{-1}), the duration of failure for the first event must be considered.

Mathematically, this results in an accident sequence likelihood index corresponding to an accident sequence likelihood with the correct dimensional units:

- accident sequence likelihood (yr^{-1}) = initiating event frequency (yr^{-1}) × initiating event duration (yr) × subsequent failure frequency (yr^{-1})

- accident sequence index = initiating event index + initiating event duration index + subsequent failure index

An example of this type of accident sequence is a criticality sequence consisting of a loss of geometry control followed by a loss of moderation control resulting from the unrelated sprinkler activation before geometry control can be restored.

P-Type Initiating Event with Subsequent P-Type IROFS Failure

Using the index method of Appendix A, a failure probability index may be applied to both the initiating event and the subsequent IROFS failure using the criteria in Table A-10. The overall likelihood index for the accident sequence is the sum of the individual likelihood indices for the two events, which includes consideration of the demand rate associated with the initiating event. This is because the total failure frequency for the initiating event depends on the frequency with which the demand occurs, as well as the associated PFOD. The subsequent IROFS is assumed to be demanded every time the initiating event occurs. For the accident sequence likelihood to have the correct units (yr^{-1}), the demand rate of the first event must be considered.

Mathematically, this results in an accident sequence likelihood index corresponding to an accident sequence likelihood with the correct dimensional units:

- accident sequence likelihood (yr^{-1}) = initiating event demand rate (yr^{-1}) × initiating event PFOD × subsequent event PFOD

- accident sequence index = initiating event index (including demand rate) + subsequent failure index

An example of this type of accident sequence is a criticality sequence consisting of the failure of an operator to sample solution before transfer in a batch operation, followed by failure of an inline concentration monitor as discussed previously.

P-Type Initiating Event with Subsequent F-Type IROFS Failure

Using the index method of Appendix A, a failure probability index may be applied to the initiating event using the criteria in Table A-10. A failure frequency index may be applied to the subsequent IROFS failure using the criteria in Table A-9. The overall likelihood index for the accident sequence is the sum of likelihood indices for the two events, which includes consideration of the demand rate associated with the initiating event and a duration index for the initiating event. This is because the failure frequency for the initiating event depends on the frequency with which the demand occurs, as well as the associated PFOD. The probability of the second event occurring concurrently with the first event is dependent on the time during which the conditions caused by the first event persist. For the accident sequence likelihood to have the correct units (yr^{-1}), both the duration of failure for the first event and its demand rate must be considered.

Mathematically, this results in an accident sequence likelihood index corresponding to an accident sequence likelihood with the correct dimensional units:

- accident sequence likelihood (yr^{-1}) = initiating event demand rate (yr^{-1}) × initiating event PFOD × initiating event duration (yr) × subsequent failure frequency (yr^{-1})

- accident sequence index = initiating event index (including demand rate) + failure duration index + subsequent failure index

An example of this type of accident sequence is a criticality sequence consisting of a uranium solution spill that results from improper preventive maintenance on a pump, followed by the loss of moderation control because of inadvertent sprinkler activation before the spill can be cleaned up.

Use of Tables A-9, A-10, and A-11 in Appendix A

As illustrated above, an accident sequence generally consists of an initiating event with a certain frequency, followed by a number of subsequent events. While the number and type of events making up the sequence may vary, the likelihood indices of the individual events are combined, with appropriate consideration for duration of failure and demand rate, to arrive at a likelihood index for the accident sequence as a whole. The basic steps in this process are outlined below:

(1) Determine the events making up the sequence (initiating event and subsequent failures).

(2) Determine whether the event is characterized by a frequency of occurrence (f-type) or a PFOD (p-type). If an f-type event, use Table A-9 to assign the indices. If a p-type event, use Table A-10 to assign the indices.

(3) If the initiating event is a p-type event, take the demand rate into account to modify the indices from Table A-9.

(4) If the subsequent event is an f-type event, take into account the duration index for the initiating event from Table A-11.

(5) Combine the appropriate indices into an overall accident sequence likelihood index.

The table below summarizes the use of Tables A-9, A-10, and A-11 to determine overall accident sequence likelihood:

Initiator Type	Subsequent Event Type	Initiator Index	Subsequent Event Index	Duration Index	Accident Sequence Index
f-type	p-type	f1: Table A-9	p2: Table A-10	NA	f1 × p2
f-type	f-type	f1: Table A-9	f2: Table A-9	d1: Table A-11	f1 × d1 × f2
p-type	p-type	p1: Table A-10*	p2: Table A-10	NA	p1 × p2
p-type	f-type	p1: Table A-10*	f2: Table A-9	d1: Table A-11	p1 × d1 × f2

* To convert PFOD indices to frequency indices, use the indices of Table A-10 modified to take demand rate into account as follows:

Demand Rate	Modify Table A-10 Index
Hundreds of times per year (daily)	Increase base index by 2
Tens of times per year (monthly)	Increase base index by 1
Once per year	Use base index
Once every 10 years	Decrease base index by 1

Users of these tables must be careful not to confuse frequency with probability. For example, it is often assumed that the initiating event occurs because soothe assumption is simpler and more conservative. This is not, however, equivalent to assigning an initiating event frequency of 1, which is an event that occurs once per year. The confusion of failure frequency (with units of inverse time) with probability (dimensionless) can lead to significant errors in the overall accident sequence likelihood.

<u>Example</u>: In this accident sequence, the initiating event is solution sampling before transfer to a tank with an unfavorable geometry. A single administrative control might have a probability index of -2 (with appropriate management measures or redundancy). Similarly, if the historical data indicated a PFOD of 10^{-2}, an index of -2 would be appropriate. However, if this operation is a batch process conducted 10 times per year, this results in an initiating event frequency of 10/yr × 10^{-2} (PFOD) = 10^{-1}/yr (for an index of -1). If the operation is conducted 100 times per year, this results in an initiating event frequency of 100/yr × 10^{-2} (PFOD) = 10^{0}/yr (for an index of 0). Use of Table A-10 without any consideration of the demand rate would result in an index of -2.

Use of the incorrect table can also lead to erroneous results. A comparison of the indices in Tables A-9 and A-10 for the same type of control (although this is not the only factor that should be considered) immediately shows that use of Table A-9 results in a higher index than does use

of Table A-10. For example, a simple administrative control (without enhancing factors such as redundancy or large margin) would have a probability index of -1 to -2 based on Table A-10, but a frequency index of 0 based on Table A-9. This is intuitively reasonable because Table A-9 is for events characterized by a frequency (which must be present on a continuous basis) and Table A-10 is for events that are demanded only under certain conditions (which must be present on occasion).

Additional Considerations in the Use of Index Tables

Assignment of a qualitative score may be based either on objective evidence of the frequency of occurrence or on certain qualitative characteristics of the process or facility (availability and reliability qualities). In accordance with this, Tables A-9 and A-10 contain two columns that represent two different methods for assigning likelihood indices. As stated in the introduction to Appendix A, this is a semiquantitative method that allows for the use of quantitative information if available.

For initiating events that are external events or internal events other than IROFS failures, the column entitled "Based on Evidence" in Table A-9 should be used in assigning indices. For IROFS failures to which Table A-9 applies, either the column entitled "Based on Evidence" or "Based on Type of IROFS" may be used. Because the type of IROFS is only one of the availability and reliability qualities on which likelihood depends, the footnote to this table indicates that the index scores applicable to a particular type of IROFS can be one value higher or lower than the index shown.[1] Thus, other specific availability and reliability qualities (as discussed in Section 3.4.3.2(9) of this SRP) should be considered in assigning the final likelihood index.[2] In the absence of sufficiently detailed information about these factors, appropriate conservatism should be used in assigning indices (e.g., using the highest index in the range). Because of the large uncertainty associated with basing likelihood on the type of IROFS, historical and/or operating evidence should be used to assign indices whenever available. The same considerations discussed above should be employed when using Table A-10 to assign likelihood indices.

The presence of two columns should not be construed to mean that the two sets of criteria may be considered equivalent except in a rough, order-of-magnitude sense (e.g., a single passive engineered IROFS does not necessarily have a PFOD of 10^{-3} to 10^{-4}). This is because the type of IROFS is only one of the availability and reliability qualities that must be considered.

Appropriate use of Tables A-9 and A-10 to assign likelihood indices also requires that attention be given to the footnotes and comments in these tables. As indicated in the footnotes, indices less than -1 should not be used unless the management measures are of high quality. This is because even though a passive engineered control may have high inherent reliability while it is installed, this control could be easily defeated by a poor configuration management program, which is administrative in nature (as are all management measures). Justification should be provided as to why the management measures are deemed to be of high quality. Also, the ISA

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[1] The title "Based on Type of IROFS" is somewhat of a misnomer in that several of the criteria also include consideration of redundancy, margin, and independence. Indices based solely on the type of IROFS would cover an even broader range.

[2] This is consistent with the caveat for Table A-4, which warns that such coarse criteria are useful only for screening purposes or making an initial estimate of the likelihood. Because IROFS meeting these criteria can have a broad range of reliability, management measures applied to all the availability and reliability qualities of the IROFS should be considered in assigning the likelihood indices.

summary should justify the use of a more negative index whenever a range of indices is possible. As the comments suggest, the more negative the index, the more justification is required. As indicated, indices of -4 and -5 can rarely be justified by evidence. Use of these indices requires substantial evidence that the IROFS are exceptionally robust.

The assignment of failure duration indices using Table A-11 should also be based on objective criteria (such as documented mean time to repair or surveillance periods established in plant procedures).

When the analysis uses demand rates to modify probability indices from Table A-10, conservative estimates of the demand rate should be used and the basis for this estimate documented and, if the rates could credibly be changed, controlled. For example, the time needed to fill a cylinder may depend on inherent physical laws and would not need specific controls. However, if the maximum allowed inventory limits the number of batches, the license or plant procedures should control this inventory.

Description of Accident Sequences and IROFS

Tables A-12 and A-13 include descriptions of accident sequences and IROFS. These must be sufficiently clear to permit the reviewer to understand the sequence of events needed for an accident to occur and how the established controls prevent the sequence from occurring. The initial failure and all subsequent failures necessary for the sequence to progress to the ultimate consequences (an accident exceeding the consequence thresholds in Title 10 of the *Code of Federal Regulations* (10 CFR) 70.61, "Performance Requirements") should be specified. In addition, any initial conditions credited in meeting the performance requirements should be specified. If important to the likelihood of the sequence, the order in which these events occur should be specified. For example, in Table A-12, sequence PPB2-1C is the reverse of the events in sequence PPB2-1A. When failure duration indices are considered, these pertain to the initiating event; therefore, the accident sequence likelihood is dependent on which event occurs first.

In describing IROFS, it is important that the safety function performed by the IROFS and the attributes of the IROFS necessary to perform the safety function be specified. For example, for the first IROFS in Table A-13, the safety function is to prevent mass from accumulating outside the hopper. Therefore, the only attribute of IROFS PPB2-C1 that must be specified is that it be designed to prevent leaks; such a design would include the use of a double gasket at the hopper's outlet. Because the material of composition, size, and other attributes of the hopper have no role in preventing this accident sequence, they need not be specified. The second IROFS is an example of a system of IROFS that collectively provides for moderation control (i.e., dual sampling, administrative exclusion of water, double piping, floor drains, and roof integrity). As in the preceding example, the size of the piping is not significant; double piping is the only feature important to preventing this accident sequence. The level of detail should be sufficient to provide assurance that safety-significant aspects of the IROFS are recognized and appropriately controlled. However, excessive detail could lead to obscuring the safety-significant aspects of IROFS and could lead to unnecessary and burdensome changes to the ISA and ISA summary. IROFS may be specified at the subcomponent level, component level, or system level, as appropriate. For example, it is not necessary to specify every geometry limited pipe in the building as an IROFS. If the safety function is to maintain geometry control, it would be sufficient to specify a systems-level IROFS with the description "all fissile material piping in the solution recovery area will be less than 2 inches in diameter."

A single piece of equipment may perform several different safety functions and be credited in several different accident sequences. In such cases, the accident sequence must clearly describe the safety function and attribute of the IROFS being credited, as well as the failure mode of the IROFS that leads to the accident.

Summary Table of Accident Sequences

Table A-7 of Appendix A is a summary table showing several accident sequences for a powder-blending process. This is one way to display the information on accident sequences obtained during performance of the ISA. As shown in Appendix A to NUREG-1718, "Standard Review Plan for the Review of an Application for a Mixed Oxide Fuel Fabrication Facility," issued August 2000, a fault tree (quantitative or qualitative) is one of the other formats that may be used. The important information that must be conveyed, however, is a list of accident sequences, identification of the initiating event, the set of subsequent events leading to the accident and the IROFS that prevent them, the likelihood of the initiating event and subsequent failures, the ultimate consequence category, and the overall assessment of compliance with the performance requirements (e.g., total risk index). Any other information needed to demonstrate that the performance requirements are met should also be specified (e.g., initial conditions, demand rate, duration indices, index modification for dependent failures). Table A-7 shows two types of accident sequences: (1) two sequences initiated by IROFS failures (both f-type initiating events with f-type subsequent failures and crediting duration indices) and (2) two sequences initiated by internal events other than IROFS failures (and crediting initiating event frequency).

While this guidance follows the structure of Appendix A to this Standard Review Plan, it also applies to Appendix A to NUREG-1718.

REFERENCES

U.S. Code of Federal Regulations, Chapter I, Title 10, "Energy," Part 70, "Domestic Licensing of Special Nuclear Material."

U.S. Nuclear Regulatory Commission, "Standard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility," NUREG-1718, August 2000.

APPENDIX B

QUALITATIVE CRITERIA FOR EVALUATION OF LIKELIHOOD

Purpose

This appendix provides additional guidance on the use of qualitative criteria in methods for evaluation of likelihood. These evaluations are used in demonstrating compliance with the performance requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 70.61, "Performance Requirements."

Introduction

The regulation in 10 CFR 70.61(b) requires that the risk of each credible high-consequence event be limited by ensuring that upon implementation of engineered or administrative controls, the event is made highly unlikely or its consequences reduced to less than high consequence. This regulation similarly requires that the risk of each credible intermediate-consequence event be limited by ensuring that the event is made unlikely, or its consequences reduced. Rather than defining the terms "highly unlikely," "unlikely," and, "credible," 10 CFR 70.65(b)(9) instead states that the applicant must include definitions of these terms in its integrated safety analysis (ISA) summary.

As stated in Section 3.4.3.2(9) of this Standard Review Plan (SRP), the applicant's definitions of these terms may be either quantitative or qualitative. The method used to evaluate accident sequence likelihood must be consistent with the definitions. Quantitative definitions require quantitative methods; qualitative definitions require qualitative methods. Qualitative methods are based on objective qualitative criteria and characteristics of the process or system being evaluated. In addition, some methods (semiquantitative methods) may rely on a mixture of qualitative and quantitative definitions, methods, and information. This appendix provides general guidance on the use of qualitative methods for evaluation of likelihood. However, the U.S. Nuclear Regulatory Commission's (NRC's) review of recently submitted ISA Summaries has revealed a lack of common understanding as to what constitutes an acceptable qualitative method.

Additional guidance is provided on the acceptance criteria for qualitative methods of evaluating likelihood, both for the failure of items relied on for safety (IROFS) and for accident sequences as a whole. Either external events or internal events (which may or may not be IROFS failures) may initiate these accident sequences. Appendix D to Chapter 3 of this SRP provides additional guidance on the use of initiating events that are natural phenomena. Appendix C to Chapter 3 offers additional guidance on the use of initiating events that are internal to the facility. That guidance may be used with the guidance in this appendix as an acceptable qualitative method for likelihood evaluation.

Discussion

Definitions of Likelihood

According to 10 CFR 70.65(b)(9), the ISA summary must define the terms "unlikely," "highly unlikely," and "credible." Section 3.4.3.2(9) of this SRP states that qualitative definitions of likelihood are acceptable if they meet two conditions: (1) they are reasonably clear and based on objective criteria and (2) they can reasonably be expected to consistently distinguish accidents that are highly unlikely from those that are merely unlikely (or not unlikely). This means that the definitions should be sufficiently clear that there is reasonable assurance that they will yield the same result when applied by different reviewers and that they can be used to make meaningful distinctions between events in different likelihood categories. Both the definitions of likelihood and the methods for likelihood determination should meet these criteria since they must work together to ensure that the performance requirements are met.

This NUREG states that "objective criteria" means that the method relies on specific identifiable characteristics of a process design, rather than subjective judgments of adequacy. Because the likelihood of an accident sequence is a function of the likelihood of the initiating event, the subsequent IROFS failures, and the relationship between the IROFS (e.g., whether the IROFS are independent), the characteristics of the process design that the method should rely on are the specific identifiable characteristics of the initiating event, IROFS failures, and other process features that affect the likelihood of the accident sequence. These features include the safety margin, type of control, type and grading of management measures, whether the system is fail-safe or failure is self-announcing, failure modes, demand rates, and failure rates for individual IROFS (whether credited as part of the initiating event or subsequent failures). These features include the degree of redundancy, independence, diversity, and vulnerability to common-cause failure for systems of IROFS. The following sections describe these features in detail. It is important that any features of the process or equipment necessary to meet the performance requirements are recognized as important to safety and appropriately maintained through the use of management measures.

Examples of acceptable qualitative definitions of likelihood are the second and third definitions of "not credible" in Section 3.4.3.2(9) of this SRP:

> A process deviation consists of a sequence of many unlikely human actions or errors for which there is no reason or motive….
>
> A convincing argument exists that, given physical laws, the process deviations are not possible, or are unquestionably extremely unlikely….

Similarly, the following is an example of an acceptable qualitative definition of "highly unlikely":

> a system of IROFS that possesses double-contingency protection, where each of the applicable qualities is present to an appropriate degree

In this definition, the qualities to be considered should be described in sufficient detail so that their effect on the overall likelihood can be evaluated. This is the meaning of "present to an appropriate degree." Other definitions are acceptable provided that they meet the two criteria specified above and provide system features to ensure that the likelihood is appropriately maintained.

Evaluation of Likelihood

Accident sequences, in general, consist of an initiating event followed by one or more subsequent events. The likelihood of an accident sequence is, therefore, a function of the likelihood of the individual events making up the accident sequence and the relationship between them (e.g., whether they are independent). Because the likelihood of the accident sequence must be compared to the likelihood definitions to determine whether it is "unlikely," "highly unlikely," or "not unlikely," qualitative methods of likelihood evaluation are acceptable if they (1) are reasonably clear and based on objective criteria and (2) can reasonably be expected to consistently distinguish accidents that are "highly unlikely" from those that are merely "unlikely." The likelihood definitions establish the standard for what is "unlikely" and "highly unlikely," and the assigned likelihood for the accident sequence is then compared to this standard. As mentioned above, the method must take into account all objective qualities of the system that can reasonably be considered to affect likelihood. These qualities are referred to in this NUREG as the "reliability and availability" qualities of IROFS or systems of IROFS.

Initiating Events and Initial Conditions

Each accident sequence begins with an initiating event. An initiating event may consist of an external event (including a natural phenomenon or external manmade event), an internal event other than an IROFS failure, or an IROFS failure. Natural phenomena may include heavy rains, winds, flooding, earthquakes, and fires. External manmade events may include impacts from nearby facilities, aircraft or vehicle crashes, fires, and loss of offsite utilities. Internal events other than IROFS failures may include spills, non-IROFS equipment failure, process deviations, industrial accidents, and loss of onsite utilities. In a qualitative method of likelihood determination, a qualitative score is associated with the initiating event based on its objective qualities. The score may be expressed in either numerical (e.g., -1, -2, -3) or nonnumerical (e.g., A, B, C, D) form but is still qualitative if based on qualitative criteria.

The likelihood of external initiating events (by definition, they are outside the control of the facility) does not rely on any design features of the facility or process and is thus characterized only by a frequency of occurrence. In a qualitative method for assigning likelihood to these events, a qualitative score is associated with the external event based on its frequency of occurrence. Events with the same frequency of occurrence should have the same score regardless of the type of event or severity of its consequences. The method should thus include a table of the scores assigned based on qualitative frequency criteria. These criteria may include qualitative descriptions of frequency, such as "100-year flood" or "1,000-year earthquake," or may include other qualitative criteria that can be correlated to a frequency, such as "design-basis earthquake" or "exceeds the mean annual rainfall by a factor of x." By contrast, quantitative or semiquantitative methods may include quantitative descriptions of frequency such as "having a frequency less than 10^{-2} per year." Because these events are beyond human control, no features have to be maintained to ensure the continued validity of the assigned likelihood. However, it may be necessary to periodically reexamine the basis of these likelihoods if it is reasonably expected that the likelihood could change (e.g., following construction of a new railroad spur next to the facility). Appendix D to Chapter 3 contains additional guidance applicable to initiating events that are natural phenomena.

By contrast, the likelihood of internal initiating events other than IROFS failures depends on specific, identifiable characteristics of the facility or process design, such as those discussed in the following sections. Scores may be assigned to such events based either on objective evidence of their frequency of occurrence or on specific identifiable characteristics of the facility

or process that can affect the frequency of occurrence. If the actual frequency of occurrence is known, this information should be used as it represents objective knowledge about the event likelihood and accounts for the cumulative effect of all characteristics that can affect likelihood. Otherwise, the features of the facility or process design that can affect the likelihood should be described. Regardless of the method used to assign a likelihood score, care must be taken that all facility and process features that can affect the event likelihood (reliability and availability qualities) are recognized as such and appropriately maintained. Appendix C to Chapter 3 contains additional guidance applicable to internal initiating events other than IROFS failures.

Similarly, the likelihood of internal initiating events that are IROFS failures also depends on specific, identifiable characteristics of the facility or process design. Scores may be assigned to such events based either on objective evidence of their frequency of occurrence or on specific identifiable characteristics of the IROFS that can affect the frequency of occurrence. If the actual frequency of occurrence is known, this information should be used. Otherwise, the features of the IROFS that can affect the likelihood should be described. Regardless of the method used to assign a likelihood score, care must be taken that all IROFS attributes that can affect the event likelihood (reliability and availability qualities) are recognized as such and appropriately maintained. The following provides guidance on specific reliability and availability qualities associated with individual IROFS.

For both types of internal initiating events, facility or process features (or physical and chemical phenomena) that can affect the initiating event likelihood may be identified as initial conditions or bounding assumptions. The important factor is that these initial conditions and bounding assumptions must be identified and, if susceptible to change over the lifetime of the facility (such as through process deviations or facility changes), must be appropriately maintained. For example, the maximum throughput or inventory in a process may change; thus, measures should be in place to maintain this throughput or inventory if it is relied on to meet the performance requirements, whereas the flow of gravity or maximum density may not require specific controls.

Individual IROFS

Section 3.4.3.2(9) of Chapter 3 of this NUREG states that the reliability and availability qualities of individual IROFS include (1) safety margin in the controlled parameter, (2) the type of IROFS (passive or active engineered, simple or enhanced administrative), (3) the type and safety grading of any management measures, (4) whether the system is fail-safe, failure is self-announcing, or the IROFS is subject to periodic surveillance, (5) failure modes, (6) demand rate, and (7) failure rate. It is very important that any qualitative (or quantitative) method of likelihood evaluation consider all applicable IROFS attributes that could affect the reliability and availability of the IROFS, such as those discussed below. For example, reliance should not be based solely on the type of IROFS (passive engineered, active engineered, simple administrative, or enhanced administrative).

In addition to those reliability and availability qualities discussed above, other factors may require consideration. For example, environmental conditions, such as extreme temperatures and pressures, corrosive atmosphere, excessive vibration, may have a significant effect on IROFS reliability and should be appropriately considered.

The level of detail describing the IROFS in the ISA summary is also important. It would be acceptable to describe the IROFS at the system level if that is sufficient to demonstrate compliance with the performance requirements. The regulation in 10 CFR 70.65(b)(6) states

that IROFS should be described "in sufficient detail to understand their functions in relation to the performance requirements." It is important that the description be sufficiently detailed to identify all attributes of the IROFS that can affect its likelihood of failure, as well as everything that is within the boundary of the IROFS. It may not be necessary to specify the model number or exact design of a pump if the only attribute relied on to meet the performance requirement is the pumping capacity or oil reservoir volume. It may be sufficient to describe the pump as "centrifugal pump limited to less than 10 liters oil." The IROFS boundary includes everything necessary for the IROFS to perform its intended safety function. For example, the boundary of an enhanced administrative IROFS includes all instrumentation (sensors, annunciators, circuitry, any controls activated by the operator) relied on to trigger the operator action; the boundary of a simple administrative control includes the equipment necessary to correctly perform the action; and the boundary of an active engineered control includes the attendant instrumentation, sensors, essential utilities, and any auxiliary equipment needed to perform its safety function. The reliability and availability qualities of every component within the IROFS boundary must be considered in evaluating the total IROFS likelihood.

Additional guidance on some of the specific reliability and availability qualities of individual IROFS is provided below.

Safety Margin in Controlled Parameter: "Safety margin" refers to the difference between the value of a parameter likely to be encountered during normal or credible abnormal conditions and the value that would allow an accident to be possible. The precise value of the margin in terms of the parameter is not meaningful; rather, for the event to be unlikely or highly unlikely based on safety margin, the margin should be several times larger than the expected process variation or uncertainty. Similarly, if the margin is much greater than the change in the parameter resulting from the worst case credible upset, this fact could be credited for ensuring that the event is unlikely or highly unlikely.

The phrase "controlled parameter" indicates that means should be provided to ensure that the safety margin is continuously present, if the margin is relied on in evaluating likelihood. Parameters that are not controlled should be considered to be at their worst case credible values.

Type of Control: Passive engineered controls are generally considered preferable to active engineered controls, active engineered controls preferable to enhanced administrative controls, and enhanced administrative controls preferable to simple administrative controls. This is because, ordinarily, passive engineered controls are the most reliable, and simple administrative controls are the least reliable. Although this is one of the factors that should be considered, evaluations of likelihood should not rely solely on the type of control. This is because the likelihood associated with passive engineered controls, for example, can vary widely depending on specific attributes of the IROFS.

Type and Safety Grading of Management Measures: The specific management measures applied to an IROFS can have a significant effect on its overall likelihood. Of particular importance is surveillance, because this can have a direct and transparent effect on the duration of failure in a method that gives credit to duration of failure. It may not be necessary to specify the frequency of preventive maintenance, testing, and calibration quantitatively in the ISA summary. For example, to take credit for generic failure rates for a piece of equipment, it may be sufficient to specify that maintenance will be performed at a frequency and in a manner consistent with the manufacturer's recommendations. Functional testing should be conducted

in a manner that ensures that everything within the IROFS boundary is working as needed for the IROFS to perform its safety function.

While the degree and type of management measures can increase or decrease the likelihood score associated with an IROFS, primary reliance should be on designing IROFS that have a certain reliability and then applying management measures to maintain that reliability. It should not be supposed that one can achieve any desired reliability by applying increasingly stringent management measures.

Fail-Safe or Self-Announcing: This is the characteristic of an IROFS that determines the degree to which failure of an IROFS is detected and appropriately corrected. For the purpose of the ISA and ISA summary, an IROFS is considered to fail only when it fails to perform its intended safety function. Thus, a valve that is an IROFS is not considered to fail in the context of the accident sequence (i.e., to contribute to the progression of an accident sequence) as long as it fails in a safe configuration (fails-safe). If the valve is designed to fail closed (and closed is the safe configuration), credit may be taken for the fact that the valve is designed to fail closed. The likelihood thus is not the likelihood that the valve fails, but the likelihood that it fails in a way other than how it is designed to fail. An IROFS that is fail-safe may include within its boundary a system designed to put the process into a safe condition upon failure of a component. An IROFS whose failure is self-announcing is one in which failure is either self-revealing (e.g., by presence of solution on a floor where operators are continuously present) or results in an alarm to alert operators. The main effect for the ISA summary is to limit the duration of failure by ensuring that the upset condition is corrected essentially immediately. Similarly, surveillance may be relied on to limit the duration of failure to a specified period.

Failure Modes: In addition to specifying the safety function that an IROFS must perform, it is necessary to consider the specific failure modes of the IROFS. A particular IROFS may be credited in several different accident sequences but may have different scores in each because of the differing failure modes leading to an accident. For example, a pipe may either plug or leak. A valve may leak, fail open, or fail closed. A complex piece of equipment such as a pump may have multiple different failure modes, each with a different likelihood, leading to several different accident sequences. The description of the accident sequence should clearly specify the conditions and failures that must occur for the undesired consequences to result.

Demand Rate: Demand rate refers to the frequency with which an IROFS having a specified probability of failure on demand is required to perform its safety function. The number of times an IROFS is required to work can have a significant effect on its likelihood of failure. For example, a particular administrative control may have a certain failure likelihood. However, whether the accident sequence is “not unlikely,” “unlikely,” or “highly unlikely” will depend on the frequency with which the action is performed. If the action is required several hundred times a year, then occurrence of the initiating event will be significantly more likely than if the action is required once per year. Similarly, a passive control (such as the integrity of a storage container) may have a certain failure likelihood. However, if there are a thousand such containers in a storage array, then the likelihood that any one container will leak is much greater than if there is only one such container. Care must be taken to specify whether the initiating event is the leak of a particular container, or any one container, in the array.

Failure Rate: Failure rate refers to the frequency with which a continuously demanded item is observed to fail. In a qualitative method for likelihood evaluation, the failure rate is described in terms of qualitative descriptors (e.g., “several failures per year,” “a few failures during facility lifetime,” “no failures in 30 years for tens of similar IROFS in industry”) used in the assignment

of qualitative likelihood scores (e.g., -1, -2, -3; A, B, C). This information is often not available with any precision, but when available, it should be used along with other qualitative information in the assignment of scores. This is because the failure rate represents an objective measure of the cumulative effect of all the reliability and availability qualities of the system. (See the discussion of qualitative and quantitative information below.)

This is not intended to be a comprehensive list of all facility- or process-specific factors that can affect the failure likelihood of individual IROFS.

Accident Sequences

Section 3.4.3.2(9) of this SRP states that there are other reliability and availability qualities that relate to characteristics of the entire system of IROFS credited in the accident sequence. This is because the accident sequence likelihood is not just a function of the likelihood of failure of the individual IROFS, but also of the relationship between the IROFS.

Additional guidance on some of the specific reliability and availability qualities applicable to the accident sequence as a whole is provided below.

Defense in Depth: Defense in depth is the degree to which multiple IROFS or systems of IROFS must fail before the undesired consequences (e.g., criticality, chemical release) can result. IROFS that provide for defense in depth may be either independent or dependent, although IROFS should be independent whenever practical because of the possibility that the reliability of any single IROFS may not be as great as anticipated. This will make the results of the risk evaluation more tolerant of error. In addition, IROFS must be independent if the method for likelihood determination assumes independence (such as methods relying on summation of indices). IROFS are independent if there is no credible single event (common-mode failure) that can cause the safety function of each IROFS to fail. Multiple independent IROFS generally provide the highest level of risk reduction. The degrees of redundancy, independence, and diversity are important factors in determining the amount of risk reduction afforded by the system of IROFS.

Degree of Redundancy: Defense in depth is provided by specifying redundant IROFS that perform the same essential safety function. Redundant IROFS may be either diverse or nondiverse; it is not necessary for them to consist of identical equipment or operator actions. However, when identical equipment or operator actions provide redundancy, it is important to ensure that all credible common-mode failures have been identified.

Degree of Independence: To qualify as independent, the failure of one IROFS should neither cause the failure nor increase the likelihood of failure of another IROFS. No single credible event should be able to defeat the system of IROFS such that an accident is possible. A systematic method of hazard identification should thus be used to provide a high degree of assurance that all credible failure mechanisms that could contribute to (i.e., by initiating or failing to prevent or mitigate) an accident have been identified. Methods commonly used for likelihood evaluation almost always assume that the chosen IROFS are independent. Examples of these methods include layer of protection analysis and the index method in Appendix A to this report. In a few cases, it may not be feasible to entirely eliminate the possibility of dependent failures. Methods that rely on independent IROFS should not be used to evaluate the likelihood of systems of IROFS with dependent failures. (Guidance applicable to the rare system with dependent failures is provided below.) If, however, the common-cause failure is sufficiently unlikely, it may be possible to treat IROFS as independent for purposes of the ISA and ISA

summary, as discussed below. Because of the added requirement to meet the double-contingency principle, this approach will not be valid for criticality accident sequences when the requirements of 10 CFR 70.64(a)(9) apply.

Many factors can lead to IROFS not being independent, and these factors can have a significant effect on the likelihood of an accident sequence. A partial list of conditions that will almost always lead to two or more IROFS not being independent follows:

- The same individual performs administrative actions.
- Two different individuals perform administrative actions but use the same equipment and/or procedures.
- Two engineered controls share a common hardware component or common software.
- Two engineered controls measure the same physical variable using the same model or type of hardware.
- Two engineered controls rely on the same source of essential utilities (e.g., electricity, instrument air, compressed nitrogen, water).
- Two engineered controls are collocated such that credible internal or external events (e.g., structural failure, forklift impacts, fires, explosions, chemical releases) can cause both to fail.
- Administrative or engineered controls are susceptible to failure because of the presence of credible environmental conditions (e.g., two operator actions defeated by corrosive atmosphere, sensors rendered inoperable because of high temperature).

The presence of any of these conditions does not necessarily mean that the IROFS cannot be considered independent, but the applicant should provide additional justification demonstrating the lack of common-mode failure. The likelihood of such conditions in relation to the overall likelihood of an accident should be factored into the determination of the significance of the common-mode failure.

Diversity: Diversity is the degree to which IROFS that perform different safety functions provide defense in depth. This means that different types of failures must occur before an accident is possible. Diverse controls may consist of controls on different parameters or different means of controlling the same parameter. In choosing redundant controls, preference should be given to diverse means of control, because they are generally less susceptible to common-mode failure than are nondiverse means. However, it is still necessary to consider all credible failure modes of the system when evaluating the overall likelihood of failure.

Vulnerability to Common-Cause Failure: Diverse means of control should be provided whenever practicable to minimize the potential for common-mode failure. For example, Chapter 5 of this SRP states that for criticality protection, a two-parameter control should be considered preferable to two controls on one parameter. Where a two-parameter control is not practicable, diverse means of controlling a single parameter should likewise be considered preferable to two redundant controls on that single parameter.

It is not always possible to provide absolute assurance that IROFS are perfectly independent. However, if the cumulative likelihood of all common-mode failures of a system of IROFS is significantly less than the independent failure of the system of IROFS, then the IROFS may be treated for all practical purposes as independent. Quantitatively, this means that the likelihood of the common-cause failure should be at least two orders of magnitude less than that of the independent failure of the system of IROFS. Qualitatively, this means that the likelihood of the common-cause failure should be sufficiently low that it does not change the score for the system of IROFS.

If credible common-mode failures cannot be neglected, as discussed above, then they must be considered in evaluating the overall accident sequence likelihood. A likelihood evaluation method (whether quantitative or qualitative) that correctly treats dependent failures should be used when such failures are present.

In general, the probability of failure of a system of two IROFS may be expressed as:

$$P(A,B) = P_{ind}(A,B) + P_{dep}(A,B) = P(A)P(B) + P_{dep}(A,B)$$

That is, there is a component to the likelihood that is the independent failure of IROFS A and B and a component that represents the common-mode failure of IROFS A and B. Independent failure of the IROFS is represented by the product P(A)P(B). Therefore, the condition that the two IROFS be considered independent may be expressed as:

$$P(A,B) \approx P(A)P(B)$$

or equivalently

$$P_{dep}(A,B) << P(A)P(B)$$

A variety of different methods may be used to treat dependent failures when the conditions above are not met. For example, in a quantitative method, the likelihood of the common-mode event may be estimated and factored into the above equation. In a qualitative scoring method, the likelihood score may be increased to reflect the existence of a common-mode failure. (In a qualitative scoring method similar to that employed in Appendix A to Chapter 3 of this SRP, summation of individual IROFS scores to determine the overall accident sequence score is permissible only if the IROFS are independent. Such a method assumes that independence should be modified as needed to correctly treat common-mode failures.) In the layer of protection analysis method, only the independent IROFS are credited in evaluating the overall accident sequence likelihood. In a qualitative fault tree method, the common-mode failure may be included as an additional basic event in the fault tree. It is permissible then to treat the independent failure of the system of IROFS as one accident sequence and the dependent failure as another. The method used to treat dependent failures should be appropriately justified.

Qualitative criteria may be used to assess the effect of dependent failures on likelihood scores. The effect of qualitative performance-shaping factors should be considered in these criteria. For example, repeated failures of identical administrative IROFS (e.g., multiple batching, multiple valving, or spacing violations) should not be considered to be independent nor receive the same score without substantial justification, as discussed below. This is because the likelihood of subsequent human failures increases once the initial failure has occurred. The set of factors

that could contribute to multiple administrative failures may include inadequate or out-of-date procedures, poor training, environmental distractions, and poor human factors design. For the same reason, the possibility of two different administrative failures by the same individual should be carefully considered for common-mode vulnerability. In assessing the vulnerability of these actions to common-mode failure, consideration may be given to any recovery factors that may be in place to interrupt the sequence of failures (e.g., supervisory checking, inspection, independent verification). Such recovery factors should be treated as measures that enhance the reliability of the administrative IROFS or ensure that repeated failures may be considered to be independent. In particular, independent verification of one administrative IROFS should not be used as a separate IROFS in the same accident sequence. For the same reasons as cited above, verification that an action has been performed correctly would be susceptible to the same factors that caused the initial failure. In addition, verification of an action is likely to be more cursory and, therefore, less reliable than performance of the original action. Moreover, in the event that the first action was performed correctly, the independent verification of that first action would not contribute to meeting the performance requirements, and therefore, the first action would constitute a sole IROFS. Thus, independent verification should be used only to increase the reliability of an IROFS and should not be treated as a separate IROFS nor credited with the same level of risk reduction.

In addition to the above, for criticality accident sequences required to comply with the double-contingency principle (see appendix 5-A of this SRP).

Use of Quantitative and Qualitative Information

Section 3.4.3.2(9) of this SRP acknowledges that a mix of quantitative and qualitative information is often available to an analyst performing an ISA. This SRP includes a list of some types of objective quantitative information and states that this information should be considered in evaluating likelihood, even in purely qualitative methods. The information listed includes (1) reports of equipment failures or procedural violations, (2) surveillance intervals, (3) functional testing intervals or audit frequencies, (4) time required to render the system safe, and (5) demand rates. In a purely qualitative method, such information, to the extent it is available, should be considered qualitatively. One example of this is using surveillance periods as part of the justification for qualitative duration indices (as in Appendix A to Chapter 3 of this SRP).

In using such objective data, facility-specific data are preferable to generic data, and process-specific data are preferable to facility-specific data because of the many environmental and other factors that can affect likelihood. For example, a manufacturer may have certified a particular pump with a given reliability rating, but the actual performance in process will depend on maintenance, electrical and mechanical loading, type of oil, ambient temperature, and vibration, among other factors. While more specific data are preferable, typically, the more specific the conditions, the fewer data are available. The amount and specificity of the data should be given appropriate weight in evaluating likelihood. For example, the use of generic failure data for a specific type of valve may be acceptable if an appropriately bounding value (i.e., the less conservative extreme of a range of values) is used. A less bounding value may be acceptable if information is available from the manufacturer on the specific model of valve. An even less bounding value may be acceptable if sufficient operating experience is available to support facility- or process-specific values. Sufficient margin to bound uncertainties in failure rates should be provided when relying on generic information.

Operating history may be credited in justifying likelihood scores for individual IROFS. Care must be taken that this credit is based on documented performance data and not anecdotal

evidence and that the operating history is applicable to the event being evaluated. For example, not having any criticality accidents in 30 years of operation would not be justification for a failure frequency for a particular component or initiating event (since the initiating event may have occurred several times during that time period without resulting in a criticality). It would also not be justification for a likelihood corresponding to a time between failures longer than 30 years. In addition, if significant facility changes occurred over the previous 30 years of operation, this information may not be meaningful. The limits and applicability of the operating data used to justify likelihood should be explained.

Especially for new processes or facilities, such objective quantitative data may not be available. Appropriate margin in plant operations and conservatism in likelihood scoring should be used and justified when such information is not available. Over the facility lifetime, however, information gained with regard to operational events and IROFS failures should be evaluated and fed back into the ISA process. This may be justification for reducing margins and conservatism over the facility lifetime.

Graded Approach to Integrated Safety Analysis

The performance requirements of 10 CFR 70.61(b) and (c) establish an acceptable level of risk, in that high-consequence events must be made “highly unlikely” and intermediate-consequence events must be made “unlikely.” In addition, 10 CFR 70.65(b)(4) requires that an applicant’s ISA summary contain a demonstration of compliance with the performance requirements of 10 CFR 70.61. The means and the level of effort required to demonstrate compliance with 10 CFR 70.61 depend on the amount of risk reduction needed to meet the likelihood thresholds in that regulation. For example, a facility that obviously has inherently low risk (even before the performance of the ISA) requires less effort to demonstrate compliance than an inherently higher risk facility. Examples would include facilities with small mass or very low enrichment of special nuclear material, low chemical inventories, or insignificant combustible loading. Thus, the ISA methods used may be graded commensurate with the risk of the facility.

The facility and process characteristics that determine inherent risk should be identified as initial conditions and/or assumptions and appropriately identified and maintained to ensure that they will be present over the lifetime of the facility, if credit is taken for them in meeting the performance requirements. For example, a possession limit on the maximum enrichment or amount of special nuclear material at the facility may be credited in ensuring low risk of criticality, because the license sets an explicit limit. Chemical inventories may be likewise credited, provided that they are limited by license or the maximum inventory is identified as important to safety and rigorously controlled. ISA methods may be graded commensurate with the amount of risk reduction required once these factors have been explicitly identified and maintained.

The following are examples of aspects of the ISA process that may be graded commensurate with risk:

- In the selection of the hazard identification method, the what-if or what-if/checklist method would be more suitable for low-risk, simple operations; hazardous operations, fault tree, and other sophisticated methods may be appropriate for more complex or higher risk operations.

- In the evaluation of the type, number, and robustness of IROFS, lower risk facilities will not require the same level of control.

- In the application of management measures, lower risk facilities will not require measures as stringent as those for higher risk facilities.

- In the evaluation of likelihood, the technical justification required to support a high degree of risk reduction is much greater than that required to support a low or moderate degree of risk reduction. Methods used to support a high degree of risk reduction should be more sophisticated, and warrant greater regulatory scrutiny, than methods used to support a lower degree of risk reduction.

In addition to the inherent risk of the facility or process, the amount of conservatism may be considered in grading ISA methods. For example, if a very conservative likelihood is assumed for all IROFS failures, then the rigor and level of detail in describing the IROFS, considering all reliability and availability qualities and treating dependent failures, would not have to be at the same level as in a facility taking more realistic credit for IROFS failures. The grading of ISA methods necessitates that the applicant demonstrate (1) that the risk is inherently low and will be maintained over the lifetime of the facility, or (2) that there is a consistent and dependable amount of conservatism in ISA methods that offsets the uncertainty arising from lack of rigor.

Regulatory Basis

The risk of each credible high-consequence event must be limited. Engineered controls, administrative controls, or both shall be applied to the extent needed to reduce the likelihood of occurrence of the event so that, upon implementation of such controls, the event is highly unlikely or its consequences are less severe than those described in 10 CFR 70.61(b)(1–4).

The risk of each credible intermediate-consequence event must be limited. Engineered controls, administrative controls, or both shall be applied to the extent needed so that upon implementation of such controls, the event is unlikely or its consequences are less than those described in 10 CFR 70.61(c)(1–4).

Each licensee or applicant shall conduct and maintain an ISA that is of appropriate detail for the complexity of the process and that identifies “the consequences and likelihood of occurrence of each potential accident sequence…and the methods used to determine the consequences and likelihoods,” as stated in 10 CFR 70.62(c)(1)(v).

The ISA summary must contain “information that demonstrates the licensee’s compliance with the performance requirements of Section 70.61,” as stated in 10 CFR 70.65(b)(4).

The ISA summary must also include the definitions of “unlikely,” “highly unlikely,” and “credible” as used in the evaluations of the ISA, as stated in 10 CFR 70.65(b)(9).

Technical Review Guidance

The reviewer should use the information contained in this appendix, as applicable, to evaluate an applicant’s or a licensee’s qualitative methods of likelihood evaluation, commensurate with the level of risk reduction required to comply with the performance requirements of 10 CFR 70.61. If the applicant is using the index method defined in Appendix A to Chapter 3 of this SRP, the reviewer should use the guidance in Appendix A to evaluate the adequacy of the applicant’s ISA summary. The purpose of the ISA summary review is not to verify the

correctness of the likelihood scores for every single accident sequence, but to verify that the applicant has an acceptable methodology that contributes to reasonable assurance of maintaining an adequate safety basis over the facility lifetime, by ensuring that the methodology results in assignment of appropriate likelihoods. Thus, the reviewer should primarily determine whether there is a justifiable basis for the scores, and whether there is reasonable assurance that this basis will be maintained over the facility lifetime, assuming the application of appropriate management measures.

The applicant's qualitative method for likelihood evaluation should be acceptable if the following are true:

- The definitions of likelihood are clear, are based on objective criteria, and can consistently distinguish events in different likelihood categories.

- The methods for likelihood evaluation are consistent with the likelihood definitions and the process being evaluated (e.g., the methods correctly treat initiating events and initial conditions, subsequent failures, and dependent failures).

- The methods for likelihood evaluation appropriately consider all availability and reliability qualities of individual IROFS and the interdependencies between them in assigning qualitative likelihood scores.

- The ISA summary describes initiating events, initial conditions, and subsequent IROFS failures in detail sufficient to demonstrate that the performance requirements will be met and maintained.

Recommendations

This guidance should be used to supplement Chapter 3 and Appendix A to this SRP.

References

U.S. Code of Federal Regulations, Title 10, "Energy," Part 70, "Domestic Licensing of Special Nuclear Material."

U.S. Nuclear Regulatory Commission, "Standard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility," NUREG-1718, August 2000.

APPENDIX C

INITIATING EVENT FREQUENCY

Purpose

This appendix addresses the measures needed to ensure the validity and maintenance of the initiating event frequencies (IEFs) used to demonstrate compliance with Title 10 of the *Code of Federal Regulations* (10 CFR) 70.61, "Performance Requirements."

Introduction

The purpose of this appendix is to clarify the use of IEFs for demonstrating compliance with the performance requirements of 10 CFR 70.61. NUREG-1718, "Standard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility," issued August 2000, and this Standard Review Plan (SRP) provide methods for reviewing integrated safety analyses (ISAs) by employing a semi-quantitative risk index method. While one of these methods is described below to illustrate the use of IEFs, applicants and licensees may use other methods that would produce similar results. No particular method is explicitly mandated, and sequences that are risk significant or marginally acceptable are candidates for more detailed evaluation by the applicant or licensee and reviewer.

Discussion

Each licensee or applicant is required to perform an ISA to identify all credible high-consequence and intermediate-consequence events. The risk of each such credible event is to be limited through the use of appropriate engineered and/or administrative controls to meet the performance requirements of 10 CFR 70.61. Such a control is referred to as an item relied on for safety (IROFS). In turn, a safety program must be established and maintained to ensure that each IROFS is available and reliable to perform its intended function when needed. The safety program may be graded such that the management measures applied are graded commensurate with the reduction of risk attributable to that item. In addition, a configuration management system must be established pursuant to 10 CFR 70.72, "Facility Changes and Change Process," to evaluate changes and to ensure, in part, that the IROFS are not removed without at least equivalent replacement of the safety function.

The risk of each credible event is determined by cross-referencing the severity of the consequence of the unmitigated accident sequence with the likelihood of occurrence in a risk matrix with risk index values. The likelihood of occurrence risk index values can be determined by considering the criteria in Tables A-9 through A-11 in Appendix A to Chapter 3 of this SRP. Accident sequences result from initiating events that are followed by the failure of one or more IROFS. Initiating events can be (1) an external event such as a hurricane or earthquake, (2) a facility event external to the process being analyzed (e.g., fires, explosions, failures of other equipment, flooding from facility water sources), (3) deviations from normal operations of the process (credible abnormal events), or (4) failures of an IROFS in the process. (Appendix D to Chapter 3 offers additional guidance regarding initiating probabilities from natural phenomena hazards.)

An initiating event does not have to be an IROFS failure. An item becomes an IROFS only if the ISA credits it for mitigation or prevention per the definition in 10 CFR 70.4, "Definitions." If an item whose failure initiates an event has strictly an operational function, it does not have to be an IROFS. This applies to external events and can apply to internal events. If the item whose failure initiates an event has solely a safety function that is credited in the ISA, then it should be an IROFS. If the item has both an operational and a safety function, the safety function should make it an IROFS (for its ISA-credited safety features only).

IEFs can play a significant role in determining whether the performance requirements of 10 CFR 70.61 are met for a particular accident sequence. Whether an initiating event results from an IROFS or a non-IROFS failure, licensees should take appropriate action to ensure that any change to the basis for assigning an IEF value to that event is evaluated on a continuing basis to ensure continued compliance with the performance requirements. For example, a non-IROFS component may not be subject to the same quality assurance (QA) program controls and other management measures that an IROFS would receive (i.e., surveillance, testing, procurement). However, appropriate management controls should be considered, in a graded manner, to provide assurance that performance requirements are met over time. The ability to identify a non-IROFS component failure, similar to that for IROFS, may be needed to provide feedback on failure rates and IEFs to the ISA process. Changes to the IEF values may result from changes to a component's design, procurement, operation, or maintenance history, as well as new or increased external plant hazards, and should be considered in a graded approach.

Regulatory Basis

This guidance relies on the following regulatory bases:

- 10 CFR 70.61
- 10 CFR 70.62, "Safety Program and Integrated Safety Analysis"
- 10 CFR 70.65, "Additional Content of Applications"
- 10 CFR 70.72, "Facility Changes and Change Process"

Applicability

This guidance is for use in those cases where an applicant or licensee chooses to use an IROFS or non-IROFS failure IEF for risk determination.

Technical Review Guidance

1. Initiating Event Frequency and Identification of an IROFS

   Example

   A licensee uses a heater/blower unit to heat a uranium hexafluoride (UF_6) cylinder in a hot box to liquefy the contents before sampling. The unmitigated accident sequence involves the failure of the controller for the heater/blower resulting in overheating of the cylinder. This results in the cylinder becoming overpressurized and rupturing, which releases the UF_6 to the surrounding process area. Analysis of such a release indicates that it would exceed the performance requirements of 10 CFR 70.61. The licensee has two basic choices: (1) assume that the initiating event probability equals 1 and provide

an appropriate level of mitigation or prevention solely through one or more IROFS or (2) assign a value to the initiating event (blower/heater controller failure) and provide one or more preventive or mitigative IROFS to bring the accident sequence risk within the performance requirements.

If the licensee chooses the second option and assigns an appropriate value to the IEF, the indices of Table A-9 in Appendix A to Chapter 3 of this SRP may be used. The controller for the heater/blower unit would be assigned an appropriate frequency index number. The licensee would then analyze the accident sequence and determine whether additional IROFS are necessary to meet the performance requirements. There are now two variables that feed into the risk determination: one or more IROFS controllers for the heater/blower unit in a manner that changes the licensee's previous determination of compliance with the performance requirements must be evaluated per 10 CFR 70.72(a).

2. Initiating Event Frequency Index Use

Indices may be used to determine the overall likelihood of an accident sequence. Table A-9 of Appendix A to Chapter 3 of this SRP identifies frequency index numbers based on specified evidence. The evidence used by applicants and licensees should be supportable and documented in the ISA summary as required by 10 CFR 70.65(b)(4). The evidence cited in the ISA documentation should not be limited to anecdotal accounts and must demonstrate compliance with the definitions of "unlikely," "highly unlikely," and "credible" as required by 10 CFR 70.65(b)(9). The rigor and specificity of the documented evidence should be commensurate with the item's importance to safety, and the data should support the frequency chosen (e.g., data from 30 years of plant operating experience based on a single component typically could not be expected to support a 10^{-2} failure probability).

An item's failure rate should be determined from actual data for that specific component or safety function in the current system design under the current environmental conditions. When specific failure data are limited or not available, the applicant or licensee may use more "generic" data with appropriate substantiation. However, when less specific failure data are available, appropriate conservatism should be exercised in assigning frequency indices. The footnote to Table A-9 that states "Indices less than (more negative than) -1 should not be assigned to IROFS unless the configuration management, auditing, and other management measures are of high quality, because without these measures, the IROFS may be changed or not maintained" should also be applied to non-IROFS IEFs. In this case, appropriate management controls should be provided to ensure that any changes to the evidence supporting IEF indices will be identified and promptly evaluated to ensure that the performance requirements of 10 CFR 70.61 are met. A graded approach may be used in applying management controls based on the IEF values; however, the ISA summary should explain how this will be done.

The licensee or applicant should periodically evaluate possible changes to IEFs, failure rates, and the assumptions they are based on to ensure that the ISA process has accounted for any change to an IEF. Over time, an IEF may change because of component aging or deterioration. Maintenance and performance experience should be fed back into the IEF evaluation. IEF changes could involve, for example, the introduction of new effects or hazards from nearby processes or new materials or

changes in design, maintenance, or operation activities. The applicant or licensee should establish management measures, which may be graded, to periodically confirm that the ISA assumptions have not changed. For example, an applicant or licensee may choose to verify that there have been no changes to hazards from maintenance activities during a certain period of time based on an appropriate documented technical review or audit under the QA program.

Whatever strategy the applicant or licensee chooses should result in timely identification and periodic evaluation of failure rates, followed by a prompt evaluation of the failure rate change on the ISA assumptions. This can be accomplished in accordance with the corrective maintenance program and/or the QA problem identification and corrective action system.

Indices particularly relied on (i.e., less than -1) for overall likelihood will be examined during the ISA review process.

3. External Initiating Event Frequencies

The applicant or licensee should periodically evaluate possible changes to nonnatural phenomena external events to ensure that the ISA process has accounted for any change to an IEF. Such changes could involve, for example, the introduction of new hazards from an adjoining industrial site or changes in adjoining transportation activities. The applicant or licensee should establish management measures, which may be graded, to periodically confirm that the ISA assumptions have not changed. For example, an applicant or licensee may choose to verify that external hazards have not changed based on a 2- to 3-year review under the QA program.

4. Assurance

The safety program required by 10 CFR 70.62(a) should have provisions for implementing the appropriate management controls to maintain the validity of the IEFs. Consideration should also be given to commitments in the QA program or a specific license condition.

References

U.S. Code of Federal Regulations, Chapter I, Title 10, “Energy,” Part 70, “Domestic Licensing of Special Nuclear Material.”

U.S. Nuclear Regulatory Commission, “Standard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility,” NUREG-1718, August 2000.

APPENDIX D

NATURAL PHENOMENA HAZARDS

Purpose

This appendix provides additional guidance addressing accident sequences that may result from natural phenomena hazards in the context of a license application or an amendment request under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 70, "Domestic Licensing of Special Nuclear Material," Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material."

Introduction

This appendix provides additional guidance for reviewing the applicant's (or licensee's) evaluation of natural phenomena hazards up to and including "highly unlikely" events for both new and existing facilities.

Discussion

For facilities processing special nuclear materials, 10 CFR 70.61, "Performance Requirements," requires that individual accident sequences resulting in high consequences to workers and the public be "highly unlikely" and that sequences resulting in intermediate consequences to these receptors be "unlikely." Although the regulations establish the threshold levels that differentiate high-consequence events from intermediate-consequence events, they do not define "highly unlikely" and "unlikely." According to 10 CFR 70.65(b)(9) and subject to staff approval, the integrated safety analysis (ISA) summary submitted by applicants and licensees must include definitions of these terms. Chapter 3 of this NUREG further describes the acceptance criteria for the definitions of these terms.

The implementation of these requirements may vary somewhat because of different definitions of likelihood proposed by different applicants (or licensees).[1] The regulation specifies quantitative consequence thresholds of the performance requirements (except for chemical releases). The regulation and its performance requirements pertain to existing facilities, as well as proposed facilities, and apply to manmade external hazards and natural phenomena hazards, in addition to process hazards. However, new facilities and new processes at existing facilities must also address the requirements of 10 CFR 70.64, "Requirements for New Facilities or New Processes at Existing Facilities," which includes the baseline design criterion for natural phenomena hazards (10 CFR 70.64(a)(2)). This baseline design criterion requires that "the design must provide for adequate protection against natural phenomena with consideration of the most severe documented historical events for the site." The Statement of Considerations describes the application of the baseline design criteria as consistent with good engineering practice, which dictates that certain minimum requirements should be applied to design and safety considerations. The baseline design criteria must be applied to the design of new

[1] For natural phenomena, deterministically defined events such as the probable maximum flood (PMF) or safe-shutdown earthquake (SSE), which are used as reactor design bases, can also be applied to 10 CFR Part 70 facilities as "highly unlikely" events. The actual probability (or likelihood) of such events may be difficult to define quantitatively and varies from site to site.

facilities and new processes at existing facilities but does not require retrofits to existing facilities or existing processes (e.g., those housing or adjacent to the new processes). Also included in 10 CFR 70.64(b) are a requirement for incorporation of defense in depth in design and a requirement to prefer engineered controls over administrative controls.

New structures associated with facilities being reviewed, such as the gas centrifuge facilities and the mixed oxide fuel fabrication facility, will be designed and constructed to meet the seismic regulatory requirements. Hence, these facilities and additional new facilities to be licensed under 10 CFR Part 70 are not expected to present designs with seismic deficiencies. New facilities can also be expected to be sited above a "highly unlikely" flood such as the PMF and can be expected to withstand tornado winds and missiles, if necessary.

Most structures at existing nuclear fuel cycle facilities are built to a model building code, which includes meeting a design-basis earthquake having an exceedance probability of $2x10^{-3}$ per year to less than 10^{-3} per year (U.S. Department of Energy (DOE) Standard-1020-2002, "Natural Phenomena Hazards Design and Evaluation Criteria for Department of Energy Facilities," Appendix C). Existing facilities are generally sited above the 100-year flood plain and are designed for wind as well as snow and ice loading as specified in applicable building codes. Extreme natural events such as "highly unlikely" floods and/or earthquakes have not been calculated for many existing sites, and it would be expensive and time consuming to do so.

The staff believes that many existing facilities can be shown to be in compliance with, or at least near compliance with, the performance requirements of the regulation by accounting for conservatisms in the seismic, flooding, and wind design of the facility. In addition, relatively minor engineered improvements and administrative measures may further enhance safety, at least with respect to the public and other offsite receptors.

Seismic Hazards

Potential damage to and/or failure of items relied on for safety (IROFS) as the result of ground movement and/or the seismic response of adjacent or interior IROFS must be considered in the ISA and ISA summary accident sequence evaluations. Damage or failures that also should be considered include the following:

- seismic-induced failure of a facility component that is not an IROFS but that can fall and damage an IROFS (for example, a heavy load drop from a crane onto a container)
- displacement of adjacent IROFS during a seismic event causing them to pound together
- displacement of adjacent components resulting in failure of connecting pipes or cables which may cause flooding, fires, and/or releases of radiological or chemical materials

Seismic event evaluations should also consider potential multiple failure of IROFS (for example, multiple failures of tanks).

DOE has also recognized the difference between earthquake design probability and the probability that a safety component cannot perform its function. To quantify this difference, DOE has developed a risk reduction factor, R, as the ratio between the seismic hazard exceedance probability and the performance goal probability. Conservatism in nuclear facility design arising from factors such as use of prescribed analysis methods, specification of material

strengths, and limits on inelastic behavior explains at least part of this apparent reduction in actual risk. Appendix C to DOE Standard-1020-2002 discusses this risk reduction factor.

For a consequence to affect the public or external site workers, licensed material or hazardous chemicals that could affect the safety of licensed material must be released through at least one, and often two, confinement barriers, such as the following:

- storage containers, glove boxes, tanks, or handling devices
- ventilation system dynamic confinement and filtration
- building structural shell

Criticalities, on the other hand, may result from the introduction of a moderator or loss of safe geometric control of confined materials.

By using risk reduction factors calculated for a facility and its specific components and/or estimating the degree of failure by comparison with the observed behavior of similarly constructed buildings during severe earthquakes, analysts can postulate reasonable scenarios. These scenarios may not release all the material at risk or present an unimpeded leak path to receptors. For example, some facilities might be able to show that, even in the case of an earthquake that is "highly unlikely," only certain types of containers or confinement systems are likely to be breached. If the amount of material contained in such containers is variable, then that probabilistic component may be factored into the overall likelihood of the accident sequence. If employing some of these mitigating considerations in the analysis requires reliance on special containers or procedures, then additional IROFS may also be needed. Another factor to consider is the likely rate of release based on the damage sustained. For example, some facilities may lose dynamic confinement but maintain building integrity. In some processes, radiologically and/or chemically hazardous material is held inside its primary containment at subatmospheric pressure. In these cases, even though the primary containments are inside a structure designed to withstand less than a "highly unlikely" earthquake, the subatmospheric conditions may be sufficient to limit both facility worker and offsite doses in the event of a greater earthquake. For example, an earthquake that results in limited subatmospheric containment losses may allow adequately trained workers to evacuate and/or take mitigative actions. The buildings containing cylinders of liquid uranium hexafluoride (UF_6) at gas centrifuge facilities are designed for a "highly unlikely" earthquake. In addition, some buildings at one of the proposed facilities are equipped with a seismically activated interlock (an IROFS) that will shut off the buildings' heating, ventilation, and air conditioning system during an event, thus limiting any leakage of UF_6 to the outside.

Flooding Hazards

Most fuel cycle licensees do not require large quantities of cooling water and, therefore, do not need to be located near large bodies of water. A site licensed under 10 CFR Part 70 does not need to meet prescriptive flood protection requirements but does have to meet the performance requirements for all credible events including flooding. A site meeting the flood protection requirements of a commercial reactor should be considered as being designed or located adequately to withstand a "highly unlikely" flooding event. Section 2.4 of NUREG-1407, "Procedural and Submittal Guidance for the Individual Plant Examination of External Events (IPEEE) for Severe Accident Vulnerability," issued June 1991, states that the design-basis flood (which for river sites is the PMF) as described in Regulatory Guide 1.59, "Design Basis Flooding for Nuclear Power Plants," is estimated to have an exceedance frequency of less than 10^{-5} per

year. Sites that do not meet this level of protection can still meet the 10 CFR 70.61 performance requirements but must be considered on an individual basis.

In an evaluation of the effects of flooding on existing facilities, the following flood-related hazards should be considered:

- river flooding
  - inundation and hydrostatic loading
  - dynamic forces
  - wave action
  - sedimentation and erosion
  - ice loading
- upstream dam failures
  - inundation and hydrostatic loading
  - dynamic forces
  - erosion and sedimentation
- precipitation/local storm runoff
  - inundation (local ponding) and hydrostatic loading
  - dynamic loads (flash flooding)
- tsunami, seiche, hurricane storm surge
  - inundation and hydrostatic loading
  - dynamic forces
  - wave action

American National Standards Institute/American Nuclear Society Standard 2.8, “Determining Design Basis Flooding at Power Reactor Sites,” issued July 1992, describes methods for determining these flooding and water-related effects for reactor sites. These methods can be applied to 10 CFR 70.61 analyses with less conservatism in some of these parameters.

A standard siting requirement for residential and commercial developments is to be above the 100-year flood plain. For large river basins, warning time and time to secure materials and evacuate personnel will probably be available. For small streams, there may be relatively little warning in regard to thunderstorms and localized rainfall. In such cases, rapid actions may be the only administrative protection available. An evaluation of the effectiveness of proposed protection will need to consider the effects of inundation, hydrostatic loading, erosion, and sedimentation. At a minimum, this would require that criticality events be prevented and materials remain confined within site structures.

At some sites, a delineation of the 500-year flood plain may also be available. If the site is above the 500-year flood plain, flooding may be considered an unlikely[2] event, depending on the quality of the estimate. In this category, criticality events should still be prevented, but the breaching of a limited number of material containers may be allowable under the performance requirements (up to 25 rem for the public, up to 100 rem for workers, and a specified release limit) for events that, in terms of likelihood, are between "unlikely" and "highly unlikely."

In addition to the facility's location relative to the 100-year or 500-year flood plains, the effects of local intense precipitation and snow load should be considered. Local intense precipitation, especially in the form of snow, can result in roof collapse and localized site flooding. Normally, protection from local precipitation and snow is relatively easy to achieve through roof design and local site drainage design.

Wind and Tornado Loading

Wind design for an existing facility if prescribed by an applicable building code would have an annual exceedance probability of greater than or equal to $2x10^{-2}$. At such relatively high probabilities, tornado design criteria are not specified. However, depending on the geographic location of the facility, the effects of a tornado with an annual exceedance probability of 10^{-5} or greater may need to be considered.

Wind forces on walls of structures should be determined using appropriate pressure coefficients, gust factors, and other site-specific adjustments. If the wind is likely to blow inside the structure, either through design or wind-driven missile vulnerability, the effects of wind on internal IROFS requires consideration. If the winds are from a tornado, the effects of the atmospheric pressure change associated with the tornado must be considered. Normally, ventilation systems are most vulnerable to atmospheric pressure change, but windows, buried tanks, and sand filters can also be affected.

For straight winds, hurricanes, and weak tornadoes, missile criteria as specified in Table 3-3 of DOE Standard-1020-2002 may be considered. The missile specified is a 15-pound plank, measuring 2 inches by 4 inches, at a specified elevation and impact velocity. For facilities that may be subjected to more severe tornado missiles, the guidance in Tables 3-4 and 3-5 of DOE Standard-1020-2002 may be followed. For the tornado, a 3,000-pound automobile rolling and tumbling on the ground should also be considered. For such evaluations, the probability of the entire sequence should be considered, and missile criteria from either Table 3-4 or 3-5 of DOE Standard-1020-2002 may be used as appropriate.

Considerations for Existing Processes at Existing Facilities

For existing processes at existing facilities, licensees are not required to address 10 CFR 70.64 baseline design criteria. However, they must still meet the performance requirements of 10 CFR 70.61, including accidents caused by natural phenomena, for which the staff may require additional IROFS to meet the performance requirements. Existing facilities can use IROFS in the form of additional administrative controls to meet the performance requirements

[2] Even if the licensee defines "unlikely" as less than 10^{-3} per year for the process sequences in the ISA summary, the conservative assumptions inherent in most flood plain hydrologic studies, such as those performed for Federal Emergency Management Agency flood insurance rate maps, should justify the consideration of flooding above the 500-year flood plain as an unlikely event.

without the need for design features normally required by accepted engineering practice. When near compliance can be achieved and complete compliance will be relatively costly, plants may request an exemption to the regulation.

As discussed earlier, many existing 10 CFR Part 70 facilities are not designed for an earthquake beyond that specified in applicable building codes. Although this design may provide fairly good seismic protection to the structure, it may not protect internal equipment. Also, an existing facility may not be designed to any specific seismic criteria, in which case its ability to withstand earthquakes can only be estimated based on comparison with similar structures or through complex structural analysis. In such cases, licensees may add IROFS to meet the performance requirements. An example of such IROFS (procedures and upgrades) being effectively implemented would be a facility where the consequences of a release of licensed material to the public in a seismic event would be from fires and/or explosions. In this case, fixes such as seismically qualified flammable gas shutoff valves or electrical shutoffs might provide a large decrease in potential seismic consequences.

In regard to flooding, flood elevations beyond that of the 100-year flood may not have been determined for the site. For sites in proximity to a river, these determinations could be expensive and time consuming. For these cases, flood warning time may allow measures such as moving material at risk and/or blocking doors and openings in the facility structure.

A facility's ability to withstand high winds, rain and snow loads, and exterior fires can likewise be improved through a combination of administrative procedures and engineered improvements. Removing material at risk from under walls or roofs that are not seismically designed can reduce potential releases in case of collapse from winds or roof loads.

Exemptions to the regulation may still be required for existing facilities even with administrative and engineered improvements. In regard to consequences to the public, complete compliance with 10 CFR 70.61 using realistic assumptions should be the goal. Compliance with 10 CFR 70.61 regarding consequences to facility workers may require a request for an exemption once personnel protective equipment, emergency procedures, and worker training are taken into account. In the evaluation of a request for an exemption to the regulation, the expected operational life of the facility should also be factored into the determination of risk.

Considerations for New Processes at Existing Facilities

The design of new processes at existing facilities must address natural phenomena hazards in accordance with 10 CFR 70.64(a)(2), as well as the performance requirements of 10 CFR 70.61. Nevertheless, new processes at existing facilities may present the same problems in demonstrating compliance with 10 CFR 70.61 in regard to accident sequences initiated by natural phenomena as do existing facilities based on the design and/or siting of the original structures. In the case of new processes, the U.S. Nuclear Regulatory Commission staff should expect compliance with the performance requirements of 10 CFR 70.61 to the extent possible, given the existing facility design and location. New processes at existing facilities also must meet the requirements of 10 CFR 70.64(b), which requires defense in depth and a preference for engineered controls over administrative controls. However, the staff cannot require structural improvements, permanent flood barriers, and other engineered improvements that could be considered retrofits to be applied to existing structures. New structural features within existing structures to prevent breaches in containment in the event of natural phenomena hazards may be considered, however. An example might be a seismically designed vault to hold radioactive materials associated with a new process. In regard to new

processes, engineered controls, where feasible, are preferred over administrative procedures that might otherwise be proposed for an existing process with a limited operational lifetime. Such engineered improvements may not be required for licensing but could be scheduled to replace administrative procedures or other long-term compensatory measures on a timely basis after the start of operations. The objective is to encourage engineered safety in new processes compared to equivalent existing processes, while recognizing the restraints of the existing structures and location. Although primarily aimed at reducing risk to the public, the emphasis on engineered safety may also be applied to worker consequences in a way consistent with the method accepted at other facilities.

Regulatory Basis

The regulation in 10 CFR 70.61 specifies performance requirements associated with risks identified by an ISA.

For new facilities or new processes at existing facilities, 10 CFR 70.64 specifies requirements, including Baseline Design Criterion (a)(2), "Natural Phenomena Hazards."

Technical Review Guidance

When examining the applicant's evaluation of the effects of natural phenomena on its facility, reviewers should recognize that estimates of "unlikely" and "highly unlikely" natural phenomena such as the PMF or SSE may not exist for the particular site. Hence, extrapolation and/or transposition of extreme event estimates made for other relatively nearby facilities (such as power reactor sites) should be allowed where feasible and technically justifiable. In addition, sophisticated probabilistic tools such as Bayesian analysis or Monte Carlo sampling methods need not be employed to improve the estimate of likelihoods of natural phenomena event sequences unless desired by the applicant (or licensee). For the purpose of determining appropriate values of extreme events, deterministic events such as the PMF or SSE can be used in place of purely probabilistically determined "highly unlikely" events and may be preferable, depending on the quality of historical data. Where extreme events need to be coupled with other probability-driven mechanisms, such as the release fraction or transport pathway, already low likelihood combinations do not have to be made even less likely by the use of conservative parameters.

For existing facilities, due credit should be given to analysis assumptions and administrative controls, emergency procedures, and active engineered controls that do not change the design bases of the facility structures to natural phenomena. If the ISA and ISA summary demonstrate that the existing facility is near compliance (within an order of magnitude of a likelihood threshold or within 50 percent of meeting a consequence threshold, but not both), an exemption to the regulation may be considered.

The annex to this appendix presents an example of an evaluation for an amendment request.

Recommendation

This guidance should be used to supplement Chapter 3 of this SRP.

References

American National Standards Institute/American Nuclear Society, “Determining Design Basis Flooding at Power Reactor Sites,” ANS-2.8, July 1992.

U.S. Code of Federal Regulations, Chapter I, Title 10, “Energy,” Part 70, “Domestic Licensing of Special Nuclear Material.”

U.S. Department of Energy, “Natural Phenomena Hazards Design and Evaluation Criteria for Department of Energy Facilities,” DOE Standard-1020-2002, 2002.

U.S. Nuclear Regulatory Commission, “Domestic Licensing of Special Nuclear Material; Possession of a Critical Mass of Special Nuclear Material,” *Federal Register*, Vol. 65, No. 181, pp. 56211–562331, September 18, 2000.

U.S. Nuclear Regulatory Commission, “Procedural and Submittal Guidance for the Individual Plant Examination of External Events (IPEEE) for Severe Accident Vulnerabilities,” NUREG-1407, June 1991.

U.S. Nuclear Regulatory Commission, “Design Basis Flooding for Nuclear Power Plants,” Regulatory Guide 1.59, Revision 2, August 1997.

ANNEX TO APPENDIX D

EXAMPLE OF NATURAL PHENOMENA HAZARD REVIEW FOR COMPLIANCE WITH 10 CFR 70.61

This example review is for an amendment to authorize operations in a blended low-enriched uranium oxide conversion building (OCB). The site is located near a river and is just above the 100-year flood plain of a nearby creek. The effluent process building was also part of the amendment but was not evaluated because the quantities of radioactive material or hazardous chemicals (that come under U.S. Nuclear Regulatory Commission (NRC) regulation) that it contained are not considered sufficient to exceed the consequence threshold for "unlikely" events given in Title 10 of the *Code of Federal Regulations* (10 CFR) 70.61, "Performance Requirements."

Seismic Evaluation

The OCB is of reinforced concrete construction and is built to seismic criteria in the Standard Building Code (SBC-1999), which is equivalent to being designed for an earthquake with a probability of exceedance of approximately 4×10^{-4} per year. Using Appendix C to U.S. Department of Energy (DOE) Standard-1020-2002, "Natural Phenomena Hazards Design and Evaluation Criteria for Department of Energy Facilities," the NRC staff determined the risk reduction factor to be 4, which gives the structure a likelihood of significant damage from an earthquake of 10^{-4} per year or less. Hence, the collapse or loss of building integrity from an earthquake may be considered to be "highly unlikely," as the probabilistic value of "highly unlikely" indicated by the applicant was a probability of exceedance of 10^{-4} to 10^{-5} per year. Within the building, the material at risk consists of low-enriched uranyl nitrate liquid, ammonium diuranate slurry, and uranium dioxide powder. All of these materials are expected to be within containers, and spillage during a seismic event is expected to be minimal. Since the building is expected to retain its integrity, the leak path factor will be relatively minor even without dynamic confinement from the ventilation system. Facility workers are expected to take actions to limit personal intake of radionuclides. The staff concludes that the OCB complies with the performance requirements of 10 CFR 70.61 with regard to seismic events.

High-Winds Evaluation

The OCB structure is also designed for wind loads in accordance with SBC-1999, and the probability of a tornado impacting the facility is less than 10^{-5} per year. Therefore, the facility needs to be evaluated only in regard to the effects of wind loads and missiles, but not for tornadoes. The NRC staff considers the reinforced concrete exterior walls of the OCB to be adequate to withstand high wind velocities, as well as the missiles (from DOE Standard-1020-2002) that should be assumed for such events. The staff considers a collapse of building walls because of wind forces such that radioactive material would escape to be "highly unlikely." In addition, the meteorological conditions likely to result in severe winds may be forecast in advance and protective measures taken. The staff concludes that the OCB complies with the performance requirements of 10 CFR 70.61 with regard to wind events.

Flooding Evaluation

The lowest floor in the OCB is 15 feet above the 100-year flood from an adjacent creek. From a review of the topography of the site area, it appears that flooding of the site could occur, most likely from flooding of the nearby river with coincident flooding of the adjacent creek, which could back up through the railroad culvert. This event is expected to have warning time and may overtop the railroad embankment to the north of the facility and flood parts of the nearby town. However, the facility is sufficiently removed from the main channel of the river that flood-induced scouring and erosion would not be expected. In addition, the hydrostatic loading from the flood on the exterior walls of the OCB would not be expected to cause collapse. The primary concern is inundation, which could float unsecured containers within the OCB but not remove them from the facility. A criticality event cannot be excluded, but it could occur only in the flooded and, therefore, evacuated section of the plant and would not affect facility workers. In addition, the warning time would allow the movement of material to reduce the likelihood of a flood-induced criticality. The staff concludes that the OCB complies with the performance requirements of 10 CFR 70.61 with regard to flooding.

REFERENCES

U.S. Code of Federal Regulations, Chapter I, Title 10, “Energy,” Part 70, “Domestic Licensing of Special Nuclear Material.”

U.S. Department of Energy, “Natural Phenomena Hazards Design and Evaluation Criteria for Department of Energy Facilities,” DOE Standard-1020-2002, 2002.

APPENDIX E

HUMAN FACTORS ENGINEERING FOR PERSONNEL ACTIVITIES

The purpose of this review is to establish that human factors engineering (HFE) is applied to personnel activities identified as safety significant, consistent with the findings of the integrated safety analysis (ISA), and the determination of whether an item relied on for safety (IROFS) has special or unique safety significance. A graded approach commensurate with the complexity and integration and operation of the control systems is appropriate. The application of HFE to personnel activities ensures that the potential for human error in the facility operations was addressed during the design of the facility by facilitating correct, and inhibiting wrong, decisions by personnel and by providing a means for detecting and correcting or compensating for error.

Title 10 of the *Code of Federal Regulations* (10 CFR) 70.61(e) requires a safety program to ensure that each IROFS will be available and reliable to perform its intended function when needed. Therefore, the applicant should identify those "personnel activities[1]" that are considered IROFS and personnel activities that support safety (e.g., maintenance). An HFE review should be performed to demonstrate compliance with 10 CFR 70.61(e). Also, the applicant should demonstrate how personnel activities will enhance safety by reducing challenges to IROFS, as required in 10 CFR 70.64(b)(2).

A human factors specialist and an ISA reviewer should conduct the human factors review. The review should also be coordinated with the reviewers of other technical areas and the reviewer of management measures, as necessary.

AREAS OF REVIEW AND ACCEPTANCE CRITERIA

Some facilities rely heavily on automated systems employing advanced digital instrumentation and control technology. These systems may be complex, with potential negative impacts on human performance activities in both operations and maintenance. The scope of review for the HFE for personnel activities should be consistent with the results of the ISA and include the following, as appropriate[2]:

A. Identification of Personnel Activities—The applicant should appropriately identify the personnel activities such that the reviewer can understand the actions, the human-systems interfaces (HSIs) involved, and the consequences.

B. HFE Design Review Planning—The applicant's approach for planning HFE design review should include the following:

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[1] For the purposes of this chapter, the phrase "personnel activities" represents personnel activities identified as IROFS and personnel activities that support safety, such as maintenance.

[2] All nine areas of review (A through I) may not be necessary for a specific application. Areas of review should be based on the applicant's provisions to address personnel activities consistent with the ISA findings, the similarity of the associated HFE issues for similar type plants, and the determination of whether an IROFS has special or unique safety significance.

i. Identification of appropriate goals and scope to ensure that HFE practices and guidelines are implemented during design, construction, and operation of the facility.

ii. Implementation by an HFE team that has the appropriate composition, experience, and organizational authority to ensure that HFE is considered in the design of HSI for personnel activities. The HFE team's responsibilities include ensuring the proper development, execution, oversight, and documentation of the HFE function. Depending on the identification of personnel activities, it may be appropriate for the HFE team to consist of a single individual.

iii. An HFE team that attains the HFE goals and scope through established processes and procedures and that tracks HFE issues. The HFE function that should ensure that all aspects of the personnel activities including the HSI are developed, designed, and evaluated on the basis of a structured approach using HFE.

C. Operating Experience Review (OER)—To the extent possible, the applicant should identify safety-related HFE events or potential events in existing facilities that are similar to the proposed facility. The applicant should do all of the following:

i. Review the HFE-related events or potential events for relevance.

ii. Analyze the HSI technology employed for the relevant HFE events or potential events.

iii. Conduct (or review existing) operator interviews and surveys on the HSI technology for the relevant HFE events or potential events.

D. Functional Allocation Analysis and Task Analysis

i. The functional allocation analysis should be based on the OER. Personnel activities should be functionally allocated to take advantage of human strengths and to avoid demands that are not compatible with human capabilities.

ii. The task analysis should include the task analysis scope, identification, and analysis of critical tasks; detailed description of personnel demands (e.g., input, processing, and output); iterative nature of the analysis; and incorporation of job design issues. The task analysis should address each operating mode for each personnel activity (e.g., startup, normal operations, emergency operations, and shutdown). The task analysis results support the functional allocation.

E. HSI Design, Inventory, and Characterization—The HSI design should incorporate the functional allocation analysis and task analysis into the detailed design of safety-significant HSI components (e.g., alarms, displays, controls, and operator aids) through the systematic application of HFE. The HSI design should include the overall work environment, the work space layout (e.g., control room and remote shutdown facility layouts), the control panel and console design, the control and display device layout, and information and control interface design details. The HSI design process should ensure the application of HFE to the HSI required to perform personnel activities. The HSI

design process should exclude the development of extraneous controls and displays. The HSI design documentation should include a complete HSI inventory and the basis for the HSI characterization.

F. Staffing—Staffing should be based on a review of the number and qualifications of personnel for each personnel activity during all plant operating conditions. The applicant should conduct this review in a systematic manner that incorporates the functional allocation and task analysis results.

Categories of personnel should be based on the types of personnel activities. Staffing considerations should include issues identified in the OER, functional allocation, HSI design, procedure development, and verification and validation (V&V).

G. Procedure Development—The applicant's procedure development for personnel activities should incorporate HFE principles and criteria, along with all other design requirements, to develop procedures that are technically accurate, comprehensive, explicit, easy to use, and validated consistent with the acceptance criteria in this Standard Review Plan. Because procedures are considered an essential component of the HSI design, they should be derived from the same design process and analyses as the other components of the HSI (for example, displays, controls, operator aids) and subject to the same evaluation processes. Procedures to support the personnel activity may include generic technical guidance, plant and system operations, abnormal and emergency operations, tests (for example, preoperational, startup, and surveillance), and alarm response.

H. Training Program Development—The applicant's training program development should address all personnel activities. The training program development indicates how the knowledge and skill requirements of personnel will be evaluated, how the training program development will be coordinated with the other activities of the HFE design process, and how the training program will be implemented in an effective manner consistent with human factors principles and practices.

The training program development should address the areas of review and acceptance criteria described in Chapter 11 of this SRP and should result in a training program that provides personnel with qualifications commensurate with their activities.

I. Verification & Validation—V&V confirms that the design incorporates HFE to HSI in a manner that enables the successful completion of personnel activities. The V&V should be applied to personnel activities (see item A) and HSI design (see item E). The V&V process should consist of the following:

i. HSI task support verification: HSI components should be appropriately provided for personnel activities through HSI task support verification. The verification should show that each HSI has identified the task analysis (see item D(ii)) and that the HSI design (see item E) is appropriately provided, yet minimizes the incorporation of information, displays, controls, and embellishments that unnecessarily complicate personnel activities.

ii. HFE design verification: The HFE design verification should show that each HSI identified for a personnel activity has incorporated HFE into the design. Deviations from accepted HFE principles and guidelines should be justified or documented for resolution or correction. If HFE design verification does not address all HSI components, then an alternative multidimensional sampling

methodology should be used to ensure comprehensive consideration of the safety significance of HSI components. The sample size should be sufficient to identify a range of significant safety issues.

iii. Integrated system validation: The applicant should conduct a performance-based evaluation of the integrated design to ensure that the HFE/HSI supports safe operation of the plant. Integrated system validation is performed after HFE problems identified in HFE design activities are resolved or corrected because these may negatively affect performance and, therefore, validation results. Validation is performed by evaluating personnel activities using appropriate measurement tools. All personnel activities should be tested and found to be adequately supported in the design, including personnel activities outside the control room.

iv. Human factors issue resolution verification: The applicant should verify that HFE issues identified during the design process were addressed and resolved. Issue resolution verification should be documented in the HFE issue tracking system established by the HFE team (see item B). Issues that cannot be resolved until the HSI design is constructed, installed, and tested should be identified and incorporated into the final HFE/HSI design verification.

v. Final HFE/HSI design verification: The applicant should commit to performing a final HFE/HSI design verification if the applicant cannot demonstrate that it has fully evaluated the actual installation of the final HSI design in the plant through the V&V activities described above. Final HFE/HSI design verification should demonstrate that in-plant HFE design implementation conforms to the HFE design (see item E) as modified by V&V activities. V&V activities should be performed in the order listed above, as necessary. However, the applicant may find that it is necessary to repeat the activities in order to address design corrections and modifications that occur during V&V.

REFERENCES

U.S. Code of Federal Regulations, Chapter I, Title 10, “Energy,” Part 70, “Domestic Licensing of Special Nuclear Material.”

U.S. Nuclear Regulatory Commission, “Standard Review Plan for the Review of a License Application for a Mixed Oxide Fuel Fabrication Facility,” NUREG-1718, August 2000.

4. RADIATION PROTECTION

4.1 Purpose of Review

The purpose of this review is to determine, consistent with Title 10, "Energy," of the *Code of Federal Regulations* (10 CFR) 70.23(a)(2), (3), and (4), 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 Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations"; 10 CFR Part 20, "Standards for Protection Against Radiation"; 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material", and 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

The content and level of detail in this chapter are generally greater than in other chapters because this chapter provides acceptance criteria for evaluating compliance with 10 CFR Part 20, which has very specific requirements. The applicant should also incorporate, and the U.S. Nuclear Regulatory Commission (NRC) reviewer should consider, insights gained from the conduct of the integrated safety analysis (ISA) and information contained in the ISA summary in developing and reviewing the acceptability of the applicant's radiation-protection program. In addition, the reviewer should evaluate the adequacy of the ISA summary with respect to ensuring that the application meets the radiation exposure performance criteria of 10 CFR 70.61(b) and (c). Chapter 9 of this Standard Review Plan (SRP), which discusses environmental protection, contains the review procedures and acceptance criteria for the applicant's program for protecting members of the public and controlling effluent releases.

4.2 Responsibility for Review

Primary: Health Physicist

Secondary: Licensing Project Manager, Environmental Reviewer

Supporting: Fuel Cycle Facility Inspector

4.3 Areas of Review

The radiation protection program must address the occupational radiation protection measures in 10 CFR Parts 19, 20, 70, and 71. Specifically, licensees must develop, document, and implement a radiation protection program in accordance with 10 CFR 20.1101, "Radiation Protection Programs." Additionally, 10 CFR 20.2102, "Records of Radiation Protection Programs," requires licensees to keep records of the radiation protection program, including a description of the program components, audits, and other aspects of program implementation. The reviewer should also refer to the ISA summary to identify those facility operations analyzed in the ISA that have radiological consequences and the associated items relied on for safety (IROFS) and management measures implemented to prevent or mitigate such radiological risks. The ISA review should include a judgment as to the comprehensiveness of evaluations performed by the licensee.

The staff will review an applicant's commitments regarding the following components of the radiation protection program:

1. Establish, maintain, and implement a radiation protection program.

2. Keep occupational exposures to radiation as low as reasonably achievable (ALARA).

3. Appoint radiological protection staff who are suitably qualified and trained in radiation protection procedures.

4. Prepare written radiation protection procedures and radiation work permits (RWPs).

5. Train employees in radiation protection, including the health protection problems associated with exposure to radiation, precautions and procedures to minimize exposure, and the purposes and functions of protective devices employed.

6. Design and implement programs to control airborne concentrations of radioactive material by using ventilation systems, containment systems, and respirators.

7. Conduct radiation surveys and monitoring programs to document radiation levels, concentrations of radioactive materials in the facility, and occupational exposures to radiation by workers.

8. Evaluate the radiological risks from accidents occurring during operations; identify IROFS that limit high and intermediate consequences, consistent with regulatory performance criteria; and have appropriate management measures in place to ensure that identified IROFS are available and reliable.

9. Maintain additional programs, including (1) a records maintenance program, (2) a corrective action program, and (3) a program for reporting to the NRC in accordance with requirements in 10 CFR Part 20 and 10 CFR Part 70.

Review Interfaces

In addition to Chapter 4 of the application, the reviewer should examine information in the following other areas to ensure that it is consistent with the information in Chapter 4:

- The emergency plan applicable to radiation protection under SRP Chapter 8.
- The safety program, ISA commitments, and ISA documentation applicable to radiation protection under SRP Chapter 3.
- The environmental and effluent monitoring, as well as any effluent controls applicable to radiation protection under SRP Chapter 9.

Procedural, document control, and training criteria may also be addressed in response to Chapter 11 as these may be considered management measures and/or IROFS.

4.4 Acceptance Criteria

4.4.1 Commitment to Radiation-Protection Program Implementation

4.4.1.1 Regulatory Requirements

Regulations in 10 CFR 20.1101 apply to the establishment of a radiation protection program.

4.4.1.2 Regulatory Guidance

The NRC regulatory guide applicable to the commitment to design and implement a radiation protection program is Regulatory Guide 8.2, "Administrative Practices in Radiation Surveys and Monitoring," issued May 2011.

4.4.1.3 Regulatory Acceptance Criteria

In accordance with Subpart B, "Radiation Protection Programs," of 10 CFR 20, the purpose of the radiation protection program is to maintain occupational and public doses below regulatory limits and ALARA. The applicant's radiation protection program will be acceptable if it includes:

1. A documented management commitment to keep exposures ALARA;

2. A trained and qualified radiation protection organization with independence from the facility's operations, well-defined responsibilities, and sufficient authority to carry out those responsibilities;

3. Adequate facilities, equipment, and procedures to effectively implement the program; and

4. The review, at least annually, of the radiation protection program's content and implementation, as required by 10 CFR 20.1101(c). The review should consider facility changes, new technologies, and other process enhancements that could improve the effectiveness of the overall program.

4.4.2 Commitment to an ALARA Program

4.4.2.1 Regulatory Requirements

Regulations in 10 CFR 20.1101 apply to the ALARA program.

4.4.2.2 Regulatory Guidance

The following NRC regulatory guides are applicable to the ALARA program:

1. Regulatory Guide 4.21, "Minimization of Contamination and Radioactive Waste Generation: Life Cycle Planning," June 2008

2. Regulatory Guide 8.2

3. Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable," Revision 1-R, May 1977

4. Regulatory Guide 8.13, "Instructions Concerning Prenatal Radiation Exposure," Revision 3, June 1999

5. Regulatory Guide 8.15, "Acceptable Programs for Respiratory Protection," Revision 1, October 1999

6. Regulatory Guide 8.29, “Instructions Concerning Risks from Occupational Radiation Exposure,” February 1996

4.4.2.3 Regulatory Acceptance Criteria

The applicant’s ALARA program is acceptable if the license application provides data and information that meet each of the following commitments:

1. Establish a written, comprehensive, and effective ALARA program.

2. Prepare policies and procedures to ensure that occupational radiation exposures are maintained ALARA and that such exposures are consistent with the requirements of 10 CFR 20.1101.

3. Outline specific ALARA program goals, establish an ALARA program organization and structure, and include written procedures for its implementation in the plant design and operations.

4. Establish an ALARA committee or equivalent organization with sufficient staff, resources, and clear responsibilities to ensure that the occupational radiation exposure does not exceed the dose limits of 10 CFR Part 20 under normal operations.[1]

5. Use the ALARA program as a mechanism to facilitate interaction between radiation protection and operations personnel.

6. Regularly review and revise, when appropriate, the ALARA program goals and objectives and incorporate, when appropriate, new approaches, technologies, operating procedures, or changes that could reduce potential radiation exposures at a reasonable cost.

4.4.3 Organization and Personnel Qualifications

4.4.3.1 Regulatory Requirements

Regulations in paragraph (a)(6) of 10 CFR 70.22, “Contents of Applications,” apply to the organization and qualifications of the radiological protection staff.

4.4.3.2 Regulatory Guidance

The following are the NRC regulatory guides applicable to the organization and personnel qualifications of radiation protection program staff:

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[1] The ALARA committee should meet at least annually, and the membership should include areas such as management, radiation protection, environmental safety, industrial safety, and production. The committee’s review of the ALARA program should include an evaluation of the results of audits made by the radiation-protection organization, reports of radiation levels in the facility, contamination levels, employee exposures, and effluent releases. The review should determine whether there are any upward trends in personnel exposure for identified categories of workers and types of operations. The review should identify any upward trends in effluent releases and contamination levels. Finally, the review should determine whether exposures, releases, and contamination levels are in accordance with the ALARA concept. The ALARA committee should document its recommendations and track them to completion.

1. Regulatory Guide 8.2

2. Regulatory Guide 8.10

4.4.3.3 Regulatory Acceptance Criteria

The applicant's commitment to organize and staff a radiation protection program is acceptable if the license application provides data and information that meet each of the following commitments:

1. Appoint radiation protection personnel and identify their authority and responsibilities for implementing the radiation protection program functions.

2. Establish clear organizational relationships among the individual positions responsible for the radiation protection program and other line managers.

3. Appoint a suitably educated, experienced, and trained radiation protection program director (typically referred to as the radiation safety officer) who (1) has direct access to the plant manager, (2) is skilled in the interpretation of data and regulations pertinent to radiation protection, (3) is familiar with the operation of the facility and radiation protection concerns of the site, (4) participates as a resource in radiation safety management decisions, and (5) will be responsible for establishing and implementing the radiation protection program.

4. Describe the minimum education, experience, and training requirements for the radiation protection program director and staff.

4.4.4 Commitment to Written Procedures

4.4.4.1 Regulatory Requirements

The regulations in 10 CFR 70.22(a)(8) apply to radiation protection procedures and RWPs.

4.4.4.2 Regulatory Guidance

The regulatory guidance applicable to procedures and RWPs appears in Regulatory Guide 8.10, Revision 1-R.

4.4.4.3 Regulatory Acceptance Criteria

The applicant's commitment to prepare written radiation protection procedures and RWPs is acceptable if the license application provides data and information that meet each of the following commitments:

1. Prepare written, approved procedures to carry out activities related to the radiation protection program. Procedures should address applicable radiation protection requirements found in 10 CFR 19, 20, 70, and 71 and any other applicable regulations.

2. Establish a process for procedure generation or modification, authorization, distribution, and training, such that changes in technology or practices are communicated effectively and in a timely manner. Review and revise procedures, as necessary, to incorporate any facility or operational changes, including changes in the ISA. The radiation safety officer, or an individual who has the qualifications of the radiation safety officer, should approve all procedures related to radiation protection.

3. Specify written, approved RWPs for activities involving licensed material that are not covered by written radiation protection procedures. RWPs should define the authorized activities, the level of approval required (a radiation specialist, as a minimum), information requirements, period of validity, expiration and termination times, and recordkeeping requirements.

4.4.5 Radiation Safety Training

The SRP addresses an applicant's commitments to employee training in several places. This chapter addresses corporate radiation protection training programs, and Chapter 11 discusses training that serves as a management measure for ensuring that an administrative control IROFS is available and reliable when required.

4.4.5.1 Regulatory Requirements

The following regulations apply to the radiation safety training program:

1. 10 CFR 19.12, "Instructions to Workers"

2. 10 CFR 20.2110, "Form of Records"

3. 10 CFR 70.22, paragraph (a)(6)

4.4.5.2 Regulatory Guidance

The following NRC regulatory guides, reports of the National Council on Radiation Protection (NCRP), and standards of the American National Standards Institute (ANSI)/Health Physics Society (HPS) and the American Society for Testing and Materials pertain to radiation protection training:

1. Regulatory Guide 8.10

2. Regulatory Guide 8.13

3. Regulatory Guide 8.29

4. ANSI/HPS N13.36, "Ionizing Radiation Safety Training for Workers," October 30, 2001, reaffirmed July 19, 2011

5. ASTM E1168-95, "Radiological Protection Training for Nuclear Facility Workers," reapproved in 2008

6. NCRP Report No. 134, "Operational Radiation Safety Training," 2000

4.4.5.3 Regulatory Acceptance Criteria

The applicant's commitment to train its employees in radiation protection is acceptable if the license application provides data and information that meet each of the following commitments:

1. Design and implement an employee radiation protection training program that complies with the requirements of 10 CFR Parts 19 and 20.

2. Provide training to all personnel and visitors entering restricted areas that is commensurate with the health risk to which they may be exposed, or provide escorts who have received the appropriate training.

3. Provide a level of training commensurate with the potential radiological health risks associated with that employee's work responsibilities.

4. Conduct refresher training, at least every 3 years that will accurately address changes in policies, procedures, requirements, and the facility ISA.

5. Incorporate into the radiation protection training program the provisions in 10 CFR 19.12 and additional relevant topics, such as the following (the asterisk denotes those topics with a basis in 10 CFR 19.12):

    a. correct handling of radioactive materials

    b. the storage, transfer, or use of radiation or radioactive material as relevant to the individual's activities*

    c. minimization of exposures to radiation or radioactive materials*

    d. access and egress controls and escort procedures

    e. radiation safety principles, policies, and procedures*

    f. monitoring for internal and external exposures

    g. radiation exposure reports available to workers*

    h. monitoring instruments

    i. contamination control procedures, including protective clothing and equipment*

    j. ALARA and exposure limits*

    k. radiation hazards and health risks*

    l. emergency response*

    m. responsibility to report promptly any condition that may lead to, or cause, a violation of regulations and licenses or create unnecessary exposure*

6. Review and evaluate the accuracy, effectiveness, and adequacy of the radiation protection training program curriculum and instructors, as applicable, at least every 3 years.

4.4.6 Ventilation and Respiratory Protection Programs

4.4.6.1 Regulatory Requirements

Subpart H, "Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas," of 10 CFR Part 20 and 10 CFR 70.22(a)(7) apply to the ventilation and respiratory protection programs.

4.4.6.2 Regulatory Guidance

The following NRC regulatory guides, ANSI standards, and other publications apply to the design of the ventilation and respiratory protection programs:

1. Regulatory Guide 4.21

2. Regulatory Guide 8.15

3. Regulatory Guide 8.24, "Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication," Revision 2, June 2012

4. American Conference of Governmental Industrial Hygienists (*ACGIH), "*Industrial Ventilation: A Manual of Recommended Practice for Design," ACGIH 2096, 2010

5. *ACGIH, "*Industrial Ventilation: A Manual of Recommended Practice for Operation and Maintenance," *ACGIH 2106,* 2007

6. American Glovebox Society, "Guideline for Gloveboxes," AGS-G001, 2007

7. American National Standards Institute, "Practices for Respiratory Protection," ANSI Z88.2-1992

8. ASME AG-1, "Code on Nuclear Air and Gas Treatment," American Society of Mechanical Engineers, New York, NY, 2009, and applicable addenda

9. AGS-G001, "Guideline for Gloveboxes," American Glovebox Society, Santa Rosa, CA, 2007

10. Energy Research and Development Administration (ERDA) 76-21, "Nuclear Air Cleaning Handbook," by C.A. Burchsted, A.B. Fuller, and J.E. Kahn, March 31, 1976

11. ANSI Z88.2-1992, "Practices for Respiratory Protection"

4.4.6.3 Regulatory Acceptance Criteria

The applicant's commitment to have ventilation and respiratory protection programs is acceptable if the license application provides data and information that meet each of the following commitments:

1. Install appropriately sized ventilation and containment systems in areas of the plant identified as having potential airborne concentrations of radionuclides that could exceed the occupational derived air concentration values specified in 10 CFR Part 20, Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," during normal operations. Air flow in buildings housing these operations should be directed towards the area(s) of highest potential contamination.

2. Describe management measures, including preventive and corrective maintenance and performance testing, to ensure that the ventilation and containment systems operate when required and are within their design specifications.

3. Describe the operations criteria for the ventilation and containment systems, including minimum flow velocity at openings in these systems, maximum differential pressure across filters, and types of filters to be used.

4. Describe the frequency and types of tests to measure the performance of ventilation and containment systems, the acceptance criteria, and the actions to be taken when the acceptance criteria are not satisfied.

5. Establish a respiratory protection program that meets the requirements of Subpart H of 10 CFR Part 20.

6. Prepare written procedures for the selection, fitting, issuance, maintenance, testing, training of personnel, monitoring, and recordkeeping for individual respiratory protection equipment and for specifying when such equipment is to be used.

7. Revise the written procedures for the use of individual respiratory protection equipment, as applicable, when making changes to processing, the facility, or the equipment.

8. Maintain records of the respiratory protection program, including training in respirator use and maintenance.

4.4.7 Radiation Surveys and Monitoring Programs

Radiation surveys are conducted for two purposes: (1) to ascertain radiation levels, concentrations of radioactive material, and potential radiological hazards that could be present in the facility and (2) to detect releases of radioactive material from plant equipment and operations. Radiation surveys will focus on those areas of the plant necessary to show compliance with the dose limits and monitoring requirements of Subpart C, "Occupational Dose Limits"; Subpart D, "Radiation Dose Limits for Individual Members of the Public"; and Subpart F, "Surveys and Monitoring," of 10 CFR Part 20.

Measurements of airborne radioactive material and bioassays are used to determine internal occupational exposures to radiation. When combined with external occupational exposure data,

the dose of record can be compared against the dose limits specified in Subpart C of 10 CFR Part 20.

Effluent and environmental monitoring, including stack monitoring and environmental radiation monitoring, may be addressed in Chapter 9, “Environmental Protection,” of this SRP.

4.4.7.1 Regulatory Requirements

The following NRC regulations in 10 CFR Part 20 apply to radiation surveys and monitoring programs:

1. Subpart C

2. Subpart F

3. Subpart L, “Records”

4. Subpart M, “Reports”

4.4.7.2 Regulatory Guidance

The following NRC regulatory guides, NUREG, and ANSI standards are applicable to radiation surveys and monitoring programs:

1. Regulatory Guide 8.2

2. Regulatory Guide 8.4, “Personnel Monitoring Device, Direct-Reading Pocket Dosimeters,” Revision 1, June 2011

3. Regulatory Guide 8.7, “Instructions for Recording and Reporting Occupational Radiation Exposure Data,” Revision 2, November 2005

4. Regulatory Guide 8.9, “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program,” Revision 1, July 1993

5. Regulatory Guide 8.24

6. Regulatory Guide 8.25, “Air Sampling in the Workplace,” Revision 1, June 1992

7. Regulatory Guide 8.34, “Monitoring Criteria and Methods To Calculate Occupational Radiation Doses,” July 1992

8. Regulatory Guide 8.40, “Methods for Measuring Effective Dose Equivalent from External Exposure,” July 2010

9. NUREG-1400, “Air Sampling in the Workplace,” September 1993

10. ANSI N323A-1997, “American National Standard Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments,” Approved April 3, 1997

11. ANSI N13.1-2011, “Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities,” approved March 30, 2011

12. ANSI N13.6-2010, “Practice for Occupational Radiation Exposure Records Systems,” approved August 3, 2010

13. ANSI N13.30-2011, “Performance Criteria for Radiobioassay,” approved December 16, 2011

14. ANSI N13.39—2001, “Design of Internal Dosimetry Programs,” approved May 24, 2001, reaffirmed July 19, 2011

15. ANSI N13.49—2001, “Performance and Documentation of Radiological Surveys,” approved August 6, 2001, reaffirmed June 10, 2011

16. ANSI N13.6-2010, “Practice for Occupational Radiation Exposure Records Systems,” Approved August 3, 2010

4.4.7.3 Regulatory Acceptance Criteria

The applicant’s commitment to implement radiation surveys and monitoring programs is acceptable if the license application provides data and information that meet each of the following commitments:

1. Provide radiation survey and monitoring programs that are necessary to comply with the requirements of 10 CFR Part 20 and that are reasonable to evaluate the magnitude and extent of radiation levels, the concentrations or quantities of radioactive material, and the potential radiological hazards.

2. Prepare written procedures for the radiation survey and monitoring programs that include an outline of the program objectives, sampling procedures, data-analysis methods, types of equipment and instrumentation, frequency of measurements, recordkeeping and reporting requirements, and actions to be taken when measurements exceed regulatory limits in 10 CFR Part 20 or administrative levels established by the applicant.

3. Design and implement a personnel monitoring program for external occupational radiation exposures that outlines methods or procedures to do the following:

    a. Identify the criteria for worker participation in the program.

    b. Identify the types of radiation to be monitored.

    c. Specify how exposures will be measured, assessed, and recorded.

    d. Identify the type and sensitivity of personal dosimeters to be used, when they will be used, and how they will be processed and evaluated.

    e. Identify the plant’s administrative exposure levels or the levels at which actions are taken to investigate the cause of exposures exceeding these levels.

4. Design and implement a personnel monitoring program for internal occupational radiation exposures based on the requirements of 10 CFR 20.1201, “Occupational Dose Limits for Adults”; 10 CFR 20.1204, “Determination of Internal Exposure”; and 10 CFR 20.1502(b) that outlines methods or procedures to do the following:

    a. Identify the criteria for worker participation in the program.

    b. Identify the type of sampling to be used, the frequency of collection and measurement, and the minimum detection levels.

    c. Specify how worker intakes will be measured, assessed, and recorded.

    d. Specify how the data will be processed, evaluated, and interpreted.

    e. Identify the plant’s administrative exposure levels or the levels at which actions are taken to investigate the cause of exposures exceeding these levels.

5. Design and implement an air-sampling program in areas of the plant identified as potential airborne-radioactivity areas to conduct airflow studies and to calibrate and maintain the airborne sampling equipment in accordance with the manufacturers’ recommendations.

6. Implement additional procedures, as may be required by 10 CFR Part 20 and the ISA summary, to control exposure to airborne radioactive material (e.g., control of access, limitation of exposure times to licensed materials, and use of respiratory protection equipment).

7. Conduct a contamination survey program in areas of the plant most likely to be radiologically contaminated; the program must include the types and frequencies of surveys for various areas of the plant and the action levels and actions to be taken when contamination levels are exceeded.

8. Implement the facility’s corrective action program when the results of personnel contamination monitoring exceed the applicant’s administrative personnel contamination levels.

9. Implement the facility’s corrective action program when any incident results in either unplanned occupational exposures exceeding the facility’s administrative limits or unplanned airborne contamination exceeding the applicable concentration in Appendix B to 10 CFR Part 20.for one week. Note that applicants utilizing soluble uranium may be more restricted by the soluble uranium intake limit in 10 CFR 20.1201(e) than the values in Appendix B to 10 CFR 20.

10. Use equipment and instrumentation with sufficient sensitivity for the type or types of radiation being measured and calibrate and maintain equipment and instrumentation in accordance with the manufacturers’ recommendations or applicable ANSI standards.

11. Establish policies to ensure that equipment and materials removed from restricted areas to unrestricted areas are not contaminated above the release levels presented in Appendix A, “Acceptable Surface Contamination Levels,” to Regulatory Guide 8.24.

12. Leak-test all sealed sources consistent with direction provided in Appendix C, “Leak Test Requirements,” to Regulatory Guide 8.24 or the applicable regulations for the materials involved (e.g., 10 CFR 31.5(c)(2) has direction for leak testing of certain byproduct devices).

13. Establish and implement an access control program that ensures that (1) signs, labels, and other access controls are properly posted and operative, (2) restricted areas are established to prevent the spread of contamination and are identified with appropriate signs, and (3) step-off pads, change facilities, protective clothing facilities, and personnel monitoring instruments are provided in sufficient quantities and locations.

14. Establish a reporting program that is consistent with the requirements of 10 CFR Part 19 and 10 CFR Part 20.

4.4.8 Control of Radiological Risk Resulting from Accidents

To be consistent with participation in the integrated review of the ISA summary performed in accordance with Chapter 3 of the SRP, the reviewer should examine, in detail, the radiological exposure and release accident sequences provided in the ISA summary to demonstrate compliance with 10 CFR 70.61, “Performance Requirements.” This review should focus on evaluation of sequences involving radiological releases or exposures with respect to the initiators and their frequency, radiological consequences, and IROFS chosen to prevent or mitigate those consequences.

The reviewer should also identify and note any items or issues that should be inspected during an operational readiness review, if such will be performed. These items may include confirming that engineered controls meet performance specifications described in the ISA summary and that administrative controls are implemented through procedures and operator training. These may also be addressed by reviewers involved with Chapter 11 of the SRP, “Management Measures.”

The reviewer should ensure that (a) the emergency plan, if one is required, adequately addresses the licensee response to a release of radioactive materials or (b) the licensee gives a proper justification that precludes the development of an emergency plan.

Finally, the reviewer should be aware that accident sequences considered “not unlikely” in the ISA summary are constricted, under the ALARA requirement in 10 CFR Part 20, to minimize exposure to personnel and the public.

4.4.8.1 Regulatory Requirements

The following NRC regulations apply to the control of radiological risk from accidents:

1. 10 CFR 70.22(i)(1) requires either an evaluation that the maximum dose to a member of the public resulting from a release of materials would not exceed 1 rem or 2 milligrams soluble uranium intake or the submission of an emergency plan for responding to the radiological hazards of a postulated accident.

2. Subpart H, “Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material,” of 10 CFR Part 70 contains requirements for performing ISAs, designating IROFS, and having management measures in place, both

to ensure that IROFS are readily available and reliable and to provide facility change management and configuration control.

3. 10 CFR 20.1101 states that licensees shall apply procedures and engineering controls to achieve exposures to workers and the public that are ALARA.

4. 10 CFR 20.1406, "Minimization of Contamination," states that licensees shall design and develop procedures for operation that will minimize contamination of the facility and the environment, facilitate eventual decommissioning, and minimize the generation of radioactive waste.

5. Subpart H of 10 CFR Part 20 discusses controls to restrict internal exposures.

4.4.8.2 Regulatory Guidance

The following guidance applies to the control of radiological risk resulting from accidents:

1. NUREG-1513, "Integrated Safety Analysis Guidance Document," May 2001

2. NUREG/CR-6410, "Nuclear Fuel Cycle Accident Analysis Handbook," March 1998

3. Chapter 3 of this SRP

4. Chapter 11 of this SRP

4.4.8.3 Acceptance Criteria

The reviewer should consider the factors listed below in determining the acceptability of the applicant's descriptions of radiological exposure or release accident sequences.

1. Accident sequences should be sufficiently described and detailed to allow an understanding of the radiological hazards (e.g., radioactive materials at risk) and the release mechanism.

2. The applicant should provide adequate descriptions of the radiological consequences (i.e., exposure estimates) for the credible high and intermediate consequence events identified in the ISA summary. The reviewer should verify that the exposure estimates are reasonable, based on the sequence description and the radioactive materials involved.

3. The applicant should justify the likelihood of the initiating event, its prevention, or mitigation of the results of an accident sequence with high or intermediate consequences, if credited in a questionable or nonconservative manner. If controls are relied on to reduce the likelihood or severity of a high- or intermediate-consequence accident sequence, they should be identified as IROFS (10 CFR 70.61).

4. Analyses that the applicant has performed as part of the ISA process should be referenced or identified for potential further review (vertical slice) by the NRC staff (10 CFR 70.61).

5. The application should demonstrate the management measures proposed to ensure that

IROFS are available and reliable, when required, by briefly describing both of the following:

a. procedures to ensure the reliable operation of engineered controls (e.g., inspection and testing procedures and frequencies, calibration programs, functional tests, corrective and preventive maintenance programs, and criteria for acceptable test results) (10 CFR 70.62(d))

b. procedures to ensure that administrative controls will be correctly implemented when required (e.g., employee training and qualification in operating procedures, refresher training, safe work practices, development of standard operating procedures, and training program evaluations) (10 CFR 70.62(d))

6. The application shall include either of the following:

a. an evaluation that demonstrates that public exposures resulting from offsite releases of material are less than 1 rem or 2 milligrams soluble uranium intake (10 CFR 70.22(i)(1)(i))

b. an emergency plan that includes sufficient detail for responding appropriately to an offsite release of radioactive materials (10 CFR 70.22(i)(1)(ii))

4.4.9 Additional Program Commitments

4.4.9.1 Regulatory Requirements

The following regulations are applicable to the additional program commitments:

1. Subpart L of 10 CFR Part 20

2. Subpart M of 10 CFR Part 20

3. 10 CFR 20.1906, “Procedures for Receiving and Opening Packages”

4. 10 CFR 20.2006, “Transfer for Disposal and Manifests”

5. 10 CFR 70.74, “Additional Reporting Requirements”

6. 10 CFR Part 71, “Packaging and Transportation of Radioactive Material”

7. 49 CFR, “Transportation”

4.4.9.2 Regulatory Guidance

1. NUREG-1660, “U.S.-Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments,” January 1999

2. Regulatory Guide 7.4, “Leak Tests on Packages for Shipment of Radioactive Materials,” Revision 1, March 2012

3. Regulatory Guide 7.7, “Administrative Guide for Verifying Compliance with Packaging Requirements for Shipping and Receiving of Radioactive Material,” Revision 1, March 2012

4. Regulatory Guide 7.10, “Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material,” Revision 2, March 2005

4.4.9.3 Acceptance Criteria

The applicant’s commitment to implement additional program features is acceptable if the license application provides data and information that meet each of the following commitments:

1. Maintain records of the radiation protection program (including program provisions, audits, and reviews of the program content and implementation), radiation survey results (air sampling, bioassays, external exposure data from monitoring of individuals, internal intakes of radioactive material), results of corrective action program referrals, RWPs, and planned special exposures.

2. Establish a program to report to the NRC, within the timeframe stated in regulations, incidents specified in 10 CFR 20.2202, “Notification of Incidents,” and safety significant events specified in 10 CFR 70.74. Refer reportable incidents or events to the facility’s corrective action program and report to the NRC both the corrective action(s) taken (or planned) to protect against a recurrence and any proposed schedule to achieve compliance with applicable license conditions.

3. Prepare and submit to the NRC an annual report of the results of individual monitoring, as required by 10 CFR 20.2206(b). Establish a program that will assure shipment and receipt of radioactive materials consistent with regulations in 10 CFR 20, 10 CFR 71, 49 CFR, and others, as applicable. This includes having (a) qualified personnel performing these operations, (b) procedures to implement the program and generate and maintain appropriate records, and (c) a supporting quality assurance function.

4.5 Review Procedures

4.5.1 Acceptance Review

During the acceptance review of a license application, the reviewer should examine the submittals to identify major deficiencies in the information provided for each area of review specified in SRP Section 4.3. Reviewers must decide whether they have enough information to proceed with a detailed review. Less significant errors or deficiencies that can be addressed in a request for additional information should be accepted. However, before the NRC performs a detailed review, the applicant should correct major deficiencies that would require several requests for additional information to resolve.

Reviewers should record whether each area of review is adequately addressed in the application, is adequately addressed in a referenced document, is not applicable to the application, or has a major deficiency.

4.5.2 Safety Evaluation

The primary reviewer will perform a safety evaluation with respect to the acceptance criteria in Section 4.4. During the initial review, the reviewer should draft the safety evaluation report (SER) described below. A request for additional information (RAI) will be prepared when clarification and additional information are needed to determine whether the licensee's submittals comply with the regulations. The primary reviewer should coordinate with the licensing project manager in preparing RAIs. For existing facilities, the reviewer will consult with the cognizant NRC inspector for radiation protection to identify and resolve any issues of concern related to the licensing review. Additional information submitted by the applicant will be evaluated and a final SER will be provided to the licensing project manager.

4.6 Evaluation Findings

The regulations in 10 CFR 70.23, "Requirements for the Approval of Applications," and 10 CFR 70.66, "Additional Requirements for Approval of License Application," state that an application for a license will be approved if the Commission can make the general findings listed in those sections. The basis for the general findings is an evaluation of whether the application adequately addresses all of the applicable regulatory requirements. More specifically, the basis for the general findings is an evaluation of all the detailed regulatory requirements that apply to the application. The staff's evaluation should determine whether the licensing submittals provide sufficient information to satisfy the regulatory requirements listed in Section 4.4 of this SRP and whether the applicant has appropriately addressed the regulatory acceptance criteria in satisfying the requirements also described in this SRP section. The reviewer will write an SER addressing each topic reviewed and explaining 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 are adequately protected. The SER should state how the applicable regulatory requirements have been met based on the acceptance criteria described in this chapter of the SRP. If the applicant chooses to use an alternative approach, the reviewer should discuss in the SER whether the proposed approach satisfies the applicable regulatory requirements. The reviewers should use the following approach to document their evaluation:

1. State a specific regulatory requirement that applies to the application. Detailed acceptance criteria may be included where appropriate or necessary.

2. Identify the areas where the regulatory requirement is addressed in the application, including the areas where the specific acceptance criteria described in this SRP are addressed.

3. Describe your evaluation of the application, the basis for your conclusion, and whether regulatory requirements are met.

4. Repeat these steps for every regulatory requirement that applies to the application.

There are three possible outcomes to the staff's licensing review: (1) approval of the applicant's application or amendment request, (2) denial of the application or request, or (3) approval with conditions. If the reviewer cannot make a finding of a reasonable assurance of safety, the reviewer may consider proposing a license condition. Absent an NRC order, license conditions must be agreed upon with the licensee or applicant before becoming part of the license. A license condition should only be proposed if there is reasonable assurance that, if the licensee meets the condition, all regulatory requirements will be satisfied. Thus, license

conditions should not be used to cover major deficiencies in an application. License conditions should be unambiguous, inspectable, and enforceable. They should only require those actions necessary to ensure compliance with applicable regulations. The basis for license conditions must be documented in the SER.

The applicant has committed to an acceptable radiation protection program that includes the following:

- an effective documented program to ensure that occupational radiological exposures are ALARA
- an organization with adequate qualification requirements for the radiation protection personnel
- approved written radiation protection procedures and RWPs for radiation protection activities
- radiation protection training for all personnel who have access to restricted areas
- a program to control airborne concentrations of radioactive material with engineering controls and respiratory protection
- a radiation survey and monitoring program that includes requirements for controlling radiological contamination within the facility and monitoring external and internal radiation exposures
- other programs to maintain records; report to the NRC in accordance with 10 CFR Part 20 and 10 CFR Part 70; and appropriately respond to, investigate, and prevent incidents and accidents involving radiological exposures or uncontrolled releases of radioactive material

The NRC staff concludes that the applicant's radiation protection program is adequate and meets the requirements of 10 CFR Part 19, 10 CFR Part 20, 10 CFR Part 70, and 10 CFR Part 71. Conformance to the license application and license conditions will ensure safe operation.

The applicant has accurately evaluated, in the ISA summary, those accident sequences with intermediate and high radiological consequences. The applicant has also identified controls and management measures that reduce the likelihood or consequences of accident sequences and meet the performance criteria of 10 CFR 70.61.

4.7 References

U.S. Code of Federal Regulations, Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," Part 19, Chapter I, Title 10, "Energy."

U.S. Code of Federal Regulations, "Standards for Protection Against Radiation," Part 20, Chapter I, Title 10, "Energy."

U.S. Code of Federal Regulations, "Domestic Licensing of Special Nuclear Material," Part 70, Chapter I, Title 10, "Energy."

U.S. Code of Federal Regulations, "Packaging and Transportation of Radioactive Material," Part 71, Chapter I, Title 10, "Energy."

U.S. Code of Federal Regulations, Title 49, "Transportation."

American Conference of Governmental Industrial Hygienists (ACGIH), *"*Industrial Ventilation: A Manual of Recommended Practice for Design," *ACGIH 2096, Cincinnati, OH,* 2010.

ACGIH, *"*Industrial Ventilation: A Manual of Recommended Practice for Operation and Maintenance," *ACGIH 2106, Cincinnati, OH,* 2007.

American Glovebox Society, *"*Guideline for Gloveboxes," AGS-G001*, Santa Rosa, CA,* 2007.

American National Standards Institute (ANSI), "Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities," ANSI N13.1-2011, Washington, DC, 2011.

ANSI, "Practice for Occupational Radiation Exposure Records Systems," ANSI N13.6-2010, Washington, DC, 2010.

ANSI, "Performance Criteria for Radiobioassay," ANSI N13.30-2011, Washington, DC, 2011.

ANSI, "Design of Internal Dosimetry Programs," ANSI N13.39-2001, Washington, DC, 2001.

ANSI, "Performance and Documentation of Radiological Surveys," ANSI N13.49-2001, Washington, DC, 2001.

ANSI, "Radiation Protection Instrumentation Test and Calibration," ANSI N323A-1997, Washington, DC, 1997.

ANSI, "Practices for Respiratory Protection," ANSI Z88.2-1992, Washington, DC, 1992.

ANSI and the Health Physics Society, "Ionizing Radiation Safety Training for Workers," ANSI/HPS N13.36, McLean, VA, October 30, 2001, reaffirmed July 19, 2011.

ASME (formerly the American Society of Mechanical Engineers), *"*Code on Nuclear Air and Gas Treatment," ASME AG-1 and applicable addenda, New York, NY, 2009.

ASTM International (formerly the American Society for Testing and Materials), "Radiological Protection Training for Nuclear Facility Workers," ASTM E1168-95, West Conshohocken, PA, reapproved 2008.

Burchsted, C.A., A.B. Fuller, and J.E. Kahn, "Nuclear Air Cleaning Handbook," Energy Research and Development Administration (ERDA) 76-21, Washington, DC, March 31, 1976.

National Council on Radiation Protection and Measurements, "Operational Radiation Safety Training," NCRP Report No. 134, Bethesda, MD, October 2000.

U.S. Nuclear Regulatory Commission, “Air Sampling in the Workplace,” NUREG-1400, September 1993.

U.S. Nuclear Regulatory Commission, “Integrated Safety Analysis Guidance Document,” NUREG-1513, May 2001.

U.S. Nuclear Regulatory Commission, “U.S.-Specific Schedules of Requirements for Transport of Specified Types of Radioactive Material Consignments,” NUREG-1660, January 1999

U.S. Nuclear Regulatory Commission, “Nuclear Fuel Cycle Facility Accident Analysis Handbook,” NUREG/CR-6410, March 1998.

U.S. Nuclear Regulatory Commission, “Minimization of Contamination and Radioactive Waste Generation: Life Cycle Planning,” Regulatory Guide 4.21, June 2008.

U.S. Nuclear Regulatory Commission, “Leak Tests on Packages for Shipment of Radioactive Materials,” Regulatory Guide 7.4, Revision 1, March 2012.

U.S. Nuclear Regulatory Commission, “Administrative Guide for Verifying Compliance With Packaging Requirements for Shipping and Receiving of Radioactive Material,” Regulatory Guide 7.7, Revision 1, March 2012.

U.S. Nuclear Regulatory Commission, “Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material,” Regulatory Guide 7.10, Revision 2, March 2005.

U.S. Nuclear Regulatory Commission, “Administrative Practices in Radiation Surveys and Monitoring,” Regulatory Guide 8.2, May 2011.

U.S. Nuclear Regulatory Commission, “Personnel Monitoring Device--Direct-Reading Pocket Dosimeters,” Regulatory Guide 8.4, Revision 1, June 2011.

U.S. Nuclear Regulatory Commission, “Instructions for Recording and Reporting Occupational Radiation Exposure Data,” Regulatory Guide 8.7, Revision 2, November 2005.

U.S. Nuclear Regulatory Commission, “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program,” Regulatory Guide 8.9, Revision 1, July 1993.

U.S. Nuclear Regulatory Commission, “Operating Philosophy for Maintaining Occupational Radiation Exposures as Low as Is Reasonably Achievable,” Regulatory Guide 8.10, Revision 1-R, May 1977.

U.S. Nuclear Regulatory Commission, “Instructions Concerning Prenatal Radiation Exposure,” Regulatory Guide 8.13, Revision 3, June 1999.

U.S. Nuclear Regulatory Commission, “Acceptable Programs for Respiratory Protection,” Regulatory Guide 8.15, Revision 1, October 1999.

U.S. Nuclear Regulatory Commission, “Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication,” Regulatory Guide 8.24, Revision 2, June 2012.

U.S. Nuclear Regulatory Commission, “Air Sampling in the Workplace,” Regulatory Guide 8.25, Revision 1, June 1992.

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

U.S. Nuclear Regulatory Commission, “Monitoring Criteria and Methods To Calculate Occupational Radiation Doses,” Regulatory Guide 8.34, July 1992.

U.S. Nuclear Regulatory Commission, “Methods for Measuring Effective Dose Equivalent from External Exposure,” Regulatory Guide 8.40, July 2010.

5. NUCLEAR CRITICALITY SAFETY

5.1 Purpose of Review

The primary purpose of the review is to determine, with reasonable assurance, whether the applicant has designed a facility that will provide adequate protection against criticality hazards related to the storage, handling, and processing of licensed materials, as required by Title 10, "Energy," of the *Code of Federal Regulations* (10 CFR) Part 70, "Domestic Licensing of Special Nuclear Material." The facility design must adequately protect the health and safety of workers and the public from the risk of accidental criticality during both normal and credible abnormal conditions.[1]

To support this primary purpose, the review should also determine, with reasonable assurance, whether the licensee's or applicant's Nuclear Criticality Safety (NCS) Program is adequate to meet the regulatory requirements of 10 CFR Part 70 and to support the safe possession and use of special nuclear material (SNM) at the facility. The review should therefore examine the parts of the license application that describe the NCS Program. The review should also ensure that, if applicable, the requirements pertaining to performance of an Integrated Safety Analysis (ISA) (e.g., 10 CFR 70.61, "Performance Requirements") are satisfied, and that the contents of the ISA summary required by 10 CFR 70.65, "Additional Content of Applications," are adequate with regard to the evaluation of NCS-related hazards.

5.2 Responsibility for Review

Primary: NCS License Reviewer / Nuclear Process Engineer (Criticality)

Secondary: NCS Inspector / Nuclear Process Engineer (Criticality)
Other U.S. Nuclear Regulatory Commission (NRC) staff cognizant in NCS
Licensing Project Manager

5.3 Areas of Review

Regulations in 10 CFR 70.62(a) require the applicant to establish and maintain a safety program that will adequately protect worker and public health and safety and the environment and that demonstrates compliance with the performance requirements of 10 CFR 70.61. In addition, as specified in 10 CFR 70.22(a)(8), licensees must describe, in their license application, procedures to protect health and minimize danger to life or property, including procedures to avoid accidental criticality. These requirements are implemented by establishment of an NCS program as described in this chapter of the SRP. Applicants must also perform an ISA and submit an ISA summary that meets the requirements of 10 CFR 70.65.

A. For a new application or a license-renewal application, the specific areas of review are as follows:

[1] Throughout Chapter 5 of this SRP and its appendices, the term "credible" as used in "credible abnormal conditions" in 10 CFR 70.61(d) should be understood in the context of meeting the double-contingency principle. This is not necessarily quantitatively equivalent to "credible" as used in 10 CFR 70.61(b) and (c). See Appendix 5-A for more details.

1. The sections of the license application describing the licensee's or applicant's[2] license commitments with regard to the NCS Program. This includes identification of the organization and administration of the NCS Program, management measures, and methodologies and technical practices.

2. The sections of the ISA summary describing how the applicant meets the performance requirements for NCS hazards. This includes the applicant's methodology for performing the ISA, as it is applied to NCS hazards, and the results of applying that methodology to analyzing NCS hazards and scenarios and demonstrating subcriticality under normal and credible abnormal conditions.

3. The sections of the license application and ISA summary describing the applicant's criticality accident alarm system (CAAS) and emergency response measures for protecting workers and the public from the consequences of accidental criticality events.

4. The applicant's quality assurance plan, emergency plan, and criticality code validation report, if applicable and to the extent that they have provisions related to NCS. These items support but are not part of the license application, and the reviewer should ensure that all necessary commitments have been included, either explicitly or by reference, in the license application.

5. ISA documentation, including the applicant's process-hazard analyses, criticality safety evaluations (CSEs),[3] and calculations and other supporting technical documents, that demonstrate the adequacy of the applicant's license commitments and demonstrate that the applicant meets the performance requirements of 10 CFR 70.61. These will generally be examined in a sampling review as part of an in-office or onsite vertical slice review.

B. For a license amendment, the specific areas of review are as follows:

1. Those portions of the license application affected by the change. The reviewer should ensure that the effectiveness of any license commitments is not reduced, or that the licensee has provided an adequate justification that there is still adequate protection against the risk of an accidental criticality.

2. Those portions of the ISA summary affected by the change. The reviewer should verify that any changed facility operations still comply with the performance requirements of 10 CFR 70.61. This includes examining any changes to process descriptions, new or changed assumptions, controlled parameters, safety limits, controls, or safety margin, as well as new or changed criticality accident sequences and items relied on for safety.

3. Any portions of the license application and ISA summary pertaining to the licensee's CAAS and emergency response measures affected by the change. The reviewer should verify that the applicant still complies with the requirements of 10 CFR 70.24, "Criticality Accident Requirements."

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[2] Hereinafter referred to for simplicity as "the applicant," except where it is clear the staff is referring solely to an existing licensee.

[3] The specific terms used in each applicant's NCS Program will vary (NCS analyses, NCS evaluations, etc.). The term "CSE" is used generically in this chapter for formal and structured analyses performed to demonstrate subcriticality for a nuclear system. This may consist of a single document or multiple documents.

4. Any relevant portions of the quality assurance plan, emergency plan, or criticality code validation report affected by the change, if applicable. With regard to quality assurance, the reviewer should verify that criticality controls have appropriate management measures applied. With regard to the emergency plan, the reviewer should verify that it appropriately protects personnel from the consequences of a criticality accident. With regard to the validation, the reviewer should verify that calculations pertaining to changed operations are still within the licensee's validated area of applicability, or that the area of applicability has been appropriately extended, and that the licensee's margin of subcriticality for safety remains valid.

5. Justification for the change, including revised criticality safety basis documents (process hazard analyses, CSEs, calculations, and other supporting technical documents) that are needed to demonstrate adequate protection against the risk of accidental criticality.

Review Interfaces

The criticality reviewer should examine information in the following other areas to determine whether it is consistent with Chapter 5 of the application. The listed standard review plan (SRP) sections interface with this section as follows:

- Review facility and process descriptions applied to criticality safety under SRP Chapter 1.
- Review the organization structure and qualifications and responsibilities of key personnel under SRP Chapter 2.
- Review ISA methodology for applicability to criticality hazards under SRP Chapter 3.
- Review the emergency plan as applied to criticality safety under SRP Chapter 8.
- Review management measures applied to criticality-related items relied on for safety (IROFS) under SRP Chapter 11.

The specific acceptance criteria and review procedures are contained in the referenced SRP sections.

5.4 Acceptance Criteria

The applicant should provide NCS commitments and describe how the commitments will be implemented. Commitments and descriptions are expected when the acceptance criteria are relevant to the safety of special nuclear material.

5.4.1 Regulatory Requirements

Acceptance criteria are based on meeting the relevant requirements of the following regulations:

1. The general and additional contents that an application must contain are stated in 10 CFR 70.22, "Contents of Applications," and 70.65. General information that must be included in the license application is described in 10 CFR 70.22. Information that must be included in the ISA summary is described in 10 CFR 70.65.

2. The requirements for approval of the application are stated in 10 CFR 70.23, "Requirements for the Approval of Applications," and 70.66, "Additional Requirements for New Facilities or New Processes at Existing Facilities."

3. The requirements for a CAAS and emergency response procedures are stated in 10 CFR 70.24.

4. The requirements for demonstrating adequate protection against the risk of a nuclear criticality accident are stated in 10 CFR 70.61.

5. The requirements for establishing and maintaining a safety program are stated in 10 CFR 70.62, "Safety Program and Integrated Safety Analysis."

6. The requirements for new facilities or new processes at existing facilities requiring a license amendment under 10 CFR 70.72, "Facility Changes and Change Process," are stated in 10 CFR 70.64, "Requirements for New Facilities or New Processes at Existing Facilities," and include adherence to the double-contingency principle.

7. The requirements to report certain conditions affecting the safety of licensed material are in 10 CFR 70.50, "Reporting Requirements," and Appendix A, "Reportable Safety Events," to 10 CFR Part 70.

5.4.2 Regulatory Guidance

The following additional guidance may be used to supplement the review of the NCS Program:

1. NUREG-1513, "Integrated Safety Analysis Guidance Document," May 2001

2. NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook," March 1998

3. NUREG/CR-6698, "Guide for Validation of Nuclear Criticality Safety Calculational Methodology," January 2001

4. NRC Regulatory Guide (RG) 3.71, "Nuclear Criticality Safety Standards for Fuels and Material Facilities," December 2010

5.4.3 Regulatory Acceptance Criteria

Specific criteria acceptable to meet the relevant requirements of the NRC's regulations identified above are as follows for each review described in subsection 5.4 of this SRP section.
The SRP is not a substitute for the NRC's regulations, and compliance with it is not required. The SRP provides one acceptable method for demonstrating compliance with the regulatory requirements for obtaining a materials license for a fuel cycle facility, though it might not apply in every case. An applicant that does not meet applicable guidance in this SRP should describe and justify an acceptable alternative to meet the regulations. The reviewer should consider the applicant's commitments in a given area to be acceptable if the applicant has met the following acceptance criteria or has identified and justified an acceptable alternative approach.

5.4.3.1 License Application

The reviewer should examine the applicant's license commitments regarding the organization and administration of its NCS Program.

5.4.3.1.1 Use of Industry Standards

RG 3.71, "Nuclear Criticality Safety Standards for Fuels and Material Facilities," endorses American National Standards Institute (ANSI)/American Nuclear Society (ANS)-8 national standards, with some exceptions and qualifications. The NRC endorsement of these standards means that they provide methods and practices generally acceptable to the NRC staff for the prevention and mitigation of criticality accidents. However, application of a standard is not a substitute for detailed NCS analyses for specific operations.

If the applicant is requesting to conduct activities to which an NRC-endorsed standard applies, the reviewer should verify that the applicant addresses the subjects covered by the standard by satisfying the following acceptance criteria:

(1) The license application contains a commitment to follow the requirements (i.e., "shall" statements) of the standard, subject to any exceptions and qualifications taken by the NRC. The application clearly specifies the version of the standard and the specific parts of the standard to which the applicant is committing.

(2) If there are parts of the industry standard to which the applicant does not commit, the applicant provides sufficient information for the staff to determine that the parts of the standard are not applicable to the applicant's activities or that the license application contains other commitments that achieve an equivalent safety purpose.

The applicant may also choose to demonstrate compliance with regulatory requirements by committing to follow the recommendations (i.e., "should" statements) of a standard, though committing to the recommendations is not required for compliance with a standard.

The applicant should clarify its intent in committing to requirements expressed only as general principles in the standards by more specific commitments and descriptions of how those principles will be implemented in its license application. Applicants should generally use the most current revision of the standards that have been endorsed by the NRC in the version of RG 3.71 in effect when the license application is submitted. If the applicant commits to a standard or a version of a standard that the NRC has not endorsed or is not the most current endorsed version, or commits to unendorsed portions of an otherwise endorsed standard, the license application should contain justification for the acceptability of these commitments. The use of standards other than ANS standards (e.g., International Organization for Standardization (ISO) 1709, "Nuclear Energy—Fissile Materials—Principles of Criticality Safety in Storing, Handling and Processing," or ISO 7753, "Nuclear Energy—Performance and Testing Requirements for Criticality Detection and Alarm Systems") may be acceptable if suitably justified.

RG 3.71 endorses the following ANSI/ANS-8 national standards in full, as of the date of publication of this SRP:

– ANSI/ANS-8.5-1996 (reaffirmed in 2007), "Use of Borosilicate-Glass Raschig Rings as a Neutron Absorber in Solutions of Fissile Material"

- ANSI/ANS-8.6-1983 (reaffirmed in 2010), “Safety in Conducting Subcritical Neutron-Multiplication Measurements In Situ”
- ANSI/ANS-8.7-1998 (reaffirmed in 2007), “Nuclear Criticality Safety in the Storage of Fissile Materials”
- ANSI/ANS-8.10-1983 (reaffirmed in 2005), “Criteria for Nuclear Criticality Safety Controls in Operations with Shielding and Confinement”
- ANSI/ANS-8.12-1987 (reaffirmed in 2002), “Nuclear Criticality Control and Safety of Plutonium-Uranium Fuel Mixtures Outside Reactors”
- ANSI/ANS-8.14-2004, “Use of Soluble Neutron Absorbers in Nuclear Facilities Outside Reactors”
- ANSI/ANS-8.15-1981 (reaffirmed in 2005), “Nuclear Criticality Control of Special Actinide Elements”
- ANSI/ANS-8.19-2005, “Administrative Practices for Nuclear Criticality Safety”
- ANSI/ANS-8.20-1991 (reaffirmed in 2005), “Nuclear Criticality Safety Training”
- ANSI/ANS-8.21-1995 (reaffirmed in 2001), “Use of Fixed Neutron Absorbers in Nuclear Facilities Outside Reactors”
- ANSI/ANS-8.22-1997 (reaffirmed in 2006), “Nuclear Criticality Safety Based on Limiting and Controlling Moderators”
- ANSI/ANS-8.23-2007, “Nuclear Criticality Accident Emergency Planning and Response”
- ANSI/ANS-8.26-2007, “Criticality Safety Engineer Training and Qualification Program”
- RG 3.71 currently endorses the following ANSI/ANS-8 national standards in part:
- ANSI/ANS-8.1-1998 (reaffirmed in 2007), “Nuclear Criticality Safety in Operations with Fissionable Material Outside Reactors”
- ANSI/ANS-8.3-1997 (reaffirmed in 2003), “Criticality Accident Alarm System”
- ANSI/ANS-8.17-2004 (reaffirmed in 2009), “Criticality Safety Criteria for the Handling, Storage, and Transportation of LWR [Light-Water Reactor] Fuel Outside Reactors”
- ANSI/ANS-8.24-2007, “Validation of Neutron Transport Methods for Nuclear Criticality Safety Calculations”

The reviewer should consult the version of RG 3.71 in effect at the time the license application is submitted and determine whether newer versions of these standards or new standards have been endorsed, and should make note of any exceptions of qualifications.

5.4.3.1.2 Criticality Accident Alarm System (CAAS)

The reviewer should consider that the applicant's commitment to meet the CAAS requirements in 10 CFR 70.24 is acceptable if the applicant or licensee has met the following acceptance criteria or has identified and justified an alternative in the application:

1. The applicant describes a facility CAAS that meets the requirements of 10 CFR 70.24.

2. The applicant commits to the current endorsed version of ANSI/ANS-8.3, with exceptions as noted in RG 3.71, or to an acceptable alternative (e.g., ISO 7753) with justification:

    a. For licensees authorized to possess quantities greater than the 10 CFR 70.24 mass limits (e.g., special nuclear material containing more than 700 grams of ^{235}U), there shall be CAAS coverage in all areas in which such quantities of special nuclear material are handled, used, or stored (to be consistent with ANSI/ANS-8.3 as endorsed by RG 3.71). Controls are established to preclude such SNM from areas where coverage is not provided.

    b. Each monitored area must be covered by two criticality detectors.

    c. The monitoring system must 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 material within 1 minute.

With regard to commitments to follow specific industry practices described in ANSI/ANS-8.3, the applicant should provide additional details as follows:

1. The applicant describes a CAAS appropriate to the facility for the type of radiation detected, intervening shielding, and magnitude of the minimum accident of concern.

    The applicant's description of its CAAS should include the type of radiation detector and alarm; the detection threshold and minimum accident of concern; the detector logic used to provide dual alarm coverage, minimize false alarms, and detect failure; method used to determine radius of coverage; placement of alarms; and actions for maintaining and calibrating the system.

2. The applicant commits to designing a CAAS to be resistant to damage from anticipated adverse events such as a fire, explosion, corrosive atmosphere, seismic shock equivalent to the site-specific design-basis earthquake or equivalent value specified by the Uniform Building Code, or other adverse conditions that do not result in evacuation of the entire facility.

3. The applicant commits to providing emergency power for the CAAS or provides justification for the use of continuous monitoring with portable instruments.

4. 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 may 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., limiting access, halting movement of SNM) when the CAAS is not functional.

5.4.3.1.3 Emergency Planning and Response

In addition to meeting the CAAS requirements of 10 CFR 70.24(a), the reviewer should consider the applicant's commitments to emergency planning and response acceptable if the applicant has met the following acceptance criteria or has justified acceptable alternatives (see Chapter 8 of this SRP):

1. The applicant commits to the ANSI/ANS-8.23 standard.

2. The applicant has an emergency plan or satisfies the alternative requirements in 10 CFR 70.22(i)(1)(i).

3. The applicant commits to personnel accident dosimeters in areas that require a CAAS, pursuant to 10 CFR 70.24(b)(1). These dosimeters should be readily available to personnel responding to an emergency, and there should be a method for prompt onsite dosimeter readout.

4. The applicant describes arrangements for the on-site decontamination of personnel and the transport and medical treatment of exposed individuals, pursuant to 10 CFR 70.24(b)(2).

5.4.3.1.4 Subcriticality and Double-Contingency Principle

The reviewer should consider the applicant's commitments to demonstrating that all nuclear processes will be subcritical under normal and credible abnormal conditions to be acceptable if the applicant has met the following acceptance criteria or has justified acceptable alternatives:

1. The applicant commits to one or more of the following methods for determining subcritical limits on controlled parameters under normal conditions, or subcritical values under abnormal conditions:

    a. The applicant commits to use the subcritical values in a currently endorsed standard (e.g., ANSI/ANS-8.1, -8.5, -8.7, -8.12, or -8.15) or ANSI/ANS-8.9, "Nuclear Criticality Safety Guide for Pipe Intersections Containing Aqueous Solutions of Enriched Uranyl Nitrate" (withdrawn as an active standard).

    b. The applicant commits to use the subcritical or critical values, with appropriate margin, from widely accepted industry handbooks (e.g., Los Alamos National Laboratory's LA-10860-MS, "Critical Dimensions of Systems Containing ^{235}U, ^{239}Pu, and ^{233}U," or Atlantic Richfield Hanford Company's ARH-600, "Criticality Handbook"), experimental data, or peer-reviewed publications. The specific sources used should be referenced by name in the license application.

    c. The applicant commits to use industry-accepted hand-calculation methods (e.g., areal density, solid angle technique, etc.), subject to the limitations of those methods.

    d. The applicant commits to use deterministic or probabilistic (e.g., discrete ordinates or Monte Carlo) computer codes to calculate the effective multiplication

factor k_{eff}. These calculational methods should be validated in accordance with the ANSI/ANS-8.24 standard.

2. For each method used to demonstrate subcriticality, the applicant commits to use the method consistent with any limitations, with an appropriate margin of subcriticality and within its area of applicability. The margin of subcriticality and area of applicability are to be described in the license application.

3. The applicant commits to determine safety limits based on one of the methods listed in paragraph (1) above. The applicant commits to evaluate controlled parameters at their safety limits (or more conservatively) and to evaluate parameters that are not controlled at their most reactive credible values.

4. The applicant describes a program that complies with the double contingency principle, where practicable. This principle is defined in 10 CFR 70.4, "Definitions" (and is stated in ANSI/ANS-8.1), as follows:

   Process designs should incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.[4]

   Each process that has accident sequences leading to criticality should have sufficient engineered and administrative controls in place to ensure double-contingency protection during normal operations. If double-contingency protection is lost through the failure of one or more of these controls, the process should be halted until the controls can be reestablished. This necessitates a program that incorporates prompt detection and correction of such contingencies. The term "concurrent" means that the effect of the first process change persists when the second change occurs. It does not mean that the two events must occur simultaneously. The likelihood of criticality can be markedly reduced if control failures are promptly detected and processes are promptly rendered safe.

   The term "process conditions" encompasses the full spectrum of factors that can affect criticality safety, not just the set of controlled parameters. "Process condition" is not synonymous with "controlled parameter." Thus, double contingency protection may be provided by either (1) control of two independent parameters, or (2) control of a single process parameter, such that at least two independent failures or events involving the parameter would have to happen before a criticality accident is possible. The first method, reliance on two different parameters, is preferred because of the inherent difficulty in preventing common-mode failures when controlling only one parameter.

   The reviewer should note that double contingency does not necessarily mean that two controls are required. In some cases, it may be appropriate to credit the natural and credible course of events (e.g., unsintered powder cannot exceed a maximum theoretical density; there is no means of enriching beyond 5 wt% ^{235}U; or reliance on the low historical likelihood of flooding) without needing to establish explicit controls. Where there is no credible accident sequence leading to criticality, the double-contingency principle is met by definition. The reviewer should exercise judgment in determining

[4] Throughout Chapter 5 of this SRP and its appendices, the term "unlikely" as used in the double contingency principle is not necessarily quantitatively equivalent to "unlikely" as used in 10 CFR 70.61(c). See Appendix 5-A for more details.

whether the applicant has established sufficient measures to ensure that occurrence of the contingencies is "unlikely."

In rare instances, double-contingency protection will not be practicable. The applicant should identify any such cases in the license application and should provide justification as to why the affected processes are acceptably safe. The justification should demonstrate that the risk is sufficiently low that an exception to the general principle is warranted. The reviewer should note that the double-contingency principle is a recommendation in ANSI/ANS-8.1 and should recall that earlier statements of the principle treated it as a general design principle, rather than expecting that it had to be met in every case ("Process designs should, in general, incorporate sufficient factors of safety…."). The more important requirement is the subcriticality requirement incorporated in 10 CFR 70.61(d) ("all nuclear processes are subcritical" under both "normal and credible abnormal conditions"). Thus, as long as the applicant meets this 10 CFR 70.61(d) provision, an exception to following the double-contingency principle may be justified if the criticality risk is shown to be sufficiently low.

Additional guidance pertaining to compliance with the double-contingency principle is given in Appendix 5-A to this SRP.

5.4.3.1.5 Organization and Administration of the NCS Program

The reviewer should consider the applicant's management of the NCS program acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative approach:

1. The applicant describes and commits to implement and maintain an NCS Program to meet the applicable 10 CFR Part 70 requirements, and to ensure adequate protection against the consequences of accidental criticality events. The primary means of doing this should be prevention (i.e., ensuring that processes will be subcritical under normal and credible abnormal conditions).

2. The applicant describes the NCS Program's objectives (which should include the following) and how the applicant will meet those objectives.

    a. Performing and documenting criticality safety evaluations (CSEs) for new or changed processes and establishing safety limits and controls as necessary to ensure that processes will remain subcritical under normal and credible abnormal conditions

    b. Establishing, as practicable, double-contingency protection and defense-in-depth measures; ensuring sufficient margins of safety and subcriticality to provide additional assurance that the likelihood of criticality will be acceptably low

    c. Establishing and maintaining a CAAS system and emergency-response procedures to protect health and safety in the event criticality occurs

    d. Providing technical support to emergency response personnel in responding to and recovering from abnormal conditions and emergencies up to and including a criticality accident

    e. Verifying the adequacy of criticality controls through audits and assessments, including observation of operations and verification of equipment configuration

f. Ensuring the adequacy of CSEs through peer reviews, self-assessments, and validation and verification of calculational methods

g. Training and otherwise supporting operations in procedures to ensure the safe handling of special nuclear material

h. Supporting regulatory compliance with regard to event reporting (10 CFR 70.50 and Appendix A to 10 CFR 70), complying with the facility change process (10 CFR 70.72), and participating in the performance and documentation of the facility's ISA (10 CFR 70.61 through 70.66) insofar as they pertain to criticality safety.

3. The applicant outlines an NCS Program structure that is consistent with current industry practices (e.g., ANSI/ANS-8.1 and ANSI/ANS-8.19), including establishing the roles and responsibilities of key Program personnel (e.g., NCS Manager, NCS Senior Engineers, and NCS Engineers). While the specific titles and functions of personnel may vary from one applicant to another, specific positions should have responsibility for implementing Program objectives, including designation of an NCS Program Manager who has overall responsibility for implementing the NCS Program.

4. The applicant describes the training and qualification of key NCS Program personnel. Experience and education levels should be specified commensurate with personnel responsibilities. Training and qualification should be consistent with ANSI/ANS-8.26 as specified in RG 3.71.

5. The applicant commits to establish and maintain NCS safety limits, and to maintain any operating limits that it may establish[5], and commits to maintain management measures to ensure their continued reliability and availability.

6. The applicant commits to support operations personnel through development of training, preparation of NCS postings and other appropriate operator aids for key administrative controls (e.g., painted lines on the floor and warning lights), and review of procedures and operations to ensure they are unambiguous, easily understood, and readily achievable.

7. The applicant commits to evaluating modifications to the facility or safety program to ascertain their impact on criticality safety.

8. The applicant should describe a corporate structure in which the NCS Organization is independent of operations to the extent practical.

9. The applicant commits to requiring personnel to perform activities in accordance with written, approved procedures when the activity could affect NCS. If existing procedures do not cover a specific situation, personnel should be trained to take no action until NCS staff has evaluated the situation and provided recovery instructions.

[5] Licensees frequently establish separate operating limits to provide additional margin and ensure that safety limits established in criticality safety evaluations are unlikely to be transgressed. Established limits should take into account process uncertainty and variability, though this is not meant to imply that separate safety and operating limits are required.

10. The applicant commits to requiring its personnel to report defective NCS conditions to operations supervision and NCS Program staff. The applicant establishes management policies that reinforce operators' stop-work authority and encourage the reporting of defective conditions.

5.4.3.1.6 Management Measures Applied to the NCS Program

The reviewer should consider the applicant's commitments to its management measures for NCS acceptable if the applicant has met the following acceptance criteria or has identified and justified acceptable alternatives:

The applicant commits to following industry practices described in ANSI/ANS-8.19 and ANSI/ANS-8.20 as they pertain to training, procedures, and audits and assessments.

1. In addition, with regard to training:

    a. The applicant commits to train personnel in the areas discussed in Section 7 of ANSI/ANS-8.20.

    b. The applicant commits to train personnel with regard to procedural compliance, stop-work authority, response to alarms, and reporting of defective conditions.

2. In addition, with regard to audits and assessments[6]:

    a. The applicant commits to conducting and documenting audits (e.g.,, the observation of operations to verify compliance with criticality limits and controls) of all operating SNM process areas, such that all such areas will be reviewed at some specified frequency. The reviewer should consider the complexity of the process, the degree of process monitoring, the degree of reliance on administrative controls, and risk-significance in determining anappropriate frequency. Those operations that are no longer operating should also be reviewed at some reduced frequency to ensure that they remain in a safe condition.

    b. The applicant commits to conducting and documenting periodic NCS program audits (e.g.,, the independent review of NCS Program work products, such as CSEs, change packages, calculations, andfacility audits) at least once every 2 years. This should be done by staff independent of those who had performed the functions themselves, either internal or external to the NCS Organization.

    c. Weaknesses identified through facility or program audits should be referred to the facility's corrective-action program, which has the responsibility for promptly and effectively resolving them. A graded approach may be used to justify an alternate schedule for performing audits and assessments or for taking corrective action.

[6] This phrase encompasses all kinds of self-assessments performed as part of the NCS Program. Audits and assessments of facility operations are the subject of paragraph (a) and those of the program itself are the subject of paragraph (b). The reviewer should recognize that these take many different forms and have many different names across the nuclear industry, including walkthroughs, audits, assessments, appraisals, inspections, etc.

5.4.3.1.7 Technical Practices for NCS

Acceptance criteria applicable to the applicant's technical practices are as follows:

In evaluating the applicant's technical practices, the reviewer should not only ensure that the applicant has made the necessary commitments, but should also independently review a sampling of the applicant's analyses to confirm the adequacy of its commitments.

1. The applicant commits to perform CSEs using industry-accepted and peer-reviewed methods (e.g., in ANSI/ANS-8.1, -8.19, -8.24).

2. The applicant commits to validate calculational methods used to develop NCS safety limits, in accordance with ANSI/ANS-8.24.

3. The applicant = demonstrates an adequate margin of subcriticality for safety in accordance with 10 CFR 70.61(d).

   Additional guidance on the margin of subcriticality is provided in Appendix 5-B to this SRP.

5.4.3.1.7.1 Calculational Method Validation[7]

The applicant should include a summary description of a documented, reviewed, and approved (by the applicant's NCS Function and management) validation report for each methodology that will be used to perform an NCS analysis. For methods such as experimental data, handbooks, industry standards, and hand calculations, the validation report may consist of a demonstration of each method's applicability to the applicant's processes, including specification of any limitations or assumptions needed to ensure its validity. For methods that rely on the explicit calculation of k_{eff}, the validation report should evaluate critical benchmark experiments similar in geometry, material composition, and neutron energy spectrum to the systems to be evaluated.

For computer calculation methods, the reviewer should examine the applicant's criticality code validation report to determine whether it provides for reasonable assurance that processes evaluated to be subcritical are actually subcritical. The review should consist of a review of the applicant's selection of benchmark experiments, statistical methodology, and results (determination of the area(s) of applicability and Upper Subcritical Limit). The methods used should be consistent with the nature of the data (e.g., quantity and distribution of benchmark experiments, normality, presence or absence of any trends, and need for extrapolation or interpolation).

Acceptance criteria applicable to the applicant's summary description of its criticalitycode validation process in the license application are as follows:

A. The applicant's summary description of its criticality code validation process should include:

[7] As used in this chapter of the SRP (and its appendices), the term "validation" normally refers to the *process* of demonstrating the validity of methods used to demonstrate subcriticality with an appropriate margin, and "validation report" refers to a *document* capturing the methodology and results of that process. The term "criticality code validation report" indicates that in most cases what is being validated is a computer-based calculational method. However, as stated in the following paragraph, this guidance applies to other methods of demonstrating subcriticality as well, unless specifically stated otherwise.

1. A description of the methodology that is sufficiently detailed and clear that it may be independently reproduced, including the method used to select benchmark experiments, determine the bias and bias uncertainty, and determine the Upper Subcritical Limit.

2. A summary of the physical systems and area(s) of applicability covered by the criticality code validation report. It is not necessary to include the full range of numerical parameters that defines an area of applicability; a general description (e.g., “low-enriched homogeneous uranyl fluoride solutions”, “low-enriched fuel pellets”, or “rods containing gadolinia”) is sufficient.

3. A description of the methods used to extend the area(s) of applicability beyond the range of parameters covered by the benchmark experiments. Any such extension should be done by making use of trends in the bias, including accounting for the increased uncertainty due to the extrapolation.

4. A description of the benchmark experiments used. It is not necessary to include all benchmark experiments used; a brief description of the individual benchmark sets is sufficient.

5. A description of the margin of subcriticality for safety and justification of its adequacy. This should include a statement of the minimum margin of subcriticality and any other factors that provide reasonable assurance of subcriticality.

6. A description of the controlled software and hardware used. It is not necessary to include specific operating systems, hardware platforms, and individual workstations, though this information should be specified in the criticality code validation report itself. A general description of the computer code, release version, cross-section libraries, and type of computer hardware is sufficient.

7. A description of any limitations on use of the method (e.g., code options (such as biasing and use of albedos) or convergence criteria) necessary for validity of the method.

B. Acceptance criteria applicable to the applicant’s commitments with regard to its criticalitycode validation process are as follows:

1. The applicant’s summary description is consistent with the ANSI/ANS-8.24 standard, with exceptions and qualifications as stated in RG 3.71, or follows widely accepted industry practices with the application of an appropriate margin to account for any shortcomings (e.g., scarcity of the data, lack of normality, or extension beyond the range of benchmark experiments). This requires that the NCS reviewer remain aware of current validation practices .

2. The applicant commits to incorporating each criticality code validation report into its configuration-management program.

3. The applicant commits to and describes its verification process, including verification upon installation, in response to changes to the calculational system, and at specified periods.

4. The applicant commits to assessing the applicability of its criticalitycode validation for each nuclear system to be evaluated and to documenting its assessment in CSEs.

The above criteria strictly apply only to methods that explicitly calculate k_{eff} (deterministic and probabilistic computer codes). For other methods used to demonstrate subcriticality, the reviewer should use judgment in determining which of the aforementioned criteria are applicable to the particular method.

5.4.3.1.7.2 Criticality Safety Evaluations (CSEs)

The reviewer should consider the applicant's commitments with regard to performing CSEs acceptable if the applicant has met the following acceptance criteria or identified and justified acceptable alternatives:

1. The applicant commits to performing CSEs in accordance with documented and approved administrative procedures, which incorporate the following principles:

    a. NCS safety limits will be established based on analyses assuming optimum or the most reactive credible values of parameters (e.g., the most reactive conditions physically possible or bounding values limited by regulatory requirements) unless specified controls are implemented to limit parameters to a particular range of values. If less than the optimum values are used, and corresponding controls are not identified, the basis will be justified in the CSE.

    b. NCS operating limits maybe established as appropriate to ensure that safety limits are unlikely to be exceeded. If separate operating limits are specified, process variability and uncertainty should be considered. Additional conservatism may be applied.

    c. The specific controls and management measures necessary to enforce NCS safety limits and/or operating limits will be specified.

2. The applicant commits to providing the technical basis that demonstrates (a) subcriticality under normal and credible abnormal conditions and (b) compliance with the double-contingency principle in the CSEs.

3. The applicant commits to incorporating each CSE into its configuration-management program and its system of ISA documentation.

5.4.3.1.7.3 Evaluation and Implementation of Controlled Parameters

Parameters available for NCS control are as follows: mass, geometry, density, enrichment (or isotopics), reflection, moderation, concentration, interaction (or spacing), neutron absorption (or poison), volume, heterogeneity, physicochemical form, and process variables. The number and names of specific parameters will vary from one applicant to another.

The reviewer should consider the applicant's commitments to technical practices associated with evaluating and implementing controlled parameters acceptable if the applicant has met the following acceptance criteria or identified and justified acceptable alternatives:

1. The applicant states that the use of a single NCS control to maintain the values of two or more controlled parameters constitutes only one component necessary to meet the double-contingency principle.

2. The applicant commits to the following preferred hierarchy of controls:

   a. The applicant commits to the preferred use of passive engineered controls; in particular, passive engineered geometry control.

   b. The applicant commits to the following order of preference for NCS control: (1) passive engineered, (2) active engineered, (3) enhanced administrative, and (4) simple administrative controls.

   c. The applicant commits to preference for designating explicit NCS controls over reliance on the natural and credible course of events.

   d. The applicant commits to preference for control of two or more parameters over multiple controls on a single parameter. If relying on two or more controls on a single parameter, the applicant commits to preference for diverse over redundant means of control.

   These commitments do not mean that the applicant will follow the preferred hierarchy of controls in every case. The reviewer should examine the applicant's sets of controls to determine whether it is following this preference in the majority of cases. In general, for example, where passive controls are readily available, they should be used rather than administrative controls. It is up to the applicant to demonstrate how it is meeting these commitments (for example, by providing justification when deviating from these criteria).

3. The use of each controlled parameter should be considered acceptable if the following general criteria, in addition to the specific criteria for individual parameters listed below, are met:

   a. When a single-parameter limit is used (e.g., minimum critical mass, favorable geometry limit, or always-safe concentration), all other parameters are evaluated at their optimum or most reactive credible values. In determining single-parameter limits, it is permissible to specify a particular physicochemical form and isotopic composition.

      Examples: (1) minimum critical mass is based on spherical geometry, optimum moderation, and full water reflection; (2) favorable geometry is based on having equipment filled with optimally moderated material and full water reflection.

   b. When process variables can affect the normal or most reactive credible values of parameters, controls to maintain them within specified ranges are established.

   c. When measurement of a parameter is needed, instrumentation subject to facility management measures is used.

   d. When criticality control is based on measuring a single parameter, independent means of measurement (e.g., redundant in-line monitoring or dual independent sampling) are used.

   e. Safety limits on controlled parameters are established, taking any tolerances and uncertainty into account.

4. Acceptance criteria for the use of **mass** as a controlled parameter are as follows:

a. When mass limits are derived for a material that is modeled assuming a given weight percent of SNM, compliance with the mass limit is verified by either (1) weighing the material and ascribing the entire mass to SNM or (2) conducting physical measurements to establish the actual weight percent of SNM in the material.

b. When the dimensions of equipment or containers with a fixed geometry are used to limit the mass of SNM, a conservative process density is used to calculate the resulting mass.

c. When overbatching of SNM is credible, the largest mass resulting from a single failure is shown to be subcritical. Overbatching beyond double batching should be considered unless it requires multiple independent failures or is precluded by equipment capacity, availability of material, or other considerations.

5. Acceptance criteria for the use of **geometry** as a controlled parameter are as follows:

a. Before beginning operations, in response to changes to operations, and at periodic intervals, all dimensions relied on in demonstrating subcriticality are verified. Relevant dimensions and material properties are maintained in the facility's configuration-management program.

b. Means of losing geometry control (e.g., corrosion, leakage, bulging, transfer to unfavorable geometry, changes to a more reactive physicochemical form) are evaluated and controls established as needed if they are credible.

c. Neutron interaction with other SNM-bearing equipment is considered as part of the demonstration of subcriticality, unless individual units meet the criteria for being considered neutronically isolated. This includes the introduction of any portable SNM-bearing containers.

6. The use of **density** as a controlled parameter should be considered acceptable if the general criteria for controlled parameters described above are met.

7. *Enrichment* refers to the weight percent of ^{235}U in uranium. For mixtures involving other fissile nuclides, *isotopics* (or *isotopic abundance*) may refer to the weight percent of the fissile nuclides (e.g., ^{239}Pu and ^{241}Pu weight percent in plutonium) and to the relative ratio of different elements in the mixture (e.g., weight percent of plutonium to the total mass of SNM). While the term *enrichment* is used below for simplicity, the reviewer should recognize that the criteria below can apply to more general types of SNM.

Acceptance criteria for the use of **enrichment** as a controlled parameter are as follows:

a. Either a method of segregating enrichments is used to ensure that differing enrichments will not be interchanged, or the most limiting enrichment is applied to all material. Use of the plant-wide maximum authorized enrichment may be relied on without the need to specify explicit enrichment controls in every CSE.

Given that mixtures of differing enrichments are indistinguishable by sight and have the same chemical properties, material of differing enrichments should be segregated in different parts of the facility or should be conspicuously marked with distinctive labels.

8. **Reflection** is recognized as a particularly difficult parameter to control, and is therefore one of the least-preferred methods of criticality control. The reviewer should exercise extra caution in reviewing any instances relying on reflection control.

   Acceptance criteria for the use of reflection as a controlled parameter are as follows:

   a. In determining subcritical limits for an individual unit, the wall thickness and all adjacent reflecting materials are considered in setting up the criticality model. Any such materials should be conservatively bounded by the modeled reflection conditions.

   b. Criteria are established for determining when materials are sufficiently far away to be neglected in the criticality model. For example, in most cases materials more than 30 cm (12 inches) away may be neglected. (Care should be taken when analyzing large slabs and arrays.)

   c. When reflection is not controlled, full reflection may be represented by 30 cm (12 inches) of tight-fitting water or 60 cm (24 inches) of tight-fitting concrete. In the presence of special moderators such as deuterium, beryllium, or graphite, or if large amounts of hydrogen-rich materials (e.g., hydrocarbon oil or polyethylene, etc.) are present, it should be demonstrated that the modeled reflection conditions remain bounding.

   d. Minimum reflection conditions equivalent to a 1-inch tight-fitting water reflector are assumed to account for personnel and other transient incidental reflectors not explicitly included with fixed reflectors in the model. (A 1-inch tight-fitting water reflector is generally considered sufficient to bound any amount of reflecting material more than 30 cm (12 inches) from the surface of the unit.)

   e. When less than full reflection conditions are assumed in calculations, controls to limit reflection around individual units are established, preferably by means of rigid barriers.

   f. In evaluating subcriticality for an array of units, the maximum amount of water between units may not be the most reactive condition. Reflection should be modeled on the exterior of the array consistent with the acceptance criteria in paragraphs (8)(a) through (8)(e) above, and interstitial moderation should be considered in accordance with the criteria in paragraph (9) below.

9. Acceptance criteria for the use of **moderation** as a controlled parameter are as follows:

   a. The applicant commits to meeting the ANSI/ANS-8.22 standard.

   b. As a first preference, physical structures are designed to preclude the ingress of moderators.

   c. Moderation-controlled areas may be used to exclude moderators from whole areas. Engineered means (e.g., double roof, double-sleeved pipes, exclusion of sprinklers, raised/sloped floors) are the primary means of excluding moderators from such areas. After evaluation of all credible sources of moderator intrusion into such areas, the areas are conspicuously marked and administrative controls are established to prevent the introduction of moderators.

d. Firefighting procedures for use in moderation-controlled areas are evaluated in CSEs. Restrictions on the use of moderating firefighting agents are included in procedures and training. The effects of a fire and activation of fire suppression are evaluated.

10. **Concentration** is recognized as one of the least-preferred methods of criticality control. The reviewer should exercise extra caution in reviewing any instances relying on concentration control.

    Acceptance criteria for the use of concentration as a controlled parameter are as follows:

    a. Controls are established to limit concentration of SNM unless the process has been demonstrated to be subcritical at optimum concentration.

    b. When using a tank containing concentration-controlled solution, the tank is kept closed and locked to prevent unauthorized introduction of precipitating agents.

    c. Precautions are taken to preclude the inadvertent introduction of precipitating agents.

    d. Transfers to unfavorable geometry tanks containing concentration-controlled solutions will only be authorized based on dual independent sampling and/or in-line monitoring. No single error may result in transfer of concentrated solution to a tank with unfavorable geometry.

    e. Process variables that can affect the solubility of fissile solutions are controlled and monitored. The need to ensure homogeneity of the solution is assessed in CSEs.

11. **Interaction** must often be controlled when relying on geometry and volume control. Acceptance criteria for the use of interaction as a controlled parameter are as follows:

    a. To maintain physical separation between units, engineered controls are used. If engineered controls are not feasible, administrative controls with visual aids such as painted lines and postings may be used. However, multiple procedural errors should not by themselves lead to criticality.

    b. The structural integrity of spacers, storage racks, etc. is sufficient to ensure subcriticality under normal and credible abnormal conditions, including seismic events.

    c. Engineered devices that are moveable (e.g., birdcage drums, 55-gallon drums) are inspected periodically for deformation.

12. Neutron absorbers are often controlled in conjunction with geometry and interaction control. Fixed neutron absorbers are recognized as among the most-preferred methods of criticality control, while soluble neutron absorbers are recognized as one of the least-preferred methods. The reviewer should therefore exercise extra caution in reviewing any instances relying on soluble absorber control.

    Acceptance criteria for the use of neutron **absorption** as a controlled parameter are as follows:

a. The preferred method of absorber control is fixed neutron absorbers. When using fixed absorbers, the applicant commits to meeting the ANSI/ANS-8.21 standard.

   Whether the applicant is relying on fixed neutron absorbers does not depend on whether the absorbing materials are part of the existing structure or are added specifically for criticality control. If the material properties of the absorber must be included in the model to reduce the value of k_{eff} below the Upper Subcritical Limit (for normal or credible abnormal conditions), the material is relied on as a neutron absorber. If the material can be modeled as a void region, so that only the dimensions are needed to ensure subcriticality, it is being relied on only as a geometry control.

b. When using borosilicate glass raschig rings, the applicant commits to meet the ANSI/ANS-8.5 standard.

c. When using soluble neutron absorbers, the applicant commits to meeting the ANSI/ANS-8.14 standard.

d. In evaluating absorber effectiveness, the effect of neutron spectra on the absorption cross-section is considered (e.g., cadmium is an effective absorber for thermal neutrons but ineffective for fast neutrons).

13. When the total volume of a unit is limited to ensure subcriticality, irrespective of its shape, this constitutes volume control. When the specific dimensions are limited, this constitutes geometry control. Occasionally geometry and volume are lumped together as a single means of control. This is acceptable because the same acceptance criteria apply to both.

    Acceptance criteria for the use of **volume** as a controlled parameter are as follows:

    a. Fixed geometry is used to restrict the volume of SNM. The preferred method is limiting equipment and containers to less than a subcritical volume. Limiting material to part of a larger geometry (e.g., by active level probes or use of overflow holes) may also be used.

    b. The maximum subcritical volume is evaluated assuming the most reactive credible geometry, optimum moderation, and full water reflection. Normally, spherical geometry will be the most reactive (though this could depend on the specific boundary conditions to be applied).

14. Controlling the small-scale structure of fissile materials is particularly important at lower enrichments (below approximately 10 wt% ^{235}U). While normally referred to as heterogeneity control, generally the concern is maintaining homogeneity because the homogeneous case is usually less reactive.

    Acceptance criteria for the use of **heterogeneity** as a controlled parameter are as follows:

    a. Methods of causing a fissile material to become inhomogeneous are evaluated in CSEs and controls established as necessary (e.g., temperature and acidity on a solution, active stirring and blending of solutions or powders, or milling of powders or scrap). If heterogeneity is considered credible, its effect should be evaluated in criticality calculations. These calculations should be validated using

critical benchmarks that display heterogeneous effects, to ensure that any bias due to resonance self-shielding is taken into account.

b. Assumptions that can affect the physical scale of heterogeneity are based on observed physical characteristics of the material; process variables that can affect the scale of heterogeneity are controlled.

15. Subcritical limits on other controlled parameters are normally derived for a particular fissile material composition by assuming a bounding physicochemical form and isotopic abundance. Physicochemical form consists of controlling the physical state (i.e., solid, liquid, or gas) and form (e.g., solution, powder, green or sintered pellets, or metal) and/or chemical composition (e.g., uranium hexafluoride, uranyl fluoride, plutonium nitrate, or mixed oxide) of a particular fissile material. The physicochemical form could indirectly affect other parameters, such as density, moderation, and neutron absorption.

Acceptance criteria for the use of **physicochemical form** as a controlled parameter are as follows:

a. Either the most reactive credible physicochemical form in the facility is assumed in criticality calculations or explicit controls are established to limit the material composition to a particular form. Passive controls (e.g., filters and pellet diameter gauges), active controls (e.g., temperature and pressure gauges and mass flow totalizers), and administrative controls (e.g., titration and limitations on addition of chemical reagents) may be used.

b. Both in-situ changes in physicochemical form and the migration of material between process areas are considered in evaluating credible abnormal conditions.

c. Process variables that can change the fissile material to a more reactive physicochemical form are identified as controls in CSEs.

16. Process variables include those physical characteristics of a process that are relied on to control other parameters (e.g., furnace temperature to limit moderation, pressure to maintain physicochemical form of UF_6, and acidity to maintain homogeneity) or to monitor them (e.g., electrical load to monitor viscosity, conductivity to detect moderators, the mechanical force of a pellet press to limit density, and radiation readings to detect solution transfers).

Acceptance criteria for the use of **process variables** for criticality control are as follows:

a. Process variables relied on to control or monitor other controlled parameters are identified as controls in CSEs; sufficient management measures are applied to ensure that the associated controlled parameter safety limit is not exceeded.

b. The associated controlled parameter is explicitly identified and the correlation of process variables to the associated parameter is established by experiment or plant-specific measurements.

5.4.3.1.8 Additional NCS Program Commitments

Acceptance criteria applicable to the applicant's description of additional commitments in its NCS Program are as follows:

1. The applicant commits to assess the adequacy of engineered and administrative criticality controls as part of its facility audits and inspections, to promptly detect any NCS deficiencies, and to refer those deficiencies to the facility's corrective-action program in order to prevent recurrence.

2. The applicant commits to suspend operations or otherwise render processes safe upon loss of double contingency protection, until such protection can be restored, and to assess the adequacy of the affected controls.

3. The applicant commits to retaining records of NCS deficiencies and documenting any corrective actions taken.

4. The applicant commits to identifying all equipment and procedures needed for criticality controls to perform their safety function (i.e., to ensure their effectiveness in keeping controlled parameters within subcritical limits), and to maintaining such equipment and procedures as part of its facility management measures, including audits and inspections.

5. Acceptance criteria applicable to the applicant's description of measures to implement its facility change process (in compliance with 10 CFR 70.72) are as follows:

    a. The applicant describes a change-control process that is sufficient to ensure that the safety basis of the facility will be maintained during the facility's lifetime. The change process is documented in written procedures that specify that all changes to nuclear processes are evaluated by the NCS Organization to determine the impact on NCS, including analytic assumptions, the effectiveness of NCS controls, and the NCS of any connected processes.

    b. The applicant commits to supporting the facility's change process by evaluating whether changes are covered by existing CSEs and, if not, to performing CSEs to determine any necessary changes to processes, procedures, criticality controls, and management measures.

    c. The change-control process is integrated with its configuration-management system to ensure that any changes to the NCS basis are incorporated in procedures, postings, drawings, and other facility safety documentation as appropriate, as well as the ISA summary.

6. Acceptance criteria applicable to the applicant's description of measures to implement the event reporting requirements in 10 CFR Part 70, Appendix A, "Reportable Safety Events," are as follows:

    a. The applicant's overall event-reporting commitments are consistent with Appendix A, and:

    b. The applicant's NCS Program has a process in place for rapidly evaluating the NCS significance of events, including immediate availability of cognizant NCS staff. The evaluation of safety significance includes assessment of the event for the loss or degradation of double contingency protection.

c. The applicant's process for assessing NCS events is integrated with the overall apparatus for making the required notification to the NRC Operations Center, which is incorporated in the facility's emergency procedures.

d. The applicant commits to evaluating the significance and reportability of events based on whether the controls were lost or degraded (i.e., whether they were unreliable or unavailable to perform their safety functions), not based on whether the safety limits of the associated parameters were actually exceeded.

e. The applicant commits to treating the event as a one-hour report if it cannot ascertain within one hour whether the criteria of paragraph (a) or (b) of Appendix A to Part 70 apply.

5.4.3.2 ISA and ISA Summary Review

The reviewer should examine the applicant's ISA documentation as it pertains to the evaluation of NCS hazards. The overall review of the applicant's ISA process is covered in Chapter 3 of this SRP. The NCS reviewer's examination of the NCS-related aspects of the applicant's ISA comprises three parts: (1) review of the applicant's ISA methodology to assess its applicability to analyzing criticality hazards, (2) review of the applicant's onsite ISA documentation related to criticality hazards as part of its onsite vertical slice review, and (3) review of the applicant's discussion of criticality hazards, scenarios, and controls in its ISA summary. The purpose and scope of each of these aspects as it relates to NCS is discussed in the following sections.

The relation of the license-application review to the ISA review is that reasonable assurance of safety depends primarily on the adequacy of the applicant's commitments to its NCS Program, because the licensee is ultimately responsible for the safe operation of its facility. The reviewer therefore performs a detailed and comprehensive review of the applicant's commitments with regard to its NCS Program. The ISA review provides an additional demonstration of safety by assessing whether the applicant's NCS Program has provided adequate protection against the consequences of an accidental criticality. This review consists of a risk-informed sampling of scenarios and controls to confirm the adequacy of the applicant's implementation of its NCS Program.

5.4.3.2.1 ISA Methodology

The reviewer should examine the applicant's ISA methodology commitments, as described in the license application, to determine whether the methodology is being properly applied to the analysis of criticality hazards. Acceptance criteria applicable to the applicant's application of its ISA methodology to criticality hazards are as follows:

1. Criticality is considered a high-consequence event for the purpose of complying with the performance requirements of 10 CFR 70.61.[8] If criticality is considered less than a high-consequence event, the features relied on to mitigate the dose are identified as items relied on for safety. Only those mitigative controls capable of protecting against the immediate burst of radiation may be credited in this fashion, and their failure should be considered in the ISA.

[8] This is for the purpose of meeting the performance requirements only. For determining emergency-response procedures, a conservative estimate of the consequences of criticality, as discussed in Section 5.4.3.3 of this SRP, should be used.

If the applicant chooses to comply with the performance requirements by demonstrating subcriticality under normal and credible abnormal conditions (as discussed in Appendix 5-A of this SRP), the consequences of criticality do not need to be so characterized.

2. Nuclear processes are demonstrated to be subcritical under both normal and credible abnormal conditions. Subcriticality is based on the establishment of preventive controls that limit parameters to within specified ranges of values.

3. Protection against the consequences of an accidental criticality event is based on preventive controls, regardless of whether or not criticality is treated as a high-consequence event.

4. Subcriticality is based on methods that specify an acceptable margin of subcriticality for safety. For methods that rely on the explicit calculation of k_{eff}, this includes a minimum margin of subcriticality and any conservative assumptions, as discussed in Appendix 5-B of this SRP.

5. Controls on controlled parameters that are relied on to demonstrate subcriticality under normal and credible abnormal conditions, and/or to demonstrate that the risk of criticality is sufficiently low, are designated as items relied on for safety.

6. The applicant provides for double-contingency protection in the selection of criticality controls.

5.4.3.2.2 ISA Documentation

The reviewer should examine the applicant's onsite ISA documentation as part of its onsite vertical slice review. The onsite ISA documentation includes the safety-basis documentation used to perform the ISA and develop the ISA summary. This includes the applicant's CSEs, calculations, process-hazard analyses, and supporting technical documents, as well as any underlying process safety information (e.g., piping and instrumentation diagrams, drawings, procedures, and specifications). The purpose of this review is to confirm, on a sampling basis, whether the applicant's establishment and maintenance of criticality controls is adequate to protect against the consequences of an accidental criticality.

The ISA documentation is maintained onsite for an existing facility. For an applicant seeking to license a new facility, the full level of detail concerning hardware, procedures, and programs necessary to safely operate the facility usually would not exist at the time the ISA summary is submitted. The reviewer should use judgment in determining whether there is a sufficient level of detail to make a finding of a reasonable assurance of safety. It is expected that all aspects of the facility and process design that are safety-significant would be available for inspection before operation. The reviewer may therefore identify aspects of the design that are incomplete but have bearing on the "reasonable assurance" finding as items to be followed up on during any preoperational readiness review that may occur. (See discussion of license conditions in Section 5.6, "Evaluation Findings.")

The reviewer should use a risk-informed method to select nuclear processes and scenarios for the vertical slice review. Those areas containing high masses or concentrations of fissile material, high enrichment or fissile isotope abundance, or highly moderated materials (e.g., solutions) are normally considered areas of higher risk. Scenarios involving failures that have occurred either in criticality accidents or significant fuel facility events and those involving failures mainly of administrative controls, especially redundant controls on a single parameter

(e.g., sampling before solution transfer to unfavorable geometry), are normally considered of higher risk. The reviewer should select the higher-risk scenarios from these areas for a detailed review. The reviewer should also select some lower-risk processes and scenarios to obtain a diversity of process parameters, failure mechanisms, and control strategies to thoroughly test the ISA methodology. Consideration should be given to the type and number of controls; complexity of the controls; the applicant's familiarity with the processes, technology, and controls; whether the controls are redundant or diverse; the safety margin between normal operations and where criticality is possible; etc., in selecting scenarios for review.

The above pertains to the site-wide ISA reviewed for a new license. For a license amendment, the processes selected are limited to those affected by the amendment, and the reviewer should select those scenarios most likely to lead to accidental criticality, using criteria such as those in the previous paragraph.

Once the processes and scenarios are selected for review, the reviewer should determine, on a sampling basis, whether the applicant's controls are adequate to ensure that processes will be subcritical under normal and credible abnormal conditions and whether the applicant has provided for double contingency protection or identified and justified an acceptable alternative. This entails determining whether the relevant scenarios have been identified based on the process design, and whether controls are appropriately flowed into procedures, configuration management, and facility management measures. Evaluating the adequacy of controls may involve reviewing the applicant's criticality calculations and technical reports; it may also entail the reviewer performing independent criticality calculations to confirm the applicant's results. The reviewer may wish to consider such confirmatory analyses when the validity of those results is in doubt or when the sensitivity of those results to various parameters could have an impact on NCS. To the extent practical, the reviewer should use calculational methods different from those employed by the applicant to minimize the impact of any errors in the data or methods. Confirmatory analyses may not be feasible during a vertical slice review for a site-wide ISA, but the reviewer should perform at least some simplified bounding calculations to support a license amendment that involves a change to controlled parameters or safety limits. It is expected that amendment requests of this nature include the submittal of applicable CSEs and calculations as part of their technical basis.

Lastly, the reviewer should determine whether the applicant's criticality analysis for the selected scenarios is appropriately integrated into its ISA process. Acceptance criteria applicable to the applicant's treatment of selected NCS scenarios in its ISA are as follows:

1. The ISA Team includes facility personnel knowledgeable and experienced in NCS.

2. The CSEs, calculations, and other supporting technical information are maintained as part of the applicant's ISA documentation by including them in the facility's configuration management program and ISA program procedures.

3. Controls relied on to demonstrate subcriticality under normal or credible abnormal conditions and/or to demonstrate that the risk of individual criticality scenarios is sufficiently low are identified as IROFS.

4. Management measures are established to ensure that the occurrence of a contingency is "unlikely" as used in the context of the double-contingency principle. Management measures may be graded commensurate with an item's importance to safety.

   Management measures should be appropriate to the type, required reliability, and required availability of items relied on for safety. They include:

a. Procedures to ensure the reliable operation of engineered controls (e.g., surveillance and functional testing procedures and frequencies, calibration programs, and corrective and preventive maintenance programs)

b. Procedures to ensure that administrative controls will be correctly implemented (e.g., employee training and qualification in operating procedures, including refresher training; safe work practices; operating procedures; and postings)

c. Configuration management, audits and assessments, incident investigation, corrective actions, records management, and other quality-assurance elements (see Sections 11.3.1 through 11.3.8 of this SRP)

d. Management of records pertaining to the correct operation of the NCS Program; for example, training and qualification of NCS management and staff, NCS Program audits, document control of NCS safety-basis documents (including independent review of documents), maintenance of the CAAS, and tracking and resolution of NCS deficiencies

5.4.3.2.3 ISA Summary

The reviewer should examine the applicant's ISA summary to determine whether it meets the 10 CFR 70.65(b) requirements. The purpose of the review is to determine whether the applicant has complied with the applicable requirements specified in 10 CFR 70.66 for granting a license. This section of the SRP covers review of the NCS aspects of the ISA summary; detailed guidance for the balance of the review is found in Chapter 3 of this SRP.

Acceptance criteria applicable to the applicant's documentation of the criticality hazards in its ISA summary are as follows:

1. The ISA summary contains descriptions of the site, facility, and processes with respect to criticality safety. This may include process-flow diagrams, major process steps, and major pieces of equipment, with an emphasis on aspects of facility operations that affect criticality safety. The process description should be sufficiently simple to allow the staff an understanding of how the process works and what factors are important for criticality safety.

2. The ISA summary identifies the criticality safety basis for nuclear processes in sufficient detail to permit the reviewer to independently make a finding of reasonable assurance of safety. This includes a description of criticality-significant aspects of the process, the parameters controlled to prevent criticality, the engineered and administrative controls used to control them, their safety limits, and management measures.

3. The ISA summary demonstrates compliance with the performance requirements of 10 CFR 70.61, either by (1) demonstrating that nuclear processes will be subcritical under normal and credible abnormal conditions, or (2) demonstrating that the risk of individual criticality scenarios is sufficiently low. This includes sufficient detail to demonstrate that:

    a. All credible accident sequences that could lead to accidental criticality have been identified and adequate preventive controls established.

    b. All engineered features and operator actions that are relied on to demonstrate that nuclear processes will be subcritical under normal and credible abnormal

conditions have been identified as items relied on for safety, the description of which includes specifying their safety function and what systems and components are needed to perform their safety function.

c. Facility management measures appropriate to the type, required reliability, and required availability of items relied on for safety have been established.

4. The ISA summary demonstrates compliance with the double-contingency principle in its selection of items relied on for safety and application of management measures.

5. The ISA summary demonstrates compliance with the CAAS requirements of 10 CFR 70.24.

6. Documentation of the criticality scenarios, controls, and management measures relied on to prevent criticality complies with the applicant's commitments pertaining to the contents of its ISA summary.

5.4.3.3 Emergency Plan

Prevention is the primary means of protection against the consequences of accidental criticality, but there is still a small but finite risk that criticality events will occur. For facilities that require a CAAS in accordance with 10 CFR 70.24, the applicant must either submit an Emergency Plan or an evaluation demonstrating that an Emergency Plan is not required, in accordance with the provisions in 10 CFR 70.22(i)(1)(i) and (ii). (See Chapter 8 of this SRP for additional detail.)

If the applicant determines that a facility CAAS is not required, the reviewer should review the applicant's proposed activities to determine whether they meet the mass-based criteria of 10 CFR 70.24(a). If the criteria apply and the applicant submitted a request for exemption from the CAAS requirements of 10 CFR 70.24(a), the reviewer should evaluate whether an exemption is justified. As stated in ANSI/ANS-8.3, "installation of an alarm system implies a nontrivial risk of criticality." Whenever it is determined that criticality in a given area is credible and that it has the potential to adversely affect workers or the public, a criticality alarm is required unless an exemption is granted. False alarms and evacuations could pose a risk of injury to workers, and maintenance may expose workers who would not otherwise be exposed to occupational or potential criticality doses, so consideration may be given to whether installation of a CAAS results in a net risk benefit.

If a facility CAAS is required, the applicant must establish emergency procedures in response to activation of the alarm, in accordance with 10 CFR 70.24(a). In addition, the applicant must submit either an Emergency Plan or an evaluation demonstrating that an Emergency Plan is not required, in accordance with 10 CFR 70.22(i)(1)(i) and (ii). Acceptance criteria applicable to the applicant's emergency procedures and Emergency Plan, or to an evaluation that an Emergency Plan is not required, are as follows:

1. The applicant commits to the ANSI/ANS-8.3 and -8.23 standards.

2. The applicant has trained personnel to evacuate immediate upon activation of the alarm, and has designated assembly locations for personnel accountability. The designated assembly locations are located sufficiently away from fissile material so as to adequately protect personnel from excessive radiation doses. Evacuation routes are planned so as to minimize the potential for exposing evacuating personnel needlessly.

3. The applicant has provided monitoring equipment and procedures to monitor the dose rate in assembly locations, and to provide for safe reentry and recovery following the accident.

4. The applicant has provided for (a) monitoring to detect individuals with serious radiation exposures, (b) immediate decontamination of and first aid for exposed individuals, and (c) prompt and effective offsite medical attention.

5. The applicant has procedures in place to promptly notify local, State, and Federal authorities, including the NRC Operations Center, after an accident.

6. The applicant has procedures in place for coordination with offsite responders, including development of response plans and training in safety of nuclear materials (e.g., training in radiation hazards and restrictions on use of firefighting agents and methods).

7. The response to criticality events is commensurate with the onsite and offsite dose to individuals. Determination of a bounding radiation dose is done conservatively:

   a. A bounding number of fissions is assumed that is commensurate with the worst-case historical accidents appropriate to the type and quantity of material that could be involved.

      Estimates from historical accidents (e.g., tabulated in LA-13638, "A Review of Criticality Accidents") or calculational methods (e.g., use of NUREG/CR-6504, "An Updated Nuclear Criticality Slide Rule," or an empirical formula from peer-reviewed literature (Babry, Olsen, Tuck, Nomura)) may be used. Alternately, a more conservative estimate (e.g., the generic model in NUREG/CR-6410, if applicable) may be used.

   b. Conservative assumptions are made regarding the rate of reactivity insertion, the quantity of fissile material, the duration of the excursion, and the potential for oscillating criticality. Secondary bursts and/or a plateau should be considered a possibility if solutions or slurries are involved.

   c. Conservative assumptions are made regarding the distance from the reacting material to the site boundary, the worst credible location for fissile material, and the minimum amount of intervening shielding.

   d. Credit should not be taken for quenching mechanisms that are not ensured by physical law or the design of the process. In particular, credit should not be taken for termination or mitigation of an excursion by human intervention.

   e. Calculation of offsite doses takes into account both direct neutron and gamma radiation as well as the dose from radioactive fission products produced, and also takes into account such effects as groundshine, skyshine, and secondary gamma production.

   While the calculation of the radiation dose from criticality should be conservative, because of the uncertainty and wide variability in the severity of criticality accidents, care should be taken that calculations are not excessively conservative, which could result in personnel overreacting to an accident.

The reviewer should also coordinate with the review performed under SRP Chapter 8.

5.5 Review Procedures

For each area of review specified in subsection 5.3 of this SRP section, the review procedure is identified below. These review procedures are consistent with the identified SRP acceptance criteria. For deviations from the acceptance criteria, the staff should evaluate whether the applicant's proposed alternatives to the SRP criteria provide an acceptable method of complying with the relevant NRC requirements identified in subsection 5.4.

5.5.1 Acceptance Review

During the acceptance review of a license application, the reviewer should examine the submittals to identify major deficiencies in the information provided for each area of review specified in SRP Section 5.3. Reviewers must decide whether they have enough information to proceed with a detailed review. Less significant errors or deficiencies that can be addressed in a request for additional information should be accepted. However, before the NRC performs a detailed review, the applicant should correct major deficiencies that would require several requests for additional information to resolve.

Reviewers should record whether each area of review is adequately addressed in the application, is adequately addressed in a cited document, is not applicable to the application, or has a major deficiency.

5.5.2 Safety Evaluation

After the application has been accepted for review, the reviewer should conduct a complete review of the license application and a sampling review of the ISA summary to determine whether it meets the criteria specified in Section 5.4 of this SRP. The reviewer should consult with supporting reviewers, as appropriate, and coordinate with the reviewers for SRP Chapters 1, 2, 3, 8, and 11 to confirm the adequacy of all aspects of the application pertinent to NCS. The reviewer should also coordinate with the reviewers for other technical areas, and especially SRP Chapters 6 and 7, to ensure appropriate consideration of any cross-cutting issues. During the initial review, the reviewer should draft the safety evaluation report (SER) described below. A request for additional information (RAI) will be prepared when clarification and additional information are needed to determine whether the licensee's submittals comply with the regulations. The primary reviewer should coordinate with the licensing project manager in preparing RAIs. Additional information submitted by the applicant will be evaluated and a final SER will be provided to the licensing project manager.

5.5.2.1 License Application

The reviewer should review the pertinent sections of the license application for completeness and adequacy with respect to the requirements of 10 CFR 70.22, 70.23, 70.24, 70.61, 70.62, 70.64, and 70.65. The acceptance criteria in Section 5.4 provide a standard for acceptability with regard to the regulations. There may be some criteria that do not apply to the applicant's proposed activities. In other cases, the applicant may propose alternatives that provide an equivalent assurance of safety. In addition, a mere restatement of the acceptance criteria in the application may not be sufficient without an explanation of how the applicant intends to implement the criteria to achieve the underlying safety goals. Therefore, the reviewer should not review the application to verify compliance with the acceptance criteria, but should rather review the application to determine whether the program as a whole provides for a reasonable assurance of safety and meets the regulatory requirements, and should be guided by the acceptance criteria.

If, during the review, the reviewer identifies the need for additional information, the reviewer should coordinate development of a request for additional information with the licensing project manager. The purpose of a request for additional information is to identify information needed to make a regulatory decision (approval, denial, or conditional approval). The reviewer should also ascertain that the criticality safety approach is consistent with other sections of the license application, including those addressed by SRP Chapters 1, 2, 3, 4, 6, 7, 8, and 11.

For an existing facility, the reviewer should consult with NCS inspectors to identify any ongoing issues that could impact the licensing review. For a new facility, the reviewer should identify any issues that should be inspected during an operational readiness review, if such a review is to be performed. These items could include confirming that commitments made in the license application are properly implemented through procedures and training. For a new facility or a major new process at an existing facility, the reviewer should, if feasible, observe the actual operations under design and construction, or existing processes similar to the process under review. The reviewer should also review a sampling of criticality analysis applicable to the process under review, including calculations and supporting documentation (process-hazard analyses, piping and instrumentation diagrams, drawings, etc.). The reviewer may, if it helps him or her in reaching a licensing decision, perform independent analysis to verify the applicant's criticality evaluations. The depth and scope of such analyses should be commensurate with an area's importance to safety.

The reviewer will prepare input for the safety evaluation report (SER) during the review and provide it to the licensing project manager upon completion of the review. The SER should describe what aspects of the applicant's submittals were reviewed, how they were reviewed, and the basis for the reviewer's approval, denial, or conditional approval of the application.

5.5.2.2 ISA and ISA Summary

The reviewer should review the pertinent sections of the applicant's ISA summary, including a sampling of the criticality hazards, scenarios, and items relied on for safety together with their management measures. The ISA summary provides a supplemental demonstration of the adequacy of the criticality safety basis described in the CSEs. The reviewer should evaluate the applicant's ISA methodology, ISA documentation, and ISA summary to determine whether they demonstrate an acceptable level of safety that is consistent with the safety basis in the CSEs and whether they meet the regulatory requirements of 10 CFR 70.61, 70.62, 70.64, and 70.65.

In reviewing the ISA documentation and ISA summary, the reviewer may identify the need for additional information, as described in the previous section. For a new facility or a major new process at an existing facility, the reviewer should, in general, perform an onsite vertical slice review of the ISA documentation, including primarily the CSEs. The reviewer should ensure that any commitments necessary to make a "reasonable assurance" finding are included in the license application. The reviewer should document the ISA review as part of the SER.

5.5.2.3 Emergency Plan

The reviewer should first determine whether an Emergency Plan is required for the facility. If an Emergency Plan is required, the reviewer should review its pertinent sections to determine whether it provides for adequate protection of workers and the public against the consequences of an accidental criticality. During the review, the reviewer may identify the need for additional information, as discussed above. The reviewer should ensure that any commitments necessary to make a "reasonable assurance" finding are included in the license application. The reviewer should document the review as part of the SER.

5.6 Evaluation Findings

The regulations in 10 CFR 70.23 and 70.66 state that an application for a license will be approved if the Commission can make the general findings listed in those sections. The basis for the general findings is an evaluation of whether the application adequately addresses all of the applicable regulatory requirements. More specifically, the staff's evaluation should determine whether the licensing submittals provide sufficient information to satisfy the regulatory requirements listed in Section 5.4.1 of this SRP and whether the applicant has appropriately addressed the regulatory acceptance criteria in SRP Section 5.4.3. The SER should state how the applicable regulatory requirements have or have not been met based on the acceptance criteria described in this chapter of the SRP. If the applicant chooses to use an alternative approach, the reviewer should discuss in the SER whether the proposed approach satisfies the applicable regulatory requirements. The reviewers should use the following approach to document their evaluation:

1. State a specific regulatory requirement that applies to the application. Detailed acceptance criteria may be included where appropriate or necessary.

2. Identify the areas where the regulatory requirement is addressed in the application, including the areas where the specific acceptance criteria described in this SRP are addressed.

3. Describe your evaluation of the application, the basis for your conclusion, and whether regulatory requirements are met.

4. Repeat these steps for every regulatory requirement that applies to the application.

There are three possible outcomes to the staff's licensing review: (1) approval of the applicant's application or amendment request, (2) denial of the application or request, or (3) approval with conditions. If the reviewer cannot make a finding of a reasonable assurance of safety, the reviewer may consider proposing a license condition. Absent an NRC order, license conditions must be agreed upon with the licensee or applicant before becoming part of the license. A license condition should only be proposed if there is reasonable assurance that, if the licensee meets the condition, all regulatory requirements will be satisfied. Thus, license conditions should not be used to cover major deficiencies in an application. License conditions should be unambiguous, inspectable, and enforceable. They should only require those actions necessary to ensure compliance with applicable regulations. The basis for license conditions must be documented in the SER.

If the staff's review verifies that the NCS Program provides for a reasonable assurance of safety and meets the applicable regulatory requirements of 10 CFR Part 70, the staff will document its findings to that effect. The NRC staff may include statements and conclusions similar to those described below if appropriate to the review:

> The staff has reviewed the applicant's NCS Program, ISA, and ISA summary [or "…ISA, ISA Summary, and Emergency Plan", if appropriate] in ways consistent with SRP Chapter 5. Based on its review, the staff has reasonable assurance of the following:
>
> - The applicant will have in place an NCS Program that will be developed, implemented, and maintained to ensure that fissile material is possessed, stored,

and used safely and in accordance with the requirements of 10 CFR 70.61(b) and (d) and 70.64(a)(9).

- The applicant's conduct of operations will be based on NCS technical practices that will ensure that fissile material will be possessed, stored, and used safely and in accordance with the requirements of 10 CFR 70.61(b) and (d) and 70.64(a)(9).

- The applicant will develop, implement, and maintain a criticality accident alarm system and emergency procedures in accordance with the requirements of 10 CFR 70.24.

- The applicant will establish and implement NCS controls, and maintain them through the application of facility management measures, to ensure that nuclear processes will be subcritical under normal and credible abnormal conditions and will provide for double contingency protection, in accordance with 10 CFR 70.61(d).

Based on these conclusions, the staff has determined that the applicant's NCS Program meets the requirements of 10 CFR Part 70 and provides reasonable assurance of safety against the consequences of an accidental criticality.

The staff should recognize that this is an example only, and that the specific conclusions to be reached will vary depending on the results of the licensing review. For a denial, the reviewer may state: "*Based on its review, the staff does not have reasonable assurance of safety*…" and then summarize the reasons why. For a conditional approval, the reviewer may state: "*Based on its review, the staff has reasonable assurance of safety, subject to the following conditions*." The staff may make other such conclusions as appropriate.

5.7 References

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ANSI/ANS, "Criticality Accident Alarm System," ANSI/ANS-8.3-1997 (R2003), La Grange Park, IL, 2003.

ANSI/ANS, "Use of Borosilicate-Glass Raschig Rings as a Neutron Absorber in Solutions of Fissile Material," ANSI/ANS-8.5-1996 (R2007), La Grange Park, IL, 2007.

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Paxton, H.C., and N.L. Pruvost, “Critical Dimensions of Systems Containing ^{235}U, ^{239}Pu, and ^{233}U,” LA-10860-MS, Los Alamos National Laboratory, Los Alamos, NM, 1987.

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U.S. Nuclear Regulatory Commission, “Guide for Validation of Nuclear Criticality Safety Calculational Methodology,” NUREG/CR-6698, January 2001.

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APPENDIX A

NUCLEAR CRITICALITY SAFETY PERFORMANCE REQUIREMENTS AND DOUBLE-CONTINGENCY PRINCIPLE

Purpose

This appendix provides additional guidance on nuclear criticality safety performance requirements and the double-contingency principle. The purpose of this appendix is to clarify the relationship between the requirements in Title 10, Energy," of the *Code of Federal Regulations* (10 CFR) Part 70, "Domestic Licensing of Special Nuclear Material," Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material," to ensure nuclear criticality safety. These requirements are described in 10 CFR 70.61(b), 70.61(d), and 70.64(a)(9).

Introduction

The regulations in Subpart H of 10 CFR Part 70 contain three separate requirements to ensure nuclear criticality safety. One requirement, 10 CFR 70.64(a)(9), requires that the design of new facilities and processes provide for criticality control including adherence to the double contingency principle. A second requirement, 10 CFR 70.61(b), requires that high consequence events (which typically will include criticality accidents) be highly unlikely. A third requirement, 10 CFR 70.61(d), requires that nuclear criticality accidents be limited by assuring that under normal and credible abnormal conditions[1] all nuclear processes are subcritical, including use of an approved margin of subcriticality, and also requires that the primary means of criticality protection be prevention.

Discussion

There are three separate requirements in 10 CFR Part 70 for ensuring nuclear criticality safety. The first requirement of 10 CFR 70.64(a)(9) is more prescriptive and deterministic than the performance requirements of 10 CFR 70.61. 10 CFR 70.64 establishes baseline design criteria for new facilities and processes, similar to general design criteria in 10 CFR Part 50. One of these baseline design criteria applies directly to criticality safety. Specifically, 10 CFR 70.64(a)(9) requires that the design "provide for criticality control including adherence to the double contingency principle." Section 70.64(b) further specifies that new facilities or processes must incorporate defense-in-depth practices, which is defined as 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." Section 70.64(b)(1) specifically mentions preference for the selection of engineered controls over administrative controls to increase overall system reliability.

Another more risk-informed and performance-based requirement is contained in 10 CFR 70.61. In short, this regulation stipulates that credible high consequence events shall be made "highly

[1] As stated in the footnote on page 5-1 of this SRP, the term "credible" is as used herein should be understood in the context of meeting the double contingency principle; this is different from its usage in10 CFR 70.61(b) and (c).

unlikely" or be mitigated (10 CFR 70.61(b)) and that intermediate consequences shall be made "unlikely" or be mitigated (10 CFR 70.61(c)). High and intermediate consequence thresholds for workers and members of the public are established for both chemical and radiological events. Under this risk-informed and performance-based regulation a criticality accident would typically be considered a high consequence event to the worker since the worker could receive a dose in excess of 100 rem TEDE (total effective dose equivalent).

In addition, there is a separate provision within 10 CFR 70.61 that specifically addresses criticality safety. Section 70.61(d) states that, in addition to meeting the requirements above for high and intermediate consequence events, 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." The purpose of this is to preclude a situation where nuclear criticality would be permitted as long as the dose thresholds of § 70.61(b) and § 70.61(c) are not exceeded.

Thus, 10 CFR Part 70 contains three separate and distinct requirements related to precluding nuclear criticality (10 CFR 70.64(a)(9), 10 CFR 70.61(b), and 10 CFR 70.61(d)), besides provisions in § 70.24 and § 70.52, which pertain to mitigating the consequences of a criticality accident and reporting its occurrence.

Section 70.61(d) of 10 CFR Part 70

Section 70.61(d) requires that under normal and credible abnormal conditions all nuclear processes are subcritical including use of an approved margin of subcriticality for safety. In addition, preventive controls and measures must be the primary means of protection against criticality. Meeting this performance requirement entails a number of factors. First, all normal and credible abnormal conditions must be identified. There are many different methods that may be employed to do this, but a systematic methodology should be used to provide reasonable assurance that the complete spectrum of credible conditions has been identified.

Normal conditions are those specifically allowed for as part of the normal modes of operation in the facility design (i.e., conditions that may occur without the failure of any items relied on for safety (IROFS)). Abnormal conditions are those events not planned for as a regular occurrence in the facility or operation design. They include those undesirable conditions that are the result of external events and process deviations, including those resulting from the failure of identified IROFS. Credible abnormal events include both credible single events (e.g., an external event or failure of a single IROFS) and credible sequences of events. Credible sequences of events include, but may not be limited to, chains of independent but not unlikely process deviations (i.e., not precluded by IROFS) and chains of related failures of IROFS (i.e., failures that are not independent). Some judgment must be employed in determining what constitutes a credible abnormal condition. It is not necessary to include multiple independent failures of IROFS within the spectrum of credible abnormal conditions. Since many licensees meet the process analysis requirement from ANSI/ANS-8.1 by application of the double contingency principle the intent is that ensuring subcritical under "credible abnormal conditions" does not necessitate considering events and failures beyond that required for compliance with the double contingency principle.

The requirement that nuclear processes be subcritical is satisfied if the licensee or applicant demonstrates that the most reactive credible conditions are subcritical. To provide adequate

assurance of subcriticality, this must include margin. There are several different ways to demonstrate sub-criticality, as discussed below:

- If subcriticality is demonstrated using an appropriately validated calculation method, then k_{eff} (K effective) (including calculation's uncertainties) must be less than the approved upper subcritical limit (USL), as specified in the license. Meeting this requires that models bound actual anticipated conditions (e.g., tolerances and uncertainties appropriately taken into account, most reactive credible system parameters allowed are assumed), as specified in the license. Additional guidance is provided in the criticality chapter of NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," (Sections 5.4.3.4.1, 5.4.3.4.2, and 5.4.3.4.4).

- Subcritical margin may also be expressed in terms of system parameters rather than system k_{eff}. An example would be where the licensee or applicant has committed to use mass or dimensional limits that are some specified fraction of the critical values of those parameters. In such cases, the approach used must be approved by the NRC.

- Subcriticality may be demonstrated on the basis of subcritical limits included in the license, U.S. Nuclear Regulatory Commission (NRC) endorsed American National Standards Institute (ANSI) standards, or other documents that have been approved or endorsed by NRC. Approval or endorsement by the NRC implies that the Agency has found these references to include an acceptable margin of subcriticality for safety.

- Industry handbooks of criticality data may also be used if widely accepted in the nuclear industry and if used in accordance with any limitations of that data. The NRC, however, reserves the right to evaluate the use of such handbooks on a case-by-case basis.

The requirement that preventive controls and measures be the primary means of protection against criticality is satisfied if engineered or administrative controls relied on to meet § 70.61(d) are designed to prevent occurrence of the critical excursion rather than mitigate its consequences. By stating that prevention should be the *primary* means of protection, it is recognized that there may be extraordinarily rare occasions when prevention alone is not sufficient to meet § 70.61(d). Such cases require convincing demonstration that there is no practicable way to meet § 70.61(d) with solely preventive measures.

Some examples where the § 70.61(d) requirement has not been met:

- A process in which the most reactive credible conditions have not been modeled and have not been shown to have k_{eff} less than the approved USL.

- A process in which subcriticality is based on criticality calculations, but the model is outside the area of applicability of the calculation method.

- A process for which there is an unanalyzed or unanticipated credible abnormal condition (e.g., unanticipated failure of an IROFS or unanticipated external event).

- A process for which there is a credible common-mode event that can result in the failure of all criticality controls such that it can lead to a critical configuration.

- A process in which the designated IROFS are not sufficient to limit the system to a subcritical configuration.

Relationship of 10 CFR 70.61(b) to 10 CFR 70.61(d)

Section 70.61(b) states ". . . the risk of each credible high consequence event must be limited. . . . Controls . . . shall be applied to the extent needed to reduce the likelihood of occurrence of the event so that . . . the event is highly unlikely . . . ."

Section 70.61(d) states ". . . the risk of nuclear criticality accidents must be limited by assuring that under normal and credible abnormal conditions, all nuclear processes are subcritical, including an approved margin of subcriticality . . . ."

As written, the rule language requires both provisions (i.e., § 70.61(b) and § 70.61(d)) be met, since § 70.61(d) states "In addition to complying with paragraphs (b) and (c) of this section . . . ." However, during the 10 CFR Part 70 rulemaking, regulated industry representatives met with NRC and submitted letters in which they expressed their desire that NRC not consider criticality accidents high consequence events and not associate quantitative likelihoods with double contingency. As discussed in the release notes issued with the 10 CFR Part 70 rulemaking, in response to industry arguments accidental criticality was explicitly removed from the high consequence (§ 70.61(b)) category and a separate performance requirement for criticality (§ 70.61(d)) was created. The staff felt that in so doing, both the industry's desires as well as the staff's needs would be met. Further, the staff felt that the § 70.61(d) requirement required the same information as that required by § 70.61(b). Saying all nuclear processes must be subcritical in § 70.61(d) implies that criticality events must be prevented. Moreover, since likelihood is never zero, some likelihood must be assumed; the highly unlikely requirement in § 70.61(b) is appropriate for this. Therefore, the staff felt that by removing criticality explicitly from § 70.61(b) and creating § 70.61(d) during the rulemaking, the staff still retained its desired outcome–to prevent criticality accidents from occurring. The final rule Statement of Considerations (SOC) stated that "…the NRC believes that a separate performance requirement for nuclear criticality prevention is appropriate. The staff recognizes that many (but not all) nuclear criticality accidents would reasonably be expected to result in worker doses that exceed the high- and intermediate-consequence standards in 10 CFR 70.61(b) or (c). However, regardless of the dose directly resulting from the accident, an inadvertent nuclear criticality should be avoided. This is consistent with the Commission's goal to prevent inadvertent criticalities, as reflected in the NRC Strategic Plan (NUREG-1614) . . . ." However, there remained ambiguity regarding the relationship between § 70.61(b) and § 70.61(d). While the staff's intent was to have a single performance requirement for criticality accidents, this cannot be substantiated by a literal examination of the final rule.

Comparing the language in § 70.61(b) and (d), one concludes that § 70.61(d) is actually more restrictive than § 70.61(b). Section 70.61(d) essentially requires that there be no criticality accidents, with a high degree of assurance, whereas § 70.61(b) essentially requires that deaths and injuries (as implemented through a dose limit) be precluded (i.e., be made to be highly unlikely). If criticality accidents are prevented, then deaths and injuries are also prevented. However, the converse is not necessarily true; if deaths and injuries are prevented, criticality accidents are not necessarily prevented. Therefore, if one meets § 70.61(d), then one also automatically meets § 70.61(b); and if one meets § 70.61(b) through preventive means (that is, preventing the accident and not just the dose consequence), and also meets the additional requirements specified in § 70.61(d), then one also meets § 70.61(d).Thus, because the

spectrum of credible abnormal conditions in 10 CFR 70.61(d) need not consider upsets beyond those required for compliance with the double contingency principle, if a licensee chooses to address criticality event sequences under 10 CFR 70.61(b) and usesa preventive strategy with an approved margin of subcriticality for safety, then the licensee will have also met the requirements of10 CFR 70.61(d). However, if the licensee chooses to address criticality event sequences under 10 CFR 70.61(b) with a mitigative strategy, then the licensee will not have met the requirements under 10 CFR 70.61(d) and additional controls will have to be identified to ensure subcriticality.

Another consideration is that both § 70.61(b) and § 70.61(d) set the standard that must be met (i.e., the performance requirements), but not the methodology. Methodology requirements are contained in § 70.62. One cannot look at § 70.61 in a vacuum. All other 10 CFR Part 70 provisions must also be met, including the § 70.62(c) provision that requires the integrated safety analysis (ISA) to include radiological hazards, facility hazards, potential accident sequences, and identification of IROFS as well as the assumptions and conditions under which the IROFS are relied upon to support compliance with § 70.61 performance requirements. It also requires that the ISA team include a person with experience in criticality safety. These requirements must be met regardless of whether the licensee attempts to meet the performance requirements starting from § 70.61(b) or § 70.61(d). The three options below can be seen to be equivalent when one considers that § 70.62 must also be met for all cases.

To meet the regulations and prevent criticalities, an applicant/licensee may use one of the three approaches below (in conjunction with other 10 CFR Part 70 requirements, including those in § 70.62):

1. Demonstrate compliance with § 70.61(d); or

2. Demonstrate compliance with § 70.61(b), considering only preventive controls and including an approved margin of subcriticality; or

3. Separately demonstrate compliance with both § 70.61(d) and § 70.61(b).

Use of any of the above three approaches will satisfy the regulations.

That both § 70.61(b) and § 70.61(d) apply to criticality is supported by this SRP. In addition, there are several references to the requirement to make criticality highly unlikely.

Double Contingency Principle § 70.64(a)(9)

In addition to complying with the performance requirement in § 70.61, new facilities and processes are required to comply with the baseline design criteria in § 70.64.
Section 70.64(a)(9) requires that the design provide for criticality control, including adherence to the double contingency principle (DCP). In addition to this requirement for new facilities and processes, many existing facilities and processes have license commitments to meet the DCP for licensed activities. Although Subpart H of 10 CFR Part 70 is relatively new, this conceptual framework is not new. Licensees have historically committed to ANSI/American Nuclear Society -8.1 (ANSI/ANS-8.1). This standard also requires that nuclear processes be ensured to be subcritical under normal and credible abnormal conditions. By contrast, the DCP is stated as a recommendation of ANSI/ANS-8.1. Therefore, the standard recognizes that adherence to the DCP can be one means, but is not necessarily the only means of meeting the underlying

subcriticality requirement. The conditions under which compliance with the DCP ensures that § 70.61(d) is met are discussed below.

The double contingency principle is a design principle intended to be used in designing a facility that meets the performance requirements of § 70.61. The definition in § 70.4 ("…process designs *should* incorporate sufficient factors of safety…") implicitly recognizes that there may be some cases in which a strict adherence to the double contingency principle is not practicable. This should be an exceedingly rare situation and should be accompanied by a convincing demonstration that a strict adherence to the double contingency principle is not practicable. Section 70.64(a) allows for this in stating that licensees must maintain the application of this criterion unless the integrated safety analysis (ISA) demonstrates that it is not relied on for safety or otherwise does not require adherence. For example, the consequence of criticality may be reduced to less than a high-consequence event in a heavily shielded facility; the NRC has endorsed (in Regulatory Guide 3.71) ANSI/ANS-8.10-1983 (R2005), which states that singly contingent operation may be permitted if the whole body dose outside the shielded and confined area following criticality does not exceed 25 rem. Another example may occur in UF_6 cylinder storage yards, which have been found acceptable based on a single moderation control barrier (cylinder integrity). Yet another example may be a process involving only depleted or natural uranium, which may be singly contingent on enrichment control.

The presence of two controls may not be necessary, or may not be sufficient, to meet the DCP. The DCP does not necessarily require two controls; it requires "at least two…changes in process conditions" be needed before criticality is possible. Meeting this may necessitate one, two, or more than two controls depending on the possible conditions that can lead to criticality. In general, there will be many pathways to criticality and, therefore, more than two controls required to meet the DCP for an entire process.

In addition, § 70.64(b)(1) requires that the design must incorporate, whenever practicable, preference for the selection of engineered over administrative controls to increase overall system reliability. Passive engineered controls are generally preferable to active engineered controls, and engineered to administrative controls. In addition, process design should rely on geometry control as opposed to control of other parameters whenever practicable, and on diverse means of control (e.g., reliance on two different criticality parameters or different means of controlling one parameter) whenever practicable, to minimize the potential for common-mode failure. Cases in which these preferences cannot be complied with will generally require more justification to show adherence with the DCP. For example, one cannot claim that the double contingency principle is met with only two controls (regardless of type) if the resulting configuration fails to protect against all credible pathways to criticality or limit the risk of inadvertent criticality as required in 10 CFR 70.61(d).

Relationship between § 70.61 and § 70.64(a)(9)

As stated above, adherence to the DCP can be one means of meeting the performance requirements of § 70.61(d) (and, therefore, also § 70.61(b)). Historically, a number of different approaches to double contingency have been used. Some cases that have been used in the past may not be sufficiently robust to satisfy the performance requirements of § 70.61. Typically, this has been due to a reliance on controls that were not sufficiently robust (e.g., weak administrative controls). The purpose of this guidance is not to promote a new standard for all applications but rather to clarify when adherence to the DCP will establish a sufficient basis for

meeting the performance requirements. To facilitate this, the following guidance is provided on the various terms in the definition of the DCP:

Unlikely changes in process conditions should be expected to occur rarely, or not at all, during the lifetime of the facility. Operational events that occur regularly should not be credited as a contingency relied on to meet the DCP (although they may constitute part of a contingency if a combination of events may be considered unlikely). Therefore, the occurrence of any such event generally reveals a deficiency in the design that should result in corrective action. Determination that a contingency is unlikely should be based on objective attributes of the criticality controls, rather than on subjective judgment alone. Examples of such attributes are environmental factors that can degrade the reliability and availability of controls, margin, and redundancy and diversity of controls. (Guidance on some of the availability and reliability qualities that should be considered is provided in Section 3.4.3.2(9) of this SRP and NUREG-1718, "Standard Review Plan for the Review of a License Application for a Mixed Oxide (MOX) Fuel Fabrication Facility," Section 5.4.3.2(B)(vii).) Management measures should be provided, as needed, to ensure that the failure of the criticality controls is an unlikely contingency. (NOTE: Usage of the term "unlikely" in the DCP is not equivalent to the term as used in § 70.61(c) for intermediate consequence events.)

Independent changes in process conditions are such that one contingency neither causes another contingency nor increases its likelihood of occurrence. The existence of any credible common-mode failure of both contingencies means that it is not valid to consider them independent. For example, related actions performed by the same individual or using the same equipment will not generally be sufficiently independent to meet the DCP.

Concurrent does not mean that the two changes in process conditions must occur simultaneously, but that the effect of the first contingency persists until the second contingency occurs. Prompt detection and correction of abnormal conditions should thus be provided to restore double contingency protection. The time required to detect and correct failures should be significantly shorter than the anticipated time between failures in order for there to be significant risk reduction provided from failure detection.

Changes in process conditions do not imply that reliance on two different parameters is mandatory to meet the DCP. Reliance on two different parameters is preferable to reliance on two controls on a single parameter, however, because of the difficulty in achieving complete independence when controlling one parameter. In those cases in which single parameter control is unavoidable, great care should be taken to ensure that no common-mode failures exist.

In addition to meeting the above, the following guidance is provided to illustrate the conditions under which adherence to the double contingency principle (in terms of the guidance above) is sufficient to meet the performance requirement of 10 CFR 70.61:

- Controls are established on system parameters to preclude changes in process conditions, and these controls are designated as IROFS in accordance with § 70.61(e). (Reliance should be based on items that are designated as IROFS in the ISA Summary and not on random factors that may or may not be maintained.)

- The condition resulting from the failure of a leg of double contingency has been shown to be subcritical with an acceptable margin (e.g., k_{eff} is less than USL, parameters are within subcritical limits specified in the license or endorsed standards).

- Controls are sufficiently reliable to ensure that each change in process conditions necessary for criticality is "unlikely." Management measures are established to ensure that they are available and reliable to perform their safety function.

Because the DCP is only one means of meeting the performance requirements, it is possible to meet the DCP without meeting the conditions above (including designating criticality controls as IROFS in the ISA Summary). In this case, however, another method must be relied on to meet the § 70.61 performance requirements. However, in order to use compliance with the DCP as part of the demonstration of meeting the § 70.61 performance requirements, these conditions should be met.

Some specific examples of control systems that meet § 70.61(d) through use of the DCP follow:

A passive geometry control in which no credible failure mode (e.g., bulging, corrosion, or leakage) exists and which has been placed under configuration management:

- A favorable geometry vessel in a benign environment in which corrosion or other material degradation is not credible. In addition, the vessel is of such robust construction (e.g., thick stainless steel, steel surrounded by concrete) that it is unquestionably not going to leak, and there is no credible mechanism for the material to accumulate in an unfavorable configuration.

- A tank that is not authorized to contain fissile material is located far outside the fissile material handling areas and is physically isolated from fissile liquid processes by a blank flange or siphon break, such that backflow is not credible.

Two passive controls in which there is a credible failure mode, and there are sufficient management measures to ensure the controls continue to perform their safety functions (e.g., periodic surveillance to detect corrosion/bulging):

- A favorable geometry solution column, in which leakage of the tank is a credible upset. In addition, the column is in an area in which the solution would leak into a favorable geometry dike, and the leakage would be self-revealing (i.e., column is in a continually manned area) or the column and dike would be subject to periodic surveillance.

- A double-sleeved solution line in which leakage of the inner pipe would be quickly detected (e.g., by conductivity probe between the pipes or by transparent baffling).

- A storage array in which fissile material is stored in fixed geometry containers, and the spacing between containers is fixed by birdcages or other fixed devices, and geometry and spacing controls are ensured by configuration management and periodic walkthroughs.

One passive control under configuration management and one active engineered control whose reliability is ensured by periodic functional testing, maintenance, and an alarm to automatically indicate its failure:

- A calciner relying on geometry and moderation control in which geometry control is

provided by limiting the calciner interior to the height of a single layer of pellet boats, and moderation control is provided by monitoring of the calciner temperature. Temperature control is ensured by thermocouples that alarm if the temperature drops below a minimum set-point.

- A down-blending tank that is subcritical for uranium solutions with less than a limiting enrichment in which volume control is provided by the design of the tank and enrichment control is provided using mass flow totalizers and a mechanical stirrer. The failure of these active devices automatically stops the transfer of solution and actuates an alarm.

- A large geometry tank relying on raschig rings for criticality control in which the raschig rings are only approved up to a limiting concentration, and the concentration is controlled by an in-line sodium iodide detector that closes an isolation valve when actuated.

One engineered and one enhanced administrative control in which the instrumentation and devices included in the administrative control are subject to periodic functional testing and maintenance, and the operator action is performed routinely or reinforced by periodic drills and training:

- A powder handling glovebox relying on moderator and mass control in which moderator control is provided by the glovebox design (e.g., airtight, dry nitrogen atmosphere, sloped ventilation ductwork) and mass is procedurally controlled by limiting batch size. In addition, mass transfers must be logged into a computer tracking system that alarms if mass limits are exceeded.

- A vessel in which the volume of fissile solution is controlled by the diameter of the tank and by procedurally limiting the solution height. In addition, operator actions are backed up with a high-level switch equipped with an alarm.

One engineered control and one simple administrative control in which the reliability of the administrative control is subject to a high degree of redundancy:

- Solution transfer from favorable to unfavorable geometry relying on two controls on concentration. Two different operators are required to draw separate samples which are then analyzed in the laboratory by two different methods and shown to be within concentration limits before transfer is authorized. In addition, the area supervisor maintains control of a key to the transfer pump so that the procedure may not be inadvertently bypassed. This is backed up with an in-line sodium iodide detector that automatically closes an isolation valve if concentration limits are exceeded.

  (NOTE: Use of two independent samples is generally not considered adequate for both legs of double contingency because of the difficulty in ensuring complete independence between the samples.)

Two administrative controls that are independent (e.g., performed by different individuals or verified by a supervisor), for which human factors have been considered in the design of the process such that the operation is not prone to error, and there is sufficient margin to require multiple failures before the criticality control limit can be exceeded:

- A glovebox relying on dual mass control in which two operators or an operator and a supervisor must confirm that placing material into the glovebox will not result in the mass limit being exceeded. In addition, criticality would require the mass limit to be exceeded multiple times, which would be difficult to achieve and would be readily apparent.

- A drum storage array limited to a vertical stack of four drums in which there are no forklifts in the area capable of raising a drum above this height. In addition, the drums are very heavy and violating the stack height limit would require an immense physical effort.

- A planar storage array in which mass-controlled containers are procedurally limited to not less than 24 inches center-to-center, and in which criticality would require assembling a very large number of containers into a spherical heap and reflecting them intimately with water.

Other considerations ensuring that there is no credible event leading to criticality:

- A facility handling uranium enriched to no more than 1 weight percent (wt%) uranium-235 (^{235}U).

- A facility in which the site-wide limit is less than a minimum critical mass.

- A facility storing contaminated soil or equipment with a very low uranium concentration in which there is no known concentration mechanism that can lead to a critical configuration.

Some examples of control systems that would not meet § 70.61(d) through use of the DCP:

Double contingency consisting of two single operator actions without any supervisor verification or redundancy:

- Solution transfers that rely only on two operators drawing separate samples or in which a single procedural deviation could cause an unauthorized transfer.

- A mass controlled system in which triple batching (i.e., two successive batching errors) could result in criticality when the mass transfers are done by a single operator.

- A storage array in which two violations on administrative spacing requirements could credibly lead to criticality.

A leg of double contingency consisting of an administrative control for which correct performance of the action cannot be readily confirmed or is subjective:

- A solution vessel in which the operator is required to confirm concentration or chemical form by visually observing a color change in the solution.

- A tank in which the operator is required to verify prior to operation that the tank is "essentially empty."

A leg of double contingency consisting of complex administrative tasks composed of multiple steps that are susceptible to error:

- A glovebox in which the operator is required to calculate the mass of plastic, paper, and other miscellaneous materials in order to comply with moderator control.

- A solution transfer operation in which one leg consists solely on a single sample being correctly drawn, labeled, analyzed, recorded, and read.

- Maintenance on a dissolution process in which criticality safety relies on the correct performance of a procedure to replace an in-line filter. The procedure requires that the filter be removed, flushed, and re-installed in a multi-step process that has several opportunities for failure.

A leg of double contingency consisting of an administrative control with insufficient margin to ensure that the safety limit will not be exceeded:

- A glovebox in which mass is controlled administratively, and in which the normal mass limit is almost equal to the minimum critical mass.

- A planar storage array in which spacing between containers is administratively limited to be less than 24 inches center-to-center, and in which criticality will result if a few containers are placed 23 inches apart.

A leg of double contingency consisting of an engineered control in which there is no reasonable means to detect and correct the failure within a given time.

- A solution process in which it is plausible for concentrated solution to be allowed to accumulate undetected over a long period of time in an unfavorable geometry.

- A vessel in which geometry control is provided by a double wall, but there is no means of detecting leakage between the walls. In addition, the vessel is of a type known to have a history of leakage (e.g., heat exchanger).

A leg of double contingency consisting of a control in an environment where its safety function is degraded.

- A solution vessel relied on for geometry control, but which is subject to pressure fluctuations that can cause the vessel to bulge beyond a favorable diameter.

- Instrumentation whose performance is degraded under conditions that can be reasonably expected during normal operations (e.g., temperature, pressure, presence of corrosive gases, or loss of essential utilities such as electricity, plant air, or water).

A leg of double contingency consisting of a control where its behavior under adverse conditions is uncertain.

- An unfavorable geometry pump in which mass control relies on the presumption that the pump will malfunction before an unsafe volume of uranium accumulates in the pump oil,

and for which no failures of this type have been observed.

A leg of double contingency consisting of undeclared design features or process conditions that are not precluded by being explicitly controlled.

- A powder blending operation in which uranium oxide density that is less than the theoretical density is assumed, but the process variables affecting density (e.g., calcinations temperature, mechanical pressure of the pellet press) are not specifically controlled and there is no confirmatory sampling.

- A solvent extraction process in which nominal concentration of uranyl nitrate is assumed, but there is no in-line monitoring or confirmatory sampling.

- A vault in which the mass limit is not controlled by procedure or license limit, but is merely based on current inventory.

- A process relying on the favorable geometry of passive equipment, but for which the dimensions and/or material composition are not specifically identified as criticality controls.

This list is merely illustrative and not meant to be exhaustive. However, these examples demonstrate that double contingency that satisfies the performance requirements can be based on one, two, or more than two passive engineered, active engineered, or administrative controls, and that reliability and availability of those controls depends on management measures, safety margins, environmental conditions, human factors, and other process and control characteristics. Not every application similar to these examples will be found acceptable—determination must be made on the totality of the information available, and an analyst should consider all factors that may degrade the robustness of the controls.

Technical Review Guidance

Relationship of 10 CFR 70.61(b) and 10 CFR 70.61(d)

The reviewer needs to assure that all applicable 10 CFR Part 70 criticality provisions (including § 70.62(c)) are met. To meet the regulations and prevent criticalities an applicant/licensee may use one of the three approaches below (in conjunction with other 10 CFR Part 70 requirements, including those in § 70.62):

1. Demonstrate compliance with § 70.61(d); or

2. Demonstrate compliance with § 70.61(b), considering only preventive controls and including an approved margin of subcriticality; or

3. Separately demonstrate compliance with both § 70.61(d) and § 70.61(b).

Use of any of the above three approaches will satisfy the regulations.

Staff should not dictate which of the above three options must be met; rather, staff should assure that the applicant/licensee has met one of these options.

Double Contingency Principle

One way, but not the only way, of meeting 10 CFR 70.61 is by applying the double contingency principle (defined in 10 CFR 70.4) to accident sequences leading to criticality that are required to be developed per § 70.62. Adherence to the DCP will satisfy the performance requirement of § 70.61(d) (and therefore also § 70.61(b)) provided the following conditions are met:

- Controls are established on system parameters to preclude changes in process conditions, and these controls are designated as IROFS in accordance with § 70.61(e). (Reliance should be based on items that are designated as IROFS in the ISA Summary and not on random factors that may or may not be maintained.)

- The condition resulting from the failure of a leg of double contingency has been shown to be subcritical with an acceptable margin (e.g., k_{eff} is less than USL, parameters are within subcritical limits specified in the license or endorsed standards).

- Controls are sufficiently reliable to ensure that each change in process conditions necessary for criticality is "unlikely." Management measures are established to ensure that they are available and reliable to perform their safety function.

In the absence of meeting these conditions, an alternate demonstration of compliance with the performance requirements should be provided.

APPENDIX B

JUSTIFICATION FOR MINIMUM MARGIN OF SUBCRITICALITY FOR SAFETY

Purpose

This appendix provides additional guidance for the minimum margin of subcriticality for safety. These evaluations are used in demonstrating compliance with the performance requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 70.61, "Performance Requirements."

Introduction

The regulation in 10 CFR 70.61(d) requires, in part, that licensees or applicants (henceforth to be referred to as "licensees") demonstrate that "under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety." There are a variety of methods that may be used to demonstrate subcriticality, including use of industry standards, handbooks, hand calculations, and computer methods. Subcriticality is assured, in part, by providing margin between actual conditions and expected critical conditions. This appendix, however, applies only to margin used in those methods that rely on calculation of k_{eff}, including deterministic and probabilistic computer methods. The use of other methods (e.g., use of endorsed industry standards, widely accepted handbooks, certain hand calculations), containing varying amounts of margin, is outside the scope of this appendix.

For methods relying on calculation of k_{eff}, margin may be provided either in terms of limits on physical parameters of the system (of which k_{eff} is a function), or in terms of limits on k_{eff} directly, or both. For the purposes of this appendix, the term *margin of safety* will be used to refer to the margin to criticality in terms of system parameters, and the term *margin of subcriticality* (MoS) will refer to the margin to criticality in terms of k_{eff}. A common approach to ensuring subcriticality is to determine a maximum k_{eff} limit below which the licensee's calculations must fall. This limit will be referred to in this appendix as the *Upper Subcritical Limit* (USL). Licensees using calculational methods perform validation studies, in which critical experiments similar to actual or anticipated facility applications are chosen and then analyzed to determine the bias and uncertainty in the bias. The bias is a measure of the systematic differences between calculational method results and experimental data. The uncertainty in the bias is a measure of both the accuracy and precision of the calculations and the uncertainty in the experimental data. A USL is then established that includes allowances for bias and bias uncertainty as well as an additional margin, to be referred to in this appendix as the *minimum margin of subcriticality* (MMS). The MMS is variously referred to in the nuclear industry as *minimum subcritical margin*, *administrative margin*, and *arbitrary margin*, and the term MMS should be regarded as synonymous with those terms. The term MMS will be used throughout this appendix, and has been chosen for consistency with the rule. The MMS is an allowance for any unknown (or difficult to identify or quantify) errors or uncertainties in the method of calculating k_{eff} that may exist beyond those which have been accounted for explicitly in calculating the bias and its uncertainty.

There is little guidance in the fuel facility Standard Review Plans (SRPs) as to what constitutes sufficient technical justification for the MMS. NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," Section 5.4.3.4.4, states that there

must be margin that includes, among other uncertainties, "adequate allowance for uncertainty in the methodology, data, and bias to assure subcriticality." An important component of this overall margin is the MMS. However, there has been almost no guidance on how to determine an appropriate MMS. Partly due to the lack of historical guidance, and partly due to differences between facilities' processes and methods of calculation, there have been significantly different MMS values approved for the various fuel cycle facilities over time. In addition, the different ways licensees have of defining margins and calculating k_{eff} limits have made a consistent approach to reviewing k_{eff} limits difficult. Recent licensing experience has highlighted the need for further guidance to clarify what constitutes an acceptable justification for the MMS.

The MMS can have a substantial effect on facility operations (e.g., storage capacity, throughput) and there has, therefore, been considerable recent interest in decreasing margin in k_{eff} below what has been licensed previously. In addition, the increasing sophistication of computer codes and the ready availability of computing resources means that there has been a gradual move towards more realistic (often resulting in less conservative) modeling of process systems. The increasing interest in reducing the MMS and the reduction in modeling conservatism make technical justification of the MMS more risk-significant than it has been in the past. In general, consistent with a risk-informed approach to regulation, a smaller MMS requires a more substantial technical justification.

This appendix is only applicable to fuel enrichment and fabrication facilities licensed under 10 CFR Part 70.

Discussion

This guidance is applicable to evaluating the MMS in methods of evaluation that rely on calculation of k_{eff}. The k_{eff} value of a fissionable system depends, in general, on a large number of physical variables. The factors that can affect the calculated value of k_{eff} may be broadly divided into the following categories: (1) the geometric configuration; (2) the material composition; and (3) the neutron distribution. The geometric form and material composition of the system–together with the underlying nuclear data (e.g., ν, χ(E), cross section data)–determine the spatial and energy distribution of neutrons in the system (flux and energy spectrum). An error in the nuclear data or the geometric or material modeling of these systems can produce an error in the neutron flux and energy spectrum, and thus in the calculated value of k_{eff}. The bias associated with a single system is defined as the difference between the calculated and physical values of k_{eff}, by the following equation:

$$\beta = k_{calc} - k_{physical}$$

Thus, determining the bias requires knowing both the calculated and physical k_{eff} values of the system. The bias associated with a single critical experiment can be known with a high degree of confidence, because the physical (experimental) value is known *a priori* ($k_{physical}$ ~1). However, for calculations performed to demonstrate subcriticality of facility processes (to be referred to as "applications"), this is not generally the case. The bias associated with such an application (i.e., not a known critical configuration) is not typically known with this same high degree of confidence, because the actual physical k_{eff} of the system is usually not known. In practice, the bias is determined from the average calculated k_{eff} for a set of experiments that cover different aspects of the licensee's applications. The bias and its uncertainty must be estimated by calculating the bias associated with a set of critical experiments having geometric forms,

material compositions, and neutron spectra similar to those of the application. Because of the large number of factors that can affect the bias, and the finite number of critical experiments available, staff should recognize that this is only an estimate of the true bias of the system. The experiments analyzed cannot cover all possible combinations of conditions or sources of error that may be present in the applications to be evaluated. The effect on k_{eff} of geometric, material, or spectral differences between critical experiments and applications cannot be known with precision. Therefore, an additional margin (MMS) must be applied to allow for the effects of any unknown uncertainties that may exist in the calculated value of k_{eff} beyond those accounted for in the calculation of the bias and its uncertainty. As the MMS decreases, there needs to be a greater level of assurance that the various sources of bias and uncertainty have been taken into account, and that the bias and uncertainty are known with a high degree of accuracy. In general, the more similar the critical experiments are to the applications, the more confidence there is in the estimate of the bias and the less MMS is needed.

In determining an appropriate MMS, the reviewer should consider the specific conditions and process characteristics present at the facility in question. However, the MMS should not be reduced below 0.02. The nuclear cross sections are not generally known to better than -1-2%. While this does not necessarily translate into a 2% Δk_{eff}, it has been observed over many years of experience with criticality code validation that biases and spreads in the data of a few percent can be expected. As stated in NUREG-1520, MoS should be large compared to the uncertainty in the bias. Moreover, errors in the criticality codes have been discovered over time that have produced k_{eff} differences of roughly this same magnitude of 1-2% (e.g., Information Notice 2005-13, “Potential Non-Conservative Error in Modeling Geometric Regions in the KENO-V.a Criticality Code”). While the possibility of having larger undiscovered errors cannot be entirely discounted, modeling sufficiently similar critical experiments with the same code options to be used in modeling applications should minimize the potential for this to occur. However, many years of experience with the typical distribution of calculated k_{eff} values and with the magnitude of code errors that have occasionally surfaced support establishing 0.02 as the minimum MMS that should be considered acceptable under the best possible conditions.

Staff should recognize the important distinction between ensuring that processes are safe and ensuring that they are adequately subcritical. The value of k_{eff} is a direct indication of the degree of subcriticality of the system, but is not fully indicative of the degree of safety. A system that is very subcritical (i.e., with $k_{eff} \ll 1$) may have a small margin of safety if a small change in a process parameter can result in criticality. An example of this would be a UO_2 powder storage vessel, which is subcritical when dry, but may require only the addition of water for criticality. Similarly, a system with a small MoS (i.e., with $k_{eff} \sim 1$) may have a very large margin of safety if it cannot credibly become critical. An example of this would be a natural uranium system in light water, which may have a k_{eff} value close to 1 but will never exceed 1. Because of this, a distinction should be made between the *margin of subcriticality* and the *margin of safety*. Although a variety of terms are in use in the nuclear industry, the term *margin of subcriticality* will be taken to mean the difference between the actual (physical) value of k_{eff} and the value of k_{eff} at which the system is expected to be critical. The term *margin of safety* will be taken to mean the difference between the actual value of a parameter and the value of the parameter at which the system is expected to be critical. The MMS is intended to account for the degree of confidence that applications calculated to be subcritical will be subcritical. It is not intended to account for other aspects of the process (e.g., safety of the process or the ability to control parameters within certain bounds) that may need to be reviewed as part of an overall licensing review.

There are a variety of different approaches that a licensee could choose in justifying the MMS. Some of these approaches and means of reviewing them are described in the following sections, in no particular preferential order. Many of these approaches consist of qualitative arguments, and therefore there will be some degree of subjectivity in determining the adequacy of the MMS. Because the MMS is an allowance for unknown (or difficult to identify or quantify) errors, the reviewer must ultimately exercise his or her best judgement in determining whether a specific MMS is justified. Thus, the topics listed below should be regarded as factors the reviewer should take into consideration in exercising that judgement, rather than any kind of prescriptive checklist.[1]

The reviewer should also bear in mind that the licensee is not required to use any or all of these approaches, but may choose an approach that is applicable to its facility or a particular process within its facility. While it may be desirable and convenient to have a single k_{eff} limit or MMS value (and single corresponding justification) across an entire facility, it is not necessary for this to be the case. The MMS may be easier to justify for one process than for another, or for a limited application versus generically for the entire facility. The reviewer should expect to see various combinations of these approaches, or entirely different approaches, used, depending on the nature of the licensee's processes and methods of calculation. Any approach used must ultimately lead to a determination that there is adequate assurance of subcriticality.

(1) <u>Conservatism in the Calculational Models</u>

The margin in k_{eff} produced by the licensee's modeling practices, together with the MMS, provide the margin between actual conditions and expected critical conditions. In terms of the subcriticality criterion taken from ANSI/ANS-8.17-2004, "Criticality Safety Criteria for the Handling, Storage, and Transportation of LWR Fuel Outside Reactors" (as explained in Appendix A):

$$MoS \geq \Delta k_m + \Delta k_{sa}$$

where Δk_m is the MMS and Δk_{sa} is the margin in k_{eff} due to conservative modeling of the system (i.e., conservative values of system parameters).

Two different applications for which the sums on the right hand side of the equation above are equal to each other are equally subcritical. Assurance of subcriticality may thus be provided by specifying a margin in k_{eff} (Δk_m), or specifying conservative modeling practices (Δk_{sa}), or some combination thereof. This principle will be particularly useful to the reviewer evaluating a proposed reduction in the currently approved MMS; the review of such a reduction should prove straightforward in cases in which the overall combination of modeling conservatism and MMS has not changed. Because of this straightforward quantitative relationship, any modeling conservatism that has not been previously credited should be considered before examining other factors. Cases in which the overall MoS has decreased may still be acceptable, but would have to be justified by other means.

[1] In the discussion of these factors, the purpose is not to impose any new requirements or standards for acceptability on licensees. However, in many cases it will be necessary to go beyond the minimum requirements for a given factor, if that factor is being used as part of the technical basis for justifying a smaller MMS than would otherwise be acceptable.

In evaluating justification for the MMS relying on conservatism in the model, the reviewer should consider only that conservatism in excess of any manufacturing tolerances, uncertainties in system parameters, or credible process variations. That is, the conservatism should consist of conservatism beyond the worst-case normal or abnormal conditions, as appropriate, including allowance for any tolerances. Examples of this added conservatism may include assuming optimum concentration in solution processes, neglecting neutron absorbers in structural materials, or assuming minimum reflector conditions (e.g., at least a 1-inch, tight-fitting reflector around process equipment). These technical practices used to perform criticality calculations generally result in conservatism of at least several percent in k_{eff}. To credit this as part of the justification for the MMS, the reviewer should have assurance that the modeling practices described will result in a predictable and dependable amount of conservatism in k_{eff}. In some cases, the conservatism may be process-dependent, in which case it may be relied on as justification for the MMS for a particular process. However, only modeling practices that result in a global conservatism across the entire facility should be relied on as justification for a sitewide MMS. Ensuring predictable and dependable conservatism includes verifying that this conservatism will be maintained over the facility lifetime, such as through the use of license commitments or conditions.

If the licensee has a program that establishes operating limits (to ensure that subcritical limits are not exceeded) below subcritical limits determined in nuclear criticality safety evaluations, the margin provided by this (optional) practice may be credited as part of the conservatism. In such cases, the reviewer should credit only the difference between operating and subcritical limits that exceeds any tolerances or process variation, and should ensure that any such operating limits will be maintained over the facility lifetime, through the use of license commitments or conditions.

Some questions that the reviewer may ask in evaluating the use of modeling conservatism as justification for the MMS include:

- How much margin in k_{eff} is provided due to conservatism in modeling practices?
- How much of this margin exceeds allowance for tolerances and process variations?
- Is this margin specific to a particular process or does it apply to all facility processes?
- What provides assurance that this margin will be maintained over the facility lifetime?

(2) <u>Validation Methodology and Results</u>

Assurance of subcriticality for methods that rely on the calculation of k_{eff} requires that those methods be appropriately validated. One of the goals of criticality code validation is to determine the method's bias and the uncertainty in the bias. After this has been done, an additional margin (MMS) is specified to account for any additional uncertainties that may exist. The appropriate MMS depends, in part, on the degree of confidence in the validation results. Having a high degree of confidence in the bias and bias uncertainty requires both that there be sufficient (for the statistical method used) applicable benchmark-quality experiments and that there be a rigorous validation methodology. Critical experiments that do not rise to the level of benchmark-quality experiments may also be acceptable, but may require additional margin. If either the data or the methodology is deficient, a high degree of confidence in the results cannot be

attained, and a larger MMS may need to be employed than would otherwise be acceptable. Therefore, although validation and determining the MMS are separate exercises, they are related. The more confidence one has in the validation results, the less additional margin (MMS) is needed. The less confidence one has in the validation results, the more MMS is needed.

Any review of a licensing action involving the MMS should involve examination of the licensee's validation methodology and results. While there is no clear quantifiable relationship between the validation and MMS (as exists with modeling conservatism), several aspects of validation should be considered before making a qualitative determination of the adequacy of the MMS.

There are four factors that the reviewer should consider in evaluating the validation: (1) the similarity of critical experiments to actual applications; (2) sufficiency of the data (including the number and quality of experiments); (3) adequacy of the validation methodology; and (4) conservatism in the calculation of the bias and its uncertainty. These factors are discussed in more detail below.

Similarity of Critical Experiments

Because the bias and its uncertainty must be estimated based on critical experiments having geometric form, material composition, and neutronic behavior similar to specific applications, the degree of similarity between the critical experiments and applications is a key consideration in determining the appropriateness of the MMS. The more closely critical experiments represent the characteristics of applications being validated, the more confidence the reviewer has in the estimate of the bias and the bias uncertainty for those applications.

The reviewer must understand both the critical experiments and applications in sufficient detail to ascertain the degree of similarity between them. Criticality code validation reports generally contain a description of critical experiments (including source references). The reviewer may need to consult these references to understand the physical characteristics of the experiments. In addition, the reviewer may need to consult process descriptions, nuclear criticality safety evaluations, drawings, tables, input files, or other information to understand the physical characteristics of applications. The reviewer must consider the full spectrum of normal and abnormal conditions that may have to be modeled when evaluating the similarity of the critical experiments to applications.

In evaluating the similarity of experiments to applications, the reviewer must recognize that some parameters are more significant than others to accurately calculate k_{eff}. The parameters that have the greatest effect on the calculated k_{eff} of the system are those that are most important to match when choosing critical experiments. Because of this, there is a close relationship between similarity of critical experiments to applications and system sensitivity. Historically, certain parameters have been used to trend the bias because these are the parameters that have been found to have the greatest effect on the bias. These parameters include the moderator-to-fuel ratio (e.g., H/U, H/X, v^m/v^f), isotopic abundance (e.g., uranium-235 (^{235}U), plutonium-239 (^{239}Pu), or overall Pu-to-uranium ratio), and parameters that characterize the neutron energy spectrum (e.g., energy of average lethargy causing fission (EALF), average energy group (AEG)). Other parameters, such as material density or overall geometric shape, are generally considered to be of less importance. The reviewer should consider all important system characteristics that can reasonably be expected to affect the bias. For example, the critical experiments should include any materials that can have an appreciable effect on the calculated k_{eff}, so that the effect due to the cross sections of those materials is included in the

bias. Furthermore, these materials should have at least the same reactivity worth in the experiments (which may be evidenced by having similar number densities) as in the applications. Otherwise, the effect of any bias from the underlying cross sections or the assumed material composition may be masked in the applications. The materials must be present in a statistically significant number of experiments having similar neutron spectra to the application. Conversely, materials that do not have an appreciable effect on the bias may be neglected and would not have to be represented in the critical experiments.

Merely having critical experiments that are representative of applications is the minimum acceptance criterion, and does not alone justify having any particular value of the MMS. There are some situations, however, in which there is an unusually high degree of similarity between the critical experiments and applications, and in these cases, this fact may be credited as justification for having a smaller MMS than would otherwise be acceptable. If the critical experiments have geometric forms, material compositions, and neutron spectra that are nearly indistinguishable from those of the applications, this may be justification for a smaller MMS than would otherwise be acceptable. For example, justification for having a small MMS for finished fuel assemblies could include selecting critical experiments consisting of fuel assemblies in water, where the fuel has nearly the same pellet diameter, pellet density, cladding materials, pitch, absorber content, enrichment, and neutron energy spectrum as the licensee's fuel. In this case, the criticality code validation report should be very specific to this type of system, because including of the types of critical experiments could mask variations in the bias. Therefore, this type of justification is generally easiest when the area of applicability (AOA) is very narrowly defined.
The reviewer should pay particular attention to abnormal conditions. In this example, changes in process conditions such as damage to the fuel or partial flooding may significantly affect the applicability of the critical experiments.

There are several tools available to the reviewer to ascertain the degree of similarity between critical experiments and applications. Some of these are listed below:

1. NUREG/CR-6698, "Guide to Validation of Nuclear Criticality Safety Calculational Method," Table 2.3, contains a set of screening criteria for determining the applicability of critical experiments. As is stated in the NUREG, these criteria were arrived at by consensus among experienced nuclear criticality safety specialists and may be considered to be conservative. The reviewer should consider agreement on all screening criteria to be justification for demonstrating a very high degree of critical experiment similarity. (Agreement on the most significant screening criteria for a particular system should be considered as demonstration of an acceptable degree of critical experiment similarity.) Less conservative (i.e., broader) screening criteria may also be acceptable, if appropriately justified.

2. Analytical methods that systematically quantify the degree of similarity between a set of critical experiments and applications in pair-wise fashion may be used. One example of this is the TSUNAMI code in the SCALE 5 code package. One strength of TSUNAMI is that it calculates an overall correlation that is a quantitative measure of the degree of similarity between an experiment and an application. Another strength is that this code considers all the nuclear phenomena and underlying cross sections and weights them by their importance to the calculated k_{eff} (i.e., sensitivity of k_{eff} to the data). The NRC staff currently considers a correlation coefficient of $c_k \sim 0.95$ to be indicative of a very high degree of similarity. This is based on the staff's experience comparing the results from

TSUNAMI to those from a more traditional screening criterion approach. The NRC staff also considers a correlation coefficient between 0.90 and 0.95 to be indicative of a high degree of similarity. However, owing to the amount of experience with TSUNAMI, in this range use of the code should be supplemented with other methods of evaluating critical experiment similarity. Conversely, a correlation coefficient less than 0.90 should not be used as a demonstration of a high or very high degree of critical experiment similarity. Because of limited use of the code to date, all of these observations should be considered tentative and thus the reviewer should not use TSUNAMI as a "black box," or base conclusions of adequacy solely on its use. However, it may be used to test a licensee's statement that there is a high degree of similarity between experiments and applications.

3. Traditional parametric sensitivity studies may be employed to demonstrate that k_{eff} is highly sensitive or insensitive to a particular parameter. For example, if a 50% reduction in the ^{10}B cross section is needed to produce a 1% change in the system k_{eff}, then it can be concluded that the system is highly insensitive to the boron content, in the amount present. This is because a credible error in the ^{10}B cross section of a few percent will have a statistically insignificant effect on the bias. Therefore, in the amount present, the boron content is not a parameter that is important to match in order to conclude that there is a high degree of similarity between critical experiments and applications.

4. Physical arguments may demonstrate that k_{eff} is highly sensitive or insensitive to a particular parameter. For example, the fact that oxygen and fluorine are almost transparent to thermal neutrons (i.e., cross sections are very low) may justify why experiments consisting of UO_2F_2 may be considered similar to UO_2 or UF_4 applications, provided that both experiments and applications occur in the thermal energy range.

The reviewer should ensure that those parameters which can reasonably be expected to significantly affect the bias are considered when assessing critical experiment similarity. For example, comparison should not be based solely on agreement in the ^{235}U fission spectrum for systems in which the system k_{eff} is highly sensitive to ^{238}U fission, ^{10}B absorption, or ^{1}H scattering. A method such as TSUNAMI that considers the complete set of reactions and nuclides present can be used to rank the various system sensitivities, and to thus determine whether it is reasonable to rely on the fission spectrum alone in assessing the similarity of critical experiments to applications.

Some questions that the reviewer may ask in evaluating reliance on critical experiment similarity as justification for the MMS include:

- Do the critical experiments adequately span the range of geometric forms, material compositions, and neutron energy spectra expected in applications?

- Are the materials present with at least the same reactivity worth as in applications?

- Do the licensee's criteria for determining whether experiments are sufficiently similar to applications consider nuclear reactions and nuclides that can have a statistically significant effect on the bias?

Sufficiency of the Data

Another aspect of evaluating the selected critical experiments for a specific MMS is evaluating whether there is a sufficient number of benchmark-quality experiments to determine the bias across the entire AOA. Having a sufficient number of benchmark-quality experiments means that: (1) there are enough (applicable) critical experiments to make a statistically meaningful calculation of the bias and its uncertainty; (2) the experiments somewhat evenly span the entire range of all the important parameters, without gaps requiring extrapolation or wide interpolation; and (3) the experiments are, preferably, benchmark-quality experiments. The number of critical experiments needed is dependent on the statistical method used to analyze the data. For example, some methods require a minimum number of data points to reliably determine whether the data are normally distributed. Merely having a large number of experiments is not sufficient to provide confidence in the validation result, if the experiments are not applicable to the application. The reviewer should particularly examine whether consideration of only the most applicable experiments would result in a larger negative bias (and thus a lower USL) than that determined based on the full set of experiments. The experiments should also ideally be sufficiently well-characterized (including experimental parameters and their uncertainties) to be considered benchmark experiments. They should be drawn from established sources (such as from the International Handbook of Evaluated Criticality Safety Benchmark Experiments (IHECSBE), laboratory reports, or peer-reviewed journals). For some applications, benchmark quality experiments may not be available; when necessary, critical experiments that do not rise to the level of benchmark-quality experiments may be used. However, the reviewer should take this into consideration and should evaluate the need for additional margin.

Some questions that the reviewer may ask in evaluating the number and quality of critical experiments as justification for the MMS include:

- Are the critical experiments chosen all high-quality benchmarks from reliable (e.g., peer-reviewed and widely-accepted) sources?

- Are the critical experiments chosen taken from multiple independent sources, to minimize the possibility of systematic errors?

- Have the experimental uncertainties associated with the critical experiments been provided and used in calculating the bias and bias uncertainty?

- Is the number and distribution of critical experiments sufficient to establish trends in the bias across the entire range of parameters?

- Is the number of critical experiments commensurate with the statistical methodology being used?

Validation Methodological Rigor

Having a sufficiently rigorous validation methodology means having a methodology that is appropriate for the number and distribution of critical experiments, that calculates the bias and its uncertainty using an established statistical methodology, that accounts for any trends in the bias, and that accounts for all apparent sources of uncertainty in the bias (e.g., the increase in

uncertainty due to extrapolating the bias beyond the range covered by the experimental data.) Examples of deficiencies in the criticality code validation methodology may include: (1) using a statistical methodology relying on the data being normally distributed about the mean k_{eff} to analyze data that are not normally distributed; (2) using a linear regression fit on data that has a non-linear dependence on a trending parameter; (3) use of a single pooled bias when very different types of critical experiments are being evaluated in the same validation study. These deficiencies serve to decrease confidence in the validation results and may warrant additional margin (i.e., a larger MMS). Additional guidance on some of the more commonly observed deficiencies is provided below. The assumption that data is normally distributed is generally valid, unless there is a strong trend in the data or different types of critical experiments with different mean calculated k_{eff} values are being combined. Tests for normality require a minimum number of critical experiments to attain a specified confidence level (generally 95%). If there is insufficient data to verify that the data are normally distributed, or the data are shown to be not normally distributed, a non-parametric technique should be used to analyze the data.

The critical experiments chosen should ideally provide a continuum of data across the entire validated range, so that any variation in the bias as a function of important system parameters may be observed. The presence of discrete clusters of experiments having a calculated k_{eff} lower than the set of critical experiments as a whole should be examined closely to determine if there is some systematic effect common to a particular type of calculation that makes use of the overall bias non-conservative. Because the bias can vary with system parameters, if the licensee has combined different subsets of data (e.g., solutions and powders, low- and high-enriched, homogeneous and heterogeneous), the bias for the different subsets should be analyzed. In addition, the goodness-of-fit for any function used to trend the bias should be examined to ensure it is appropriate to the data being analyzed.

If critical experiments do not cover the entire range of parameters needed to cover anticipated applications, it may be necessary to extend the AOA by making use of trends in the bias. Any extrapolation (or wide interpolation) of the data should be done by means of an established mathematical methodology that takes into account the functional form of both the bias and its uncertainty. The extrapolation should not be based on judgement alone, such as by observing that the bias is increasing in the extrapolated range, because this may not account for the increase in the bias uncertainty that will occur with increasing extrapolation. The reviewer should independently confirm that the derived bias is valid in the extrapolated range and should ensure that the extrapolation is not large. NUREG/CR-6698 states that critical experiments should be added if the data must be extrapolated more than 10%. There is no corresponding guidance given for interpolation; however, if the gap represents a significant fraction of the total range of the data (e.g., more than 20% of the range of the data), then the reviewer should consider this to be a wide interpolation. If the extrapolation or interpolation is too large, new factors that could affect the bias may be introduced as the physical phenomena in the system change. The reviewer should not view validation as a purely mathematical exercise, but should bear in mind the neutron physics and underlying physical phenomena when interpreting the results.

Discarding an unusually large number of critical experiments as outliers (i.e., more than 1-2%) should also be viewed with some concern. Apparent outliers should not be discarded based purely upon judgement or statistical grounds (such as causing the data to fail tests for normality), because they could be providing valuable information on the method's validity for a particular application. The reviewer should verify that there are specific defensible reasons, such as reported inconsistencies in the experimental data, for discarding any outliers. If any of

the critical experiments from a particular data set are discarded, the reviewer should examine other experiments included to determine whether they may be subject to the same systematic errors. Outliers should be examined carefully especially when they have a lower calculated k_{eff} than the other experiments included.

NUREG-1520 states that the MoS should be large compared to the uncertainty in the bias. The observed spread of the data about the mean k_{eff} should be examined as an indicator of the overall precision of the calculational method. The reviewer should ascertain whether the statistical method of validation considers both the observed spread in the data and the experimental and calculational uncertainty in determining the USL. The reviewer should also evaluate whether the observed spread in the data is consistent with the reported uncertainty (e.g., whether $\chi_2/N \sim 1$). If the spread in the data is larger than, or comparable to, the MMS, then the reviewer should consider whether additional margin (i.e., a larger MMS) is needed.

As a final test of the code's accuracy, the bias should be relatively small (i.e., bias ~2 percent), or else the reason for the bias should be determined. No credit should be taken for positive bias, because this could result in making changes in a non-conservative direction without having a clear understanding of those changes. If the absolute value of the bias is very large–and especially if the reason for the large bias cannot be determined–this may indicate that the calculational method is not very accurate, and a larger MMS may be appropriate.

Some questions that the reviewer may ask in evaluating the rigor of the criticality code validation methodology as justification for the MMS include:

- Are the results from use of the methodology consistent with the data (e.g., normally distributed)?

- Is the normality of the data confirmed prior to performing statistical calculations? If the data does not pass the tests for normality, is a non-parametric method used?

- Does the assumed functional form of the bias represent a good fit to the critical experiments? Is a goodness-of-fit test performed?

- Does the method determine a pooled bias across disparate types of critical experiments, or does it consider variations in the bias for different types of experiments? Are there discrete clusters of experiments for which the bias appears to be non-conservative?

- Has additional margin been applied to account for extrapolation or wide interpolation? Is this done based on an established mathematical methodology?

- Have critical experiments been discarded as apparent outliers? Is there a valid reason for doing so?

Performing an adequate criticality code validation is not by itself sufficient justification for any specific MMS. The reason for this is that the validation analysis determines the bias and its uncertainty, but not the MMS. The MMS is added after the validation has been performed to provide added assurance of subcriticality. However, having a validation methodology that either

exceeds or falls short of accepted practices for validation may be a basis for either reducing or increasing the MMS.

Statistical Conservatism

In addition to having conservatism in k_{eff} due to modeling practices, licensees may also provide conservatism in the statistical methods used to calculate the USL. For example, NUREG/CR-6698 states that an acceptable method for calculating the bias is to use the single-sided tolerance limit approach with a 95/95 confidence (i.e., 95% confidence that 95% of all future critical calculations will lie above the USL). If the licensee decides to use the single-sided tolerance limit approach with a 95/99.9 confidence, this would result in a more conservative USL than with a 95/95 confidence. This would be true of other methods for which the licensee's confidence criteria exceed the minimum accepted criteria. Generally, the NRC has accepted 95% confidence levels for criticality code validation results, so using more stringent confidence levels may provide conservatism. In addition, there may be other reasons a larger bias and/or bias uncertainty than necessary has been used (e.g., because of the inclusion of inapplicable critical experiments that have a lower calculated k_{eff}).

The reviewer may credit this conservatism towards having an adequate MoS if: (1) the licensee demonstrates that this translates into a specific Δk_{eff}; and (2) the licensee demonstrates that the margin will be dependably present, based on license or other commitments.

(3) Additional Risk-Informed Considerations

Besides modeling conservatism and the criticality code validation results, other factors may provide added assurance of subcriticality. These factors should be considered in evaluating whether there is adequate MoS and are discussed below.

System Sensitivity and Uncertainty

The sensitivity of k_{eff} to changes in system parameters can be used to assess the potential effect of errors on the calculation of k_{eff}. If the calculated k_{eff} is especially sensitive to a given parameter, an error in that parameter could have a correspondingly large contribution to the bias. Conversely, if k_{eff} is very insensitive to a given parameter, then an error may have a negligible effect on the bias. This is of particular importance when assessing whether the chosen critical experiments are sufficiently similar to applications to justify a small MMS.

The reviewer should not consider the sensitivity in isolation, but should also consider the magnitude of uncertainties in the parameters. If k_{eff} is very sensitive to a given parameter, but the value of that parameter is known with very high accuracy (and its variations are well-controlled), the potential contribution to the bias may still be very small. Thus, the contribution to the bias is a function of the product of the the k_{eff} sensitivity with the uncertainty. To illustrate this, suppose that k_{eff} is a function of a large number of variables, x_1, x_2,..., x_N. Then the uncertainty in k_{eff} may be expressed as follows, if all the individual terms are independent:

$$\delta k^2 = \sum_{i=1}^{N} \left(\frac{\partial k}{\partial x_i}\right)^2 \delta x_i^2$$

where the partial derivatives $\partial k/\partial x_i$ are proportional to the sensitivity and the terms δx_i represent the uncertainties, or likely variations, in the parameters. (If not all variables are dependent, then there may be additional terms.) Each term in this equation then represents the contribution to the overall uncertainty in k_{eff}.

There are several tools available to the reviewer to ascertain the sensitivity of k_{eff} to changes in the underlying parameters. Some of these are listed below:

1. Analytical tools that calculate the sensitivity for each nuclide-reaction pair present in the problem may be used. One example of this is the TSUNAMI code in the SCALE 5 code package. TSUNAMI calculates both an integral sensitivity coefficient (i.e., summed over all energy groups) and a sensitivity profile as a function of energy group. The reviewer should recognize that TSUNAMI only calculates the k_{eff} sensitivity to changes in the underlying nuclear data, and not to other parameters that could affect the bias and should be considered. (See section on Critical Experiment Similarity for caveats about using TSUNAMI.)

2. Direct sensitivity calculations may be used, in which system parameters are perturbed and the resulting impact on k_{eff} determined. Perturbation of atomic number densities can also be used to confirm the sensitivity calculated by other methods (e.g., TSUNAMI). Such techniques are not limited to considering the effect of the nuclear data.

There are also several sources available to the reviewer to ascertain the uncertainty associated with the underlying parameters. For process parameters, these sources of uncertainty may include manufacturing tolerances, quality assurance records, and experimental and/or measurement results. For nuclear data parameters, these sources of uncertainty may include published data, uncertainty data distributed with the cross section libraries, or the covariance data used in methods such as TSUNAMI.

Some systems are inherently more sensitive to changes in the underlying parameters than others. For example, high-enriched uranium systems typically exhibit a greater sensitivity to changes in system parameters (e.g., mass, moderation) than low-enriched systems. This has been the reason that HEU (i.e., >20wt% ^{235}U) facilities have been licensed with larger MMS values than LEU (≤10wt% ^{235}U) facilities. This greater sensitivity would also be true of weapons-grade Pu compared to low-assay mixed oxides (i.e., with a few percent Pu/U). However, it is also true that the uncertainties associated with measurement of the ^{235}U cross sections are much smaller than those associated with measurement of the ^{238}U cross sections. Both the greater sensitivity and smaller uncertainty would need to be considered in evaluating whether a larger MMS is needed for high-enriched systems.

Frequently, operating limits that are more conservative than safety limits determined using k_{eff} calculations may beestablished to prevent those safety limits from being exceeded. For systems in which k_{eff} is very sensitive to the system parameters, more margin between the operating and safety limits may be needed. Systems in which k_{eff} is very sensitive to the process parameters may need both a larger margin between operating and safety limits and a larger MMS. This is because the system is sensitive to any change, whether it be caused by normal process variations or caused by unknown errors. Because of this, the assumption is often made that the MMS is meant to account for variations in the process or the ability to control the process parameters. However, the MMS is meant only to allow for unknown (or difficult to quantify) uncertainties in the calculation of k_{eff}. The reviewer should recognize that determination of an

appropriate MMS is not dependent on the ability to control process parameters within safety limits (although both may depend on the system sensitivity).

Some questions that the reviewer may ask in evaluating the system sensitivity as justification for the MMS include:

- How sensitive is k_{eff} to changes in the underlying nuclear data (e.g., cross sections)?
- How sensitive is k_{eff} to changes in the geometric form and material composition?
- Are the uncertainties associated with these underlying parameters well-known?
- How does the MMS compare to the expected magnitude of changes in k_{eff} resulting from uncertainties in these underlying parameters?

Knowledge of the Neutron Physics

Another important consideration that may affect the appropriate MMS is the extent to which the physical behavior of the system is known. Fissile systems which are known to be subcritical with a high degree of confidence do not require as much MMS as systems where subcriticality is less certain. An example of a system known to be subcritical with high confidence is a light-water reactor fuel assembly. The design of these systems is such that they can only be made critical when highly thermalized. Due to extensive analysis and reactor experience, the flooded isolated assembly is known to be subcritical. In addition, the thermal neutron cross sections for materials in finished reactor fuel have been measured with a very high degree of accuracy (as opposed to cross sections in the resonance region). Other examples of systems in which there is independent corroborating evidence of subcriticality may include systems consisting of very simple geometric shapes, or other idealized situations, in which there is strong evidence that the system is subcritical based on comparison with highly similar systems in published sources (e.g., standards and handbooks). In these cases, the MMS may be significantly reduced due to the fact that the calculation of k_{eff} is not relied on alone to provide assurance of subcriticality.

Reliance on independent knowledge that a given system is subcritical necessarily requires that the configuration of the system be fixed. If the configuration can change from the reference case, there will be less knowledge about the behavior of the changed system. For example, a finished fuel assembly is subject to strict quality assurance checks and would not reach final processing if it were outside specifications. In addition, it has a form that has both been extensively studied and is highly stable. For these reasons, there is a great deal of certainty that this system is well-characterized and is not subject to change. A typical solution or powder system (other than one with a simple geometric arrangement) would not have been studied with the same level of rigor as a finished fuel assembly. Even if they were studied with the same level of rigor, these systems have forms that are subject to change into forms whose neutron physics has not been as extensively studied.

Some questions that the reviewer may ask in evaluating the knowledge of the neutron physics as justification for the MMS include:

- Is the geometric form and material composition of the system fixed and very unlikely to change?

- Is the geometric form and material composition of the system subject to strict quality assurance, such that tolerances have been bounded?

- Has the system been extensively studied in the nuclear industry and shown to be subcritical (e.g., in reactor fuel studies)?

- Are there other reasons besides criticality calculations to conclude that the system will be subcritical (e.g., handbooks, standards, published data)?

- How well-known is the nuclear data (e.g., cross sections) in the energy range of interest?

Likelihood of the Abnormal Condition

Some facilities have been licensed with different sets of k_{eff} limits for normal and abnormal conditions. Separate k_{eff} limits for normal and abnormal conditions are permissible, but are not required. There is some low likelihood that processes calculated to be subcritical will, in fact, be critical, and this likelihood increases as the MMS is reduced (though it cannot in general be quantified). NUREG-1718, "Standard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility," states that abnormal conditions should be at least unlikely from the standpoint of the double contingency principle. Then, a somewhat higher likelihood that a system calculated to be subcritical is, in fact, critical is more permissible for abnormal conditions than for normal conditions, because of the low likelihood of the abnormal condition being realized. The reviewer should verify that the licensee has defined abnormal conditions such that achieving the abnormal condition requires at least one contingency to have occurred, that the system will be closely monitored so that it is promptly detected, and that it will be promptly corrected upon detection. Also, there is generally more conservatism present in the abnormal case, because the parameters that are assumed to have failed are analyzed at their worst-case credible condition.

The increased risk associated with having a smaller MMS for abnormal conditions should be commensurate with, and offset by, the low likelihood of achieving the abnormal condition. That is, if the normal case k_{eff} limit is judged to be acceptable, then the abnormal case limit will also be acceptable, provided the increased likelihood (that a system calculated to be subcritical will be critical) is offset by the reduced likelihood of realizing the abnormal condition because of the controls that have been established. Note that if two or more contingencies must occur to reach a given condition, there is no requirement to ensure that the resulting condition is subcritical. If a single k_{eff} limit is used (i.e., no credit for unlikelihood of the abnormal condition), then the limit must be found acceptable to cover both normal and credible abnormal conditions. The reviewer should always make this finding considering specific conditions and controls in the process(es) being evaluated.

(4) Statistical Justification for the MMS

The NRC does not consider statistical justification an appropriate basis for a specific MMS. Previously, some licensees have attempted to justify specific MMS values based on a comparison of two statistical methods. For example, the USLSTATS code issued with the SCALE code package contains two methods for calculating the USL: (1) the Confidence Band with Administrative Margin approach (calculating USL-1), and (2) the Lower Tolerance Band approach (calculating USL-2). The value of the MMS is an input parameter to the Confidence Band approach, but is not included explicitly in the Lower Tolerance Band approach. In this particular justification, adequacy of the MMS is based on a comparison of USL-1 and USL-2 (i.e., the condition that USL-1, including the chosen MMS, is less than USL-2). However, the reviewer should not accept this justification.

The condition that USL-1 (with the chosen MMS) is less than USL-2 is necessary, but is not sufficient, to show that an adequate MMS has been used. These methods are both statistical methods, and a comparison can only demonstrate whether the MMS is sufficient to bound any statistical uncertainties included in the Lower Tolerance Band approach but not included in the Confidence Band approach. There may be other statistical or systematic errors in calculating k_{eff} that are not included in either statistical treatment. Because of this, an MMS value should be specified regardless of the statistical method used. Therefore, the reviewer should not consider such a statistical approach an acceptable justification for any specific value of the MMS.

(5) Summary

Based on a review of the licensee's justification for its chosen MMS, taking into consideration the aforementioned factors, the staff should make a determination as to whether the chosen MMS provides reasonable assurance of subcriticality under normal and credible abnormal conditions. The staff's review should be risk-informed, in that the review should be commensurate with the MoS and should consider the specific facility and process characteristics, as well as the specific modeling practices used. As an example, approving an MMS value greater than 0.05 for processes typically encountered in enrichment and fuel fabrication facilities should require only a cursory review, provided that an acceptable criticality code validation has been performed and modeling practices at least as conservative as those in NUREG-1520 have been utilized. The approval of a smaller MMS will require a somewhat more detailed review, commensurate with the MMS that is requested. However, the MMS should not be reduced below 0.02 due to inherent uncertainties in the cross section data and the magnitude of code errors that have been discovered. Quantitative arguments (such as modeling conservatism) should be used to the extent practical. However, in many instances, the reviewer will need to make a judgement based at least partly on qualitative arguments. The staff should document the basis for finding the chosen MMS value to be acceptable or unacceptable in the Safety Evaluation Report (SER), and should ensure that any factors upon which this determination rests are ensured to be present over the facility lifetime (e.g., through license commitment or condition).

Technical Review Guidance

Determination of an adequate MMS is strongly dependent upon specific processes, conditions, and calculational practices at the facility being licensed. Judgement and experience must be employed in evaluating the adequacy of the proposed MMS. In the past, an MMS of 0.05 has generally been found acceptable for most typical low-enriched fuel cycle facilities without a detailed technical justification. A smaller MMS may be acceptable but will require some level of technical review.[2] However, for reasons stated previously, the MMS should not be reduced below 0.02.

An MMS of 0.05 should be found acceptable for low-enriched fuel cycle processes and facilities if:

1. A criticality code validation study has been performed that meets accepted industry guidelines (e.g., meets the requirements of ANSI/ANS-8.24, NUREG/CR-6361, and/or NUREG/CR-6698).

2. There is an acceptable number of critical experiments with similar geometric forms, material compositions, and neutron energy spectra to applications. These experiments cover the range of parameters of applications, or else margin is provided to account for extensions to the AOA.

3. The processes to be evaluated include materials and process conditions similar to those that occur in low-enriched fuel cycle applications (i.e., no new fissile materials, unusual moderators or absorbers, or technologies new to the industry that can affect the types of systems to be modeled).

The reviewer should consider any factors, including those enumerated in the discussion above, that could result in applying additional margin (i.e., a larger MMS) or may justify reducing the MMS. The reviewer must then exercise judgement in arriving at an MMS that provides for adequate assurance of subcriticality.

Some of the factors that may serve to justify reducing the MMS include:

1. There is a predictable and dependable amount of conservatism in modeling practices, in terms of k_{eff}, that is assured to be maintained (in both normal and abnormal conditions) over the facility lifetime.

2. Critical experiments have nearly identical geometric forms, material compositions, and neutron energy spectra to applications, and the criticality code validation is specific to this type of application.

[2] For high-enriched and plutonium or other fuel cycle facilities, no general guidance on the appropriate MMS is given. The reviewer should consider any relevant differences between these facilities and low-enriched uranium facilities (e.g., generally increased sensitivity of k_{eff}, generally reduced cross section uncertainty) on a case-by-case basis.

3. The criticality code validation methodology substantially exceeds accepted industry guidelines (e.g., it uses a very conservative statistical approach, considers an unusually large number of trending parameters, or analyzes the bias for a large number of subgroups of critical experiments).

4. The system k_{eff} is demonstrably much less sensitive to uncertainties in cross sections or variations in other system parameters than typical low-enriched fuel cycle processes.

5. There is reliable information besides results of calculations that provides assurance that the evaluated applications will be subcritical (e.g., experimental data, historical evidence, industry standards or widely-accepted handbooks).

6. The MMS is only applied to abnormal conditions, which are at least unlikely to be achieved, based on credited controls.

Some of the factors that may necessitate increasing (or not approving) the MMS include:

1. The technical practices employed by the licensee are less conservative than standard industry modeling practices (e.g., do not adequately bound reflection or the full range of credible moderation, do not take geometric tolerances into account).

2. There are few similar critical experiments of benchmark quality that cover the range of parameters of applications.

3. The criticality code validation methodology substantially falls below accepted industry guidelines (e.g., it uses less than a 95% confidence in the statistical approach, fails to consider trends in the bias, fails to account for extensions to the AOA).

4. The criticality code validation results otherwise tend to cast doubt on the accuracy of the bias and its uncertainty (i.e., the critical experiments are not normally distributed, there is a large number of outliers discarded ($\gtrsim$2%), there are distinct subgroups of experiments with lower k_{eff} than the experiments as a whole, trending fits do not pass goodness-of-fit tests, etc.).

5. The system k_{eff} is demonstrably much more sensitive to uncertainties in cross sections or other system parameters than typical low-enriched fuel cycle processes.

6. There is reliable information that casts doubt on the results of the calculational method or the subcriticality of evaluated applications (e.g., experimental data, reported concerns with the nuclear data).

The purpose of asking the questions in the individual discussion sections is to ascertain the degree to which these factors either provide justification for reducing the MMS or necessitate increasing the MMS. These lists are not all-inclusive, and any other technical information that demonstrates the degree of confidence in the calculational method should be considered.

ANNEX TO APPENDIX B

ANSI/ANS-8.17 CALCULATION OF MAXIMUM k_{eff}

American National Standards Institute (ANSI)/American Nuclear Society (ANS)-8.17-2004, "Criticality Safety Criteria for the Handling, Storage, and Transportation of LWR Fuel Outside Reactors," contains a detailed discussion of the various factors that should be considered in setting k_{eff} limits. This is consistent with, but more detailed than, the discussion in ANSI/ANS-8.1-1998 and ANSI/ANS-8.24-2007.

The subcriticality criterion from Section 5.1 of ANSI/ANS-8.17-2004 is:

$$k_s \leq k_c - \Delta k_s - \Delta k_c - \Delta k_m$$

where k_s is the calculated k_{eff} corresponding to the application, Δk_s is its uncertainty, k_c is the mean k_{eff} resulting from the calculation of critical experiments, Δk_c is its uncertainty, and Δk_m is the MMS. The types of uncertainties included in each of these "delta" terms is provided, and includes the following:

Δk_s = (1) statistical uncertainties in computing k_s; (2) convergence uncertainties in computing k_s, (3) material tolerances; (4) fabrication tolerances; (5) uncertainties due to limitations in the geometric representation used in the method; and (6) uncertainties due to limitations in the material representations used in the method.

Δk_c = (7) uncertainties in the critical experiments; (8) statistical uncertainties in computing k_c; (9) convergence uncertainties in computing k_c; (10) uncertainties due to extrapolating k_c outside the range of experimental data; (11) uncertainties due to limitations in the geometric representations used in the method; and (12) uncertainties due to limitations in the material representations used in the method.

Δk_m = an allowance for any additional uncertainties (MMS).

To the extent that not all 12 sources of uncertainty listed above have been explicitly taken into account, they may be allowed for by increasing the value of Δk_m. The more of these sources of uncertainty that have been taken into account, the smaller the necessary additional margin Δk_m. As a general principle, however, the MMS should be large compared to known uncertainties in the nuclear data and limitations of the methodology. However, a value of the MMS below 0.02 should not be used.

Frequently, the terms in the above equation relating to the application are grouped on the left-hand side of the equation, so that the equation is rewritten as follows:

$$k_s + \Delta k_s \leq k_c - \Delta k_c - \Delta k_m$$

where the terms on the right-hand side of the equation are often lumped together and termed the Upper Subcritical Limit (USL), so that the USL = $k_c - \Delta k_c - \Delta k_m$.

Relation to the Minimum Subcritical Margin (MMS)

The MoS has been defined as the difference between the actual value of k_{eff} and the value of k_{eff} at which the system is expected to be critical. The expected (best estimate) critical value of k_{eff} is the mean k_{eff} value of all critical experiments analyzed (i.e., k_c), including consideration of the uncertainty in the bias (i.e., Δk_c). The calculated value of k_{eff} for an application generally exceeds the actual (physical) k_{eff} value due to conservative assumptions in modeling the system. In terms of the above USL equation, the MoS may be expressed mathematically as:

$$MoS = k_c - \Delta k_c - (k_s - \Delta k_{sa}) - \Delta k_s$$

where the term in parentheses is equal to the actual (physical) k_{eff} of the application, k_{sa}. A term, Δk_{sa}, has been added to represent the difference between the actual and calculated value of k_{eff} for the application (i.e., Δk_{sa} = change in k_{eff} resulting from modeling conservatism). In terms of the USL:

$$MoS = USL + \Delta k_m - k_s + \Delta k_{sa} - \Delta k_s$$

The minimum allowed value of the MoS is reached when the calculated k_{eff} for the application, $k_s + \Delta k_s$, is equal to the USL. When this occurs, the minimum value of the MoS is:

$$MoS \geq \Delta k_m + \Delta k_{sa}$$

Thus, adequate margin (MoS) may be assured either by conservatism in modeling practices or in the explicit specification of Δk_m (MMS). This is discussed in the appendix section on modeling conservatism.

APPENDIX C

EXAMPLE PROCEDURE FOR SUBCRITICALITY EVALUATION

Purpose

This appendix provides the U.S. Nuclear Regulatory Commission (NRC) reviewer with an example of one method for licensees to perform an integrated safety analysis (ISA) for a nuclear process that meets the requirements of Title 10, "Energy," of the *Code of Federal Regulations* (10 CFR) 70.61, "Performance Requirements," for criticality safety hazards. The purpose of this appendix is to provide an example of an acceptable method to perform this evaluation of subcriticality. It employs a conservative, deterministic method for demonstrating that a process will be subcritical under normal and credible abnormal conditions. This example is an illustration of the use of the criticality hazard evaluation method discussed in Appendix 5-A to this SRP. This method is applicable only to criticality safety, whereas other hazards at facilities, such as chemical hazards, may be evaluated in accordance with the risk-index method of Appendix A to Chapter 3 of this SRP.

Introduction

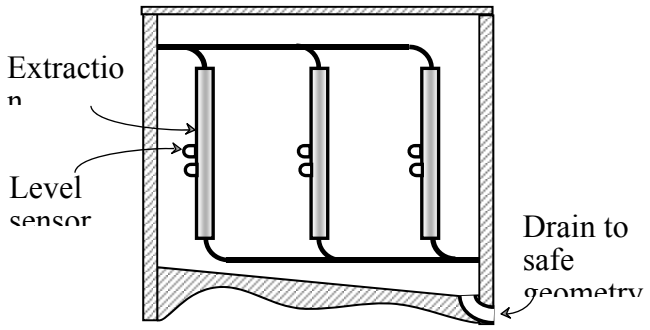
The appendix presents an example of how the deterministic method can be applied to a uranium solvent-extraction process. It describes one method of evaluating compliance with the subcriticality requirement of 10 CFR 70.61(d) and discusses the 10 CFR 70.64(a)(9) baseline-design criterion, under which the designs of new facilities, and the design of new processes at existing facilities, must provide for 6criticality control by adherence to the double-contingency principle. In this regard, the method described here of evaluating compliance with these requirements is intended to show how subcriticality may be demonstrated in accordance with use of the double-contingency principle. This method should not be interpreted as a requirement that the applicant use any particular methodology to meet the regulatory requirements. Note that most existing fuel facilities have committed to follow the double-contingency principle as the historically preferred means of ensuring subcriticality under normal and credible abnormal conditions.

This appendix is not a "format and content guide" for either the criticality safety evaluation (CSE) or the ISA summary. It simply presents one method of analysis of credible abnormal conditions leading to criticality. If the applicant evaluates normal and abnormal conditions using a different method, the method should produce similar results in terms of conditions identified. However, once the upset conditions are identified, the applicant has choices as to (a) which of the various parameters (as listed in Section 5.4.3.1.7.3) are most advantageous to control, (b) the means of controlling those parameters and (c) to what values to control those parameters. Therefore, the specific controls and limits associated with a similar solvent-extraction process may differ significantly from those provided in this example. The example should be regarded as illustrative of the method, and not as a definitive statement of the adequacy of a particular set of controls for a similar solvent-extraction operation.

Process Description

Solvent-extraction processes are frequently used in uranium recovery operations to recover purified uranyl nitrate for fuel-fabrication purposes. The main process control used in this example is geometry control, normally by means of favorable geometry process equipment.

The process for this example is pictured below.



A single-pass solvent-extraction process typically consists of a set of three favorable geometry column: an extraction column, a scrubbing column, and a stripping column. Uranium is dissolved (e.g., in tray dissolvers) with nitric acid (HNO_3) and piped into the extraction process, in which it is mixed with an organic and diluent mixture (such as tributyl phosphate (TBP) and kerosene) to separate any impurities from the uranium. This process does not exist in isolation, but rather is connected to both upstream and downstream processes, utilities, and waste processes. These include:

Connected processes:
- Tray dissolution
- Wet conversion

Utilities:
- Electrical power
- Process water
- Nitric acid supply
- Chemical makeup
- Organic conditioning

Waste processes:
- Raffinate storage
- Wastewater storage

NOTE: This list is not meant to be exhaustive, and neither is the list of upset conditions or controls; it is merely illustrative of the approach.

Criticality Safety Hazard Identification

As the first step in performing an ISA for the solvent-extraction process described above, an applicant typically determines the extent of the system to be analyzed. As stated above, the process does not exist in isolation, but interacts with connected processes through the flow of matter and energy, and possibly through neutron interaction, between adjacent systems. The part of the process to be covered by the CSE is pictured above, and consists of a set of three columns, the connected piping, and the surrounding room. The floor of the room is sloped and drains to a favorable geometry collection tank. The process is neutronically isolated from other processes by thick concrete walls.

Next, an applicant typically considers the initial process design and identifies an initial set of controlled parameters and criticality controls. This is only the initial set of controls because, in general, the performance of the CSE is an iterative process. The columns individually have diameters less than the subcritical diameter limits in ANSI/ANS-8.1, so they are considered to have favorable geometry. However, the entire system should be shown to be subcritical and so the columns cannot be considered only in isolation, because of the possibility of neutron interaction. An applicant would therefore construct a normal condition of the three columns together with the floor and walls. Under normal conditions, the material in the columns consists of uranyl nitrate solution (consisting of uranyl nitrate, water, and nitric acid) at various concentrations, TBP, and kerosene, in various proportions. The applicant may choose to model

the fissionable material without consideration for the TBP and kerosene, based on a sensitivity study showing that a pure uranyl nitrate solution is the most reactive. The applicant may then perform another sensitivity study to determine the optimal concentration of the uranyl nitrate solution (~1100 gU/l (grams of uranium per liter) for low-enriched solution and ~500 gU/l for high enriched solution).

Having decided on the fissionable material involved, the applicant may then make several choices about how to model the geometric configuration of the system. Initially, the applicant may model the three columns with solution to the outer diameter, taking tolerances in diameter and spacing between columns into account. The columns may also be modeled as infinitely long columns resting on a concrete floor 60 cm thick, 12 inches away from concrete walls that are 30 cm thick. The model will also necessarily make certain simplifying assumptions, such as ignoring small-diameter piping, flanges on the columns, the roughness of the concrete walls, etc. Small piping in particular is typically ignored, based on an analyst's professional judgment and experience and the fact that the piping is less than ½ inch in diameter and runs at right angles to the axis of each column, so neutron interaction is negligible. The applicant may perform a sensitivity analysis for interstitial moderation and determine that a 50% water density is the most reactive. The applicant may perform a calculation using this model and determine that it cannot meet the k_{eff} limit submitted in its license application.

An applicant may choose to construct the most conservative model it can, which generally minimizes the number of process characteristics that need to be controlled as well as the number of IROFS. In this example, however, it is assumed that the applicant is unable to demonstrate subcriticality for the system as originally envisioned. The applicant now has several choices, such as taking credit for the borosilicate glass in the columns, taking credit for concentration or excess acid in the solution, taking credit for the distance of the column from the floor, etc. In this example, it is supposed that the applicant then decides to shorten the column, raise the column off the floor, and model the solution to the inner diameter which maintaining an optimal material composition (modeling the void between the inner and outer diameter). It is then supposed that the resulting model is indeed subcritical.

An applicant then generally determines what parameters need to be controlled and what the controls on those parameters should be, to ensure subcritical for the normal condition. One common way to do this is to go through the list of controlled parameters, as in the following list (for illustrative purposes):

Concentration and density: not controlled, because the columns have been demonstrated to be subcritical with an optimal mixture.

Mass and volume: not controlled, because the columns have sufficient mass and volume to attain criticality (if geometry control is lost).

Enrichment: if solution is high-enriched, enrichment is not controlled; if solution is low-enriched, it might technically be being controlled, but if the maximum facility enrichment is used, this will be a global limit and there might be no credible way of exceeding it (especially in a non-enrichment facility). It is therefore generally unnecessary for an applicant to identify enrichment as a separate contingency in a non-enrichment facility.

Geometry: several of the dimensions included in the model are evaluated for whether they should be turned into geometry controls. The most crucial of these is the inner diameter of the column, which is controlled by specifying a maximum outer diameter and minimum thickness. The length of the columns, while shortened in the model, is such that their height-to-diameter

(H/D) ratio is ~15, and therefore effectively infinite (k_{eff} being insensitive to the actual length). Thus, it is not necessary in this example to designate the column height as a control.

Interaction: the spacing between columns, the distance between the columns and the floor, and the distance of the columns from the concrete walls are all used in the normal-condition model and therefore are potentially interaction controls. The most significant of these is spacing between the columns, which is identified as a criticality control. By professional judgment, the applicant may consider the distance of the columns from the walls to be the more significant, and the distance from the floor to most likely be insignificant. The applicant could choose to make these all criticality controls, but instead it is supposed that the applicant performs a sensitivity analysis showing that there is a minimum distance from the walls necessary for subcriticality, but that the columns are subcritical even when resting on the floor. Therefore, the spacing between columns and distance of the columns from the walls are designated as criticality controls in this example.

Reflection: not controlled. Rather than model each column with a one-inch tight-fitting water reflector, the applicant chooses to model the entire space surrounding the columns with varying densities of water, from a void to fully flooded conditions. Assuming the flooded condition is subcritical, it is not necessary to control water reflection. The concrete walls also provide some reflection. The floor thickness is not significant because k_{eff} has been shown to be insensitive to the columns' distance from the floor and 60-cm of concrete provides full reflection. The wall thickness is not significant based on the sensitivity analysis for interaction.

Moderation: not controlled. The applicant models the solution as an optimal mixture, and the columns are subcritical with optimal interstitial moderation.

Absorber: not controlled, because the applicant is presumed to have demonstrated subcriticality without taking credit for the material composition of the glass columns. If the applicant had explicitly modeled the glass, it would then have had to determine whether the glass should be a neutron-absorber control. Not making the glass a neutron-absorber control could be justified based on whether a sensitivity analysis demonstrated that none of the glass is needed for subcriticality. If only half the glass were needed, the applicant would then have to either make the glass an absorber control or decide whether it is credible that the composition could be reduced by such a large proportion.

Heterogeneity: not controlled, if the solution is highly enriched. If the solution is low-enriched, consideration would be given to flocculation and precipitation. Precipitation in this example is not a concern, because it will only result in achieving a less-reactive under-moderated condition. Suspended flocculates could result in a modest increase in reactivity, but the applicant determined that the margin of safety resulting from use of a higher-than-normal concentration and neglecting free acid is sufficient to account for any uncertainty caused by the homogeneity of the fissile mixture.

Physicochemical form: While the solution as modeled is presumed to have the most reactive composition for a uranyl nitrate solution, a change to a more reactive form needs to be considered. The applicant is presumed to have determined that a UO_2-water mixture is the most reactive physicochemical form that could exist in the columns (there being no credible way to form a metal-water mixture). Process deviations resulting from incomplete dissolution could lead to such a condition. In this example, the applicant therefore identified two upstream filters between the dissolution and extraction processes as criticality controls. No chemical reagents resulting in a more reactive form are presumed to have been identified.

Process variables: These mainly control the efficiency of the extraction process. Incomplete extraction could lead to the presence of concentrated uranium in the raffinate stream. Process variables that can affect extraction efficiency include temperature, acidity (pH), flow rate of TBP, power output of the pulsing pump, etc. For simplicity, because there is a downstream sodium iodide detector between the favorable geometry raffinate columns and wastewater tanks, it is assumed there are no additional process variable controls are needed.

Based on the above consideration of parameters associated with the normal-condition model, the applicant is presumed to have identified the following controlled parameters: geometry, interaction, and physicochemical form (and possibly enrichment). Not controlling other parameters is justified in the CSE. Based on the normal-condition model, the following criticality controls could be identified:

GEOMETRY:
- Outer column diameter
- Column wall thickness

INTERACTION:
- Column spacing
- Distance between columns and walls

PHYSICOCHEMICAL FORM:
- Upstream dual filters

NOTE: This list of controls is for illustrative purposes only and should not be considered an exhaustive list.

Criticality Safety Hazard Evaluation

The applicant must also demonstrate subcriticality under credible abnormal conditions. Once the initial suite of criticality controls is determined, an applicant should have demonstrated that all foreseeable ways they could fail so as to result in criticality have been considered. The following contingencies were identified. Again, this is an illustrative and not an exhaustive list. (Other scenarios[1] have already been discussed and dismissed above, such as precipitation, and are not considered further below.)

GEOMETRY

GEO-01: *A column or pipe leaks, ruptures, corrodes, or overflows onto the floor*

GEO-02: *A column leaks into the recirculation pumps*

GEO-03: *A column bulges beyond a safe diameter*

GEO-04: *A column overflows to unfavorable supply tanks*

GEO-05: *A transfer of solution to raffinate columns and unfavorable wastewater tanks*

INTERACTION

INT-01: *A seismic event reduces spacing between columns or between columns and walls*

INT-02: *A container bearing fissile material is placed adjacent to a column*

[1] The term "scenario" is deliberately chosen, to distinguish the concept here from the idea of identifying an "accident sequence." A "scenario" is a hypothetical event that could result in a change in process conditions (i.e., a "contingency"); a "sequence" is a string of events that eventually can result in an accident. The former is focused on the conditions achieved, while the latter is focused on how such conditions may be achieved.

PHYSICOCHEMICAL FORM

PC-01: *Incomplete upstream dissolution of scrap material*

ENRICHMENT

[No identified scenarios that can credibly lead to criticality]

Each of these possible scenarios would typically be considered in turn, and the conditions resulting therefrom shown to be subcritical, in accordance with the double-contingency principle. (An alternate but equally permissible approach is to combine some or all of these abnormal conditions into a single conservative model, which is then shown to be subcritical. As in the selection of how detailed a model to construct, the tradeoff is between analytic simplicity and safety margin.) The following table provides the results of an example evaluation and several additional controls that could be identified during this iterative process. Some of these controls (e.g., siphon breaks) may result in a design change, whereas others (e.g., floor drains) may result in existing features now being credited as controls.

Double-Contingency Discussion	Associated Criticality Controls
GEOMETRY Scenarios *Normal-condition controls*: Configuration (dimensions, spacing, and arrangement) of process equipment as modeled ensures subcriticality under normal conditions. Specific geometry attributes are the column outer diameter and wall thickness.	
GE0-01: *Column or pipe leaks, ruptures, corrodes, or overflows onto the floor*	
If the column's ability to contain fissile material within safe dimensions is compromised, solution will drain to the floor. The floor is sized in such a way that the full volume of any single column and all associated piping will accumulate to less than a safe depth. The floor is sloped and drains to a favorable geometry collection tank. In addition, a level sensor will alarm and alert operators that the solution level is unacceptably low; the operators are required to stop the process.	1st Control: Outer diameter and wall thickness of the columns. 2nd Control: Area and slope of the floor, diameter of the drain and collection tank. Defense-in-Depth (DID): Level sensors with alarms

Double-Contingency Discussion	Associated Criticality Controls
GEO-02: *Column leaks into recirculation pumps*	
In the event a favorable geometry column leaks, solution may enter the recirculation pumps. These pumps have been evaluated to be subcritical when filled with optimally moderated solution.	1st Control: Outer diameter and wall thickness of the columns. 2nd Control: Oil reservoir of pumps is safe volume, pumps are separated by 18 inches center-to-center. Additional Safety Margin (SM): Pump internals displace some of the pump volume.
GEO-03: *Column bulges beyond a safe diameter*	
Based on sensitivity analysis, there is no credible way that a column will bulge sufficiently to exceed the k_{eff} limit. Columns are hydrostatically tested to ensure they will not bulge to beyond the subcritical diameter. There are also no credible ways of pressurizing a column because the columns are vented.	1st Control: Outer diameter of the column; column composed of stainless steel of specified minimum thickness; verified by hydrostatic testing. 2nd Control: Columns are vented; vents consist of 1-inch diameter transparent tubing. DID: Operators are frequently if not continuously present in the area, and would notice conditions leading to column bulging within one shift. Braces and other supports credited for seismic events also would protect against column bulging.
GEO-04: *Column overflows to unfavorable supply tanks*	
As stated for Scenario GEO-03, no credible means of pressurizing a column have been identified. In addition, a siphon break has been installed on each column.	Control: Siphon breaks on all columns.
GEO-05*: Transfer to raffinate columns and unfavorable wastewater tanks*	

Double-Contingency Discussion	Associated Criticality Controls
The chemistry of the extraction process primarily protects against getting concentrated uranium in the raffinate storage columns. Dual independent samples are taken on the storage columns before authorization is granted to transfer their contents to unfavorable geometry wastewater treatment tanks. In the event, concentrated solution is inadvertently transferred, an active interlock making use of a sodium iodide detector will close valves on the transfer line and trip the transfer pump before an unsafe mass can be transferred.	1st Control: Dual independent sampling of raffinate storage columns before transfer may be granted. 2nd Control: In-line sodium iodide detector shuts the isolation valves and trips the transfer pump. DID: Chemistry of the extraction process is closely monitored (temperature, pH, TBP proportion, etc.). Operators trained to notice yellow liquid in raffinate storage columns.

Double-Contingency Discussion	Associated Criticality Controls
INTERACTION Scenarios *Normal-condition controls:* Configuration of process equipment as modeled ensures subcriticality under normal conditions. Specific interaction attributes are the spacing between columns and distance between the columns and walls.	
INT-01: *Seismic event reduces spacing between columns or between columns and walls*	
The building is designed in accordance with the Uniform Building Code in effect at the time of its construction, so as to withstand a design-basis earthquake. The supports are reinforced and a structural analysis shows that they will withstand greater than a 100-year earthquake. In addition, if the column supports fail, it would require more than two columns to come to rest against each other along their entire length, or more than one such column to rest flat against the wall. It is far more likely that an energetic seismic event would cause the columns to be randomly arranged. In addition, moving the columns more than 18 inches would almost certainly cause the piping to break, and the solution would therefore likely drain to the floor, as analyzed in GEO-01 above.	Sub-scenario INT-01a: *Supports fail but columns remain intact.* External Event (EE)): A seismic event capable of causing structural supports of the columns to fail is judged to be at least *unlikely* (as used in the Double Contingency Principle). 1st Control: Design of column supports to withstand specified load is credited in IC likelihood. Natural and Credible Course of Events (NCCE): It is at least *unlikely* for columns to come to rest in such a way as to exceed the k_{eff} limit. Sub-scenario INT-01b: *Supports fail and columns or piping leak to the floor.* *Upon further evaluation, this scenario is bounded by GEO-01 (so same controls apply).* NCCE: Displacement of columns by 18 inches or more would almost certainly result in failure of the piping and column connections, leading to a leak.
INT-02: *Container bearing fissile material placed adjacent to a column*	

Double-Contingency Discussion	Associated Criticality Controls
Calculations show that a geometrically controlled 5-gallon mop bucket, vacuum cleaner, etc., placed next to a column can exceed the k_{eff} limit (if placed on the midline between two columns, or between a column and the wall). (Containers with volumes larger than 5 gallons are prohibited in the solution area unless specifically evaluated to be subcritical). Administrative controls prohibit the introduction of solution-bearing equipment closer than 12 inches to the columns. There is no reason for an operator to raise such a necessarily heavy container off the floor, and it is unlikely (because of the location of flanges, small-diameter piping, etc.) that such a container would be placed against a column. However, a design change is being made so that a mesh barrier will be affixed to prevent placing such a container between the columns or between a column and the wall.	1st Control: Operators are prohibited from placing solution-bearing equipment closer than 12 inches to the extraction columns. 2nd Control: Mesh barrier affixed to the columns to prevent placing a container between the columns or between a column and the wall. 3rd Control: Containers larger than 5 gallons are prohibited in solution areas. DID: Location of flanges, piping, etc., is such that it is very impractical to place a container against the columns. Columns are raised 12 inches above the floor, so the scenario would require manually lifting a container weighing a minimum of 40 lb (5 gallons of pure water) off the floor.
PHYSICOCHEMICAL Scenarios *Normal-condition controls:* The nature of the process.	
PC-01: *Incomplete upstream dissolution of scrap material*	
The failure to use sufficient nitric acid, achieve the right temperature, properly agitate the scrap-acid mixture, or wait the required time period could result in incomplete dissolution, which can result in piping a heterogeneous UO_2-water mixture into the extraction columns. Double-contingency protection is provided by dual filters to prevent the introduction of undissolved solids into the extraction process. The filters must be installed by separate individuals and their correct installation independently verified. They will be subject to monthly surveillance to detect degradation.	1st Control: Filter to prevent undissolved UO_2 from reaching the extraction process subject to independent verification. 2nd Control: Second independently verified filter to prevent undissolved UO_2 from reaching the extraction process. DID: Procedural controls on nitric acid and mixing time in the dissolution process. Temperature alarm on the acid bath. Any undissolved solids will tend to settle at the bottom of the columns.

Double-Contingency Discussion	Associated Criticality Controls
ENRICHMENT Scenarios *Normal-condition controls*: Facility-wide limit on enrichment is used in evaluating this process.	
[There are no identified enrichment scenarios; the highest facility enrichment is used, and this is not an enrichment facility.]	

The example double-contingency discussion is necessarily abbreviated, because it neglects any number of complicating factors that could arise in actual plant conditions. Such an evaluation would also generally be supported by criticality calculations demonstrating abnormal-condition subcriticality, system drawings, piping and instrumentation diagrams, specifications, test/operating data, supporting technical evaluations, and other information that comprises the ISA documentation for this process. Defense-in-depth controls and additional safety margin are discussed in this table; while a good practice, they are ordinarily not tabulated along with the criticality controls but would rather be embedded in the calculations and other supporting information.

After several iterations resulting in the above double-contingency table, a final list of criticality controls for such a process is given below (new controls in italics):

GEOMETRY:

- Outer column diameter
- Column wall thickness
- *Area of the floor/room*
- *Floor is sloped ≥5°*
- *Floor drain less than 4 inches in diameter*
- *Floor drain leads to an 8-inch collection tank*
- *Oil reservoirs less than a safe volume*
- *Columns composed of borosilicate glass*[2]
- *Columns must be hydrostatically tested (to specified pressure)*
- *Columns are vented*
- *Columns equipped with siphon breaks*
- *Dual independent sampling on raffinate before transfer*
- *In-line active interlock on wastewater tanks*

INTERACTION:

- Column spacing
- Distance between columns and walls
- *Spacing between pumps*
- *Column supports*
- *Containers not to be placed against column*
- *Mesh barrier around columns*
- *Containers must be < 5 gallons*

PHYSICOCHEMICAL FORM:

- Upstream dual filters

[2] Not for, as is typically done, neutron absorption (which is not controlled), but to ensure that the materials of composition are consistent with the chemical environment to prevent corrosion.

The description of controls has been simplified, such as by not specifying specific associated subcritical limits or measures required to ensure that failure is unlikely (e.g., surveillance or maintenance, etc.). In addition, defense-in-depth controls have not been included in this list. (For example, the overflow lines will also prevent backflow, but only the siphon break is needed to satisfy double contingency.) The following are also noted: (1) the large number of controls needed to prevent a change in fissile-material geometry and (2) the number of choices the analyst had at several junctions as to what controls to put in place (e.g., the analyst could have credited the dissolution temperature alarm rather than two filters, could have chosen to limit interstitial moderator, or could have established an absorber control rather than install a mesh barrier around the columns). Some such choices would be made in accordance with the preferred control hierarchy—engineered over administrative, passive over active—and some would typically be made out of convenience or operational necessity.

Demonstration of Satisfaction of ISA Requirements

The above evaluation of hazards associated with a hypothetical solvent extraction process was based on demonstrating subcriticality under both normal and credible abnormal conditions. The double contingency principle was applied throughout, establishing criticality controls and taking credit for process characteristics and the natural and credible course of events as needed. The choice of controls was also done largely in adherence to the preferred control hierarchy, as a majority of controls in the above list are engineered controls, and in that preference is strongly for geometry over other less desirable means of control. (It is noted that each scenario listed above contains at least one passive engineered control (e.g., fixed geometry or neutron absorption).)

As stated in Appendix 5-A to this SRP, adherence to the double-contingency principle may be presumed to meet the performance requirements of 10 CFR 70.61(b) if application of double contingency is in accordance with the guidance in Appendix 5-A and Chapter 5 of the SRP, and if controls relied on to demonstrate double contingency are designated as items relied on for safety in the ISA summary, with sufficient management measures applied to render changes in process conditions “unlikely.” Assuming that this is the complete set of criticality scenarios and necessary controls to meet double contingency, consistent with the guidance for being unlikely, independent, etc., all that remains is to designate these controls as items relied on for safety and to apply management measures appropriate to the types and characteristics of those controls. The applicant has already made the choice of what system features need to be designated as “controls”, such as in choosing to control interaction over absorption or justifying why k_{eff} is not sensitive to certain system dimensions. Such a set would represent the minimum set of items relied on for safety required to comply with 10 CFR 70.61(e). In addition, the applicant identified no controls that are the sole item preventing or mitigating an accident sequence leading to criticality, because (1) the design adheres in all cases to the double-contingency principle, and (2) the analysis was based on a consideration of normal and abnormal conditions, rather than a consideration of individual accident sequences.

The example in this appendix illustrates the essential difference between a parameter-based and sequence-based approach to demonstrating safety and compliance with the performance requirements of 10 CFR 70.61. In a parameter-based approach—which is the traditional way of evaluating criticality safety—the normal condition is described in terms of parameters and limits on those parameters, and the focus is on whether deviations from those conditions will result in criticality. This can be thought of as a top-down approach, because one starts by asking what parameters are necessary to control to prevent criticality from occurring, and then establishing controls on those parameters. A sequence-based approach can be thought of as a bottom-up approach, because an applicant starts by considering all credible deviations from normal

conditions and then determining what sequences of events result and whether they lead to criticality. Both of these approaches may in principle be used, but the parameter-based approach tends to be the most conservative and gives greater assurance with less work of having considered everything. If the most reactive credible change in a controlled parameter still results in the system being subcritical, it is not necessary for the applicant to explicitly enumerate all the possible ways that such a change in the parameter could occur. Because it is also a deterministic approach, based on assuming that the optimal or most reactive credible conditions occur, it also eliminates the uncertainty that is associated with trying to estimate the likelihood of all of the possible sequences. It recognizes the historical fact that it is not the identification of sequences or estimation of likelihood that has led to the low incidence of criticality, but rather the defense-in-depth and safety margin associated with this very conservative approach. The difficulty with applying a sequence-based approach to criticality is two-fold: (1) the large number of physical variables upon which system reactivity depends can make the number of possible events that should be considered voluminous; and (2) many of these physical variables are interrelated to such an extent that it can be nearly impossible to identify discrete items relied on for safety.

It is this second difficulty with which an applicant must contend in designating the items relied on for safety. While pertinent column dimensions have been identified as criticality controls in the example, geometry is not independent from interaction or physicochemical form. There is no single control listed above that ensures subcriticality, but it is rather the entire interlocking system of controls that performs this overarching safety function. The individually safe columns are only subcritical because they are spaced a certain distance apart. They are only geometrically safe assuming they contain one fissile medium and not another. What ensures subcriticality is therefore the configuration of the system as a whole. As stated in Appendix 5-A, it is not the configuration of the system as it exists in the plant, but the configuration of the system as modeled, that is used to demonstratesubcriticality. Further, only those inputs to the model that have a significant effect on system reactivity (based on a sensitivity analysis or other justification)may need to be designated as controls. Recognizing this distinction is the key to avoiding the extreme of labeling every section of pipe and every nut and bolt as an item relied on for safety. The list of items relied on for safety in the example therefore includes:

SX-01: *Configuration of the solvent-extraction process contained in Room XYZ. The following specific dimensions of equipment shall be limited:*

- *Outer diameter of the extraction, scrubbing, and stripping columns shall be < 10 inches*
- *Wall thickness of the extraction, scrubbing, and stripping columns shall be > 0.25 inches*
- *Columns shall be spaced in a single row > 18 inches apart center-to-center*
- *Columns shall be spaced > 12 inches from the concrete walls*
- *The floor area of Room XYZ shall be greater than 100 square feet*
- *The floor of Room XYZ will be sloped ≥ 5° towards the corner*
- *The diameter of the floor drain shall be < 4 inches*
- *The diameter of the drain collection tank shall be < 8 inches*
- *Pumps will be spaced in a single row > 18 inches apart center-to-center*
- *Pump oil reservoirs shall have volumes of < 5 gallons*
- *Fissile solution piping shall be < ½ inch in diameter, and shall be run perpendicular to the column axes for at least a distance of 6 inches from the column surface.*

No single item listed ensures subcriticality alone. Rather, these are—with the exception of the last item—the dimensions of process equipment that are included in the model and together are limited to ensure subcriticality. An applicant could also choose to define “the configuration of the system” (which must already be under configuration control) generically as an item relied on

for safety. The definition of the system includes all equipment included in the model, which is the equipment in Room XYZ subject to neutron interaction. The specific attributes of this item relied on for safety are as enumerated. The safety function is to keep fissile material within specified dimensions to ensure subcriticality. The last item, restricting the configuration of the piping associated with the solvent-extraction process, was added by the hypothetical applicant in recognition that it pertains to the conditions under which something does *not* need to be included in the model. All of the above attributes are needed to ensure that the models demonstrating subcriticality will remain bounding. It is noted that the configuration of the system is an item relied on for safety, but is not the sole item preventing or mitigating an accident sequence, because there is no credible failure that can lead to criticality. In addition, because minimum and maximum dimensions are specified, a change that keeps the system within the description above (e.g., a change to the outer column diameter that does *not* exceed 10 inches) does not alter its safety function.

Other items relied on for safety would also generally exist (e.g., restriction on portable containers, siphon break, or upstream filters). Some of these could also in principle be included in "the configuration of the system" because they ensure the conservative nature of the models demonstrating subcriticality under normal and abnormal conditions. The combining or separation into one, two, or multiple items relied on for safety is arbitrary because they all have the same underlying safety function.

The final step by an applicant is typically to specify sufficient management measures to ensure that changes in process conditions will be subcritical. Management measures appropriate to passive engineered components include configuration management (includingchange control) and surveillance. If the columns are presumed to be composed of a material that is consistent with the chemical environment, corrosion would not be a concern and the periodic surveillance committed to as part of the NCS Program in the license application would be sufficient. This periodic surveillance would not be to ensure the reliability of any specific item relied on for safety, but rather to verify that no design changes have been made that could negatively affect criticality safety. Quality-assurance measures, such as use of procurement specifications for attributes important to criticality safety, may also be specified by an applicant. Items such as the in-line filters might need more frequent surveillance and specific maintenance instructions. For the active interlock, periodic maintenance and functional testing would also generally be required. For administrative controls (mainly restrictions on container movement), management measures would generally consist of operator training, procedures, postings, and periodic audits and inspections. Conspicuous labeling of permitted containers may also be used to enhance the reliability of this control.

For this example, the following additional items relied on for safety are presumed to have been specified, in addition to "the configuration of the system," SX-01:

<u>Passive Engineered</u>

NOTE: Configuration of the raffinate storage columns (dimensions, spacing, arrangement in a line) are presumed to be covered by another CSE. They are in another room and do not interact with process equipment in Room XYZ. This is established as RAF-01 in the other CSE.

SX-02: *Physical integrity of the extraction, scrubbing, and stripping columns, and associated piping. Columns will be composed of borosilicate glass, and piping of stainless steel 316, of sufficient thickness to withstand a hydrostatic pressure of at least 300 psig.*
SX-03: *Each column will be equipped with transparent overflowsof diameter > 1 inch, at or below the elevation of piping leading to the unfavorable geometry supply or wastewater tanks.*

SX-04: *Piping leading to each column will be equipped with a siphon break, placed between the columns and their common supply header.*

SX-05: *Column supports shall be shown to be capable of withstanding a 100-year seismic event without failing catastrophically (i.e., allowing the column to become detached from its support).*

SX-06: A *mesh barrier shall be affixed to the columns to prevent portable containers from being placed between the columns or between a column and the wall.*

SX-07: *Dual metal filters shall be installed on the header from the dissolution trays to the extraction process. They will be installed by different individuals and their installation independently verified. They will be inspected monthly.*

Active Engineered

SX-08: *In-line sodium iodide detector closes isolation valves between the raffinate storage columns and unfavorable geometry wastewater treatment tanks and trips the transfer pump upon detection of > 0.05 gU/l.*

Administrative

SX-09: *Dual independent sampling on raffinate storage columns before authorizing transfer to wastewater treatment tanks.*

SX-10: *Portable containers with volumes > 5 gallons are prohibited from Room XYZ, with the exception of movable equipment with dedicated CSEs (e.g., vacuum cleaners).*

SX-11: *Portable containers are prohibited from being placed adjacent to a column.*

Based on the foregoing subcriticality analysis, such a system of controls may be designated as items relied on for safety in the ISA summary, with appropriate management measures specified. The performance requirements would therefore then be satisfied.

6. CHEMICAL PROCESS SAFETY

6.1 Purpose of Review

The primary purpose of the review is to determine whether the applicant's proposed facility design and operations adequately protects the health and safety of workers and the public from chemical hazards. Such hazards are those that are related to the storage, handling, and processing of licensed materials which are within the NRC's regulatory jurisdiction. The proposed facility design and operations must adequately protect the health and safety of workers and the public from the chemical risks in the facility during normal operations and credible accident conditions. The applicant must ensure that its facility is adequately protected against conditions that could affect the safety of licensed materials and thus present an increased radiation or chemical risk (e.g., a chemical that incapacitates operators and prevents their entry into an area of the facility where licensed materials are handled). "Hazardous chemicals produced from licensed materials" is a defined term in 10 CFR 70.4, "Definitions." As indicated in the wording of this definition, an example of such a hazardous chemical is hydrogen fluoride that is produced by the reaction of uranium hexafluoride and water.

Chemical safety issues are evaluated as part of the applicant's integrated safety analysis (ISA) summary. As required in 10 CFR 70.65, "Additional Contents of Applications," the ISA summary must include the evaluation of credible accident sequences at the facility, identification of items relied on for safety (IROFS) where necessary to reduce the likelihood of accident occurrence or to mitigate the consequences of accidents, and identification of the management measures that provide reasonable assurance of the availability and reliability of IROFS when needed.
To begin the chemical safety review, the reviewer should examine the license application, the facility and process description discussed in Chapter 1 of this standard review plan (SRP), and the ISA summary discussed in Chapter 3 of the SRP to gain familiarity with the following:

- process information and accident sequences leading to conditions that could pose chemical hazards
- IROFS and sole IROFS[1] used to reduce the likelihood or consequences of accidents involving chemical hazards
- proposed procedures to protect public health and safety and the environment (e.g., a high-level programmatic description of how the licensee or applicant proposes to operate, maintain, or manage the facility)
- the definitions of "unlikely," "highly unlikely," and "credible" as used in the ISA evaluations
- quantitative standards used to assess the consequences to an individual from acute chemical exposure to licensed material or a chemical produced from licensed materials that are onsite or expected to be onsite

[1] Sole IROFS are those that are the sole item preventing or mitigating an accident for which the consequences could exceed the performance requirements of 10 CFR 70.61, "Performance Requirements."

- management measures proposed for ensuring that the IROFS will be available and reliable when required

6.2 Responsibility for Review

Primary: Chemical Process Safety Reviewer (all sections of this chapter)

Supporting: Licensing Project Manager
Fuel Cycle Facility Inspection Staff (as needed)
Health Physicist (for uranium and transuranic toxicity issues)
Primary Reviewers of Chapters 1, 3, 8, 9, and 11 of this SRP

6.3 Areas of Review

Regulations in 10 CFR 70.62(a) require an applicant to establish and maintain a safety program that will adequately protect worker and public health and safety and the environment from the chemical hazards from licensed material. Although it is not required to establish a separate chemical process safety program, the applicant must demonstrate that it has considered chemical hazards and accident sequences that could affect licensed material and has adequately prevented or mitigated them in accordance with 10 CFR 70.61, "Performance Requirements." Applicants must conduct an ISA and provide an ISA summary that meets the requirements of 10 CFR 70.65.

The staff's chemical process safety review should focus on the chemical safety-related accident sequences described in the ISA summary (SRP Chapter 3), the proposed IROFS, and the corresponding management measures (SRP Chapter 11). The review should determine whether the applicant's equipment, facilities, and management measures are adequate to protect against releases and chemical exposures of licensed material, hazardous chemicals produced from licensed material, and chemical risks of plant conditions that affect the safety of licensed material. The review must verify that classification of IROFS important to safety or grading of management measures proposed by the applicant in accordance with 10 CFR 70.62(a) is appropriate to the accident risk that the IROFS are designed to reduce.

The 2013 memorandum of understanding between the NRC and the Occupational Safety and Health Administration (OSHA) states that the NRC oversees chemical safety issues related to (1) radiation risks of licensed materials, (2) chemical risks of licensed materials, and (3) plant conditions that affect or may affect the safety of licensed materials and thus present an increased radiation risk to workers. OSHA oversees plant conditions that do not affect or involve the safety of licensed materials.

The staff's review should cover the following topics which are required to be in the ISA summary:

1. description of the site, facility, and chemical processes with respect to chemical safety for normal operations. The information should include a discussion of process chemistry, flow diagrams, discussion of major process steps, and identification of major pieces of equipment

2. chemical hazards and chemical accident sequences, including unmitigated accident sequences involving hazardous chemicals and licensed materials

3. chemical accident likelihood and consequences of accident sequence, including the applicant's interpretation of the qualitative chemical risk levels and the assumptions, bases, and methods the applicant used to estimate the accident likelihood and consequences to workers and the public

4. IROFS and sole IROFS relied on for chemical safety and a description of their safety function

5. management measures, including those management measures to ensure the reliability and availability of chemical safety IROFS

Review Interfaces

In addition to Chapter 6 of the application, the chemical reviewer should examine information in the following other areas to ensure that it is consistent with the information in Chapter 6:

- facility and process description applied to chemical safety, as described in Chapter 1 of this SRP

- safety program, ISA commitments, and ISA documentation applied to chemical safety under SRP Chapter 3

- emergency plan applied to chemical safety under SRP Chapter 8

- dispersion models used for consequence modeling under SRP Chapter 9 as appropriate

- configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, record management, and other quality assurance elements, as described in SRP Chapter 11

6.4 Acceptance Criteria

6.4.1 Regulatory Requirements

Acceptance criteria are based on meeting the relevant requirements of the following regulations:

1. The general and additional contents of an application with respect to chemical process safety are in 10 CFR 70.22, "Contents of Applications," and 10 CFR 70.65 respectively. General information that must be included in the license application appears in 10 CFR 70.22. Information that must be included in the ISA summary appears in 10 CFR 70.65.

2. The requirements for the approval of the application are in 10 CFR 70.23, "Requirements for the Approval of Applications," and 10 CFR 70.66, "Additional Requirements for Approval of License Application."

3. The chemical process safety review should provide reasonable assurance of compliance with the performance requirements in 10 CFR 70.61.

4. Requirements to maintain and establish a safety program appear in 10 CFR 70.62, "Safety Program and Integrated Safety Analysis."

5. The requirements for new facilities or new processes at existing facilities are in 10 CFR 70.64, "Requirements for New Facilities or New Processes at Existing Facilities."

6.4.2 Regulatory Guidance

The following regulatory guidance is relevant to chemical process safety:

1. NUREG-1391, "Chemical Toxicity of Uranium Hexafluoride Compared to Acute Effects of Radiation," February 1991

2. NUREG-1513, "Integrated Safety Analysis Guidance Document," May 2001

3. NUREG-1601, "Chemical Process Safety at Fuel Cycle Facilities," August 1997

4. NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook," March 1998

5. NUREG/CR-6481, "Review of Models Used for Determining Consequences of UF_6 Release," November 1997

6.4.3 Regulatory Acceptance Criteria

The reviewer should find the applicant's chemical process safety information acceptable if there is reasonable assurance that it adequately addresses and satisfies the acceptance criteria presented below. The applicant may elect to incorporate some or all of the requested chemical process information in the facility and process description (SRP Section 1.1) or the ISA summary. Either approach is acceptable, as long as adequate information is presented.

6.4.3.1 Chemical Process Description

The regulation in 10 CFR 70.65(b)(3) requires the ISA summary to include a description of each process in the facility. The applicant's descriptions of the chemical processes are acceptable if they meet the following conditions:

1. Process descriptions are sufficiently detailed to allow an understanding of the chemical process hazards (including radiological hazards caused by or involving chemical accidents) and to allow the development of potential accident sequences.

2. Process descriptions are sufficiently detailed to allow an understanding of the theory of operation.

6.4.3.2 Chemical Hazards and Accident Sequences

The identification of chemical hazard and accident sequences in the ISA summary is acceptable in the following circumstances:

1. The applicant identifies hazardous chemical inventory and location and describes the hazards and accident sequences involving hazardous chemicals produced from licensed material. The applicant also identifies chemical risks that could affect the safety of licensed materials.

2. The applicant identifies the chemical accident sequences that could result in a high- or intermediate-consequence event. Each accident sequence identified by the applicant should include a description of how the hazardous chemical could come in contact with facility personnel and offsite personnel. The hazard evaluation should use appropriate accepted methods.

6.4.3.3 Chemical Accident Sequence Likelihood and Consequences

A. The reviewer should consider the following criteria in evaluating whether the applicant's chemical accident likelihood and consequence estimates are acceptable:

   1. The applicant estimates the accident likelihood in a manner that is consistent with the definitions of likelihood presented in the ISA summary and reviewed under Chapter 3 of this SRP.

   2. The applicant identifies and uses appropriate techniques and appropriate assumptions in estimating the concentrations of released hazardous chemicals produced from licensed material or by abnormal plant conditions that could affect the safety of licensed materials.

   3. The applicant provides evidence that the dispersion models used to determine whether a release of chemicals might affect worker or public health and safety are appropriate to the process and the physical setting. The applicant should demonstrate that the models used for chemical reaction and dispersion analysis lead to a conservative estimate of potential consequences.[2]

   4. The applicant develops consequence estimates using, where appropriate, the guidance on atmospheric and consequence modeling in NUREG/CR-6410. The applicant may also use alternative methods if accompanied by adequate supporting information.

   5. The application describes the quantitative standards used to assess the unmitigated and mitigated consequences to an individual outside the control area (public) or to a worker from acute chemical exposure to licensed material, chemicals produced from licensed materials, or chemicals in contact with licensed materials that are onsite or expected to be on-site.

   6. Acceptable exposure standards include, but are not limited to, the Emergency Response Planning Guidelines established by the American Industrial Hygiene Association, the Acute Exposure Guideline Levels established by the National Advisory Committee for Acute Guideline Levels for Hazardous Substances, and

[2] Source term and vapor dispersion models used to calculate the concentration of uranium hexafluoride (UF_6) and its reaction products conform to any relevant guidance in NUREG/CR-6481.

the exposure limits established by OSHA. The applicant needs to verify that the selected standard applies to the worker or the individual outside the control area. Note that all the standards mentioned above apply to airborne exposure to gases, vapors, and particulates. Those limits are not intended to evaluate consequences for chemical exposures through other exposure paths.

7. The applicant may propose alternate exposure standards if accompanied by supporting documentation to justify its use.[3]

To ensure compliance with the performance requirements in 10 CFR 70.61, consideration should be given to multiple exposure pathways (e.g., inhalation and dermal) of the hazardous chemicals. In addition to the standards mentioned above, the Material Safety Data Sheets contain useful information about toxicity and health effects as well as first aid, reactivity, protective equipment, and spill or leak procedures. Therefore, it is recommended that the the Material Safety Data Sheets of the hazardous chemicals at the facility be reviewed when accessing chemical consequences.

B. The reviewer should confirm the following:

1. Consequence categorization is consistent with the performance requirements in 10 CFR 70.61(b) and 10 CFR 70.61(c).

2. The application includes definitions of “unlikely,” “highly unlikely,” and “credible,” as used in the evaluations in the ISA.

6.4.3.4 Chemical Process IROFS and Sole IROFS

The applicant must provide in the ISA summary a list of chemical process safety controls (i.e., IROFS) that are necessary to meet the performance requirements of 10 CFR 70.61. The applicant should identify IROFS for any unmitigated hazardous chemical accident sequences that would lead to consequences that exceed the performance requirements. The applicant should describe the IROFS in sufficient detail to permit an understanding of their safety functions.

The applicant must demonstrate, pursuant to 10 CFR 70.61(b), that any identified IROFS reduces the likelihood of each credible high-consequence event involving hazardous chemicals so that, upon implementation of IROFS, the event will be “highly unlikely” to occur. Alternatively, any such IROFS must make the event’s consequences less severe than those specified in 10 CFR 70.61(b)(4).

The applicant must demonstrate, pursuant to 10 CFR 70.61(c), that any identified IROFS reduces the likelihood of each credible intermediate-consequence event involving hazardous chemicals so that, upon implementation of IROFS, the event will be “unlikely” to occur. Alternatively, any such IROFS must make the event’s consequences less severe than those specified in 10 CFR 70.61(c)(4).

[3] Note that 10 CFR 70.61 requirements are for “acute chemical exposures,” and OSHA permissible exposure limits are typically time-weighted average values. Consequently, for ISA purposes, acute chemical release limits may not be adjusted by the time-weighted average calculation (which involves concentration and duration of exposure) unless the ISA summary provides a rational basis for doing so.

If the applicant takes a graded approach to safety, in accordance with 10 CFR 70.62(a), the reviewer should establish that the grading of management measures applied to IROFS is appropriate and sufficient to protect against chemical process risks. For example, the applicant should consider reliance on passive controls of active systems and defense in depth, in accordance with 10 CFR 70.64(b). To reduce common-mode failures in critical safety areas, the applicant should consider the use of independent sources of motive force for items such as control actuators, jet pumps, eductors, and ejectors. The applicant should also consider fail-safe controls wherever practical.

6.4.3.5 Chemical Process Management Measures

The applicant must describe the management measures proposed to ensure the availability and reliability of IROFS and sole IROFS when they are required to perform their safety functions. Management measures may be graded, commensurate with the safety significance of the IROFS to which they are applied.

The application should meet the following criteria:

1. The application should describe the engineering approach, basis, or schemes employed to maintain safety during normal operations.

2. The ISA summary should identify the administrative and engineered controls selected to prevent or mitigate a chemical risk, the hazard being mitigated, and the risk category. The applicant should also explain how IROFS have been classified, how management measures have been graded, and how such classification and grading is commensurate with the reduction in risk that the IROFS are designed to achieve.

3. The application should demonstrate that the management measures ensure that IROFS are available and reliable by briefly describing the following:

    a. procedures to ensure the reliable operation of engineered controls (e.g., inspection and testing procedures and frequencies, calibration programs, functional tests, corrective and preventive maintenance programs, and criteria for acceptable test results)

    b. procedures to ensure that administrative controls will be correctly implemented, when required (e.g., employee training and qualification in operating procedures, refresher training, safe work practices, development of standard operating procedures, and training program evaluation)

6.4.3.6 Requirements for New Facilities or New Processes at Existing Facilities

10 CFR 70.64(a) states that the application must address the baseline design criteria (BDC) for new facilities or new processes at existing facilities that require a license amendment under 10 CFR 70.72, “Facility Changes and Change Process.” 10 CFR 70.64(c) further states that the applicant must apply the BDC to the design of new processes, but is not required to retrofit existing facilities or existing processes; however, all facilities and processes must comply with the performance requirements in 10 CFR 70.61. Section 2.4 of NUREG-1601 contains a list of items that should be considered during facility design. Additionally, regarding chemical safety in

particular, 10 CFR 70.64(a)(5) states that the design must provide for adequate protection against chemical risk from licensed material, facility conditions that affect the safety of licensed material, and hazardous chemicals produced from licensed material. With respect to chemical process safety, the application should be considered acceptable if it includes the following information (or references other sections of the application that include this information):

1. A description of how the applicant performed the ISA for the new process and how the ISA satisfies the principles of the BDC of 70.64(a) for chemical safety hazards and the performance requirements in 10 CFR 70.61. The applicant also explains how it applies defense-in-depth requirements of 70.64(b), particularly higher risk accident sequences with chemical hazards. Acceptable defense-in-depth principles for the chemical process safety design are those that support a hierarchy of controls: prevention, mitigation, and operator intervention, in order of preference.

2. A description of any proposed facility-specific or process-specific relaxations or additions to BDC, along with justifications for relaxations.

3. The ISA summary describes how the applicant applied the chemical safety BDC in establishing the design principles, features, and control systems of the new process.

6.5 Review Procedures

6.5.1 Acceptance Review

During the acceptance review of a license application, the reviewer should examine the submittals to identify major deficiencies in the information provided for each area of review specified in SRP Section 6.3. Reviewers must decide whether they have enough information to proceed with a detailed review. Less significant errors or deficiencies that can be addressed in a single request for additional information should be accepted. However, before the NRC performs a detailed review, the applicant should correct major deficiencies that would require several requests for additional information to resolve.

Reviewers should record whether each area of review is adequately addressed in the application, is adequately addressed in a referenced document, is not applicable to the application, or has a major deficiency.

6.5.2 Safety Evaluation

During the safety evaluation, the reviewer determines whether the application comprehensively describes the chemical safety of the licensed activity, as identified in SRP Section 6.3. For deviations from the specific acceptance criteria, the staff should review the applicant's explanation of how the proposed alternatives to the SRP criteria provide an acceptable method of complying with the relevant NRC requirements identified in Section 6.4.

During the license application and ISA summary review, the reviewer should identify and note any items or issues that should be inspected during an operational readiness review, if such a review will be performed. These items could include confirming that the applicant implemented engineered controls through procedures and operator training.

The primary reviewer will prepare input to the safety evaluation report (SER) for the licensing project manager in support of the licensing action. During the initial review, the reviewer should draft the safety evaluation report (SER) described below. A request for additional information (RAI) will be prepared when clarification and additional information are needed to determine whether the licensee's submittals comply with the regulations. For an existing facility, the reviewer may consult NRC inspectors to identify and resolve any issues related to the licensing review. For a planned facility, the reviewers may wish to consult with the facility design team to gain a better understanding of the process, its potential hazards, and its safety approaches. The reviewers should coordinate these interactions through the licensing project manager as well as in preparing RAIs. Additional information submitted by the applicant will be evaluated and a final SER will be provided to the licensing project manager.

6.5.2.1 Chemical Process Description

The results of the ISA are the basis for the chemical process safety evaluation. The reviewer should establish that the applicant's facility design, operations, and IROFS for chemical safety provide reasonable assurance that they will function as intended and ensure the safe handling of licensed material at the facility. The reviewer must verify that the applicant's proposed equipment and facilities are adequate to protect public health and safety and the environment. The reviewer should examine the mechanisms that will allow the applicant to identify and correct potential problems.

6.5.2.2 Chemical Hazard and Accident Sequences

The ISA summary shall contain the potential accident sequences caused by process deviations or other events internal to the facility and credible external events, including natural phenomena. Whenever possible, a licensee should use its own experience to supplement the identification of potential chemical hazards. The review may cover a selected number of lower risk chemical safety-related accident sequences not identified in the ISA summary.

6.5.2.3 Chemical Accident Likelihood and Consequences

The reviewer must verify that the estimation of event likelihood is developed in a manner that is consistent with the methods and definitions reviewed and approved under Chapter 2 of this SRP.

The reviewer must verify that the proposed quantitative standards used to assess the consequences to an individual from acute chemical exposure are acceptable. Events with high and intermediate consequences should be identified as well as the IROFS proposed to reduce the likelihood or the consequences of the event. The reviewer needs to ensure that the selected standards are correctly applied to the worker or the member of the public.

6.5.2.4 Chemical Process IROFS and Sole IROFS

The staff reviews the chemical process safety IROFS to ensure their adequacy in protecting against all unmitigated sequences identified in the ISA summary. The reviewer should establish that the applicant's proposed controls (IROFS) for chemical safety provide reasonable assurance that they will function as intended and ensure the safe handling of licensed material at the facility.

6.5.2.5 Chemical Process Management Measures

The staff review should verify that the application describes the management measures that the licensee will take to provide reasonable assurance that the chemical safety IRFOS are available and reliable to perform their function. The technical reviewer should verify the applicant's commitment to retaining records for chemical-process safety compliance and reporting commitments for chemical releases. In addition, the reviewer should verify the applicant's commitment to refer any unacceptable performance deficiency to those responsible for the facility's corrective action function, in accordance with Chapter 11 of this SRP.

If the applicant has applied a graded approach to safety, the reviewer should establish that the grading of management measures and classification of IROFS is appropriate and sufficient to protect against chemical process risks (see Chapter 11 of this SRP).

6.5.2.6 Requirements for New Facilities or New Processes at Existing Facilities

The staff reviews the applicant's commitments to adhere to the BDC according to 10 CFR 70.64(a) and to the defense-in-depth requirements of 70.64(b) for the design of new facilities or new processes at an existing facility that require a license amendment under 10 CFR 70.72.

6.6 Evaluation Findings

The regulations in 10 CFR 70.23 and 70.66 state that an application for a license will be approved if the Commission can make the general findings listed in those sections. The basis for the general findings is an evaluation of whether the application adequately addresses all of the applicable regulatory requirements. More specifically, the staff's evaluation should determine whether the licensing submittals provide sufficient information to satisfy the regulatory requirements listed in Section 6.4.1 of this SRP, and whether the applicant has appropriately addressed the regulatory acceptance criteria in SRP Section 6.4.3. The SER should state how the applicable regulatory requirements have been met based on the acceptance criteria described in this chapter of the SRP. If the applicant chooses to use an alternative approach, the reviewer should discuss in the SER whether the proposed approach satisfies the applicable regulatory requirements. The reviewers should use the following approach to document their evaluation:

1. State a specific regulatory requirement that applies to the application. Detailed acceptance criteria may be included where appropriate or necessary.

2. Identify the areas where the regulatory requirement is addressed in the application, including the areas where the specific acceptance criteria described in this SRP are addressed.

3. Describe your evaluation of the application, the basis for your conclusion, and whether regulatory requirements are met.

4. Repeat these steps for every regulatory requirement that applies to the application.

There are three possible outcomes to the staff's licensing review: (1) approval of the applicant's application or amendment request, (2) denial of the application or request, or (3) approval with

conditions. If the reviewer cannot make a finding of a reasonable assurance of safety, the reviewer may consider proposing a license condition. Absent an NRC order, license conditions must be agreed upon with the licensee or applicant before becoming part of the license. A license condition should only be proposed if there is reasonable assurance that, if the licensee meets the condition, all regulatory requirements will be satisfied. Thus, license conditions should not be used to cover major deficiencies in an application. License conditions should be unambiguous, inspectable, and enforceable. They should only require those actions necessary to ensure compliance with applicable regulations. The basis for license conditions must be documented in the SER.

The SER should include a summary statement of what the NRC staff evaluated and the basis for the reviewer's conclusions that is similar to the following:

> The staff has evaluated the application using the criteria listed previously. Based on the review of the license application, the NRC staff has concluded that the applicant has adequately described and assessed accident consequences that could result from the handling, storage, or processing of licensed materials and that could have potentially significant chemical consequences and effects. The applicant has constructed a hazard analysis that identified and evaluated those chemical-process hazards and potential accidents and established safety controls to provide reasonable assurance of safe facility operation. To ensure that the performance requirements in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material,"[4] are met, the applicant has provided reasonable assurance that controls are 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 both 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.

6.7 References

American Industrial Hygiene Association, "Emergency Response Planning Guidelines," as revised. The latest available list of approved guidelines, dated May 31, 2013, is available at http://www.aiha.org/get-involved/AIHAGuidelineFoundation/EmergencyResponsePlanningGuidelines/Documents/2013ERPGValues.pdf (accessed on 5/12/14).

U.S. Environmental Protection Agency, "Acute Exposure Guideline Levels (AEGLs)," http://www.epa.gov/oppt/aegl/pubs/chemlist.htm (accessed on 5/12/2014).

U.S. Nuclear Regulatory Commission, "Inspection of the Nuclear Chemical Process Safety Program at Fuel Cycle Facilities," Inspection Manual Chapter 2603, as revised.

U.S. Nuclear Regulatory Commission, "Chemical Toxicity of Uranium Hexafluoride Compared to

[4] The title of 10 CFR Part 70 may be omitted if the title has already been stated in the same chapter of the SER.

Acute Effects of Radiation," NUREG-1391, February 1991.

U.S. Nuclear Regulatory Commission, "Integrated Safety Analysis Guidance Document," NUREG-1513, May 2001.

U.S. Nuclear Regulatory Commission, "Chemical Process Safety at Fuel Cycle Facilities," NUREG-1601, August 1997.

U.S. Nuclear Regulatory Commission, "Nuclear Fuel Cycle Facility Accident Analysis Handbook," NUREG/CR-6410, March 1998.

U.S. Nuclear Regulatory Commission, "Review of Models Used for Determining Consequences of UF_6 Release," NUREG/CR-6481, November 1997.

U.S. Nuclear Regulatory Commission/Occupational Safety and Health Administration, "Memorandum of Understanding between the U.S. Nuclear Regulatory Commission and the Occupational Safety and Health Administration," September 6, 2013.

7. FIRE SAFETY

7.1 Purpose of Review

The purpose of this review is to determine with reasonable assurance that the applicant has designed a facility that provides adequate protection against fires and explosions that could affect the safety of licensed materials and thus present an increased radiological or chemical risk. The review should also establish that the applicant has considered the radiological and chemical consequences of the fires and will institute suitable safety controls to protect workers, the public, and the environment.

Fire-safety issues are initially evaluated as part of the applicant's integrated safety analysis (ISA) summary. The ISA summary must evaluate credible accident sequences at the facility; identify items relied on for safety (IROFS) to prevent the occurrence or to mitigate the consequences of accidents; and include the management measures that provide reasonable assurance of the availability and reliability of IROFS when needed. Reviewers assess the applicant's approach to protecting against fire and explosion hazards by examining the license application and the ISA summary to gain familiarity with the following:

1. process information and accident sequences leading to conditions that could pose fire hazards

2. IROFS and sole IROFS used to prevent or mitigate such fire hazards

3. management measures applied to ensure that IROFS will be available and reliable when required

7.2 Responsibility for Review

Primary: Fire Safety Specialist

Secondary: Criticality Safety Specialist
Environmental Specialist
Chemical Safety Specialist
Physical Security Specialist
Licensing Project Manager

Supporting: Regional, Resident, and Fuel Cycle Inspection Staff

7.3 Areas of Review

Title 10 of the *Code of Federal Regulations* (10 CFR) 70.62(a) requires an applicant to develop, implement, and maintain a safety program that will reasonably protect public health and safety and the environment from the fire and explosive hazards associated with processing, handling, and storing licensed materials during normal operations, anticipated operational occurrences, and credible accidents. The fire protection program must address these process-specific risks and general fire prevention, protection, and management issues. Although 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," does not require a separate fire safety

program, an applicant should provide commitments pertaining to fire safety in the following areas:

1. Fire safety management includes safety organization, engineering review, and fire prevention; inspection, testing, and maintenance; prefire plans; and personnel qualifications, drills, and training.

2. Fire risk identification includes the fire hazards analysis (FHA) and the ISA summary.

3. Facility design includes information on building construction, fire areas, life safety, ventilation, and electrical system design. The facility design should also consider competing requirements among fire safety and security, criticality, and environmental concerns.

4. Process fire safety involves design considerations to prevent an accident or to mitigate the consequences of an accident resulting from the use of process chemicals, combustible metals, flammable and combustible liquids and gases, high-temperature equipment, hot cells and glove boxes, and laboratories.

5. Fire protection systems include fire detection, alarm, and suppression systems; portable extinguishers; water supplies; and emergency response organizations.

Review Interfaces

In addition to Chapter 7 of the application, the reviewer should examine information in the following other areas to ensure that it is consistent with the information in Chapter 7:

- Review information about the facility and process descriptions related to fire safety as required under Chapter 1 of this Standard Review Plan (SRP).

- Review information on the safety program, ISA commitments, and ISA documentation applied to fire safety as required under SRP Chapter 3.

- Review information on controls applied to chemical processes for fire safety as required under SRP Chapter 6.

- Review information on configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, record management, and other quality assurance (QA) elements as required under SRP Chapter 11 as related to fire safety.

7.4 Acceptance Criteria

An applicant that meets the acceptance criteria defined in this section or that has provided an acceptable alternative should be considered as having provided reasonable assurance of an acceptable fire protection program.

7.4.1 Regulatory Requirements

The regulatory basis for the fire safety review should be the requirements of 10 CFR 70.22, "Contents of Applications," and 10 CFR 70.65, "Additional Content of Applications." In addition, the fire safety review should focus on providing reasonable assurance of compliance with 10 CFR 70.61, "Performance Requirements"; 10 CFR 70.62, "Safety Program and Integrated Safety Analysis"; and 10 CFR 70.64, "Requirements for New Facilities or New Processes at Existing Facilities."

7.4.2 Regulatory Guidance

The relevant regulatory guidance for fire safety includes the following U.S. Nuclear Regulatory Commission (NRC) and industrial standards:

1. National Fire Protection Association (NFPA) 801, "Standard for Fire Protection for Facilities Handling Radioactive Materials," latest edition

2. NUREG-1513, "Integrated Safety Analysis Guidance Document," May 2001

3. NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook," March 1998

7.4.3 Regulatory Acceptance Criteria

Partial acceptability of the application and the ISA summary will be contingent on the NRC staff's review of the applicant's commitments to control and mitigate fire hazards. The staff will focus on whether the application is risk informed, addresses the applicant's procedures for maintaining an acceptable level of fire safety, and demonstrates that the applicant is prepared to react quickly and safely to extinguish fires. An applicant may use a graded approach to define fire safety, but it must provide sufficient documentation and commitments to ensure that it will adequately protect workers, the public, and the environment from fire events.

The applicant may incorporate these acceptance criteria in the information supplied to satisfy SRP Chapter 3 (regarding ISA) or other SRP chapters as long as it provides clear cross-references (information need not be repeated). The staff's fire safety specialist will review the application, ISA summary and other documentation, as needed, regarding these acceptance criteria.

The reviewer(s) will use nationally recognized codes and standards, as appropriate, in evaluating a reasonable assurance of fire safety. These codes and standards include, but are not limited to, the NFPA "National Fire Codes"; Factory Mutual Research Corporation data sheets and approval guide; Underwriters Laboratories, Inc., standards and building material directory; American National Standards Institute standards; and American Society for Testing and Materials standards. Commitments to specified standards will normally be considered an acceptable means of meeting the acceptance criteria.

The NRC staff will review the application to ensure that it meets the acceptance criteria discussed below.

7.4.3.1 Fire Safety Management Measures

An adequate application documents how the applicant will administer and ensure fire safety at the licensed facility. The application should reflect a commitment to ensure that the IROFS, as identified in the ISA Summary, are available and reliable and that the facility maintains fire safety awareness among employees, controls transient ignition sources and combustibles, and maintains a readiness to extinguish the fire or limit its consequences. These measures are unique to fire safety and, therefore, are not included in the acceptance criteria for SRP Chapter 11.

An adequate application identifies a senior-level manager who has the authority and staff to ensure that fire safety receives appropriate priority. A facility safety committee or fire safety review committee staffed by managers of different disciplines should integrate facility modifications. (The facility safety committee can do the work of a fire safety review committee.) As described in the application, an individual with sufficient practical fire safety experience in nuclear facilities should supervise day-to-day fire safety.

NFPA 801 specifies the following fire safety management measures:

1. fire prevention

2. inspection, testing, and maintenance of fire protection systems

3. emergency response organization qualifications, drills, and training

4. prefire plans

An adequate application documents the fire safety management measures in sufficient detail to identify their relationship to, and functions in, normal operations, anticipated (off-normal) events, and accident safety (i.e., IROFS). The staff recognizes NFPA 801 as one acceptable standard for fire safety management measures; however, the applicant may use other nationally recognized codes and standards if appropriate.

7.4.3.2 Fire Hazards Analysis

7.4.3.2.1 Development of a Fire Hazard Analysis as a Tool for Evaluating Fire Hazards

Knowing the fire risk allows an applicant to apply the appropriate level of fire protection to ensure the safety of workers, the public, and the environment from fire-induced radiological or chemical hazards. To be risk informed, a licensee should conduct an FHA for each facility or part thereof that, if totally consumed by fire, could release special nuclear material (SNM) in quantity and form that could cause at least an intermediate consequence, as defined in 10 CFR 70.61. The FHA should develop bounding credible fire scenarios for each fire area containing significant fire loading and then assess the consequences of an unmitigated fire. The staff recognizes NFPA 801 as one standard that provides guidance for conducting FHAs; however, the applicant may use other nationally recognized codes and standards if appropriate. The FHA should include a description, by fire area, of the fuel loading, fire scenarios, methods of consequence analysis, and potential consequences, as well as a description of the mitigative or preventive controls or both.

The FHA should also contain an inventory of IROFS that are susceptible to fire damage from credible fires (taking into account transient and temporary conditions) within each fire area. Loss of systems such as ventilation, cooling, or electrical power that could cause failures elsewhere in the facility should be evaluated. The FHA should also consider the improper operation of equipment and IROFS due to spurious signals induced by fire damage. In addition, the effects of combustion products, manual firefighting efforts, and the activation of automatic fire suppression systems should be assessed.

The FHA is used to identify possible fire initiators and accident sequences leading to radiological consequences or toxic chemical consequences resulting from interaction with SNM. In developing accident sequences that will be reported in the ISA summary, the ISA team will consider the FHA results and assign likelihoods to the various events in the accident sequences. With respect to fire safety, the ISA summary is acceptable if it identifies the credible fire hazards (e.g., from the FHA) for each process fire and if it provides details as to how the applicant considered and addressed (i.e., the management measures and IROFS) each fire hazard for each process accident sequence whose consequence could exceed the performance requirements in 10 CFR 70.61. Thus, the FHA is a fundamental tool for evaluating fire hazards as input to the ISA evaluation.

7.4.3.2.2 Deviations from National Fire Protection Association Codes and Standards

When the applicant or licensee states that its design “meets the NFPA code(s)” or “meets the intent of the NFPA codes” and does not identify any deviations from such codes, the NRC expects that the design conforms to the codes and is subject to inspection against the NFPA code of record. A design that “meets the intent of the code” should specify those sections of the code with which it does not conform. A licensee may apply the equivalency concept in meeting the provisions of the NFPA codes or standards. Nothing in the NFPA codes or standards is intended to prevent the use of methods, systems, or devices of equivalent or superior quality, strength, fire resistance, durability, and safety as alternatives to those prescribed by the codes or standards, provided that technical documentation demonstrates equivalency and that the method, system, or device is listed or approved for the intended purpose. Recent editions of the NFPA codes require submittal of technical documentation to the “authority having jurisdiction” to demonstrate equivalency of an alternative system, method, or device. The NRC does not require review and approval of equivalency evaluations before their implementation during construction. However, the licensee should document these evaluations and make them available for NRC inspection. The NRC recognizes that fire protection systems and controls may be required to meet State or local codes and may need to be approved by code enforcement officials. Where such systems and controls are not required to meet the performance requirements of 10 CFR 70.61 (i.e., not designated as IROFS), a State or local code enforcement official may be designated as the authority having jurisdiction (as described in NFPA documents). However, the NRC must review and inspect IROFS and any code deviations relative to their effect on nuclear safety. The authority having jurisdiction refers to the NRC Director of the Office of Nuclear Material Safety and Safeguards (or his or her designee).

7.4.3.3 Facility Design

Building construction, fire area determination, electrical installation, life safety, ventilation, drainage, and lightning protection are all facility design features that affect fire safety. The staff recognizes NFPA 801 as one standard that specifies acceptable facility fire safety design criteria; however, the applicant may use other nationally recognized codes and standards, if

appropriate. An adequate application documents the fire safety considerations used in the general design of fuel cycle facilities.

A. The NRC normally reviews the following design information related to fire safety in a license application:

1. the type of construction (as required under NFPA 220, "Standard on Types of Building Construction," for a new building) and applicable building codes (for an existing building) with a comparison to NFPA 220 building types

2. the identification of building material, the fire duration rating (if known), and a description of exterior openings

3. the overall description of the fire detection system, including the degree of compliance with NFPA 72, "National Fire Alarm and Signaling Code," for design, installation, surveillance, testing, and maintenance

4. the overall description of the automatic fire suppression system, applicable design standards, the system design basis, and identification of standards for surveillance, testing, and maintenance procedures

5. the description of the water distribution system, including descriptions of fire pumps, fire mains, the location of sectionalizing valves, maximum fire demand, and compliance with applicable NFPA standards

B. In addition to standard industrial fire safety concerns, the application should also address the following nuclear safety, environmental protection, and physical security issues:

1. Criticality concerns may exclude water extinguishing systems from process areas. However, during major fire events, the fire may easily overcome the extinguishing capability of portable extinguishers, and hose lines may be needed to extinguish the fire. Consequently, applicants should consider using total flooding gaseous systems in water-exclusion areas with significant fire risks. An adequate application addresses the methodology for extinguishing fires in water-exclusion areas.

2. Environmental concerns include the potential for thousands of gallons of fire water to be contaminated with nuclear material during a fire event. Consequently, diked areas and drainage of process facilities may be needed. NFPA 801 provides guidance on how to calculate the potential amount of runoff to properly size drainage and containment systems. An adequate application documents any measures used to control fire water runoff.

3. Physical security concerns include the need to design buildings and facilities to provide safe egress in case of fire. Physical security requirements for SNM may inadvertently delay worker egress and firefighter access. Physical security procedures should allow offsite fire departments quick and efficient access to fire emergencies. An adequate application documents the design criteria used for

worker egress and procedures for firefighter access. The staff recognizes NFPA 801 as one standard that specifies acceptable worker egress design criteria; however, the applicant may use other nationally recognized codes and standards, if appropriate.

The design and construction should be consistent with the guidance provided in NFPA 801 or other appropriate nationally recognized fire protection codes and standards.

7.4.3.4 Process Fire Safety

Many hazardous chemicals and processes used by fuel cycle facilities contribute to the fire hazards. In areas that have fire hazards that may threaten licensed material, the application should identify the hazardous chemicals, processes, and design standards used to ensure fire safety. The staff recognizes NFPA 801 as one standard that provides acceptable design criteria for radiological process areas that may contain hazardous material, laboratories, high-temperature equipment, hot cells, and glove boxes. However, the applicant may use other nationally recognized codes and standards, if appropriate.

The following are a few of the more common hazardous materials used at fuel cycle facilities:

1. Anhydrous ammonia is an explosive, flammable, and toxic gas used to make hydrogen.

2. Fluorine reacts violently with organic material or metal powders and water vapor.

3. Hydrogen is an explosive and flammable gas used in reduction processes.

4. Hydrogen peroxide off-gases hydrogen and oxygen and is incompatible with some extinguishers.

5. Nitric acid nitrates organic material, which lowers the ignition temperature of combustibles.

6. Sulfuric acid absorbs water from organic material in an exothermic reaction, thereby causing ignition.

7. Zirconium is a combustible metal that burns at elevated temperatures.

8. Calciners and incinerators are sources of heat that have initiated fires at fuel cycle facilities.

The applicant should identify fire and explosion hazards, fire and explosion parameters of hazardous materials, and the degree of compliance with applicable codes (e.g., NFPA 30, “Flammable and Combustible Liquids Code”; NFPA 69, “Standard on Explosion Prevention Systems”; and NFPA 86, “Standard for Ovens and Furnaces”).

In addition to participating in the integrated review of the ISA summary performed in accordance with Chapter 3 of this SRP, the reviewer should also examine in detail the fire-initiated release scenarios provided in the ISA summary to demonstrate compliance with 10 CFR 70.61. This review should follow the guidance provided in applicable subsections of SRP Chapter 3 to include a detailed evaluation of these scenarios, including a review of fire initiators, fire-induced

consequences, the likelihoods of such consequences, and IROFS chosen to prevent or mitigate those consequences.

7.4.3.4.1 Fire-Initiated Accident Sequences

The review should consider the following factors in determining the acceptability of the applicant's descriptions of fire-initiated accident sequences:

1. The applicant provided enough detail in its fire hazard descriptions to permit an understanding of the fire hazards sufficient to allow an evaluation of potential accident sequences.

2. The applicant adequately described the consequences and likelihoods of accident sequences identified in the ISA summary involving fire, including risks from hazardous chemicals produced from licensed material and risks from radioactive materials.

3. The applicant provided enough detail in its justification of the initiation probability for the reviewer to make an independent verification for those scenarios in which the initiation probability appears to be nonconservative. If a facility relies on controls to achieve this initiation probability, the applicant should identify these controls as IROFS, as appropriate.

4. Controls that are used to mitigate or prevent the scenario are identified as IROFS or as defense-in-depth measures. For those controls that are IROFS, reliability and associated management measures must be indicated.

5. Analyses that the applicant has performed as part of the evaluation are part of the ISA and referenced.

7.4.3.4.2 Items Relied on for Safety and the Associated Management Measures

Based on a comparison of the unmitigated fire protection accident sequence consequences with the performance criteria of 10 CFR 70.61, the applicant should identify (in the ISA summary) fire protection safety controls suitable to prevent or mitigate potential accidents. If the applicant takes a graded approach to safety in accordance with 10 CFR 70.62(a), the reviewer should establish that the classification of IROFS and grading of the associated management measures are appropriate and sufficient to protect against fire-related risks. A minimum acceptable level of requirements for management measures (e.g., QA for fire protection systems) is the level that NFPA codes require, such as the use of equipment listed by an acceptable organization (e.g., Underwriters Laboratories, Inc., or Factory Mutual Global). Installation and initial testing should also be that specified by the appropriate code.

The NRC staff should also review those management measures that ensure the availability and reliability of such IROFS when they are required to perform safety functions. The ISA summary should demonstrate that the proposed management measures ensure that IROFS are available and reliable when required by briefly describing the following:

1. measures to ensure the reliable operation of engineered controls (e.g., inspection and testing procedures and frequencies, calibration programs, functional tests, corrective and preventive maintenance programs, and criteria for acceptable test results)

2. measures to ensure that administrative controls will be correctly implemented when required (e.g., employee training and qualification in operating procedures, refresher training, safe work practices, development of standard operating procedures, and training program evaluations)

3. the compliance of IROFS with all applicable NFPA or industry consensus fire codes and standards

At minimum, IROFS should comply with those sections of the codes or standards affecting the reliability and effectiveness of the IROFS. For example, fire protection systems do not need to be seismically designed beyond what is required by the applicable NFPA code if they are not intended to function during a seismic event.

7.4.3.5 Fire Protection and Emergency Response

The application should document the fire protection systems and fire emergency response organizations provided for licensed facilities. The ISA summary should identify the fire protection IROFS. An adequate application describes the fire protection for areas in which licensed material is present. The application should describe which standards the fire protection systems and equipment meet. The staff recognizes NFPA's national fire codes as acceptable standards for the design, installation, testing, and maintenance of the fire protection systems and equipment. However, the applicant may use other nationally recognized codes and standards, if appropriate.

Facilities with the potential for rapidly developing fires that do not have an adequate nearby emergency responder may need an onsite fire emergency response team. One acceptable standard is NFPA 600, "Standard on Industrial Fire Brigades." However, the applicant may use other nationally recognized codes and standards, if appropriate. If offsite fire departments are needed for facility fire safety, periodic training with the fire departments is necessary so that offsite departments will become familiar with facility access procedures, facility layout, and prefire plans. A memorandum of understanding between the applicant and the fire departments is recommended to define the required protection. The staff's fire safety specialist will review the adequacy of the applicant's fire protection and emergency response commitments.

7.4.3.6 Requirements for New Facilities or New Processes at Existing Facilities

10 CFR 70.64(a) states that the application must address the baseline design criteria (BDC) for new facilities or new processes at existing facilities that require a license amendment under 10 CFR 70.72, "Facility Changes and Change Process." 10 CFR 70.64(a) further states that the applicant must apply the BDC to the design of new processes, but is not required to retrofit existing facilities or existing processes; however, all facilities and processes must comply with the performance requirements in 10 CFR 70.61. With respect to fire safety in particular, 10 CFR 70.64(a)(3) states that the design must provide for adequate protection against fires and explosions.

10 CFR 70.64(b) states that facility and system design must be founded on defense-in-depth practices and must incorporate, to the extent practicable: (1) preference for engineered controls over administrative controls and (2) reduction of challenges to IROFS. Thus, facility and system designs relying only on administrative controls, or relying on IROFS that are frequently or

continuously challenged, are not acceptable, unless the application provides a justification showing that alternatives to achieve the design criteria are not practicable.

In accordance with the above requirements, the application should be considered acceptable if it includes the information listed below (or references other sections of the application that include this information):

1. The application should briefly describe how the ISA was performed for the new process, including its 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 fire safety design would be those that support the hierarchy of controls with preference for prevention of releases (over mitigation of consequences) and engineered controls over administrative controls.

2. The ISA summary should describe how the applicant applied 10 CFR 70.64(a)(3) in establishing the design principles, features, and control systems of the new process. This will normally involve a commitment to follow appropriate codes and standards for design, testing, surveillance, and maintenance of fire protection systems, including those that are not IROFS but may involve nuclear processes or buildings housing nuclear material.

7.5 Review Procedures

7.5.1 Acceptance Review

During the acceptance review of a license application, the reviewer should examine the submittals to identify major deficiencies in the information provided for each area of review specified in SRP Section 7.3. Reviewers must decide whether they have enough information to proceed with a detailed review. Less significant errors or deficiencies that can be addressed in a request for additional information should be accepted. However, before the NRC performs a detailed review, the applicant should correct major deficiencies that would require several requests for additional information to resolve.

Reviewers should record whether each area of review is adequately addressed in the application, is adequately addressed in a referenced document, is not applicable to the application, or has a major deficiency.

7.5.2 Safety Evaluation

During the safety evaluation, the primary and secondary reviewers determine whether the application comprehensively describes the fire safety of the licensed activity as identified in SRP Section 7.3 and assess the commitments made in response to the criteria specified in SRP Section 7.4. During the initial review, the reviewer should draft the safety evaluation report (SER) described below. A request for additional information (RAI) will be prepared when clarification and additional information are needed to determine whether the licensee's submittals comply with the regulations. The primary reviewer should coordinate with the licensing project manager in preparing a RAI. Additional information submitted by the applicant will be evaluated and a final SER will be provided to the licensing project manager.

Reviewers should note that NFPA 801 uses “administrative control” in a different sense than how the term is used in 10 CFR Part 70 and elsewhere in this SRP. In 10 CFR Part 70, an administrative control is an IROFS if it is the human action necessary to meet safety performance requirements and if it is supported by management measures (e.g., training, QA, and procedures) that ensure that the action will be taken if needed. In NFPA 801, “administrative controls” refer to the training, qualifications, and procedures behind the human action; however, these elements are referred to as “management measures” in 10 CFR Part 70 and in this SRP.

For an existing facility, the reviewer may consult with cognizant NRC inspectors to identify and resolve any issues related to the licensing review. For a planned facility, the reviewers may wish to consult with the facility design team to gain a better understanding of the process, its potential hazards, and safety approaches.

7.5.2.1 Fire-Related Risks and Accident Sequences

The results of the ISA are the basis for the fire safety evaluation. The reviewer should assess the fire risks identified in the ISA summary and ensure that the level of safety is reflected in the design and the operational plans for the facility. The reviewer should establish that the applicant’s facility design, operations, and IROFS for fire and explosion safety provide reasonable assurance that they will function as intended and will provide for the safe handling of licensed material at the facility.

7.5.2.2 Items Relied on for Safety and Management Measures

The staff reviews the fire and explosion IROFS to ensure their adequacy in protecting against all unmitigated sequences identified in the ISA summary.

If the applicant has applied a graded approach to safety, the reviewer should establish that the classification of IROFS or grading of management measures is appropriate and sufficient to protect against fire and explosion risks.

7.5.2.3 Requirements for New Facilities or New Processes at Existing Facilities

The staff reviews the applicant’s commitments as required to satisfy the BDC in 10 CFR 70.64(a) for the design of new facilities or new processes at an existing facility that require a license amendment under 10 CFR 70.72.

7.6 Evaluation Findings

The regulations in 10 CFR 70.23 and 10 CFR 70.66, “Additional Requirements for Approval of License Application,” state that an application for a license will be approved if the Commission can make the general findings listed in those sections. The basis for the general findings is an evaluation of whether the application adequately addresses all of the applicable regulatory requirements. More specifically, the staff’s evaluation should determine whether the licensing submittals provide sufficient information to satisfy the regulatory requirements listed in Section 7.4.1 of this SRP and whether the applicant has appropriately addressed the regulatory acceptance criteria in SRP Section 7.4.3. The SER should state how the applicable regulatory requirements have been met based on the acceptance criteria described in this chapter of the SRP. If the applicant chooses to use an alternative approach, the reviewer should discuss in

the SER whether the proposed approach satisfies the applicable regulatory requirements. The reviewers should use the following approach to document their evaluation:

1. State a specific regulatory requirement that applies to the application. Detailed acceptance criteria may be included where appropriate or necessary to clarify the requirement.

2. Identify the areas where the regulatory requirement is addressed in the application, including the areas where the specific acceptance criteria described in this SRP are addressed.

3. Describe your evaluation of the application, the basis for your conclusion, and whether regulatory requirements are met.

4. Repeat these steps for every regulatory requirement that applies to the application.

There are three possible outcomes to the staff's licensing review: (1) approval of the applicant's application or amendment request, (2) denial of the application or request, or (3) approval with conditions. If the reviewer cannot make a finding of a reasonable assurance of safety, the reviewer may consider proposing a license condition. Absent an NRC order, license conditions must be agreed upon with the licensee or applicant before becoming part of the license. License conditions should only be proposed if there is reasonable assurance that, if the licensee meets the condition, all regulatory requirements will be satisfied. Thus, license conditions should not be used to cover major deficiencies in an application. License conditions should be unambiguous, inspectable, and enforceable. They should only require those actions necessary to ensure compliance with applicable regulations. The basis for license conditions must be documented in the SER.

The SER should include summary statements of what was evaluated and the basis for the reviewers' conclusions that are similar to the following:

- The applicant has established a fire-protection function meeting the acceptance criteria in SRP Chapter 7. The function includes a facility safety review committee responsible for integrating modifications to the facility and a fire-safety manager responsible for day-to-day program implementation. Fire prevention; inspection, testing, and maintenance of fire-protection systems; and the qualification, drills, and training of facility personnel are in accordance with applicable NFPA codes and standards. (Note that SER Section 11.3 describes fire-protection training requirements.)

- The applicant has conducted risk analyses 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 IROFS (in particular, wet pipe sprinkling in the process areas, isolation of the high-temperature equipment within fire barriers, and a fire brigade meeting NFPA 600). A memorandum of understanding with the fire department documents the required assistance and the annual exercises. Procedures are in place to allow the fire department efficient access to process areas during fire emergencies. Worker egress is designed and maintained in accordance with NFPA 101, "Life Safety Code."

- The applicant has demonstrated that it incorporated appropriate fire-safety considerations in the design of its facilities. The applicant has also demonstrated that the facility has appropriate active fire-protection systems.

- The staff concludes that the applicant's submittals provide sufficient information in accordance with the requirements of 10 CFR 30.33 and 10 CFR 40.32, both entitled "General Requirements for Issuance of Specific Licenses," and with the requirements of 10 CFR 70.22 and 10 CFR 70.65 regarding potential fire hazards, consequences, and required controls for the proposed processes. The NRC staff determined that the applicant demonstrated compliance with the performance requirements of 10 CFR 70.61 for fire protection related to postulated accident scenarios. The design that the applicant proposes also satisfies the requirements of 10 CFR 70.64(a)(3) and the defense-in-depth requirements of 10 CFR 70.64(b) (as required).[1]

7.7 References

U.S. Code of Federal Regulations, "Domestic Licensing of Special Nuclear Material," Part 70, Chapter I, Title 10, "Energy."

National Fire Protection Association (NFPA), "Flammable and Combustible Liquids Code," NFPA 30, Quincy, MA, 2008.

NFPA, "Standard on Explosion Prevention Systems," NFPA 69, Quincy, MA, 2008.

NFPA, "National Fire Alarm and Signaling Code," NFPA 72, Quincy, MA, 2010.

NFPA, "Standard for Ovens and Furnaces," NFPA 86, Quincy, MA, 1999.

NFPA, "Life Safety Code®," NFPA 101, Quincy, MA, 2007.

NFPA, "Standard on Types of Building Construction," NFPA 220, Quincy, MA, 2009.

NFPA, "Standard on Industrial Fire Brigades," NFPA 600, Quincy, MA, 2010.

U.S. Nuclear Regulatory Commission, "Uranium Oxide Fires at Fuel Cycle Facilities," Information Notice 92-14, February 21, 1992.

U.S. Nuclear Regulatory Commission, "Integrated Safety Analysis Guidance Document," NUREG-1513, May 2001.

U.S. Nuclear Regulatory Commission, "Nuclear Fuel Cycle Facility Accident Analysis Handbook," NUREG/CR-6410, March 1998.

[1] Add the titles of 10 CFR 70.22, 70.61, and/or 70.65 to this paragraph if this is the first time one of these regulatory sections is cited in this chapter of the SER.

8. EMERGENCY MANAGEMENT

8.1 Purpose of Review

The purpose of reviewing the applicant's emergency management plan is to determine if the applicant has established, before the start of operations, adequate emergency management facilities and procedures to protect workers, the public, and the environment. In preparing its emergency plan, the applicant may use either this standard review plan (SRP) or Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," issued January 1992. The applicant may provide the information requested for the emergency plan once and then cross-reference it in other sections.

Regulations in Title 10 of the *Code of Federal Regulations* (10 CFR) 70.22, "Contents of Application," impose a special content requirement on any application to possess (1) enriched uranium or plutonium for which a criticality accident alarm system is required, (2) uranium hexafluoride in excess of 50 kilograms (kg) (110 pounds (lb)) in a single container or a total of 1,000 kg (2,200 lb), or (3) plutonium in excess of 2 curies in unsealed form or on foils or plated sources. Section 70.22(i) states that such applications must contain either an emergency plan or an evaluation showing that the maximum dose to a member of the public due a release of radioactive material would not exceed 0.01-sievert (Sv) (1-rem) effective dose equivalent or an intake of 2 milligrams (mg) of soluble uranium.
The baseline design criteria (BDC) of 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," incorporate emergency capability. The criteria are intended to ensure the control of licensed material, the evacuation of personnel, and the availability of emergency facilities.

8.2 Responsibility for Review

Primary: Emergency Preparedness Specialist

Secondary: Licensing Project Manager

Supporting: Regional Emergency Preparedness Inspector
ISA Reviewer
Fuel Facility Inspection Staff

8.3 Areas of Review

The U.S. Nuclear Regulatory Commission (NRC) staff should review the applicant's submittal to determine if the special content requirement in 70.22(i) applies. If it does, the emergency plan/evaluation should be reviewed using the requirements and guidance specified below to determine if the application contains sufficient information to proceed with a detailed review, as described in Section 8.3.1 and 8.3.2 below:

8.3.1 Emergency Plan

If the applicant submits an emergency plan, the staff should evaluate the emergency plan against 10 CFR 70.22(i)(1)(ii), 70.22(i)(3), 70.22(i)(4), and Regulatory Guide 3.67, which

provides a standard format and content for an emergency plan. Elements in the emergency plan to be reviewed include the following:

1. a facility description (including both onsite and offsite emergency facilities)
2. the types of accidents
3. the classification of accidents (alert or site area emergency)
4. the detection of accidents
5. the mitigation of consequences
6. the assessment of releases
7. the responsibilities of licensee personnel
8. notification and coordination
9. information to be communicated and parties to be contacted
10. training
11. safe shutdown (recovery and facility restoration)
12. exercises and drills
13. certification of compliance with the Emergency Planning and Community Right-to-Know Act
14. comments from offsite response organizations

8.3.2 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 information against 10 CFR 70.22(i)(1)(i) and 70.22(i)(2). It should be consistent with evaluations in NUREG-1140, "A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees" dated January 1, 1988. NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook," issued March 1998, also contains methods considered acceptable for evaluating accidents. Areas evaluated should include the following:

1. a description of the facility
2. the types of materials used, including both radioactive material and hazardous chemicals
3. the types of accidents
4. the detection of accidents
5. site-specific information used to support the evaluation
6. an evaluation of the consequences

<u>Review Interfaces</u>

In addition to Chapter 8 of the application, the reviewer should examine information in the following other areas to ensure that it is consistent with the information in Chapter 8:

- Review information about the facility, process description, geography, and demographics as applied to emergency planning under SRP Chapter 1.

- Review information on the safety program, ISA commitments, and ISA documentation applied to emergency planning under SRP Chapter 3.

- Review information about radiological releases under SRP Chapter 4.

- Review information about response to criticality alarms under SRP Chapter 5.

- Review information about chemical releases under SRP Chapter 6.
- Review information about fire response under SRP Chapter 7.
- Review information on configuration management, maintenance, training and qualifications, procedures, audits and assessment, incident investigations, record management, and other quality assurance elements under SRP Chapter 11.

8.4 Acceptance Criteria

8.4.1 Regulatory Requirements

The regulation at 10 CFR 70.22(i)(1) states when a special content requirement applies to an applications. If the requirement applies, the additional content should be reviewed against the provisions in 10 CFR 70.22(i)(2) – (i)(4). In addition, 10 CFR 70.64(a)(6) requires some applicants to address the control of licensed material, the evacuation of personnel, and the availability of emergency facilities for the design of new facilities.

8.4.2 Regulatory Guidance

Regulatory guidance for evaluating accidents and preparing an emergency plan includes the following sources:

1. Regulatory Guide 3.67
2. NUREG-1140
3. NUREG/CR-6410

There is no formal guidance for evaluating the baseline design criteria in 10 CFR 70.64(a)(6). Reviewers should refer to the acceptance criteria in Section 8.4.3.3.

8.4.3 Regulatory Acceptance Criteria

8.4.3.1 Emergency Plan

The reviewer should evaluate the adequacy of the proposed emergency plan against the requirements in 10 CFR 70.22(i)(3) and the specific acceptance criteria provided in Sections 8.4.3.1.1 through 8.4.3.1.14 of this SRP. The reviewer should find the applicant's emergency plan acceptable if it meets the regulatory requirements and the acceptance criteria described below.

8.4.3.1.1 Facility Description

The emergency plan should describe the facility and site, the area near the site, and the licensed activities. These descriptions should include the following:

1. a detailed drawing of the site showing the following features:

a. onsite and near offsite (within 1.61 kilometers (km) (1 mile (mi))) 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

e. water bodies within approximately 1.61 km (1 mi)

2. a general area map covering a radius of approximately 16.1 km (10 mi), a U.S. Geological Survey topographical quadrangle (7½-minute series, including the adjacent quadrangle(s) if the site is located less than 1.61 km (1 mi) from the edge of the quadrangle), and a map or aerial photograph indicating onsite and near-site structures within a radius of approximately 1.61 km (1 mi)[1]

3. stack heights, typical stack flow rates, and 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 that are normally onsite, by location (use and storage) and building, and hazardous characteristics (exposure rates, pH, temperature, and other characteristics) that are important to emergency management.

5. description of the area near the site. On maps or photographs, indicate the following:

a. locations of population centers (towns, cities, office buildings, factories, schools, arenas, stadiums, etc.)

b. locations of facilities that could present potential protective action problems (schools, arenas, stadiums, prisons, nursing homes, hospitals)

c. identification of primary routes for access of emergency equipment or for evacuation, as well as potential impediments to traffic flow (rivers, draw bridges, railroad crossings, etc.)

d. locations of fire stations, police stations, hospitals, and other emergency support organizations

e. the sites of potential emergency significance (liquefied petroleum gas terminals, chemical plants, pipelines, electrical transformers, and underground cables)

f. identification of the types of terrain and the land-use patterns around the site.

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[1] The map should include the location of sensitive facilities near the site, such as hospitals, schools, nursing homes, nearest residents, fire departments, prisons, environmental sampling locations, and other structures and facilities that are important to emergency management.

8.4.3.1.2 Onsite and Offsite Emergency Facilities

The emergency plan should list and describe onsite and offsite facilities that could be relied on in an emergency. The emergency plan should include the following:

1. a list and description of both onsite and offsite emergency facilities, by location and purpose

2. a description of emergency monitoring equipment that is available for personnel and area monitoring and for assessing the release to the environment of radioactive or hazardous chemicals incident to the processing of licensed material

3. a description of the onsite and offsite services that support emergency response operations, including the following:

    a. decontamination facilities
    b. medical treatment facilities
    c. first-aid personnel
    d. fire fighters
    e. law enforcement assistance
    f. ambulance services

8.4.3.1.3 Types of Accidents

For each general type of accident identified in the ISA summary for which protective actions may be needed, the emergency plan should describe the following:

1. the process and physical location(s) where the accidents could occur

2. complicating factors and possible onsite and offsite consequences, including releases of nonradioactive hazardous chemicals incident to the processing of licensed material that could impact emergency response efforts

3. the accident sequence that has the potential for the greatest radiological or toxic chemical impact

4. figure(s) projecting doses and toxic substance concentrations as a function of distance and time for various meteorological stability classes, including a description of how the applicant projected such doses or concentrations (e.g., computer models and assumptions)

8.4.3.1.4 Classification of Accidents

The emergency plan should classify accidents as follows:

1. The emergency plan classification system should include the following two classifications:

a. 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 processing of licensed material; however, the release is not expected to require a response by an offsite response organization to protect persons offsite.

b. 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 processing of licensed material and that could require a response by offsite emergency response organizations to protect persons offsite.

2. The emergency plan should identify the classification (alert or site area emergency) expected for each accident identified in the emergency plan.

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 the performance of emergency response measures. The applicant's EALs should be consistent with Appendix A to Regulatory Guide 3.67 and should be comparable to the U.S. Environmental Protection Agency (EPA) Protective Action Guides described in EPA 400-R-92-001, "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents," issued May 1992. Transportation accidents more than 1.61 km (1 mi) from the facility should not be classified.

4. The emergency plan should designate the personnel positions and alternates with the responsibility for accident classification during normal operations and back shifts.

8.4.3.1.5 Detection of Accidents

For each type of accident identified, the emergency plan should describe the following:

1. the means of detecting the accident

2. the means of detecting any release of radioactive material or hazardous chemicals incident to the processing of licensed material

3. the means of alerting the operating staff

4. the anticipated response of the operating staff

8.4.3.1.6 Mitigation of Consequences

For each accident identified in the ISA summary, the emergency plan should briefly describe measures and equipment to be used for safe shutdown and the mitigation of consequences to workers onsite and offsite and to the public offsite.

8.4.3.1.7 Assessment of Releases

The emergency plan should describe the following aspects of the applicant's procedures to be used to promptly and effectively assess the release of radioactive material or hazardous chemicals incident to the processing of licensed material:

1. procedures for estimating or measuring the release rate or source term

2. valid computer codes used to project doses or concentrations to the public or environment and their associated assumptions, along with adequate justifications to show the validity of the assumptions

3. types, methods, frequencies, implementation times, and other details of onsite and offsite sampling and monitoring that will be performed to assess a release of radioactive materials or hazardous chemicals incident to the processing of licensed material

4. the method for assessing collateral damage to the facility (especially items relied on for safety)

The emergency plan should describe the applicant's procedure for validating any code used to assess releases of radioactive material or hazardous chemicals incident to the processing of licensed material.

8.4.3.1.8 Responsibilities

The emergency plan should describe the emergency response organization and administration that ensure effective planning, implementation, and control of emergency preparedness activities. Reviewers should evaluate whether the description addresses the following issues:

1. Procedures clearly define the organizational structure and chain of command.

2. Staffing and resources are sufficient to accomplish all assigned tasks.

3. Procedures clearly define responsibilities and authority for each management, supervisory, and professional position. Responsibility is assigned for the coordination of onsite and offsite emergency response preparedness.

4. Procedures clearly define interfaces with supporting groups, both onsite and offsite.

5. Mutual cooperation agreements exist or will be entered into with local agencies, such as fire, police, ambulance and rescue, and medical units.

6. Plant management measures audit and assess emergency preparedness to ensure site readiness to handle emergencies and to identify and correct problems.
7.

The onsite emergency response organization provides effective command and control of the site during the assessment, mitigation, and recovery phase of an accident.
8. A system provides timely 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.

9. Emergency preparedness procedures are available to support startup and operation of new processes and facilities onsite.

8.4.3.1.9 Notification and Coordination

A. 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, on the basis of the following:

1. A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate.
2. A commitment to establish a control point.
3. Emergency action levels are established to quickly classify events.
4. Notification procedures include concise, preformatted messages.
5. Information on the nature and magnitude of the hazards is made available to the appropriate emergency response personnel.
6. Radiological and chemical source term data are made available to offsite response organizations and the NRC.
7. Recommendations for protective actions offsite have been prepared using Protective Action Guides and will be communicated with the initial notification to offsite response organizations.
8. A system is established to provide the public with timely information.
9. The notification and coordination is planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee commits to notify the NRC operations center immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

B. The emergency plan should describe who will take the following actions and how he or she will act promptly and effectively:

1. the decision to declare an alert or site area emergency
2. the activation of the onsite emergency response organization during all shifts
3. the 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 of classification)
4. the notification to the NRC Operations Center (as soon as possible and, in any case, no later than 1 hour after a declared emergency)

5. the decision regarding which onsite protective actions to initiate

6. the decision regarding which offsite protective actions to recommend

7. the decision to request support from offsite organizations

8. the decision to terminate the emergency or enter recovery mode

8.4.3.1.10 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 releases or hazardous chemicals incident to the processing of licensed material, 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 taken by offsite organizations for each accident treated in the emergency plan

8.4.3.1.11 Training

The emergency plan should describe the frequency, performance objectives, and plans for the emergency response training that the licensee will provide to workers. The plan should describe the following:

1. the topics and general content of training programs for the licensee's 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, the 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

5. any special instructions and orientation tours that the licensee would offer to fire, police, medical, and other nonlicensee emergency personnel who may be required to respond

to an emergency to ensure that they know the emergency plan, assigned duties, and effective response to an actual emergency

8.4.3.1.12 Safe Shutdown (Recovery and Facility Restoration)

The emergency plan should describe the following aspects of the applicant's plans for adequately restoring the facility to a safe status after an accident and recovery after an emergency:

1. the methods and responsibilities for assessing the damage to and status of the facility's capabilities to safely control radioactive material or hazardous chemicals associated with the process

2. the procedures for promptly determining the actions necessary to reduce any ongoing releases of radioactive material or hazardous chemicals incident to the processing of licensed material and to prevent further incidents

3. the provisions for promptly and effectively accomplishing required restoration actions

4. key positions in the recovery organization including the person responsible for compiling evaluating, and retaining records associated with the incident.

8.4.3.1.13 Exercises and Drills

The emergency plan should state the applicant's commitment to conduct exercises and drills to test the adequacy of implementing procedures and emergency equipment, and to ensure that emergency personnel are familiar with their duties. An adequate plan should describe provisions for the following objectives:

1. Qualified individuals for each position in the emergency response organization demonstrate task-related knowledge through periodic participation.

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 predrill briefings are conducted.

4. Scenario data and exercise messages provided by the controllers effectively maintain the timeline 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. The prestaging of equipment and personnel is minimized to realistically test the activation and staffing of emergency facilities.

7. Critiques are conducted promptly and include a followup plan for correcting any identified weaknesses and improving training effectiveness.

8. Emergency drills demonstrate that resources are effectively used to control the site, mitigate further damage, control radiological releases, perform required onsite activities under simulated radiation/airborne and other emergency conditions, accurately assess the facility's status during an accident, and initiate recovery.

9. Emergency drills demonstrate personnel protection measures, including controlling and minimizing hazards to individuals during fires, medical emergencies, mitigation activities, search and rescue, and other similar events.

10. The emergency drills demonstrate that onsite communications effectively support emergency response activities.

11. The emergency drills demonstrate that the emergency organization provides the public with accurate, reliable, timely, and understandable information.

12. Provisions are made for conducting quarterly communications checks with offsite response organizations.

13. Offsite organizations are invited to participate in the biennial onsite exercise, which tests the major elements of the emergency plan and response organizations.

14. Certification by the plant manager (or the individual authorized by the applicant) that the applicant has met all responsibilities under the 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)

8.4.3.1.14 Responsibilities for Developing and Maintaining the Emergency Program and Its Procedures

The emergency plan should describe the following aspects of the responsibilities for developing and maintaining the emergency program and its procedures:

1. the means for ensuring that revisions to the emergency plan and the procedures used to 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

2. the provisions for approving 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 the emergency procedures [2]

3. procedures for allowing offsite response organizations 60 days to comment on an emergency plan before it is submitted to the NRC. Any comments received within the 60 days shall be provided to NRC with the emergency plan.

[2] Provisions for approving changes to the emergency plan and the procedures and the individuals authorized to make those changes should be clearly stated.

8.4.3.2 Evaluation that No Emergency Plan Is Required

The staff should review the adequacy of the evaluation that no emergency plan is required against the 10 CFR 70.22(i)(1)(i) and 10 CFR 70.22(i)(2) requirements, and the acceptance criteria given below.

8.4.3.2.1 Facility Description

The evaluation should describe the facility and site, the area near the site, and the licensed activities conducted at the facility. To be considered sufficient to support the evaluation, these descriptions should include the following:

1. a detailed drawing of the site showing (1) onsite and near offsite (within 1.61 km (1 mi)) structures, with building numbers and labels; (2) roads and parking lots onsite and main roads near the site; (3) site boundaries, including fences and gates; (4) major site features, (5) water bodies within approximately 1.61 km (1 mi); and (6) the location(s) of the nearest residents

2. the stack heights, typical stack flow rates, and 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 material used

8.4.3.2.2 Types of Accidents

The evaluation should describe each type of accident that has maximum offsite consequences that exceed the limit specified in 10 CFR 70.22(i)(1)(i). In addition, the following information should be available for review:

1. the process and physical location where the accident could occur

2. complicating factors and offsite consequences, including the release of nonradioactive hazardous chemicals incident to the processing of licensed material

3. the accident sequence that has the potential for the greatest radiological and toxic chemical impact

8.4.3.2.3 Detection of Accidents

To support the use of factors such as engineered safety features and operating procedures, the evaluation should describe the following:

1. the means of detecting the accident

2. the means of detecting any release of radioactive or hazardous chemicals incident to the processing of licensed material

3. the means of alerting the operating staff

4. the anticipated response of the operating staff

8.4.3.2.4 Evaluation of Maximum Public Exposure

In addition to the information discussed above, the evaluation should make available the following information sufficient to allow for independent verification:

1. the maximum source term

2. the solubility of material

3. the facility design or items relied on for safety and the proposed release fraction

4. the location and distance of the nearest member of the public to the facility

5. the dose model and process used to verify the reliability of the model and the validity of the assumptions

6. the assumed worst case weather condition

7. the maximum calculated exposure to a member of the public at the facility boundary

The evaluation should list and describe the factors in 10 CFR 70.22(i)(2) that the applicant considered in evaluating the maximum dose to members of the public. The applicant should demonstrate why the factors used in the evaluation are appropriate when compared with the factors in NUREG-1140. If the factors and evaluation show that the maximum dose to a member of the public offsite from a release of radioactive materials could not exceed a 0.01-Sv (1-rem) effective dose equivalent or the intake of 2 mg of soluble uranium, no emergency plan is required in accordance with 10 CFR 70.22(i)(1)(i).

8.4.3.3 Requirements for New Facilities or New Processes at Existing Facilities

The application should address the BDC for new facilities or new processes at existing facilities that require a license amendment under 10 CFR 70.72, “Facility Changes and Change Process.” Regulations in 10 CFR 70.64(a) state that the BDC must be applied to the design of new processes but do not require retrofits to existing facilities or existing processes; however, all facilities and processes must comply with the performance requirements in 10 CFR 70.61, “Performance Requirements.” In accordance with 10 CFR 70.64(a)(6)(i-iii), the licensee or applicant must show that the design of the facility or process provides for the emergency capability to maintain control of the following:

1. licensed material and hazardous chemicals produced from licensed material. In this regard, an application should include:

    a. how the facility design prevents or mitigates releases during an emergency

    b. how the facility design helps licensee emergency workers (fire brigades, etc.) respond to emergencies

2. evacuation of onsite personnel. In this regard, an application should includethe criteria used in designing the facility to allow personnel to evacuate (e.g., time, dose, and ease of egress).

3. onsite emergency facilities and services that facilitate the use of available offsite services. In this regard, an application should include:

    a. the offsite services that will be needed in an emergency at the facility

    b. the criteria used to design the facility to detect accidents

    c. the criteria used to design the facility to alert facility staff of an accident

    d. the criteria used to design the facility to notify and coordinate with both onsite and offsite personnel

    e. the criteria used to design the facility to allow for the transportation of injured personnel to onsite and offsite medical facilities

10 CFR 70.64(b) states that facility and system design must be founded on defense-in-depth practices and must incorporate, to the extent practicable: (1) preference for engineered controls over administrative controls and (2) reduction of challenges to IROFS. Thus, facility and system designs relying only on administrative controls, or relying on IROFS that are frequently or continuously challenged, are not acceptable, unless the application provides a justification showing that alternatives to achieve the design criteria are not practicable.

8.5 Amendments or Changes to the Emergency Plan

The applicant may make changes to the approved emergency plan without NRC approval if the changes do not decrease the effectiveness of the plan and the applicant submits copies of the changes to the NRC and appropriate organizations within 6 months of making the changes in accordance with 10 CFR 70.32(i). The applicant may not implement proposed changes that decrease the effectiveness of the emergency plan without prior application to and approval of the NRC.

8.6 Review Procedures

8.6.1 Acceptance Review

During the acceptance review of a license application, the reviewer should examine the submittals to identify major deficiencies in the information provided for each area of review specified in SRP Section 8.3. Reviewers must decide whether they have enough information to proceed with a detailed review. Less significant errors or deficiencies that can be addressed in a request for additional information should be accepted. However, before the NRC performs a detailed review, the applicant should correct major deficiencies that would require several requests for additional information to resolve.

Reviewers should record whether each area of review is adequately addressed in the application, is adequately addressed in a referenced document, is not applicable to the application, or has a major deficiency.

8.6.2 Safety Evaluation

After determining that the application is acceptable for review in accordance with Section 8.6.1 above, the primary reviewer should perform a safety evaluation against the acceptance criteria described in Section 8.4 above. During the initial review, the reviewer should draft the safety evaluation report (SER) described below. A request for additional information (RAI) will be prepared when clarification and additional information are needed to determine whether the licensee's submittals comply with the regulations. The primary reviewer should coordinate with the licensing project manager in preparing RAIs. Additional information submitted by the applicant will be evaluated and a final SER will be provided to the licensing project manager.

8.6.2.1 Emergency Plan

After the NRC staff receives an acceptable application from the applicant, the primary reviewer should conduct a complete review of the applicant's emergency plan and assess its acceptability in accordance with Section 8.4.3.1 above. The reviewer should verify that emergency planning is consistent with the potential accident sequences described in the ISA summary. The ISA summary reviewer and emergency plan reviewer should coordinate their efforts to ensure the resolution of any issues concerning the emergency plan relative to ISA summary information.

Although the section of the licensee's submittal entitled "Emergency Management Program" should contain the bulk of this information, the primary and secondary reviewers should gain familiarity with the site, including its demography, land use, facility design and layout, and major accidents postulated by the applicant, as presented in relevant sections of the application. The primary and secondary reviewers should also become familiar with proposed radiation protection activities and other operational matters that interface with emergency plans (particularly the functions reviewed using SRP Chapters 4 and 11). The reviewers should consult draft and final environmental statements for the proposed facility. This information may be supplemented by a personal visit to the site by the reviewer and meetings with the applicant. As the final step, the primary reviewer should prepare a safety evaluation report (SER) section in accordance with Section 8.7 below.

8.6.2.2 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 summary, historical information in NUREG-1140 and guidance in NUREG/CR-6410. The ISA summary reviewer and the primary reviewer should coordinate their efforts to ensure the resolution of any issues concerning the evaluation relative to ISA information. Significant concerns with the evaluation should be raised early to allow the applicant to resolve the issues or submit an emergency plan. As the final step, the primary reviewer should prepare an SER section in accordance with SRP Section 8.7 below.

8.7 Evaluation Findings

The regulations in 10 CFR 70.23, "Requirements for the Approval of Applications," and 70.66, "Additional Requirements for Approval of License Application," state that an application for a license will be approved if the Commission can make the general findings listed in those sections. The basis for the general findings is an evaluation of whether the application adequately addresses all of the applicable regulatory requirements. More specifically, the staff's evaluation should determine whether the licensing submittals provide sufficient information to satisfy the regulatory requirements listed in Section 8.4.1 of this SRP and whether the applicant has appropriately addressed the regulatory acceptance criteria in SRP Section 8.4.3. The SER should state how the applicable regulatory requirements have or have not been met based on the acceptance criteria described in this chapter of the SRP. If the applicant chooses to use an alternative approach, the reviewer should discuss in the SER whether the proposed approach satisfies the applicable regulatory requirements. The reviewers should use the following approach to document their evaluation:

1. State a specific regulatory requirement that applies to the application. Detailed acceptance criteria may be included where appropriate or necessary.

2. Identify the areas where the regulatory requirement is addressed in the application, including the areas where the specific acceptance criteria described in this SRP are addressed.

3. Describe your evaluation of the application, the basis for your conclusion, and whether regulatory requirements are met.

4. Repeat these steps for every regulatory requirement that applies to the application.

There are three possible outcomes to the staff's licensing review: (1) approval of the applicant's application or amendment request, (2) denial of the application or request, or (3) approval with conditions. If the reviewer cannot make a finding of a reasonable assurance of safety, the reviewer may consider proposing a license condition. Absent an NRC order, license conditions must be agreed on with the licensee or applicant before becoming part of the license. A license condition should only be proposed if there is reasonable assurance that, if the licensee meets the condition, all regulatory requirements will be satisfied. Thus, license conditions should not be used to cover major deficiencies in an application. License conditions should be unambiguous, inspectable, and enforceable. They should only require those actions necessary to ensure compliance with applicable regulations. The basis for license conditions must be documented in the SER.
The report includes a summary statement describing what was evaluated and why the reviewer finds the submittal acceptable that is similar to one of the following statements:

> The staff has evaluated the application dated [insert dates including any supplements]. The requested possession limits are less than the threshold quantities specified in 10 CFR 70.22(i). Therefore, neither an emergency plan nor an evaluation of the dose to a member of the public from a release of radioactive material is required.
>
> OR

The staff has evaluated the application dated [insert dates including any supplements]. Based on it review of the evaluation as documented above, the staff finds that the evaluation meets the requirement in 10 CFR 70.22(i)(1)(i) and is acceptable. Specifically, the evaluation demonstrates that the dose to a member of the public from a release of radioactive material would not exceed 1 rem effective dose equivalent or an intake of 2 milligrams of soluble uranium. Therefore, no emergency plan is required.

OR

The staff has evaluated the application dated [insert dates including any supplements]. Based on its review of the emergency plan as documented above, the staff finds that it meets the requirements on 10 CFR 70.22(i) and 10 CFR 70.32(i); and therefore, the plan is acceptable.

8.8 References

U.S. Code of Federal Regulations, "Domestic Licensing of Special Nuclear Material," Part 70, Chapter I, Title 10, "Energy."

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

U.S. Nuclear Regulatory Commission, "Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees, Final Rule" *Federal Register*, Vol. 54, No. 66, April 7, 1989, pp. 14051–14059 (54 FR 14051).

U.S. Nuclear Regulatory Commission, "Response Technical Manual (RTM) 96," NUREG/BR-0150, Vol. 1, Revision 4, March 1996.

U.S. Nuclear Regulatory Commission, "A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees," NUREG-1140, August 1991.

U.S. Nuclear Regulatory Commission, "Nuclear Fuel Cycle Accident Analysis Handbook," NUREG/CR-6410, March 1998.

9. 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 the environment and public health and safety and to comply with the regulatory requirements imposed by the U.S. Nuclear Regulatory Commission (NRC) in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 20, "Standards for Protection against Radiation," and 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." If the environmental-protection information of the safety evaluation report (SER) is to be used in the preparation of an environmental document pursuant to the separate requirements of the National Environmental Policy Act (NEPA) and under the requirements of 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," the staff preparing the NEPA document is responsible for independently evaluating whether the information in the SER can also to be used for that independent purpose.

Accordingly, this chapter does not address the specific requirements of 10 CFR Part 51. NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs," issued August 2003, which provides general procedures for the environmental review of licensing actions regulated by the Office of Nuclear Material Safety and Safeguards (NMSS). The staff of the Division of Fuel Cycle Safety, Safeguards, and Environmental Review (FCSE) should coordinate the preparation of an environmental assessment (EA) and finding of no significant impact (FONSI) or an environmental impact statement (EIS) with the Environmental Review Branch in FCSE. If the licensee proposes that a requested action is a categorical exclusion under the provisions of 10 CFR 51.22, "Criterion for Categorical Exclusion; Identification of Licensing and Regulatory Actions Eligible for Categorical Exclusion or Otherwise Not Requiring Environmental Review," the FCSE staff should confirm that the action meets the applicable criteria in 10 CFR 51.22(c).

9.2 Responsibility for Review

Primary: Environmental Engineer/Scientist

Secondary: Licensing Project Manager

Supporting: Fuel Cycle Facility Inspector
Radiation Safety Reviewer
Integrated Safety Analysis (ISA) Primary Reviewer
Fire Protection Reviewer
Criticality Safety Reviewer
Chemical Safety Reviewer
NEPA Reviewer or Project Manager

9.3 Areas of Review

The environmental safety program should address the environmental protection measures, including the control and monitoring of gaseous and liquid effluents and the management of solid waste. The environmental program should also provide for the monitoring of the facility

environment, including ambient air, surface water, ground water, soils, and vegetation that can be affected by facility effluents. This SRP chapter addresses the areas of review for environmental protection measures, and for environmental monitoring measures, which should be contained in Chapter 9 of the application. Although information regarding environmental monitoring may be used by the staff as part of a larger set of information considered in the preparation of an EIS, this SRP chapter is not intended to satisfy the independent information needs of the staff to prepare an EIS or EA under the separate requirements of NEPA. The Environmental Project Manager or designee should coordinate its review with the FCSE safety and safeguards reviewer to assure consistency of their respective reviews and information needs from the applicant (e.g., RAIs).

If the application includes an ISA summary as required by Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material," of 10 CFR Part 70, the environmental reviewer will review the ISA summary accident sequences that could result in high or intermediate consequences to an individual located outside the controlled area or that could result in a 24-hour averaged release of radioactive material outside the restricted area in concentrations exceeding 5,000 times the values in Table 2 of Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," to 10 CFR Part 20. Section 9.3.2.3 below addresses areas of review for the ISA summary specific to environmental protection.

The regulatory requirements for environmental protection appear in 10 CFR Part 20 and 10 CFR Part 70. The NRC staff focuses its environmental review on that part of the plant wide safety program that the applicant establishes to control and assess the level of radioactive and nonradioactive releases (gaseous, liquid, and solid) to the environment. Therefore, the staff reviews the effluent control portion of the applicant's radiation protection program and the applicant's effluent and environmental monitoring practices from a safety, not NEPA-related, perspective.

If the application is for authorization to perform an activity identified in 10 CFR 70.60, then an applicant must also perform an ISA and prepare an ISA summary in accordance with Subpart H of 10 CFR Part 70. SRP Chapter 3 presents guidance on the ISA. The environmental safety review of the ISA summary will examine the identified potential accident sequences that result in radiological and non-radiological releases to the environment, the items relied on for safety (IROFS) that the applicant specifies to reduce the environmental risk of those accidents, and the associated management measures that provide reasonable assurance that the IROFS will perform their designated safety functions. It is critical for SRP Chapter 3 to specify that offsite impacts of accidents have been considered in its evaluation and to provide an assessment of those impacts, if any. The environmental-specific information in Chapter 3 is to be used to support the review for Section 9.3.2 below.

Thus, environmental protection encompasses three main components, as necessary: (1) effluent and environmental controls and monitoring, (2) the ISA summary and other ISA documentation as described in Sections 9.3.1 and 9.3.2 below, and (3) management measures in the license application.

9.3.1 Effluent and Environmental Controls and Monitoring

A. The staff's review of the environmental radiation protection program described in the application encompasses the following areas:

1. as low as reasonably achievable (ALARA) goals for effluent control
2. effluent controls to maintain public doses ALARA
3. ALARA reviews and reports to management
4. waste minimization practices and, for new operations, design plans for waste minimization

B. The staff's review of the applicant's effluent and environmental monitoring program described in the application encompasses the following areas:

1. in-place filter-testing procedures for air-cleaning systems
2. known or expected concentrations of radionuclides in effluents
3. physical and chemical characteristics of radionuclides in discharges
4. discharge locations
5. environmental media to be monitored and the sample locations
6. sampling collection and analysis procedures, including the minimum detectable concentrations of radionuclides
7. action levels and actions to be taken when the levels are exceeded
8. permits, including air discharge and National Pollutant Discharge Elimination System permits
9. leak detection systems for ponds, lagoons, and tanks
10. pathways analysis methods to estimate public doses
11. recording and reporting procedures
12. solid waste handling and disposal programs

9.3.2 Integrated Safety Analysis Summary

The staff's review of the applicant's ISA summary related to environmental protection includes the following areas:

1. accident sequences (and associated facility processes) that, if unmitigated, would result in releases to the environment

2. likelihood and environmental consequences of these accident sequences

3. controls relied on to reduce the unmitigated risk from high or intermediate risk to an acceptable level

4. availability and reliability of controls

9.3.3 Environmental Protection Management Measures

The staff's review of the applicant's management measures related to environmental protection includes the following areas:

1. a method for grading management measures commensurate with the reduction in risk attributable to each control or control system

2. a commitment to design, implement, and maintain the controls and control systems to ensure that they are available and reliable to perform their functions when needed

Review Interfaces

In addition to the information contained in Chapter 9 of the application, the environmental reviewer should also examine information in the following other areas to ensure that it is consistent with the information in Chapter 9. Note that the staff assessment of the information identified below is to be found in the respective chapters of the SER, not in Chapter 9:

- facility and process descriptions applied to environmental protection as described in SRP Chapter 1

- the safety program, ISA commitments, and ISA documentation applied to environmental protection as described in SRP Chapter 3

- the radiation safety program as described in SRP Chapter 4

- chemical processes applied to environmental protection as described in SRP Chapter 6

- fire-initiated accident sequences that have the potential to result in high or intermediate consequences as described in SRP Chapter 7

- configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, record management, and other quality assurance elements as described in SRP Chapter 1[1]

[1] Section 9.3.3 addresses areas of review for management measures applied to environmental protection.

9.4 Acceptance Criteria

Sections 9.4.3.1 through 9.4.3.3 describe acceptance criteria for the effluent and environmental controls and monitoring, the ISA summary, and management measures. If the acceptance criteria for the other sections of the SER have been met, then the information is also acceptable under Chapter 9.

9.4.1 Regulatory Requirements

To be considered acceptable, the application must satisfy the following regulatory requirements for environmental protection:

1. Subpart B, "Radiation Protection Programs"; Subpart D, "Radiation Dose Limits for Individual Members of the Public"; and Subpart F, "Surveys and Monitoring," of 10 CFR Part 20 specify the effluent control and treatment measures necessary to meet the dose limits and dose constraints for members of the public. Subpart F also states the survey requirements. Subpart K, "Waste Disposal," specifies the waste disposal requirements; Subpart L, "Records," specifies the records requirements; and Subpart M, "Reports," specifies the reporting requirements.
2. 10 CFR 70.21(f) requires that an application for an activity which the Commission has determined requires an EIS, listed in 10 CFR 51.20, must be accompanied by an Environmental Report required under Subpart A of part 51. The application must be filed at least 9 months prior to commencement of construction, as defined in 10 CFR 70.4.
3.
4. 10 CFR Part 70 requires the applicant to 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 the environment and public health and safety, as specified in 10 CFR 70.22(a)(7).
5. 10 CFR Part 70 also provides that the applicant for a license to possess and use SNM in a plutonium processing and fuel fabrication plant (as defined in 10 CFR 70.4, "Definitions") must submit a safety assessment of the design basis of the principal structures, systems, and components of the plant, including provisions for protection against natural phenomena, as specified in 10 CFR 70.22(f).
6. 10 CFR Part 70 also provides that an applicant for authorization for an activity listed in 10 CFR 70.60 must provide an ISA summary that includes a list of the IROFS established by the applicant and other elements, as described in 10 CFR 70.65(b).
7. 10 CFR 70.59, "Effluent Monitoring Reporting Requirements," outlines the reporting requirements for radiological-effluent monitoring for a 10 CFR Part 70 licensee.
8. 10 CFR 70.21(f) requires that an application for an activity which the Commission has determined requires an EIS, listed in 10 CFR 51.20, must be accompanied by an Environmental Report required under Subpart A of part 51. The application must be filed at least 9 months prior to commencement of construction, as defined in 10 CFR 70.4. Environmental Reports are also required for actions listed in 10 CFR 51.60. The Environmental Report must contain the information specified in section 51.45, Additional guidance for Environmental Reports is contained in NUREG-1748,

"Environmental Review Guidance for Licensing Actions Associated with NMSS Programs."

9.4.2 Regulatory Guidance

The regulatory guidance for environmental protection appears in the following NRC and industry documents:

1. NRC Regulatory Guide 4.15, "Quality Assurance for Radionuclide Monitoring Programs (Inception through Normal Operations to License Termination)—Effluent Streams and the Environment," Revision 2, July 2007

2. 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," December 1985

3. NRC Regulatory Guide 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," December 1996

4. NRC Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," July 1993

5. NRC Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage under the Revised 10 CFR Part 20," January 28, 1994

6. NRC Information Notice 94-23, "Guidance to Hazardous, Radioactive, and Mixed Waste Generators on the Elements of a Waste Minimization Program," March 25, 1994

7. American National Standards Institute (ANSI) N13.1-1982, "Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities"

8. ANSI N42.18-1980, "Specification and Performance of On-Site Instrumentation for Continuously Monitoring Radioactive Effluents"

9. National Council on Radiation Protection and Measurements (NCRP) Report No. 123, "Screening Models for Releases of Radionuclides to Atmosphere, Surface Water, and Ground," Volumes I and II, January 1996

10. NUREG-1513, "Integrated Safety Analysis Guidance Document," May 2001

11. NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs," August 2003

12. NUREG/CR-6410, "Nuclear Fuel Cycle Accident Analysis Handbook," March 1998

9.4.3 Regulatory Acceptance Criteria

9.4.3.1 Environmental Report or Categorical Exclusion

An environmental report is required for actions listed in 10 CFR 51.60(b). NUREG-1748 discusses the acceptance criteria for the environmental report to satisfy NEPA requirements.

An environmental report is not required for licensing actions that meet the requirements for a categorical exclusion, as defined in 10 CFR 51.22(c). 10 CFR 51.22(c) lists 25 actions that the Commission has declared to be categorical exclusions. A licensing ction can be categorically excluded under any one of the listed actions. Some of the categorical exclusions commonly used for fuel cycle licensing actions include the following:

a. An updated decommissioning funding plan may be excluded under 51.22(c)(10).

b. Administrative, organizational, or procedural changes may be excluded under 10 CFR 51.22(c)(11), as well as or changes in process operations or equipment that meet the four criteria in 10 CFR 51.22(c)(11).

c. A revised physical security plan, or fundamental nuclear material control plan, may be excluded under 51.22(c)(12).

d. Use of SNM for research and development may be excluded under 51.22(c)(14).

e. Approvals of direct or indirect license transfers are excluded under 51.22(c)(21).

f. Granting exemptions may be excluded under 51.22(c)(25).

If under 10 CFR 51.22(c)(11) 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) for changes in process operations or equipment, the applicant must demonstrate that the action will not result in significant effects on the environment. NUREG-1748 gives the acceptance criteria for this categorical exclusion.

If a license application indicates a significant increase in the potential for, or consequences of, radiological accidents, then the licensing action is NOT categorically excluded from review under the National Environmental Policy Act. The application must include an environmental report and the staff must prepare an EA.

9.4.3.2 Effluent and Environmental Controls and Monitoring

An applicant's proposed environmental protection measures are acceptable if they provide for qualified and trained staff, effluent control, and effluent and environmental monitoring in accordance with the NRC's requirements. Using the acceptance criteria defined in Standard Review Plan (SRP) Chapter 11, the NRC staff will review qualifications and training that the applicant has established for plant personnel who are associated with environmental protection. This review will include the qualification and training of managers, supervisors, technical staff, operators, technicians, and maintenance personnel whose levels of knowledge are important to

the environment and protect public health and safety. The NRC will expect managers and staff to have levels of education and experience commensurate with the responsibilities of their positions.

9.4.3.2.1 Effluent Controls and Waste Minimization

In accordance with 10 CFR 20.1101, "Radiation Protection Programs," each licensee must implement a radiation protection program, which is discussed in detail in SRP Chapter 4. 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 appears in Regulatory Guide 8.37.

Specifically, 10 CFR 20.1101(d) requires the applicant to establish constraints on airborne emissions of radioactive material to the environment, excluding radon-222 and its decay products. Such constraints must ensure that the individual member of the public who is likely to receive the highest dose will not be expected to receive a total effective dose equivalent (TEDE) in excess of 0.1 millisievert (10 millirem) per year from these emissions. To meet the reporting requirements of 10 CFR 20.2203, "Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits," the applicant must have (and describe) procedures for reporting to the NRC when these dose constraints are exceeded and must take prompt appropriate corrective action to prevent recurrence. NRC guidance on compliance with this regulation can be found in Regulatory Guide 4.20.

The environmental review of the radiation protection program also focuses on the applicant's waste minimization practices. Applicants for new licenses are required to comply with 10 CFR 20.1406, "Minimization of Contamination," which states that the applicant must describe how facility design procedures for operation will, to the extent practicable, minimize contamination of the facility and the environment, facilitate eventual decommissioning, and minimize the generation of radioactive waste. Applicants 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 (Volume 62 of the *Federal Register*, page 39,082 (62 FR 39082); July 21, 1997).

NRC Information Notice 94-23 offers guidance for waste minimization programs. SRP Chapter 10 offers more information on compliance with the decommissioning aspects of the waste minimization regulations.

The proposed radiation protection program is acceptable if it satisfies the following criteria:

1. Radiological (ALARA) Goals for Effluent Control

   ALARA goals are set at a modest fraction (10 to 20 percent) of the values in Table 2, Columns 1 and 2, and Table 3 of Appendix B to 10 CFR Part 20 and the external exposure limit in 10 CFR 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, "Dose Limits for Individual Members of the Public," through a calculation of the 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 if the applicant's description of the constraint approach

provides sufficient detail to demonstrate specific application of the guidance to proposed routine and nonroutine operations, including anticipated events.

2. Effluent Controls to Maintain Public Doses ALARA

The applicant describes and commits to the use of effluent controls (e.g., procedures, engineering controls, and process controls) to maintain public doses ALARA. Common control practices include filtration, encapsulation, adsorption, containment, recycling, leakage reduction, and 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 must demonstrate a commitment to reduce unnecessary exposure to members of the public and releases to the environment.

Engineering options that do not substantially reduce the collective dose and require unreasonable costs are not required. "Reasonableness" can be founded on qualitative or quantitative cost/benefit analyses. Quantitative analyses may use a value of 2,000 per person-rem (person-centisievert), as discussed in NUREG-1530, "Reassessment of the NRC's Dollar per Person-Rem Conversion Factor Policy," issued December 1995.

3. ALARA Reviews and Reports to Management

The applicant commits to an 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 commits to reporting the results to senior management, along with recommendations for changes in facilities or procedures that are necessary to achieve ALARA goals.

4. Waste Minimization

To comply with 10 CFR 20.1406, applications for new licenses must describe how the facility's design procedures for operation will minimize, to the extent practicable, the contamination of the facility and the environment and the generation of radioactive waste. Waste minimization programs proposed by applicants for both new and existing licenses are acceptable if the programs include the following:

a. top management support

b. the methods used to characterize waste generation (including types and amounts) and waste management costs (including costs of regulatory compliance, paperwork, transportation, treatment, storage, and disposal)

c. periodic waste minimization assessments to identify waste minimization opportunities and solicit employee or external recommendations

d. provisions for technology transfer to seek and exchange technical information on waste minimization

e. the methods used to implement and evaluate waste minimization recommendations

9.4.3.2.2 Effluent and Environmental Monitoring

A. The applicant's effluent monitoring is considered acceptable, for purposes of the SER, if it meets the following criteria. However, the applicant's environmental monitoring program must be independently assessed to determine whether the information is also acceptable for NEPA documentation purposes:

1. The known or expected concentrations of radioactive materials in airborne and liquid effluents are ALARA *and* are below the limits specified in Table 2 of Appendix B to 10 CFR Part 20 or the site-specific limits established in accordance with 10 CFR 20.1302(c).

   If, in accordance with 10 CFR 20.1302(c), the applicant proposes to adjust the effluent concentrations in Appendix B to 10 CFR Part 20 to account for the actual physical and chemical characteristics of the effluents, the applicant must provide information on aerosol size distributions, solubility, density, radioactive decay equilibrium, and chemical form. This information must be complete and accurate to justify the derivation and application of the alternative concentration limits for the radioactive materials.

2. If the applicant proposes to demonstrate compliance with 10 CFR 20.1301 using a calculation of the TEDE to the individual who is likely to receive the highest dose in accordance with 10 CFR 20.1302(b)(1), it must support the calculation of the TEDE by pathway analyses with appropriate models, codes, and assumptions that accurately represent the facility, site, and the surrounding area. In addition, the assumptions must be reasonable, input data must be accurate, all applicable pathways must be considered, and the results must be interpreted correctly.

   NCRP Report No. 123 provides acceptable methods for calculating the dose from radioactive effluents. The use of computer codes is acceptable for pathway analyses if the applicant can demonstrate that any code it has used has undergone validation and verification to demonstrate the validity of estimates developed using the codes for established input sets. Dose conversion factors are acceptable for use in the pathway analyses if they are based on the methodology described in International Commission on Radiological Protection 30, "Limits for Intakes of Radionuclides by Workers," 1982, as reflected in the U.S. Environmental Protection Agency's Federal Guidance Report No. 11, "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," issued September 1988. Such methods are acceptable for determining the dose to the maximally exposed individual during normal facility operations and anticipated events.

3. The applicant identifies and monitors all liquid and airborne effluent discharge locations and identifies monitoring locations. For those effluent discharge points that have input from two or more contributing sources within the facility, sampling each contributing source is considered necessary for effective process and effluent control.

4. The applicant continuously samples airborne effluents from all routine and nonroutine operations and from anticipated events associated with the plant, including effluents from areas that are not used for processing SNM, such as laboratories, experimental areas, storage areas, and fuel element assembly areas.

   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 its radioactivity is not significant. For the purposes of this SRP, radioactivity in an effluent is significant if the concentration averaged over a calendar quarter is equal to 10 percent or more of the appropriate concentration listed in Table 2 of Appendix B to 10 CFR Part 20.

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 the applicant obtains representative samples using appropriate sampling equipment and sample collection and storage procedures. For liquid effluents, the applicant collects representative samples at each release point to determine the concentrations and quantities of radionuclides that are released to an unrestricted area, including discharges to sewage systems. For continuous releases, the applicant collects samples continuously at each release point. For batch releases, the applicant collects a representative sample of each batch. If the applicant uses periodic sampling in lieu of continual sampling, it shows that the samples are representative of actual releases. Monitoring instruments are calibrated at least annually, or more frequently if suggested by the manufacturer.

6. The applicant performs radionuclide-specific analyses on selected composite samples unless either of the following criteria exists:

   a. The gross alpha and beta activities are so low that individual radionuclides could not be present in concentrations greater than 10 percent of the concentrations specified in Tables 2 or 3 of Appendix B to 10 CFR Part 20.

   b. The radionuclide composition of the sample is known through operational data, such as the composition of the feed material.

      Monitoring reports in which the quantities of individual radionuclides are estimated on the basis of methods other than direct measurement include an explanation and justification of how the results were obtained.

      Operational data may not be adequate for determining radionuclide concentration in certain cases. Such cases include, but are not limited to:

(1) plants that process uranium in which extraction, ammonium diuranate precipitation, ion exchange, or other separation process could result in the concentration of thorium isotopes (principally thorium-234); (2) plants that process uranium of varying enrichments; and (3) plants that process plutonium in which significant variation in the plutonium-238/plutonium-239 ratio among batches and the continuous ingrowth of americium-241 would preclude the use of feed material data to determine the radionuclide composition of effluents.

The applicant performs radionuclide analyses more frequently than usual (1) at the beginning of the monitoring program (until it establishes a predictable and consistent radionuclide composition in effluents); (2) whenever there is a significant, unexplained increase in gross radioactivity in effluents; and (3) whenever a process change or other circumstance might cause a significant variation in the radionuclide composition.

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 must be 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 validate the analytical results. These procedures include the use of established standards, such as those provided by the National Institute of Standards and Technology, and standard analytical procedures, such as those established by the National Environmental Laboratory Accreditation Conference.

9. The proposed action levels and actions to be taken if the action levels are exceeded are appropriate. The action levels are incremental, such that each increasing action level results in a more aggressive action to ensure effluent control. A slightly higher than normal concentration of a radionuclide in an effluent triggers an investigation into the cause of the increase. The specified action level will result in the shutdown of an operation if the specified level is exceeded. These action levels are selected on the basis of the likelihood that a measured increase in concentration could indicate potential violation of the effluent limits.

10. The applicant completely and accurately describes all applicable Federal and State standards for discharges and any permits issued by Federal, State, or local governments for gaseous and liquid effluents.

11. The systems for detecting leakage from ponds, lagoons, and tanks are adequate to detect and ensure against any unplanned releases to groundwater, surface water, or soil.

12. The applicant controls and maintains releases to sewer systems to meet the requirements of 10 CFR 20.2003, “Disposal by Release into Sanitary Sewerage,” including the following:

    a. The material is water soluble.

    b. Known or expected discharges meet the effluent limits specified in Table 3 of Appendix B to 10 CFR Part 20.

    c. The known or expected total quantity of radioactive material released into the sewer system in a year does not exceed 5 curies (Ci) (185 gigabecquerels (GBq)) of hydrogen-3, 1 Ci (37 GBq) of carbon-14, and 1 Ci (37 GBq) of all other radioactive materials combined.

    d. 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 in Regulatory Guide 4.16. The applicant provides reports that include the concentrations of principal radionuclides released to unrestricted areas in liquid and gaseous effluents and the MDC for the analysis and the error for each data point.

14. The applicant’s procedures and facilities for solid and liquid waste handling, storage, and monitoring result in safe storage and timely disposition of the material.

B. The scope of the applicant’s environmental monitoring is acceptable (for purposes of the SER) if it is commensurate with the scope of activities at the facility and the expected impacts from operations as identified in the environmental report and if it 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 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. The applicant commits to an instrument maintenance and calibration program that is appropriate to the given instrumentation. If the applicant proposes to use its own analytical laboratory for the analysis of environmental samples, the applicant commits to providing third-party verification of the laboratory’s methods (such as that obtained by participation in a round-robin measurement program).

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 on the basis of a pathway analysis that demonstrates that, below those concentrations, doses to the public will be ALARA *and* below the limits specified in Subpart B to 10 CFR Part 20. 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 on the basis of action levels to ensure that sampling and analytical methods are sensitive and reliable enough to support the application of the action levels.

7. Data analysis methods and criteria that the applicant will use to evaluate and report 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 facility 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 high- and intermediate-consequence accident sequences in the ISA.

9.4.3.3 Integrated Safety Analysis Summary

A. In accordance with 10 CFR 70.60, "Applicability," applicants requesting authorization to possess greater than a critical mass of SNM and to engage in the listed activities are required to perform an ISA and submit an ISA summary to the NRC for approval. The applicant's treatment of environmental protection in the ISA is acceptable if it fulfills the following criteria:

   1. The ISA provides a complete list of accident sequences that result in radiological and nonradiological releases to the environment.

   2. The ISA uses acceptable methods to estimate environmental effects that may result from accident sequences and to determine whether the effects are high or intermediate consequences as defined in 10 CFR 70.61, "Performance Requirements." NUREG/CR-6410 describes acceptable methods for estimating environmental effects from accident sequences.

   3. The ISA provides a reasonable estimate of the likelihood and consequences of each accident sequence identified.

   4. The ISA identifies adequate engineering or administrative controls or both for each accident sequence of environmental significance. These controls will prevent or mitigate high- and intermediate-consequence accident sequences to

an acceptable level. (Consequence categories are defined in 10 CFR 70.61 and in SRP Chapter 3.) IROFS provide the indicated level of protection.

5. The ISA affords adequate levels of assurance so that IROFS will satisfactorily perform their safety functions. Configuration management, training, and maintenance activities contribute to achieving this assurance.

6. For an ISA summary of a facility that has not yet been constructed, the specifications for IROFS may not be complete at the time the ISA summary is submitted. The IROFS functions should be described in sufficient detail for the reviewer to determine their adequacy to prevent or mitigate the accident sequence. For example, the description of an in-line gamma monitor used to alert an operator of an off-normal condition should define the range of gamma activity that the monitor needs to detect. A description of a ventilation system that controls the consequences of an enclosure spill should include its air-moving capacity. The description of a stack sampler that detects excessive airborne releases should include the capacities of the sampler.

In addition to participating in the integrated review of the ISA performed in accordance with SRP Chapter 3, the reviewer should also examine, in detail, the fire-initiated release scenarios provided in the ISA summary to demonstrate compliance with 10 CFR 70.61, because fire-initiated accident scenarios have the potential for environmental consequences. This review should follow the guidance provided in applicable sections of SRP Chapter 3 to give a detailed evaluation of these scenarios, including a review of fire-induced consequences to the environment, the likelihood of such consequences, and IROFS chosen to prevent or mitigate those consequences.

B. The reviewer should consider the following factors in determining the acceptability of the applicant's descriptions of fire-initiated accident sequences:

1. Scenario descriptions are sufficiently detailed to allow an understanding of the fire hazards that permits an evaluation of potential accident sequences.

2. The applicant has adequately described the environmental consequences and likelihood of accident sequences identified in the ISA summary involving fire, including risks from hazardous chemicals produced from licensed material and risks from radioactive materials.

3. All controls that are used to mitigate or prevent the scenario are identified as IROFS or as defense-in-depth measures. For those controls that are IROFS, reliability and associated management measures should be indicated.

4. Analyses that the applicant has performed as part of the evaluation should be part of the ISA and should be referenced or identified for potential further review by the NRC staff.

9.4.3.4 Environmental Protection Management Measures

The management measures applied to IROFS designated to prevent or mitigate accident sequences in which the IROFS are needed are acceptable for purposes of the SER if they meet the acceptance criteria in SRP Chapter 11.

9.5 Review Procedures

9.5.1 Review Procedures

The staff will review the environmental report, environmental protection measures, ISA summary, and management measures to verify that they meet the acceptance criteria defined in SRP Section 9.4. During the acceptance review of a license application, the reviewer should examine the submittals to identify major deficiencies in the information provided for each area of review specified in SRP Section 9.3. Reviewers must decide whether they have enough information to proceed with a detailed review. Less significant errors or deficiencies that can be addressed in a request for additional information should be accepted. However, before the NRC performs a detailed review, the applicant should correct major deficiencies that would require several requests for additional information to resolve.

Reviewers should record whether each area of review is adequately addressed in the application, is adequately addressed in a referenced document, is not applicable to the application, or has a major deficiency.

9.5.2 Effluent and Environmental Controls and Monitoring

An environmental specialist will review the applicant's environmental protection measures in coordination with the Environmental Project Manager and the fuel cycle facility inspector responsible for environmental protection. Any comments or concerns that the environmental reviewer or inspector identifies will be addressed and resolved, and the safety evaluation report (SER) (described in Section 9.6) for the licensing action will contain a statement indicating whether the inspection staff has any objections to the approval of the proposed licensing action. In addition, the review will include an evaluation of inspection reports and semiannual effluent reports, submitted in accordance with 10 CFR 70.59, to ensure licensee performance in environmental protection.

9.5.3 Integrated Safety Analysis Summary

As part of the environmental protection review, the environmental specialist will review the ISA summary, including all identified accident sequences that can have significant environmental consequences, to determine whether the list completely and properly identifies all potential accidents. The environmental specialist will coordinate this review with the ISA reviewer who is responsible for assuring that the required information is contained in Chapter 3 of the SER. A detailed review will be conducted of (1) the accident sequences that, when left unmitigated, are rated as "high" consequence to an individual located outside the controlled area, (2) approximately 10 percent of the "intermediate" consequence sequences, and (3) a smaller number of accident sequences in which the consequences are less than intermediate. However, additional intermediate and low consequence sequences may be evaluated on the basis of the results of the initial review.

An evaluation of the ISA summary requires coordination with other technical reviewers. The environmental review of the IROFS will be coordinated with the reviewers for the specific assurance functions, such as training and maintenance. The review of the ISA summary may require the examination of the ISA and of detailed supporting ISA documents located at the facility. On the basis of these reviews, the reviewer should decide what supporting documents need to be reviewed. The reviewer will clearly identify in the SER either the materials examined and the descriptions and commitments considered and relied on or the basis for the staff's safety decision.

9.5.4 Management Measures

The environmental reviewer should review the classification assigned to the IROFS to ensure that the management measures described in SRP Chapter 11 are used to determine whether the licensee has established adequate management measures to apply to all IROFS designated to prevent or mitigate high or intermediate accident consequences to a member of the public or intermediate consequences to the environment in accordance with 10 CFR 70.61(b)(2), 10 CFR 70.61(c)(2), and 10 CFR 70.61(c)(3). The environmental reviewer should review the classification assigned to the IROFS to ensure that the management measures are graded commensurate with the reduction of risk attributable to the IROFS.

During the application and ISA summary review, the reviewer should identify and communicate to the inspection staff any items or issues that should be inspected during an operational readiness review, if such a review will be performed. These items could include confirming that the engineered controls installed in the process actually meet the capabilities described in the ISA summary and that administrative controls are implemented through procedures and operator training.

9.5.2 Environmental Report

The NEPA reviewer should review the environmental report, if one was included in the application and follow the guidance in NUREG-1748 for preparation of and EIS or EA and finding of no significat impact. If no environmental report was provided in the application, the NEPA Reviewer should review the application to determine whether the requested action – licensing, renewal, amendment – meets any of the criteria in 51.22 for a categorical exclusion.

9.6 Evaluation Findings

An SER documents the evaluation findings of the environmental protection review of the application, including the review of the environmental protection program and the ISA summary.

The regulations in 10 CFR 70.23, "Requirements for the Approval of Applications," and 70.66, "Additional Requirements for Approval of License Application," state that an application for a license will be approved if the Commission can make the general findings listed in those sections. The basis for the general findings is an evaluation of all the detailed regulatory requirements that apply to application. The staff's evaluation should verify that the license application provides sufficient information to satisfy the regulatory requirements of Section 9.4.1 of this SRP and that the applicant has appropriately considered the regulatory acceptance criteria in Section 9.4.3 in satisfying the requirements. The staff reviewers will verify that the information submitted by the applicant is in accordance with 10 CFR Part 20, 10 CFR Part 51, and 10 CFR Part 70 and is consistent with the guidance in this SRP as it applies to

environmental protection. The SER should state how the applicable regulatory requirements have been met based on the acceptance criteria described in this chapter. If the applicant chooses to suggest an alternative approach, the reviewer should identify in the SER how the proposed approach satisfies the applicable regulatory requirements. The reviewers should use the following approach to document their evaluation:

1. State a specific regulatory requirement that applies to the application. Detailed acceptance criteria may be included where appropriate or necessary.
2. Identify the areas where the regulatory requirement is addressed in the application, including the areas where the specific acceptance criteria described in this SRP are addressed.

3. Describe your evaluation of the application, the basis for your conclusion, and whether regulatory requirements are met.

4. Repeat these steps for every regulatory requirement that applies to the application.

The environmental report and EA or EIS do not become part of the license, and license conditions should not contain references to information in the environmental report, EA, or EIS. If an EA or EIS is prepared for the licensing action prior to issuing the SER, then the environmental safety section of the SER should report the date the NEPA document was issued. If the EA results in a FONSI, the SER should include the publication date of the FONSI in the *Federal Register*. If an EIS is prepared, the SER would include the *Federal Register* publication date for the record of decision. When applicable, the SER will also document the determination that an action meets the requirements for a categorical exclusion.

As discussed in Section 3.4.9 of NUREG-1748, the environmental PM should consult with the affected State before the final EA is prepared. Appendix D to NUREG-1748 contains a suggested procedure to follow in consulting with the State. After the State has been consulted, the EA is finalized with text noting that the State was consulted along with a summary of the State's comments.

In certain circumstances, a draft EA and FONSI may be prepared. Circumstances include those where a FONSI appears warranted for the proposed action but the proposed action is similar to one which normally requires an EIS, the proposed action is without precedent, or the appropriate NRC staff director determines preparation of a draft FONSI will further the purposes of NEPA [10 CFR 51.33(b)]. The draft FONSI should be clearly marked "draft" and should be published in the *Federal Register* and distributed as described in 10 CFR 51.74(a). The *Federal Register* notice must include a request for comments and specify where the comments should be submitted and when the comment period ends (10 CFR 51.119(a)).

The following language would be appropriate for a licensing action that requires an environmental review:

> The applicant has committed to adequate environmental-protection measures, including (1) environmental and effluent monitoring and (2) effluent controls to maintain public doses ALARA as part of the radiation protection program. The NRC staff concludes, with reasonable assurance, that the applicant's conformance to the application and license conditions is adequate to protect the environment and public health and safety and to comply with the regulatory

requirements imposed by the Commission in 10 CFR Part 20, 10 CFR Part 51, and 10 CFR Part 70. The bases for these conclusions are as follows:

[State the bases for the conclusion, including any recommended license conditions. A recommended license condition should not include a reference to a NEPA document, such as the Environmental Report submitted under 70.21(f), 51.45, or 51.60, or a reply to an RAI related to the NEPA document.

If the action requires preparation of an EIS, the SER should include the following language:

The NRC staff prepared [or is preparing] an environmental impact statement (EIS) [publication date, if available] for this licensing action as required by 10 CFR 51.20. In accordance with 10 CFR 70.23(a)(7), the Director of Nuclear Material Safety and Safeguards or his/her 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. Commencement of construction as defined in section 70.4 may include non-construction activities if the activity has a reasonable nexus to radiological safety and security.

If the action requires preparation of an EA and results in a FONSI, the SER should include the following language:

The NRC staff prepared an environmental assessment (EA) for this action as required by 10 CFR 51.21. On the basis of the EA, the staff has reached a finding of no significant impact, published in the *Federal Register* on [publication date and FR citation]. [If staff published a draft EA for public comment, the SER should include the FR citation and publication date of the draft EA. The final EA should contain a list of significant comments received on the draft EA and how they were addressed in the final EA.]

If the staff determines that the action was categorically excluded from environmental review under 10 CFR 51.22, the SER should include language similar to the following :

The staff has determined that the requested action [state whether the action is issuance, renewal, amendment, or termination of license, or other action] belongs to a category of actions which the Commission, by rule or regulation, has declared to be a categorical exclusion, after first finding that the category of actions does not individually or cumulatively have a significant effect on the human environment. Therefore, in accordance with 10 CFR 51.22(c) [Insert applicable categorical exclusion citation here] neither an environmental impact statement nor an EIS is required for this action.

If the requested action involves a change in process operations and equipment, then the categorical exclusion should also include a brief discussion of how the action meets the following four criteria in 51.22(c)(11)

(1) There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite.

(2) There is no significant increase in individual or cumulative occupational radiation exposure.

(3) There is no significant construction impact.

(4) There is no significant increase in the potential for, or consequences from, radiological accidents.

[State the bases for the conclusion.]

9.7 References

U.S. Code of Federal Regulations, "Standards for Protection against Radiation," Part 20, Chapter I, Title 10, "Energy."

U.S. Code of Federal Regulations, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," Part 51, Chapter I, Title 10, "Energy."

U.S. Code of Federal Regulations, "Domestic Licensing of Special Nuclear Material," Part 70, Chapter I, Title 10, "Energy."

American National Standards Institute (ANSI), "Specification and Performance of On-Site Instrumentation for Continuously Monitoring Radioactivity in Effluents," ANSI N42.18-1980, Washington, DC, 1980 (reaffirmed 2004).

American National Standards Institute (ANSI)/Health Physics Society (HPS), "Sampling and Monitoring Releases of Airborne Radioactive Substances from the Stacks and Ducts of Nuclear Facilities," ANSI/HPS N13.1-2011, McLean, VA, 2011.

National Council on Radiation Protection and Measurements, "Screening Models for Releases of Radionuclides to Atmosphere, Surface Water, and Ground," NCRP Report No. 123, Volumes I and II, Bethesda, MD, January 1996.

U.S. Environmental Protection Agency, "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," Federal Guidance Report No. 11, Washington, DC, September 1988.

U.S. Nuclear Regulatory Commission, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage under the Revised 10 CFR Part 20," Information Notice 94-07, January 28, 1994.

U.S. Nuclear Regulatory Commission, "Guidance to Hazardous, Radioactive, and Mixed Waste Generators on the Elements of a Waste Minimization Program," Information Notice 94-23, March 25, 1994.

U.S. Nuclear Regulatory Commission, “Integrated Safety Analysis Guidance Document,” NUREG-1513, May 2001.

U.S. Nuclear Regulatory Commission, “Environmental Review Guidance for Licensing Actions Associated with NMSS Programs,” NUREG-1748, August 2003.

U.S. Nuclear Regulatory Commission, “Nuclear Fuel Cycle Accident Analysis Handbook,” NUREG/CR-6410, March 1998.

U.S. Nuclear Regulatory Commission, “Quality Assurance for Radiological Monitoring Programs (Inception through Normal Operations to License Termination)—Effluent Streams and the Environment,” Regulatory Guide 4.15, Revision 2, July 2007.

U.S. Nuclear Regulatory Commission, “Monitoring and Reporting Radioactivity in Releases of Radioactive Materials in Liquid and Gaseous Effluents from Nuclear Fuel Cycle Facilities,” Regulatory Guide 4.16, Revision 2, December 2010.

U.S. Nuclear Regulatory Commission, “Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors,” Regulatory Guide 4.20, Revision 1, April 2012.

U.S. Nuclear Regulatory Commission, “ALARA Levels for Effluents from Materials Facilities,” Regulatory Guide 8.37, July 1993.

10. DECOMMISSIONING

10.1 Purpose of Review

The purpose of the review of the applicant's decommissioning plans is to determine with reasonable assurance that the applicant will be able to decommission the facility safely and in accordance with the requirements of the U.S. Nuclear Regulatory Commission (NRC).

At the time of the initial application and at license renewal, the applicant or licensee should discuss its conceptual approach for meeting the decommissioning requirements in Title 10, "Energy," of the *Code of Federal Regulations* (10 CFR) Part 20, "Standards for Protection against Radiation," Subpart E, "Radiological Criteria for License Termination." The applicant or licensee should discuss its plans for minimizing contamination.

At the time of the initial license application and again at license renewal, the applicant or licensee may be required to submit a decommissioning funding plan (DFP) in accordance with 10 CFR 70.25(b). The purpose of the NRC's evaluation of the DFP is to determine whether the applicant or licensee has taken the following actions:

1. considered decommissioning activities that may be needed in the future

2. performed a credible site-specific cost estimate for those activities

3. presented the NRC with financial assurance to cover the cost of those activities in the future

Therefore, the DFP should contain the following:

a. an overview of the proposed decommissioning activities
b. the methods used to determine the cost estimate
c. the financial assurance mechanism

This overview must contain sufficient detail to enable the reviewer to determine whether the decommissioning cost estimate is reasonably accurate.

In the application, the applicant or licensee should discuss its plans for meeting the decommissioning recordkeeping requirements in 10 CFR 70.25(g). Under the regulations, a licensee must keep records important for decommissioning. These records include records of spills or unusual occurrences involving the spread of contamination, as-built drawings and modifications to structures and equipment in restricted areas, a list of areas designated or formerly designated as restricted areas, and records pertaining to the financial-assurance requirements.

If required by 10 CFR 70.38(g), the licensee must also submit, for NRC approval, a decommissioning plan (DP) before beginning its decommissioning actions. The DP must detail the specific decommissioning activities that the licensee will perform and describe the radiation-protection procedures that the licensee will use to protect workers, the public, and the environment during decommissioning.

This information must be sufficient to enable the reviewer to assess the appropriateness of the decommissioning activities and the adequacy of the procedures to protect the health and safety of workers, the public, and the environment. It must also update the cost estimate originally presented in the DFP to undertake the facility decommissioning. The licensee can generally obtain approval of a DP by submitting an application for a license amendment. The reviewer must determine that the applicant understands the decommissioning requirements and procedures and that it commits to protecting the health and safety of workers, the public, and the environment during decommissioning.

10.2 Responsibility for Review

Primary: Health Physics Reviewer

Secondary: Environmental Reviewer
Technical and Financial Specialists in the Division of Waste Management and Environmental Protection
Licensing Project Manager

Supporting: Fuel Facility Inspection Staff

10.3 Areas of Review

Before beginning to review the DFP or DP, the reviewer should first evaluate the applicant's proposed environmental protection measures (see Chapter 9 of this standard review plan (SRP)) and, specifically, the commitments to minimize waste associated with decommissioning. In addition, the reviewer should evaluate the applicant's radiation-protection program (see SRP Chapter 4) as it applies to radiological decontamination and the management of radiological effluents.

The staff review should cover the following areas:

1. conceptual decontamination and decontamination plan, including the decommissioning program and steps, management and organization, health and safety, radiological decommissioning criteria, waste management, security and nuclear-material control, recordkeeping, the decontamination process, and the minimization of contamination

2. decommissioning costs and financial assurance (i.e., the decommissioning cost information should be consistent with the recommendations in NUREG-1757, "Consolidated Decommissioning Guidance," issued September 2006)

The reviewer will evaluate the applicant's DFP or DP or both in accordance with NUREG-1757.

10.4 Acceptance Criteria

10.4.1 Regulatory Requirements

The following NRC regulations require planning, financial assurance, and recordkeeping for decommissioning, as well as procedures and activities to minimize waste and contamination:

1. Subpart E of 10 CFR Part 20

2. 10 CFR 30.35, “Financial Assurance and Recordkeeping for Decommissioning”

3. 10 CFR 30.36, “Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas”

4. 10 CFR 40.14, “Specific Exemptions”

5. 10 CFR 40.36, “Financial Assurance and Recordkeeping for Decommissioning”

6. 10 CFR 40.42, “Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas”

7. 10 CFR 70.17, “Specific Exemptions”

8. 10 CFR 70.22(a)(9)

9. 10 CFR 70.25, “Financial Assurance and Recordkeeping for Decommissioning”

10. 10 CFR 70.38, “Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas”

10.4.2 Regulatory Guidance

NUREG-1757 is relevant to the decommissioning of fuel cycle facilities.

10.5 Review Procedures

During the acceptance review of a license application, the reviewer should examine the submittals to identify major deficiencies in the information provided for each area of review specified in SRP Section 10.3. Reviewers must decide whether they have enough information to proceed with a detailed review. Less significant errors or deficiencies that can be addressed in a request for additional information should be accepted. However, before the NRC performs a detailed review, the applicant should correct major deficiencies that would require several requests for additional information to resolve.

Reviewers should record whether each area of review is adequately addressed in the application, is adequately addressed in a referenced document, is not applicable to the application, or has a major deficiency.

The primary reviewer will evaluate the application against the NRC requirements and acceptance criteria identified in NUREG-1757. A detailed review of any contamination- and waste minimization plans that the applicant submits in response to 10 CFR 20.1406, “Minimization of Contamination,” will supplement this review (as appropriate). The reviewer will also coordinate with the principal reviewers for environmental protection listed in SRP Chapter 9 to confirm the review of a new applicant’s plans to minimize waste and the plans for existing licensees to minimize contamination and reduce exposures and effluents as part of the radiation protection program 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 primary reviewer for consideration and resolution as part of the review discussed in SRP Chapter 9 and that any decommissioning issues that arise in the environmental review that are best suited for review using guidance in this chapter are conveyed to the primary reviewer for consideration and resolution.

If the decommissioning 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 transmitted to the applicant will specify a reasonable amount of time (e.g., 30 to 60 days) for the applicant to reply. Failure of the applicant to provide the requested information by the specified date, or on an alternative schedule that is mutually agreeable, could be grounds for terminating or suspending the application review.

The primary reviewer should coordinate with the Division of Waste Management and Environmental Protection to obtain the appropriate technical assistance in reviewing proposed DPs and financial assurance measures. The primary reviewer will coordinate with reviewers assigned by the Division of Waste Management and Environmental Protection to incorporate, as appropriate, RAIs and review findings in licensing correspondence and safety evaluation reports (SERs) related to decommissioning.

The reviewer should perform a safety review using the acceptance criteria in NUREG-1757 to ensure that the proposed decommissioning methodology, principal remediation activities, and worker and environmental radiation protection programs are acceptable.

10.5.1 Safety Evaluation

The primary reviewer will perform a safety evaluation with respect to the acceptance criteria in Section 10.4. During the initial review, the reviewer should draft the safety evaluation report (SER) described below. A request for additional information (RAI) will be prepared when clarification and additional information are needed to determine whether the licensee's submittals comply with the regulations. The primary reviewer should coordinate with the licensing project manager in preparing RAIs. Additional information submitted by the applicant will be evaluated and a final SER will be provided to the licensing project manager.

10.6 Evaluation Findings

The regulations in 10 CFR 70.23, "Requirements for the Approval of Applications," and 70.66, "Additional Requirements for Approval of License Application," state that an application for a license will be approved if the Commission can make the general findings listed in those sections. The basis for the general findings is an evaluation of whether the application adequately addresses all of the applicable regulatory requirements. More specifically, the staff's evaluation should determine whether the licensing submittals provide sufficient information to satisfy the regulatory requirements listed in Section 4.4 of this SRP and whether the applicant has appropriately addressed the regulatory acceptance criteria also described in SRP Section 4.4. This SER should address each topic area reviewed and discuss why the NRC has reasonable assurance that the DFP or DP should be considered acceptable, explaining the bases for the reviewers' conclusions. The SER should state how the applicable regulatory requirements have been met based on the acceptance criteria described in this chapter of the

SRP. If the applicant chooses to use an alternative approach, the reviewer should discuss in the SER whether the proposed approach satisfies the applicable regulatory requirements. The reviewers should use the following approach to document their evaluation:

1. State a specific regulatory requirement that applies to the application. Detailed acceptance criteria may be included where appropriate or necessary to clarify the requirement.

2. Identify the areas where the regulatory requirement is addressed in the application, including the areas where the specific acceptance criteria described in this SRP are addressed.

3. Describe your evaluation of the application, the basis for your conclusion, and whether regulatory requirements are met.

4. Repeat these steps for every regulatory requirement that applies to the application.

There are three possible outcomes to the staff's licensing review: (1) approval of the applicant's application or amendment request, (2) denial of the application or request, or (3) approval with conditions. If the reviewer cannot make a finding of a reasonable assurance of safety, the reviewer may consider proposing a license condition. Absent an NRC Order, license conditions must be agreed upon with the licensee or applicant before becoming part of the license. A license condition should only be proposed if there is reasonable assurance that, if the licensee meets the condition, all regulatory requirements will be satisfied. Thus, license conditions should not be used to cover major deficiencies in an application. License conditions should be unambiguous, inspectable, and enforceable. They should only require those actions necessary to ensure compliance with applicable regulations. The basis for license conditions must be documented in the SER.

If the submittal is acceptable, the final SER input should conclude with a statement similar to the following:

> The NRC staff has evaluated the applicant's/licensee's plans and financial assurance for decommissioning in accordance with NUREG-1757, "Consolidated Decommissioning Guidance," issued September 2006. On the basis of this evaluation, the NRC staff has determined that the applicant's/licensee's plans and financial assurance for decommissioning comply with the NRC's regulations and provide reasonable assurance of protection for workers, the public, and the environment.

10.7 References

U.S. Code of Federal Regulations, "Standards for Protection against Radiation," Part 20, Chapter I, Title 10, "Energy."

U.S. Code of Federal Regulations, "Rules of General Applicability to Domestic Licensing of Byproduct Material," Part 30, Chapter I, Title 10, "Energy."

U.S. Code of Federal Regulations, “Domestic Licensing of Source Material,” Part 40, Chapter I, Title 10, “Energy.”

U.S. Code of Federal Regulations, “Domestic Licensing of Special Nuclear Material,” Part 70, Chapter I, Title 10, “Energy.”

U.S. Nuclear Regulatory Commission, “Consolidated Decommissioning Guidance,” NUREG-1757, September 2006.

11. MANAGEMENT MEASURES

11.1 Purpose of Review

Management measures are activities performed by a licensee, generally on a continuing basis, that are applied to IROFS to provide reasonable assurance that the items relied on for safety (IROFS) will perform their intended safety function when needed to prevent accidents or mitigate the consequences of accidents to an acceptable level. The purpose of management measures is to provide reasonable assurance of compliance with Title 10 of the *Code of Federal Regulations* (10 CFR) 70.61, "Performance Measures." Reasonable assurance is established by considering factors such as necessary maintenance, operating limits, common-cause failures, and the likelihood and consequences of failure or degradation of the IROFS and the measures. As defined in 10 CFR 70.4, "Definitions," management measures include configuration management (CM), maintenance, training and qualification, procedures, audits and assessments, incident investigations, records management, and other quality assurance (QA) elements.

11.2 Responsibility for Review

Primary: Quality Assurance Reviewer

Secondary: Licensing Project Manager

Supporting: Primary Reviewers of Chapters 3 through 10 of this Standard review plan (SRP)
Fuel Cycle Facility Inspector
Technical Staff knowledgeable in equipment/facility design, construction, installation, and maintenance (e.g., digital instrumentation and control, structural integrity, etc.)

11.3 Areas of Review

In accordance with 10 CFR 70.62(d), each applicant must establish management measures to ensure that IROFS, as documented in the integrated safety analysis (ISA) summary, provide reasonable assurance that they will be designed, implemented, and maintained in such a way as to ensure that they are available and reliable to perform their intended functions, when needed, to comply with the performance requirements of 10 CFR 70.61. The degree to which measures are applied may be a function of the item's importance in meeting the performance requirements.

If a "graded" application of a particular management measure is used for IROFS of differing importance, the applicant should describe the variations and the reviewer should determine whether the measures are commensurate with the importance to safety of the IROFS. The application of a graded program for management measures should not result in either intended or effective changes to the design, configuration, or technical requirements of IROFS that would result in a loss of confidence that the IROFS' designated safety function would be performed. The guidance contained in this Chapter may be used in the development of a graded management measures program, or alternate graded controls may be proposed by the applicant. Exceptions and alternatives to these acceptance criteria may be adopted provided the applicant or licensee can demonstrate that it satisfies the management measures

requirements in 10 CFR Part 70. A program of graded management measures may be implemented by new applicants, licensees proposing new facilities or new processes at existing facilities, or by existing licensees provided that the applicant or licensee describes the application of the ranking system and graded management measures in a license application or license amendment that is reviewed and approved by the NRC staff. Guidance for graded management measures in this chapter will refer to the "applicant," to include applicants for new licenses or applicants for license amendments.

The specific areas of review are as follows:

1. Configuration Management—The U.S. Nuclear Regulatory Commission (NRC) staff review will determine whether the applicant has proposed a CM program that ensures consistency in the facility design and operational requirements, the physical configuration, and the facility documentation. The review should determine that the applicant's CM program captures formal documentation governing the design and continued modification of the site, structures, processes, systems, components, computer programs, personnel activities, and supporting management measures. The review should also ensure that the CM program is adequately coordinated and integrated with other management measures.

   The NRC staff should review the applicant's descriptions and commitments for CM, including descriptions of the organizational structure responsible for CM activities; descriptions of the process, procedures, and documentation required by the applicant for modifying the site; and descriptions of the various levels of CM to be applied to IROFS designated in the ISA summary. The staff's review should focus on the applicant's CM measures that provide reasonable assurance of the documentation of engineering, procurement, installation, and modifications; the training and qualification of affected staff; the revision and distribution of operating, test, calibration, surveillance, and maintenance procedures and drawings; and the postmodification testing. The review of the overall approach to implementing CM should include the evaluation of the CM program, design requirements, document control, change control, assessments, and design reconstitution for existing facilities.

2. Maintenance—The NRC staff's review should evaluate the applicant's description of its maintenance program. The staff will examine the applicant's commitments to inspect, calibrate, test, and maintain IROFS to a level commensurate with the items' importance to safety. The staff will review the applicant's description of how the site organization implements (1) corrective maintenance, (2) preventive maintenance (PM), (3) surveillance and monitoring, and (4) functional testing. Not every aspect of each of the four maintenance functions is necessarily required. The applicant should justify the assignment of differing degrees of maintenance to individual IROFS based on the item's contribution to risk reduction.

3. Training and Qualification—The regulations at 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," require that all personnel who perform activities relied on for safety be trained and tested so as to provide reasonable assurance that they understand, recognize the importance of, and are qualified to perform these activities in a manner that adequately protects public health and safety and the environment. As appropriate for their authority and responsibilities, these personnel should have the knowledge and skills necessary to design, operate, and maintain the facility safely.

Therefore, the application should describe the training, testing, and qualification of these personnel, and the NRC staff should review this description. The review should examine the applicant's experience and capabilities to provide this training for its personnel who will perform activities relied on for safety. The review of the training and qualification should address the following areas:

a. organization and management of the training function

b. analysis and identification of functional areas requiring training

c. position training requirements

d. development of the basis for training, including objectives

e. organization of instruction and use of lesson plans and other training guides

f. evaluation of trainee learning

g. conduct of on-the-job training

h. evaluation of training effectiveness

i. personnel qualification

j. provisions for continuing quality assurance, including the needs for retraining or reevaluation of qualification

4. Procedures—The NRC staff review should examine the applicant's process for the preparation, use, and management control of written procedures. This process should include the basic elements of identification, development, verification, review and comment resolution, approval, validation, issuance, change control, and periodic review.

5. The actual operating procedures are not part of the license, and the NRC staff would not normally review them for technical adequacy since the inspection function addresses this aspect. The NRC staff should review the license application to ensure that the applicant's process for establishing procedures adequately addresses the following areas:

a. method for identifying procedures that are needed plantwide

b. essential elements that are generic to all procedures

c. method for creating and controlling procedures within plant management control systems

d. method for verifying and validating procedures before use

e. method for periodically reverifying and revalidating procedures

f. method for ensuring that current procedures are available to personnel and those personnel are qualified to use the latest procedure

g. the commitments to audit and assessment activities

h. the use of qualified and independent audit and assessment personnel

i. the general structure of typical audits and assessments

j. the facility procedures to be used to direct and control the audit and assessment activities

k. the planned use of the results of the audit and assessment activities

l. the documentation to record and distribute the findings and recommendations of these audits and assessments

m. the planning and implementation of corrective actions based on the findings and recommendations

6. Incident Investigations—The NRC staff should review the applicant's program, procedures, and management structure for investigating abnormal events and completing appropriate corrective actions. The review should include the provisions for establishing investigating teams, the methods for determining root causes, and the procedures for tracking and completing corrective actions and for documenting the process for the purpose of applying the "lessons learned" to other operations. The applicant may describe a corrective action program, which includes the functions of audits and assessment as well as incident investigations. This approach is acceptable and the reviewer should, in that case, review the applicant's description and commitments with regard to the acceptance criteria in this SRP chapter for audits and assessments as well as incident investigations.

7. Records Management—The requirements for the management of records vary according to the nature of the facility and the hazards and risks it poses. The staff should review areas related to the handling and storage of health and safety records and the records generated or needed in the design, construction, operation, and decommissioning phases of the facility. The review should provide reasonable assurance that the records management function is adequately coordinated and integrated with other management measures. The staff should review the following:

a. the process whereby records (i.e., training records, dosimetry records, effluents records, records of classified information, records concerning facility IROFS and their failures) are created, selected, verified, categorized, indexed, inventoried, protected, stored, maintained, distributed, deleted, or preserved

b. the handling and control of various kinds of records (including contaminated and classified records) and the media in which the records are captured

c. the physical characteristics of the records storage area(s) with respect to the preservation and protection of the records for their designated lifetimes

8. Other Quality Assurance Elements—The application should address other QA elements that will be applied to IROFS and other management measures. The NRC staff should evaluate whether the application of other QA elements is adequately described. The staff's review objective is to obtain reasonable assurance that the design, procurement, construction, operation, maintenance, inspection, testing, and modification phases of a facility's life cycle implement accepted QA principles. The NRC staff should examine the applicant's commitment to overall QA, the selection of quality criteria and quality level, and the proposed method for implementation. Application of graded QA and quality levels commensurate with the risk involved should parallel the same risk levels established for maintenance and other management measures.

   The reviewer should recognize that facility safety may not be the only area at a fuel cycle facility requiring QA elements. The applicant's customers and the NRC, under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," may impose product-related QA criteria. This SRP limits the focus of the review of QA measures to ensuring the safety of workers and the public and protecting the environment (i.e., in relation to the performance requirements of 10 CFR 70.61).

Review Interfaces

Other sections of the license application may include information on CM, maintenance, training and qualification, procedures, audits and assessments, incident investigations, record management, or other QA elements applied to management measures. The NRC staff should focus its review activities on management measures associated with IROFS of high risk importance. The reviewer of this SRP chapter should coordinate with the reviewers of SRP Chapters 3 through 10 to inform the selection of management measures for more detailed review.

11.4 Acceptance Criteria

11.4.1 Regulatory Requirements

Acceptance criteria are based on meeting the relevant requirements of the regulations described in this section.

The regulatory basis for the review is 10 CFR 70.22, "Contents of Applications," and 10 CFR 70.65, "Additional Content of Applications." In addition, the management measures review should provide reasonable assurance of compliance with the following regulations:

1. 10 CFR 70.4 states that management measures include CM, maintenance, training and qualification, procedures, audits and assessments, incident investigations, records management, and other QA elements.

2. 10 CFR 70.22(a)(8) requires that each application for a license must contain proposed procedures to protect health and minimize danger to life or property.

3. 10 CFR 70.62(a)(3) states that records must be kept for all IROFS failures, describes required data to be reported, and sets time requirements for updating the records.

4. 10 CFR 70.62(d) requires an applicant to establish management measures for engineered and administrative controls and control systems that are identified as IROFS, in accordance with 10 CFR 70.61(e), so that they are available and reliable to perform their functions when needed.

5. 10 CFR 70.64(a)(1) states that, in accordance with management measures, IROFS must be designed, implemented, and maintained to provide reasonable assurance that they will be available and reliable to perform their safety function when needed. 10 CFR 70.64(a)(1) further states that appropriate records of IROFS must be maintained by the licensee throughout the life of the facility.

6. Facility change and change processes must conform to 10 CFR 70.72, "Facility Changes and Change Process."

7. 10 CFR 70.74(a) and 10 CFR 70.74(b) require incident investigation and reporting.

11.4.2 Regulatory Guidance

Regulatory guidance for compliance with Appendix B to 10 CFR Part 50 appears in American National Standards Institute/American Society of Mechanical Engineers (ANSI/ASME) NQA-1-2008 and the NQA-1a-2009 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications," as endorsed by Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)," Revision 4, issued June 2010. This guidance applies to applications for plutonium processing and fuel fabrication facilities because these facilities are required to comply with Appendix B in order to comply with the requirements of 10 CFR 70.23(b).

11.4.3 Regulatory Acceptance Criteria

The reviewer should find the applicant's management measures acceptable if the applicant has met the acceptance criteria described in the following sections or has identified and justified an alternative approach.

Applicants may propose a system of management measures that are graded commensurate with the safety significance of the IROFS to which they are applied. In proposing to reduce controls, however, certain acceptance criteria must be met: (1) the system of graded management measures must be sufficient to ensure the IROFS' design integrity and the availability and reliability of an IROFS to successfully perform its safety function, and (2) applicants choosing to apply a graded system of management measures must describe how the proposed graded system will ensure that the performance requirements of §70.61 will be met and that public health and safety will be protected. This description should include an explanation of the process used to assign IROFS to categories based on their safety significance as well as a description of how each management measure will be graded for the defined categories.

When considering the application of graded management measures, applicants should consider the essential elements of the process (such as assigning IROFS to categories based on their safety significance and identification of graded management measures) to be high safety-significant activities that are not subject to grading. Consequently, applicants should note that it is necessary to consider feedback information from performance monitoring mechanisms (such

as surveillances performed as part of the maintenance function) and corrective action elements that may necessitate the reinstatement of controls that had been previously relaxed. Due to the importance of the performance monitoring and corrective action elements in assuring the effectiveness of graded management measures, these activities should be treated as highly safety-significant and should not be subject to graded controls. As described in this NUREG, the following management measures may be subject to grading: configuration management, maintenance, training and qualification, procedures, audits and assessments, incident investigations, records management, and other QA elements.
The Quality Assurance Reviewer will review the graded controls based on the categorization of IROFS using the review guidance in this SRP Chapter. The categorization process developed to enable the ranking of IROFS according to their significance will be reviewed by technical staff using the guidance in Chapter 3 of this SRP. The reviewer should coordinate with the Chapter 3 reviewer as needed to evaluate the applicant's selection of IROFS for the application of graded management measures. Criteria that should be considered include: function or end use of the IROFS; consequence of failure of the IROFS to public health and safety or worker protection; reliability of the IROFS; complexity of the design or fabrication of the IROFS; uniqueness of the item, and/or history of supply and performance.

11.4.3.1 Configuration Management

The regulation at 10 CFR 70.4 defines CM as a management measure that provides oversight and control of design information, safety information, and records of modifications that might impact the ability of IROFS to perform their functions when needed. The applicant's description of CM is acceptable if it meets the following conditions:

1. The application describes the CM program, design requirements, document control, change control, assessments, and design reconstitution (for existing facilities only).

2. The application describes the CM program and defines the specific attributes of CM that will be applied to select IROFS.

3. The ISA summary clearly defines the IROFS to be listed under CM along with the assignment of any grades or quality levels. The applicant should indicate in the ISA summary the CM attributes that will be applied to a particular IROFS. However, in the ISA summary, this indication may consist of only an index or category designation.

4. The application describes a design process leading to drawings and other statements of requirements that proceeds logically from the design basis.

5. The application describes how design requirements and associated design bases are established and are maintained through control of the design process. It also describes technical management review and approval functions.

6. The application describes an acceptable method to create and control documents that are relied on for safety. These documents include design requirements, ISAs, as-built drawings, specifications, all procedures that are IROFS, procedures involving training, QA, maintenance, audits and assessments, emergency operating procedures, emergency response plans, system modification documents, assessment reports, and others that the applicant deems part of CM.

7. The application describes how the CM function will maintain strict consistency among the design requirements, the physical configuration, and the facility documentation.

8. The application contains a commitment to evaluate, implement, and track each change to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel.

9. The application describes an acceptable process for providing reasonable assurance 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.

10. The application describes the documentation process following changes made in accordance with 10 CFR 70.72. Changes to the affected onsite documentation should be made promptly to avoid inadvertent access by facility personnel to outdated design and other specifications for IROFS.

11. The application confirms that initial and periodic assessments of the CM function are conducted to determine the program's effectiveness and to correct deficiencies. The application indicates that such assessments are systematically planned and conducted in accordance with an overall facility audit and assessment function.

12. For existing facilities, the application may describe whatever design reconstitution has been done for the purpose of the application. The applicant has available the current design bases, including design requirements, supporting analyses, and documentation supporting all IROFS.

13. For new facilities or new processes at existing facilities, the application describes facility and system design and facility layout based on defense-in-depth practices, in accordance with 10 CFR 70.64, "Requirements for New Facilities or New Processes at Existing Facilities." Specifically, 10 CFR 70.64(b) states that facility and system design must be founded on defense-in-depth practices and must incorporate, to the extent practicable: (1) preference for engineered controls over administrative controls and (2) reduction of challenges to IROFS. Thus, facility and system designs relying only on administrative controls, or relying on IROFS that are frequently or continuously challenged, are not acceptable, unless the application provides a justification showing that alternatives to achieve the design criteria are not practicable. Defense-in-depth practices should be applied early through the completion of design by providing successive levels of protection such that health and safety will not wholly depend on any single element of the design, construction, maintenance, or operation of the facility.

The process of evaluating facility changes through the configuration management program is important to ensure the availability and reliability of IROFS, all of which must be described in the ISA summary pursuant to 10 CFR 70.65(b)(6).). Applicants choosing to apply a graded system of management measures for configuration management activities must describe elements of configuration management that will be applied in a graded manner to IROFS based on their safety significance. Any change to site, structures, processes, systems, equipment, components, computer programs, and activities of personnel must be evaluated by the licensee as specified in 10 CFR 70.72(a) before the change is implemented. Therefore, the configuration

management process must be applied to all IROFS regardless of their safety significance. However, measures associated with configuration management may be suitable for graded application. Grading of configuration management may include a system in which the level of configuration management applied to items, processes, equipment, software, and personnel activities is based on the importance of the item or activity to safety. For example, graded configuration management controls may entail a less intensive review process for changes associated with items of lower safety significance (e.g., less rigorous scope of review, review performed by a skilled design engineer versus design manager, etc.).

11.4.3.2 Maintenance

As required by 10 CFR 70.62(d), engineered and administrative controls that are identified as IROFS must be designed, implemented, and maintained to ensure that they are available and reliable when needed.

The regulation at 10 CFR 70.64(a)(8) requires that IROFS for new facilities or new processes at existing facilities receive adequate inspection, testing, and maintenance to ensure their availability and reliability when needed.

A. The reviewers should find the applicant's submittal acceptable if the application includes the following information:

1. descriptions of corrective maintenance, PM, surveillance and monitoring, and functional testing

2. description of how the maintenance function will be designed to ensure that the objective of preventing failures through maintenance is appropriately balanced against the objective of minimizing unavailability of IROFS because of monitoring or PM

3. discussion of how the maintenance function uses, interfaces with, or is linked to the various management measures

4. justifications for assignment of differing degrees of maintenance to individual IROFS, based on the item's contribution to the reduction of risk

5. for IROFS identified in the ISA summary, description of the surveillance function and its conduct at a specified frequency

6. description of how the surveillance activity supports the determination of performance trends for IROFS, thus providing data useful in determining PM frequencies

7. description of the applicant's retention of records of the current surveillance schedule, performance criteria, and test results for all IROFS

8. for surveillance tests that can be done only while IROFS are out of service, description of the proper compensatory measures that will be prescribed for the continued normal operation of a process

9. description of how the results of incident investigations, the review of failure records required by 10 CFR 70.62(a)(3), and identified root causes are used to modify the affected maintenance function and eliminate or minimize the root cause

10. documentation of the approach to performing corrective actions or repairs on IROFS

11. description of how the maintenance function provides a planned, systematic, integrated, and controlled approach for the repair and replacement activities associated with identified unacceptable performance deficiencies of IROFS

12. description of the PM function that demonstrates a commitment to conducting preplanned and scheduled periodic refurbishing, or partial or complete overhaul, of IROFS to minimize occurrences of their unanticipated losses

13. description of the applicant's retention of records showing the PM schedule and results for all IROFS subject to this maintenance component

14. general description of the methods used and the commitment to perform functional testing, as needed, of IROFS after PM or corrective maintenance

15. as necessary, a commitment to conduct functional tests designed to include all operational aspects of the IROFS that are important to safety during startup of new processes

16. description of how the applicant will maintain records showing the functional test schedule and results for all IROFS subject to this maintenance component

17. general discussion of how the applicant will verify that the administrative controls identified as IROFS are available and reliable to perform their intended safety function over extended periods of operation

B. Applicants choosing to apply a graded system of management measures for maintenance activities must describe elements of maintenance that will be applied in a graded manner to IROFS based on their safety significance.

Grading of maintenance activities may include elements such as the following:

1. Reduced frequency for surveillance and monitoring activities used to ensure the continued integrity and functionality of the IROFS;

2. Implementation of preventative maintenance activities commensurate with the reliability of the item (lower importance of the item to safety and lower susceptibility of the item to failure allows reduced frequency or rigor for PM); and

3. Extended calibration intervals (not to exceed manufacturer recommendations or accepted industry standards or practice).

11.4.3.3 Training and Qualification

The application should be acceptable regarding personnel training and qualification if it satisfies the criteria described below. In addition to the regulatory acceptance criteria, the SRP provides additional specific criteria for (1) training and qualification for radiation safety personnel in Section 4.4.5, (2) criticality safety in Section 5.4.3.2, and (3) emergency planning in Section 8.4.3.1.11. Similarly, some of the information specified below may appear in other sections of the application and may be incorporated by reference.

A. Review criteria include the following:

1. The application should include the following commitments regarding organization and management of training:

    a. Line management is responsible for the content and effective conduct of the training.

    b. The application clearly defines job function, responsibility, authority, and accountability of personnel involved in managing, supervising, and implementing training.

    c. The applicant uses performance-based training as the primary management tool for analyzing, designing, developing, conducting, and evaluating training.

    d. The applicant documents and implements procedures to provide reasonable assurance that all phases of training are conducted reliably and consistently.

    e. The applicant ensures that training documents are linked to the CM system to provide reasonable assurance that the training reflects design changes and modifications.

    f. The applicant grants exemptions from training to trainees and incumbents only when justified, documented, and approved by management.

    g. The applicant maintains both programmatic and individual training records. These records support management information needs and provide required data on each individual's training and qualification.

2. The applicant should provide formal training for each position or activity that is relied on for safety. Training may be classroom or on-the-job training or both. The application should state what training will be conducted and which personnel will be required to complete it. The application should also demonstrate the following:

    a. The applicant ensures that each activity selected for training (initial or continuing) from the facility-specific activities is correlated with supporting procedures and training materials.

b. The applicant reviews facility-specific activities selected for training and compares training materials on an established schedule, updating them as necessitated by changes in procedures, facility systems and equipment, or job scope. The applicant monitors and evaluates change actions (e.g., procedure changes, equipment changes, facility modifications) for their impact on the development or modification of initial and continuing training and incorporates such change actions in a timely manner.

3. The application should contain commitments regarding personnel qualification for managers, supervisors, designers, technical staff, construction personnel, facility operators, technicians, maintenance personnel, and other staff who perform regulated activities.

4. The application should contain commitments regarding minimum qualifications for personnel. Minimum qualifications should be commensurate with the assigned functional responsibility and authority of the respective personnel as detailed below:

   a. Managers should have a bachelor of science (B.S.), bachelor of art (B.A.), or equivalent degree. Each manager should have either management or technical experience in a facility similar to the facility identified in the application.

   b. Supervisors should have at least the qualifications required of personnel being supervised.

   c. Technical professional staff whose actions or judgments are critical to satisfying the performance requirements identified in 10 CFR Part 70 should have a B.S., B.A., or equivalent degree in the appropriate technical field.

   d. Construction personnel, facility 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. The applicant should require candidates for process operators to meet the minimum qualifications described in the application. The applicant should require candidates for job functions other than process operators to meet minimum qualifications, but the application need not describe these minimum qualifications.

5. Training objectives should state the knowledge, skills, and abilities that the trainee should acquire; the conditions under which required actions will take place; and the standards of performance the trainee should achieve upon completion of the training activity.

6. Lesson plans and other training guides should provide guidance to ensure the consistent conduct of training activities and should be based on required learning objectives derived from specific job performance requirements.

7. The applicant should use lesson plans or guides for all training, and these lesson plans or guides should include standards for evaluating acceptable trainee performance. The evaluation of trainee accomplishment is acceptable if the applicant evaluates trainees periodically during training to determine their progress toward full capability to perform the job requirements and at the completion of training to determine their capability to perform the job requirements.

8. The applicant should establish review and approval requirements for all lesson plans or guides and other training materials before their issue and use.

9. The application should describe any on-the-job training used for activities relied on for safety.

10. The applicant should conduct on-the-job training using well-organized and current training materials. Designated personnel who are competent in the program standards and training methods should conduct the training.

11. 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.

12. Provisions for continuing assurance of personnel training and qualification are acceptable if the application addresses periodic requalification of personnel by training or testing or both, as necessary, to provide reasonable assurance that personnel continue to understand, recognize the importance of, and be qualified to perform activities that are relied on for safety.

13. An evaluation of training effectiveness and its relation to job performance is acceptable if it provides reasonable assurance that the training 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. The application should also demonstrate the following:

    a. Qualified individuals should periodically conduct a comprehensive evaluation of individual training to identify strengths and weaknesses. The applicant should use feedback from trainee performance during training and from former trainees and their supervisors to evaluate and refine the training.
    b. The applicant should initiate, evaluate, track, and incorporate improvements and changes to initial and continuing training to correct training deficiencies and performance problems.

B. Applicants choosing to apply a graded system of management measures for training and qualification activities must describe the elements of training and qualification that will be applied in a graded manner to IROFS based on their safety significance.

Grading of training and qualification activities may include elements such as the following:

1. Qualifications for personnel performing activities associated with graded IROFS may be subject to a different set of minimum training, education, and/or qualification requirements compared to personnel performing activities associated with IROFS determined to be of high significance.

Graded training and qualification requirements should be designated commensurate with the functional responsibility and authority assigned to personnel and the importance of the skill or activity to safety. Training and qualification activities, even when applied in a graded manner, should be documented; performed in accordance with procedures, lesson plans, and/or written guidance; assessed periodically to determine continued effectiveness; and should include measures for evaluating trainee performance.

11.4.3.4 Procedures

The regulation at 10 CFR 70.22(a)(8) requires that the application contain procedures to protect public health and safety. The application is acceptable in this regard if it describes the applicant's process for developing and implementing procedures and satisfies the following:

1. The applicant provides information regarding the procedure categories used at the facility. The categories typically include management control, operating, maintenance, and emergency procedures.

2. The applicant writes or plans procedures for the operation of IROFS and for all management measures supporting those IROFS.

3. The applicant includes the following commitment regarding procedure adherence: "Activities involving licensed SNM and/or IROFS will be conducted in accordance with approved procedures."

4. The applicant develops procedures for sitewide safe work practices to control processes and operations with licensed special nuclear material (SNM) and/or IROFS and/or hazardous chemicals incident to the processing of licensed material.

5. The applicant has existing or planned procedures to direct the following activities: (1) design, (2) CM, (3) procurement, (4) construction, (5) radiation safety, (6) maintenance, (7) QA elements, (8) training and qualification, (9) audits and assessments, (10) incident investigations, (11) records management, (12) criticality safety, (13) fire safety, (14) chemical process safety, and (15) reporting requirements.

6. Procedures are required for operator actions that are necessary to prevent or mitigate accidents identified in the ISA summary. The applicant provides a listing of the types of activities that are covered, or are planned to be covered, by written procedures. The listing includes the topics of administrative procedures; system procedures that address

startup, operation, and shutdown; abnormal operation or alarm response; maintenance activities that address system repair, calibration, inspection, and testing; and emergency procedures. Appendix A to this SRP chapter provides an acceptable listing of the items to be included under each topic.

7. The applicant describes the method for identifying, developing, approving, implementing, and controlling operating procedures as follows:

   a. The applicant considers the ISA in identifying needed procedures.

   b. The procedure specifies operating limits and IROFS.

   c. Procedures include required actions for off-normal conditions of operation, as well as normal operations.

   d. If needed, procedures identify safety checkpoints, as appropriate.

   e. The applicant uses field tests to validate procedures.

   f. The management personnel who are responsible and accountable for the operation approve the procedures.

   g. The applicant specifies a mechanism for revising and reissuing procedures in a controlled manner.

   h. QA elements and CM functions at the facility provide reasonable assurance that current procedures are available and used at all work locations.

   i. The training program instructs the required personnel in the use of the latest procedures.

8. Procedures should incorporate the following elements:

   a. title and identifying information, such as number, revision, and date

   b. statement of applicability and purpose

   c. prerequisites

   d. precautions (including warnings, cautions, and notes)

   e. important human actions

   f. limitations and actions

   g. acceptance criteria

   h. checkoff lists

   i. reference material

9. Maintenance procedures involving IROFS commit to the topics listed below for corrective and preventive maintenance and functional testing after maintenance and surveillance activities:

   a. Premaintenance activities involve reviews of the work to be performed, including procedure reviews for accuracy and completeness.

   b. Steps require notification of all affected parties (operators and supervisors) before performance of work and on completion of maintenance work. The discussion includes potential degradation of IROFS during the planned maintenance.

   c. Control of work is ensured by comprehensive procedures to be followed by maintenance technicians. The various safety disciplines, including criticality, fire, radiation, industrial, and chemical process safety, review maintenance procedures. The procedures describe 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 (should be controlled by the CM function to ensure like-kind replacement and adherence to 10 CFR Part 21, "Reporting of Defects and Noncompliance")

      iii. postmaintenance testing to verify operability of the equipment

      iv. tracking and records management of maintenance activities

      v. safe work practices (e.g., moderation control or exclusion area; radiation or hot work permits; and criticality, fire, chemical, and environmental issues)

10. The applicant has formal requirements governing the use of temporary procedures. Temporary procedures may be issued only when permanent procedures do not exist to (1) direct operations during testing, maintenance, and modifications, (2) provide guidance in unusual situations not within the scope of permanent procedures, and (3) provide assurance of orderly and uniform operations for short periods when the facility, system, or component is performing in a manner not covered by permanent procedures. The discussion establishes a timeframe for use of the temporary procedure and sets the same level of review and approval as for permanent procedures.

11. The applicant verifies that the procedures are technically accurate and can be performed as written. The applicant periodically reviews the procedures to ensure their continued accuracy and usefulness and establishes the timeframe for reviews of the various types of procedures.

12. 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.

13. The applicant reviews procedures after unusual incidents, such as an accident, unexpected transient, significant operator error, or equipment malfunction, or after any modification to a system and revises procedures as needed.

14. The applicant need not control program and administrative procedures and other nonoperational procedures that do not impact IROFS or other environmental, safety, and health concerns with the stringency applied to operating procedures or management control procedures associated with IROFS specified by the ISA summary. The applicant should specify the applicability of less stringent procedure control to avoid misunderstandings in implementation.

Applicants choosing to apply a graded system of management measures for activities associated with the development, implementation, and maintenance of procedures must describe the elements of procedure-related activities that will be applied in a graded manner to IROFS based on their safety significance. Because activities involving licensed SNM and/or IROFS must be conducted in accordance with approved procedures, no detailed guidance is provided on grading procedures. Procedures and written guidance should be sufficiently detailed in nature to describe expectations for the conduct of activities associated with IROFS to ensure their availability and reliability. Such procedures should be subject to a review and approval process and periodic reviews to ensure their continued effectiveness and suitability for the activities to which they apply.

11.4.3.5 Audits and Assessments

A. The NRC reviewers should find the application acceptable in terms of audits and assessments if it provides reasonable assurance that the following are adequately addressed and satisfied:

    1. The application describes program directives covering the audit and assessment function (i.e., the activities to be audited, audit frequency, guidance in conducting the audit or assessment, assigned responsibilities for each phase of the work, and procedures for recording the results and recommending actions to be taken).

    2. The application contains a commitment to conduct internal audits and independent assessments of activities significant to facility safety and environmental protection.

    3. The application states that audits will be performed to verify that operations are being conducted in accordance with regulatory requirements and license commitments.

    4. The application states that independent assessments will be conducted by offsite 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.

5. The application states that audits and assessments will be conducted for the areas of radiation safety, nuclear criticality safety, chemical safety, fire safety, environmental protection, emergency management, QA, CM, maintenance, training and qualification, procedures, incident investigation, and records management.

6. The application states that qualified personnel without direct responsibility for the function and area being audited or assessed will perform the audits and assessments. The application specifies the staff positions and committees responsible for audits and assessments and describes the levels of management to which results are reported. The systems to provide corrective actions are also described.

B. Applicants choosing to apply a graded system of management measures for audit and assessment activities must describe the elements of audits and assessments that will be applied in a graded manner to IROFS based on their safety significance.

Grading of audits and assessments may include elements such as the following:

1. Reduced audit and assessment frequency for graded IROFS; and

2. Performance of assessment activities associated with graded IROFS by personnel knowledgeable of the trade or skill involved in conduct of the activity in lieu of personnel with specific training in the conduct of assessments.

11.4.3.6 Incident Investigations

The applicant's description of its incident investigations activities and commitments in the application will be acceptable if the reviewer finds reasonable assurance of the following:

1. The applicant will establish a formal procedure to investigate abnormal events that may occur during operation of the facility to determine their specific or generic root cause(s), generic implications, and risk significance; to recommend corrective actions; and to report to the NRC as required by 10 CFR 70.50, "Reporting Requirements," and 10 CFR 70.74, "Additional Reporting Requirements." Appendix B to this SRP chapter presents guidance regarding the contents of an incident investigation program or procedure.

2. The applicant will monitor and document corrective actions through completion and ensure that corrective actions are taken within a reasonable period to resolve findings from abnormal event investigations.

3. The applicant will maintain documentation related to abnormal events for the life of the operation so that "lessons learned" may be applied to future operations of the facility. Details of the event sequence will be compared with accident sequences already considered in the ISA, and the ISA summary will be modified to include evaluation of the risk associated with accidents of the type actually experienced.

Applicants choosing to apply a graded system of management measures for incident investigation activities must describe the elements of incident investigations that will be applied

in a graded manner to IROFS based on their safety significance. Because it is important to investigate abnormal events occurring at a licensed facility to ensure that reporting requirements are met and public health and safety is ensured, no detailed guidance is provided on grading incident investigation activities. Rather, the management measures program should take into account risk significance of an incident as part of the investigation process, thereby providing a means of grading the incident investigation process in relation to the IROFS significance.

11.4.3.7 Records Management

The reviewer will find the applicant's records management system acceptable if the application describes the following criteria:

1. The applicant prepares, verifies, characterizes, and maintains records.

2. The applicant ensures that records are legible, identifiable, and retrievable for their designated lifetimes.

3. The applicant categorizes records by relative safety importance to identify record protection and storage needs and to designate the retention period for individual kinds of records.

4. The applicant protects records against tampering, theft, loss, unauthorized access, damage, or deterioration while in storage.

5. The applicant establishes and documents procedures specifying the requirements and responsibilities for record selection, verification, protection, transmittal, distribution, retention, maintenance, and disposition.

6. The applicant implements procedures that (1) assign responsibilities for records management, (2) specify the authority needed for records retention or disposal, (3) specify which records must have controlled access and provide the controls needed, (4) provide for the protection of records from loss, damage, tampering, and theft or during an emergency, and (5) specify procedures for ensuring that the records management system remains effective.

7. The applicant puts procedures in place to promptly detect and correct any deficiencies in the records management system or its implementation.

8. The applicant must maintain and update records of IROFS failures in accordance with 10 CFR 70.62(a)(3). The applicant must make record revisions necessitated by postfailure investigation conclusions promptly after completion of the investigation.

9. For computer codes and computerized data used for activities relied on for safety, as specified in the ISA summary, the applicant establishes procedure(s) for maintaining readability and usability of older codes and data as computing technology changes. The procedures could include transfer of the older forms of information and codes for older computing equipment to contemporary computing media and equipment.

Appendix C to this SRP chapter lists the types of records that the system should include.

Applicants choosing to apply a graded system of management measures for records management activities must describe the elements of records management will be applied in a graded manner to IROFS based on their safety significance. It is expected that records management functions will be applied to all IROFS regardless of their safety significance. Further, the preparation, issuance, and modification of quality-affecting documents must be performed in accordance with a controlled system for all IROFS. However, certain aspects of recordkeeping may be subject to grading for IROFS of low safety significance. For example, unless required by other regulation, record retention times may be lower for IROFS of lower safety significance. Similarly, design and procurement records may be less detailed for IROFS with less complex designs and low safety significance.

In all cases, measures for the designation, protection, storage, maintenance, and retention of records should be applied to IROFS in a manner appropriate to ensure the capability to (1) maintain plant design and configuration control, and (2) evaluate failures, perform root cause analyses, and determine appropriate corrective actions.

11.4.3.8 Other Quality Assurance Elements

To be acceptable, the applicant's QA elements should be structured to apply appropriate measures to IROFS. The NRC staff expects applicant and licensee QA elements to differ based on the purpose and complexity of the facility and processes.

A. Other QA may include some or all of the following elements:

1. Organization—The applicant may describe the organizational structure, functional responsibilities, lines of authority, and lines of communication for control of activities affecting quality. The organization responsible for ensuring that appropriate QA has been established should have sufficient authority, access to work areas, and organizational independence to perform its responsibilities.

2. QA Program—The applicant may describe its application of QA elements in the form of a QA program, in which the applicant commits to meet the relevant requirements of applicable standards. The commitment may describe the applicant's graded approach to QA, in which measures are implemented commensurate with an item's importance to safety, or the commitment may describe a QA program applied to all IROFS. The applicant should fully document, plan, implement, and maintain QA elements to provide reasonable assurance that, together with other management measures, IROFS will be available and reliable when needed.

3. Design Control—The applicant should define, control, and verify its design controls. The applicant should specify and correctly translate design inputs to design documents. Controlled measures, commensurate with those applied to the original design, should govern the adequacy of design and design changes. (See Sections 11.3, 11.4.3.1, 11.5.1, and 11.6.1 of this SRP for details on CM.)

4. Procurement Document Control—Documents associated with the procurement of items and services include or reference the applicable 10 CFR Part 21 ("Reporting of Defects and Noncompliance") reporting requirements, and other

design, technical, regulatory, and administrative requirements, (such as specifications, codes, standards, tests, inspections, and special processes) necessary to ensure adequate quality. Procurement documents identify requirements applicable to suppliers of items and services relied on for safety, such as QA program requirements.

5. Instructions, Procedures, and Drawings—The applicant should ensure that activities affecting the quality of IROFS are prescribed by and performed in accordance with documented instructions, procedures, or drawings appropriate for the circumstances and reference appropriate quantitative or qualitative acceptance criteria. (See Sections 11.3, 11.4.3.4, 11.5.4, and 11.6.4 of this SRP for details on procedures.)

6. Document Control—The applicant's document control system describes the preparation, issuance, and modification of documents that specify quality requirements or prescribe activities affecting quality. The document control system is controlled in a manner that ensures that authorized personnel review documents and changes thereto for adequacy and approve them for release. (See Sections 11.3, 11.4.3.1, 11.5.1, and 11.6.1 of this SRP for details on CM and Sections 11.3, 11.4.3.4, 11.5.4, and 11.6.4 for details on procedures.)

7. Control of Purchased Material, Equipment, and Services—The applicant may describe controls for the procurement of items and services to ensure that they conform to procurement requirements and/or design documents and specifications. Descriptive controls of purchased items and services include, as appropriate, source evaluation and selection, source inspection, audit, the examination of items or services upon delivery or completion, mechanisms for control of changes in items or services, commercial-grade item requirements, and control of supplier nonconformance.

8. Identification and Control of Items—The applicant establishes controls to ensure that only the correct items are used or installed. The applicant may describe provisions to identify and maintain traceability of items.

9. Control of Special Processes—The applicant establishes controls of processes affecting the safety of IROFS or related services. Qualified personnel using qualified procedures in accordance with specified requirements perform special processes that control activities, such as welding, heat treating, and nondestructive examination.

10. Inspection—When inspections are used to verify conformance of an IROFS item or activity, the applicant should specify the characteristics to be inspected and the inspection methods to be used and plan and execute the inspection. The applicant should then document the inspection results. Qualified personnel other than those who performed or directly supervised the work being inspected should perform the inspections. (See Sections 11.3, 11.4.3.4, 11.5.4, and 11.6.4 of this SRP for details on procedures and Sections 11.3, 11.4.3.3, 11.5.3, and 11.6.3 for details on training and qualification.)

11. Test Control—The applicant should conduct tests performed to verify conformance of an IROFS or computer program to specified requirements and demonstrate availability and reliability of performance. The applicant should specify the characteristics to be tested and test methods to be used. Test results should be documented and evaluated against the test requirements and acceptance criteria. (See Sections 11.3.1, 11.4.3.4, 11.5.4, and 11.6.4 of this SRP for details on procedures and Sections 11.3, 11.4.3.3, 11.5.3, and 11.6.3 for details on training and qualification.)

12. Control of Measuring and Test Equipment—The applicant should establish controls for tools, gauges, instruments, and other measuring and test equipment used for IROFS and activities affecting IROFS. Controls of measuring and test equipment should consider methods and frequency of calibration, and the applicant should adjust such controls to maintain accuracy within specified limits.

13. Handling, Storage, and Shipping—The applicant should consider methods to ensure that handling, storage, cleaning, packaging, shipping, and preservation of IROFS are controlled to prevent damage or loss and to minimize deterioration.

14. Inspection, Test, and Operating Status—The applicant should identify the status of inspection and test activities for IROFS, either in the item or in documents traceable to IROFS. The applicant should specify the use of status-indicating devices such as tags, markings, shop travelers, stamps, and inspection records. The applicant should establish provisions to ensure that required inspections and tests are performed and ensure that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated.

15. Control of Nonconforming Items—The applicant should describe provisions that specify when IROFS do not conform to specified requirements. The applicant should control items that do not conform to prevent inadvertent installation or use of nonconforming material, parts, equipment, or services. The applicant should specify provisions for identification, documentation, evaluation, segregation, and disposition of nonconforming IROFS and for appropriate notification to affected organizations.

16. Corrective Action—The applicant should specify provisions for promptly identifying conditions adverse to quality and correcting them as soon as practicable. (See Sections 11.3, 11.4.3.5, 11.5.5, and 11.6.5 of this SRP for details on audits and assessments and Sections 11.3, 11.4.3.6, 11.5.6, and 11.6.6 for details incident investigations.)

17. Quality Assurance Records—QA records and records management systems may be used in lieu of or in conjunction with each other. In either case, the applicant should describe the methods used to document, prepare, maintain, and manage records. The applicant should describe the methods used to protect records against damage, deterioration, or loss. In addition, the applicant should establish and document the requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition. (See Sections 11.3, 11.4.3.7, 11.5.7, and 11.6.7 of this SRP for details on records management.)

18. Audits—The applicant should plan and schedule audits and assessments to verify compliance with, and to determine the effectiveness of, its QA elements. The applicant should identify responsibilities and procedures for assessing, auditing, documenting, and reviewing results. (See Sections 11.3, 11.4.3.5, 11.5.5, and 11.6.5 of this SRP for details on audits and assessments.)

Pursuant to 10 CFR 70.65(b)(6), the ISA summary must briefly describe each IROFS in sufficient detail to understand its functions relative to the 10 CFR 70.61 performance requirements. In this regard, the ISA summary should identify the IROFS, the degree of their importance to safety, and related activities that are required for safety. An applicant may choose to apply all QA elements at the highest level to all IROFS or may grade the application in proportion to the item's importance to the achievement of safety. The application should describe quality assurance elements that will be applied in a graded manner to IROFS based on their safety significance.

B. Grading of other quality assurance elements for IROFS determined to be of lower significance may include features such as the following:

1. QA Program – An applicant's description of their QA program may describe a program in which quality assurance elements and management measures are applied to IROFS in a manner commensurate with the IROFS' safety significance.

2. Design Control – Design inputs must be correctly selected and incorporated into the design for all IROFS, and changes to final designs (including field changes and modifications) and dispositions of nonconforming items to use-as-is or repair are subject to design control measures commensurate with those applied to the original design for all IROFS. However, IROFS of lower safety significance may lend themselves to a greater reliance on nationally accepted codes and standards as part of the design input selection or use of certain accredited bodies as input to the design verification process.

3. Procurement Document Control – Procurement documents issued for items and services must contain all applicable technical, regulatory, administrative, and reporting requirements necessary to ensure the quality of the item or service; for IROFS of lower safety significance, there may be a smaller population of requirements needed in procurement documents to ensure the quality of the item or service.

4. Instructions, Procedures, and Drawings – It is necessary to develop and implement documented guidance for the conduct of activities affecting the quality of IROFS. The level of detail in instructions, procedures, and drawings should be commensurate with the complexity of the IROFS or activity being described.

5. Document Control – The preparation, issuance, and modification of quality-affecting documents must be performed in accordance with a controlled system for all IROFS. While a document control system must be applied to all documents that provide evidence of the availability and reliability of IROFS, document control measures may differ depending on the safety significance of the documents being controlled. For example, documents associated with

IROFS of lower safety significance may be less detailed or may require a lower level of review for issuance or modification.

6. Control of Purchased Material, Equipment, and Services – For IROFS of lower safety significance, procurement-related activities such as auditing, qualifying suppliers, and receipt inspection may be graded as appropriate. Within this area, compliance with 10 CFR Part 21 is mandatory for items designated as basic components and not subject to grading; however, certain activities performed in relation to procurement and commercial grade dedication may be graded. This would exclude the designation of critical characteristics but may include grading of verification activities (e.g., by use of reduced sampling plans or alternative testing techniques). If grading is applied to procurement activities, licensees should be vigilant in ensuring that they adequately evaluate the ability of graded controls to ensure the availability and reliability of IROFS, the quality of procured services affecting quality, and the extent to which items and activities are credited in preventing common cause failures.

7. Inspection— When inspections are used to verify conformance of an IROFS item or activity, the applicant may apply graded controls for IROFS of lower safety significance. Graded application of inspection activities may include reduced frequency or scope of inspections paired, as appropriate, with use of monitoring or surveillance to demonstrate IROFS availability and reliability, and use of peer inspectors. It is noted that, although the use of peer inspectors may be acceptable for lower safety significant IROFS, the inspectors must still be qualified to perform inspections and be independent of the work activity being inspected. Additionally, periodic oversight of peer inspectors is necessary in order to ensure their capability to perform inspection activities to the appropriate skill level. Documented guidance should specify the characteristics to be inspected and the inspection methods to be used. The results of any inspections performed to verify conformance or acceptability of IROFS must be documented.

8. Test Control—Tests should be performed as appropriate on all IROFS, regardless of quality level, to verify that IROFS conform to specified requirements and will be available and reliable to perform their safety function when called upon. The applicant should specify the characteristics to be tested and test methods to be used. Test results should be documented and evaluated against the test requirements and acceptance criteria. Identification of characteristics to be tested, delineation of test methods, and documentation recorded in association with tests should be adequate to ensure suitable testing of items is performed and sufficient documentation is available to attest to test methods and results. Grading of test control activities may include use of trained, skilled personnel as appropriate for test activities. Grading may also include performing testing on a sample basis in accordance with accepted sampling guidelines (i.e., EPRI guidance).

9. Control of Measuring and Test Equipment—The applicant should establish controls to ensure that the accuracy of tools, gauges, instruments, and other measuring and test equipment used for IROFS and activities affecting IROFS is maintained regardless of the risk significance of the IROFS. However, the frequency of periodic activities such as calibration may be adjusted as

appropriate, but not to exceed manufacturer's specifications or accepted industry practices, in a graded management measures program. Graded programs may entail the use of commercial-grade calibration services based, in part, on a supplier's accreditation status (i.e., accreditation from laboratory accreditation programs administered by the National Institute of Standards and Technology and by the American Association for Laboratory Accreditation, as recognized through the mutual recognition arrangement of the International Laboratory Accreditation Program (ILAC) (See NRC Safety Evaluation (Accession No. ML052710224).

10. Handling, Storage, and Shipping—The applicant should control the handling, storage, cleaning, packaging, shipping, and preservation of all IROFS to prevent damage or loss and to minimize deterioration. Controls for handling, storage, and shipping should be established commensurate with the susceptability of the item to deterioration, damage, or loss and may take into consideration the safety function of the item. Graded controls may be applied as long as they do not result in a detrimental effect on the availability or reliability of an IROFS.

11. Corrective Action— Corrective actions may be applied to IROFS in a graded manner and prioritized commensurate with the safety significance of the IROFS and the adverse condition. The applicant's corrective action program or process should result in the prompt identification of conditions adverse to quality, regardless of the IROFS significance. The correction of adverse conditions may be graded to allow the application of corrective actions in a timeframe commensurate with the significance of the IROFS to safety. Documentation associated with corrective actions should be sufficiently detailed to describe the condition(s) and action(s) taken to enable appropriate follow-up, regardless of significance.

12. Quality Assurance Records— Records associated with IROFS should be sufficiently detailed in order to provide a complete record of the facility design and to enable effective configuration management. QA records associated with IROFS of lower risk significance may be less detailed than those records associated with IROFS of higher significance due to the nature of the items (lower complexity, less failure mechanisms, etc.); however, the applicant should ensure that appropriate records are maintained to enable the evaluation of failures and determination of corrective actions. The applicant's records management program should describe (1) the methods used to protect records against damage, deterioration, or loss; (2) the requirements and responsibilities for record transmittal, distribution, retention, maintenance, and disposition; and (3) the extent to which graded controls will be applied to these activities.

13. Audits—The applicant should plan and schedule audits and assessments to verify compliance with, and to determine the effectiveness of, its QA elements. For IROFS of lower significance, audit activities may be graded by reducing the frequency of audit activities as appropriate. The applicant may also develop a program in which surveillances, performance monitoring, assessments, and trend data are used in lieu of or in combination with periodic audits. The applicant should ensure that the results of audit, assessment, and other oversight activities

are evaluated periodically to determine if the frequency, scope, or depth of the oversight needs to be adjusted to ensure the availability and reliability of IROFS.

C. There are some QA elements that are not conducive to grading due to their programmatic nature or generic applicability to all IROFS. Examples include:

1. Organization – It is unlikely that multiple organizational structures would be applied to activities based on the significance of IROFS associated with the activities.

2. Identification and Control of Items - The applicant must establish controls to ensure that only the correct items (e.g., equipment, components) are used or installed. These controls must be applied to all IROFS in order to provide reasonable assurance that the performance requirements of §70.61 will be met. While controls may vary for different IROFS, practices must be sufficient to ensure proper identification of IROFS and prevent unintended/improper installation or use of IROFS.

3. Control of Special Processes - Where used, special processes such as welding, heat treating, and nondestructive examination should be performed by qualified personnel using qualified procedures. Given the specialized nature of these activities, grading is not appropriate in this area due to the need to use specially trained personnel and procedures appropriate to the task.

4. Inspection, Test, and Operating Status—The status of inspection and test activities for each IROFS should be clearly indicated either on the item or in documents traceable to the item. Mechanisms for grading this QA element are not readily apparent as the element pertains to using measures to indicate the status of inspections and tests performed on IROFS in order to ensure that inspections and tests are performed as required (and not inadvertently bypassed). These measures can include stamps, tags, labels, routing cards, inspection/test records, or other suitable means; the means selected for indication of necessary inspections and tests should be appropriate to the IROFS (i.e., use of tags for valves) and robust enough to stay in place and perform the indication function.

5. Control of Nonconforming Items—The applicant should establish measures to control items that do not conform to specified requirements in order to prevent inadvertent installation or use of nonconforming material, parts, equipment, or services. Because it is necessary to appropriately control any IROFS that does not conform to specified requirements, this element is not conducive to grading because relaxed controls for identifying, segregating, and controlling nonconforming items may be less effective in ensuring the availability and reliability of IROFS.

11.5 Review Procedures

11.5.1 Acceptance Review

During the acceptance review of a license application, the reviewer should examine the submittals to identify major deficiencies in the information provided for each area of review specified in SRP Section11.3. Reviewers must decide whether they have enough information to proceed with a detailed review. Less significant errors or deficiencies that can be addressed in a request for additional information should be accepted. However, before the NRC performs a detailed review, the applicant should correct major deficiencies that would require several requests for additional information to resolve.

Reviewers should record whether each area of review is adequately addressed in the application, is adequately addressed in a referenced document, is not applicable to the application, or has a major deficiency.

11.5.2 Safety Evaluation

For each area of review specified in Section 11.3, the review procedure is identified below. These review procedures are based on the identified SRP acceptance criteria. For deviations from these specific acceptance criteria, the staff should review the applicant's evaluation of how the proposed alternatives to the SRP criteria provide an acceptable method of complying with the relevant NRC requirements identified in Section 11.4.

During the review of the license application and ISA summary for a planned facility, the reviewer should identify and note any items or issues that should be inspected during an operational readiness review, if such a review will be performed. These items could include confirming that the engineered controls are implemented through procedures and operator training.

For an existing facility, the reviewer may consult NRC inspectors to identify and resolve any issues related to the licensing review. For a planned facility, the reviewer may wish to consult with the facility design team to gain a better understanding of the process, its potential hazards, and safety approaches. The reviewer should coordinate these interactions through the licensing project manager.

The primary reviewer will prepare safety evaluation report (SER) input for the licensing project manager in support of the licensing action.

11.5.3 Configuration Management

The reviewer should evaluate the six areas of CM described in the next sections.

11.5.3.1 Configuration Management Program

The reviewer should consider whether the CM plan acceptably states management commitments, gives the program directive, and defines key responsibilities, terminology, and equipment scope.

The reviewer should determine whether the applicant's description of overall CM functions covers the following topics: (1) the scope of the IROFS and management measures to be

included (coordinating with the reviewer of Chapter 3 of this SRP as necessary), (2) the description and objectives of each CM activity, and (3) the organizational structure and staffing interfaces.

The reviewer should determine that IROFS identified in the ISA summary are subject to the CM function.

The reviewer should check for appropriate interfaces both within the CM function and with external organizations and functions. In particular, the review should examine functional interfaces with QA, maintenance, and training (including qualification).

The reviewer should look for the applicant's identification of necessary databases and the rules for their maintenance.

11.5.3.2 Design Control Requirements

The 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 which an appropriate authority within the organization has reviewed and approved.

The reviewer should verify that specific personnel are assigned the responsibility for maintaining the design bases and requirements.

The reviewer should verify that the requirements documents clearly define the IROFS to be listed under CM, along with the assignment of any grades or quality levels. The reviewer should coordinate this part of the review with the ISA primary reviewer.

Note that the reviewer, in conjunction with the appropriate technical reviewers, is responsible for determining the adequacy of the reduced levels the applicant would apply to IROFS for accident sequences with lesser consequences.

11.5.3.3 Document Control

The reviewer should evaluate the application to determine whether the CM system captures documents that are relevant and important to safety. These documents should include the design requirements, the ISA, the ISA summary, as-built drawings, specifications, all operating procedures important to safety, procedures involving training, maintenance, audits and assessments, emergency operating procedures, emergency response plans, system modification documents, assessment reports, and other documents that the applicant deems pertinent to the CM function.

The reviewer should examine information describing a controlled document database used to control documents and track document change status.

The reviewer should confirm that rules of storage for originals or master copies of documents within the scope of the CM function follow the guidance of records management.

11.5.3.4 Change Control

The reviewer should verify that the description of change control within the CM function commits to acceptable methods for (1) the identification of changes in configurations that are IROFS, (2) technical and management review of changes, and (3) 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 other QA elements.

11.5.3.5 Assessments

The reviewer should verify that both document assessments and physical assessments (system walk-downs) will be conducted periodically to check the adequacy of the CM functions. The reviewer should also confirm that the applicant will document all assessments and followups.

11.5.3.6 Design Reconstitution (Existing Facilities Only)

Design reconstitution may be necessary for existing facilities if current design information is not adequate.

The reviewer should examine 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. This includes the methods used to evaluate, verify, and validate reconstituted design data for IROFS.

The reviewer will seek evidence that the applicant (1) investigated the need for design-bases reconstitution, (2) accomplished reconstitution as necessary, and (3) properly incorporated the new or revised documentation into the CM function.

11.5.4 Maintenance

The reviewer will evaluate the applicant's description of how the maintenance function will coordinate with and use the other management measures listed in this chapter. The primary reviewer should consult with supporting reviewers to identify common weaknesses in the applicant's approach and consider these in the review.

11.5.5 Training and Qualification

Recognizing that the training objectives and methods and the required personnel qualifications may be graded to correspond to the hazard potential of the facility, the reviewer performs a safety evaluation against the acceptance criteria described in Section 11.4. In particular, the review should accomplish the following:

1. The review should evaluate the adequacy of training and qualification on the basis of how well it fulfills the applicant's training objectives, especially when human factors are relied on for safety.

2. 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.

3. The reviewer should focus on the training and qualification of personnel who will perform activities relied on for safety.

4. The supporting reviewers should become familiar with the applicant's personnel training and qualification commitments and determine whether ongoing activities correspond to them.

5. The review should determine whether there is reasonable assurance that the applicant's personnel training and qualification will result in only properly trained and qualified personnel performing activities relied on for safety.

11.5.6 Procedures

The reviewer will evaluate whether the applicant has adequately addressed the acceptance criteria listed in Section 11.4. The reviewer will document in an SER that the applicant has committed to the following:

1. The applicant includes a statement to follow approved procedures while processing licensed SNM.

2. Procedures important to safety are independently verified and validated before use, and this is documented in a program on procedures.

3. Procedures exist for the notification of operations personnel before and after maintenance is performed on IROFS, and procedures are in place to control activities.

4. An independent, multidisciplinary safety review team reviews and approves changes to operating, management measure, or maintenance procedures controlled by the CM function.

11.5.7 Audits and Assessments

The reviewer will determine whether the applicant has adequately planned for audits and assessments to be accomplished and whether necessary programs, personnel, and procedures will be established.

If the applicant refers to other sections of the application when describing its audits and assessments, the reviewer should examine these other sections of the application to determine the applicant's overall commitment to audits and assessments and the proposed method for implementation. The reviewer should confirm that the applicant's audit and assessment commitments are consistent with other sections of the submittal.

11.5.8 Incident Investigations

The reviewer will verify that the applicant has described a comprehensive incident investigation function based on the areas of review in Section 11.3 and the acceptance criteria in Section 11.4 of this SRP. For existing facilities, the reviewer should consult with the NRC

inspection staff and review any historical information regarding the adequacy of the applicant's incident investigation process.

11.5.9 Records Management

The review should determine whether the applicant has adequately implemented a records management system. For fuel cycle facilities that are parts of larger organizations, certain documents may be retained or stored at a site other than the facility 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, particularly the storage areas for records related to IROFS for high-consequence accident sequences.

11.5.10 Other Quality Assurance Elements

The reviewer should evaluate the applicant's submittal with regard to QA elements against the acceptance criteria in Section 11.4. Supporting reviewers should determine whether IROFS within their areas of review are specified to be within the appropriate QA elements and level. The reviewer should measure the effectiveness of the QA elements design, rather than just verifying the existence of appropriate QA elements.

The reviewer will document in the SER the results of the following:

1. The reviewer should determine whether there is reasonable assurance that the applicant's QA elements, maintenance, and CM are coordinated and that the QA elements are an integral part of everyday work activities.

2. The reviewer should determine whether there is reasonable assurance that the applicant will be able to monitor the effectiveness of the implementation of QA elements and will make needed adjustments promptly.

3. The reviewer should determine that the applicant has specified the QA elements criteria, the basis for choosing the criteria, and the proposed method for implementation.

4. The reviewer should determine that the applicant's QA elements are sufficient, in combination with the other seven management measures, to ensure the availability and reliability of IROFS. For example, other QA elements address the design, selection, procurement, installation, and testing of IROFS.

5. If the applicant refers to other sections of the application when describing its QA elements, the reviewer should examine these sections to determine the applicant's commitment to the QA elements and the proposed method for implementation.

11.6 Evaluation Findings

The regulations in 10 CFR 70.23 and 70.66 state that an application for a license will be approved if the Commission can make the general findings listed in those sections. The basis for the general findings is an evaluation of whether the application adequately addresses all of the applicable regulatory requirements. More specifically, the staff's evaluation should determine whether the licensing submittals provide sufficient information to satisfy the regulatory

requirements of Section 11.4.1 of this SRP and whether the applicant has appropriately addressed the regulatory acceptance criteria in SRP Section 11.4.3. On the basis of this information, the reviewers should write material suitable for inclusion in the SER prepared for the entire application. The SER should state how the applicable regulatory requirements have or have not been met based on the acceptance criteria described in this chapter of the SRP. If the applicant chooses to use an alternative approach, the reviewer should discuss in the SER whether the proposed approach satisfies the applicable regulatory requirements. The reviewers should use the following approach to document their evaluation:

1. State a specific regulatory requirement that applies to the application. Detailed acceptance criteria may be included where appropriate or necessary.

2. Identify the areas where the regulatory requirement is addressed in the application, including the areas where the specific acceptance criteria described in this SRP are addressed.

3. Describe your evaluation of the application, the basis for your conclusion, and whether regulatory requirements are met.

4. Repeat these steps for every regulatory requirement that applies to the application.

Where the graded application of management measures has been requested by the applicant or licensee, the staff's evaluation findings should include a comprehensive assessment of the graded controls, the basis for the controls, provisions for adjusting the graded controls based on implementation feedback, and the extent and limitations of the graded measures. The staff's evaluation should also include a comprehensive assessment of the IROFS categorization process and its basis, which will be performed by reviewers in accordance with SRP Chapter 3. Applications seeking to apply graded QA controls without sufficient basis should not be granted.

There are three possible outcomes to the staff's licensing review: (1) approval of the applicant's application or amendment request, (2) denial of the application or request, or (3) approval with conditions. If the reviewer cannot make a finding of a reasonable assurance of safety, the reviewer may consider proposing a license condition. Absent an NRC order, license conditions must be agreed upon with the licensee or applicant before becoming part of the license. A license condition should only be proposed if there is reasonable assurance that, if the licensee meets the condition, all regulatory requirements will be satisfied. Thus, license conditions should not be used to cover major deficiencies in an application. License conditions should be unambiguous, inspectable, and enforceable. They should only require those actions necessary to ensure compliance with applicable regulations. The basis for license conditions must be documented in the SER.

If the submittal is acceptable, the final SER input should conclude with statements similar to the following:

11.6.1 Configuration Management

The staff has reviewed the CM function for [name of facility] according to Chapter 11 of the SRP (NUREG-1520). [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 IROFS. Management-level policies and procedures, including an analysis and independent safety review of any proposed activity involving IROFS, are described and will provide reasonable assurance that consistency among 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. Configuration Management

   The applicant has put in place or committed to the organizational structure, procedures, and responsibilities necessary to implement CM.

2. Design Control Requirements

   The applicant has documented, and supported by analysis, design requirements and bases. Furthermore, the applicant has ensured that the documentation remains current.

3. Document Control

   The applicant has stored documents, including drawings, in an appropriate and accessible manner. Drawings and related documents captured by the system are those necessary and sufficient to adequately describe IROFS.

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. The applicant has put in place methods for suitable analysis, review, approval, and implementation of identified changes to IROFS. This includes appropriate CM controls to ensure configuration verification, functional tests, and accurate documentation for equipment or procedures that have been modified.

5. Assessments

   The applicant has committed to an adequate function that includes both initial and periodic assessments, as described in the acceptance criteria in the SRP. The assessments are expected to verify and ensure the adequacy of the CM function.

6. Design Reconstitution (Existing Facilities Only)

   The applicant has adequately described the design reconstitution performed. Current design bases are available and verified for all IROFS, such that the configuration is consistent with the as-built facility documentation.

11.6.2 Maintenance

The applicant has committed to maintenance of IROFS. The applicant's maintenance commitments contain the basic elements to maintain availability and reliability: corrective maintenance, PM, functional testing, equipment calibration, and work control for maintenance of IROFS. The applicant's maintenance function is proactive, using maintenance records, PM records, and surveillance tests to analyze equipment performance and to seek the root causes of repetitive failures.

The surveillance and monitoring, PM, and functional testing activities described in the license application provide reasonable assurance that the IROFS identified in the ISA summary will be available and reliable 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, QA, and the rules of CM, (3) uses the ISA summary to identify IROFS that require maintenance and determine the level of maintenance needed, (4) justifies the PM intervals in terms of the equipment reliability goals, (5) provides for training that emphasizes the importance of IROFS identified in the ISA summary, regulations, codes, and personnel safety, and (6) creates documentation that includes records of all surveillance, inspections, equipment failures, repairs, and replacements of IROFS.

The staff concludes that the applicant's maintenance functions meet the requirements of 10 CFR Part 70 and provide reasonable assurance of public health and safety and the protection of the environment.

11.6.3 Training and Qualification

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 concludes that the applicant has adequately described and assessed its personnel training and qualification in a manner that satisfies the regulatory requirements and is consistent with the guidance in this SRP.

Reasonable assurance exists 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 meets the requirements of 10 CFR Part 70.

11.6.4 Procedures

The application describes a suitably detailed process for the development, approval, and implementation of procedures. It has addressed IROFS, as well as items important to the health of facility workers and the public and to the protection of the environment. The staff concludes that the applicant's plan for procedures meets the requirements of 10 CFR Part 70.

11.6.5 Audits and Assessments

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 concludes that the applicant has adequately described its audits and assessments. The staff has reviewed the applicant's plan for audits and assessments and finds it acceptable.

The staff concludes that the applicant's plan for audits and assessments meets the requirements of 10 CFR Part 70 and provides reasonable assurance of protection of the health and safety of the public, workers, and the environment.

11.6.6 Incident Investigations

The applicant has committed to and established an organization responsible for (1) performing incident investigations of abnormal events that may occur during operation of the facility, (2) determining the root cause(s) and generic implications of the event, and (3) recommending corrective actions for ensuring a safe facility and safe facility operations, in accordance with the acceptance criteria of Section 11.4 of the SRP.

The applicant has committed to monitoring and documenting corrective actionsthrough to completion.

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 Records Management

The staff has reviewed the applicant's records management system against the acceptance criteria and concludes that the system (1) will be effective in collecting, verifying, protecting, and storing information about the facility and its design, operations, and maintenance 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 health and safety 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 provide reasonable assurance that any deficiencies in the records management system or its implementation will be detected and corrected promptly.

11.6.8 Other Quality Assurance Elements

The SER should include a summary statement of what the NRC evaluated and the basis for the reviewer's conclusions. The review should demonstrate the adequacy of the applicant's use of other QA elements, as applied to IROFS, for design, construction, and operations. The SER should include statements like the following:

The NRC staff concludes that the applicant has adequately described the application of other QA elements (and the applicable QA elements of its principal contractors). The staff also concludes the following:

- The applicant has established and documented a commitment to an organization responsible for developing, implementing, and assessing the management measures for providing reasonable assurance of safe facility operations, in accordance with the criteria in Section 11.4 of the SRP.

- The applicant has established and documented a commitment to QA elements, and the administrative measures for staffing, evaluating performance, assessing findings, and implementing corrective action are in place.

- The applicant has developed a process for preparation and control of written administrative plant procedures, including procedures for evaluating changes to procedures, IROFS, and tests. The applicant has committed to implement and maintain a process for review, approval, and documentation of procedures.

- The applicant has established and documented surveillances, tests, and inspections to provide reasonable assurance of satisfactory in-service performance of IROFS.

- The applicant will ensure that periodic independent audits are conducted to determine the effectiveness of the management measures. Management measures will provide for documentation of audit findings and implementation of corrective actions.

- The applicant has established and documented training requirements to provide employees with the skills to perform their jobs safely. The applicant has also provided management measures for the evaluation of the effectiveness of training against predetermined objectives and criteria.

- The organizations and persons performing QA element functions have the required independence and authority to effectively carry out their QA element functions without undue influence from those directly responsible for process operations.

- QA elements cover the IROFS, as identified in the ISA summary, and the applicant has established measures to prevent hazards from becoming pathways to higher risks and accidents.

Accordingly, the staff concludes that the applicant's use of other QA elements meets the requirements of 10 CFR Part 70 and provides reasonable assurance that public health and safety and the environment are protected.

11.7 References

American National Standards Institute/American Society of Mechanical Engineers Standard, "Quality Assurance Requirements for Nuclear Facility Applications," ANSI/ASME NQA-1a-2009.

U.S. Code of Federal Regulations, Chapter I, Title 10, "Energy," Part 50, "Domestic Licensing of Production and Utilization Facilities."

U.S. Code of Federal Regulations, Chapter I, Title 10, "Energy," Part 70, "Domestic Licensing of Special Nuclear Material."

U.S. Code of Federal Regulations, Chapter I, Title 10, "Energy," Part 21, "Reporting of Defects and Noncompliance."

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,* Vol. 54, No. 53, pp. 11590−11598, March 21, 1989.

U.S. Nuclear Regulatory Commission, "Suggested Guidance Relating to Development and Implementation of Corrective Action," Information Notice 96-28, May 1966.

U.S. Nuclear Regulatory Commission, "Human Factors Engineering Program Review Model," NUREG-0711, Revision 2, February 2004.

APPENDIX A

CHECKLIST FOR PROCEDURES

Written procedures should cover all activities listed below. This list is not intended to be all-inclusive or to imply that procedures must be developed with the same titles as those on the list.

1. Management Control Procedures

- training
- audits and assessments
- incident investigation
- records management
- configuration management
- quality assurance
- equipment control (lockout/tagout)
- shift turnover
- work 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

- 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
  - facility utilities (air, other gases, cooling water, fire water, steam)
  - temporary changes in operating procedures
- 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 (IROFS)
   - testing of criticality alarm units
   - calibration of IROFS
   - high-efficiency particulate air filter maintenance
   - functional testing of IROFS
   - relief valve replacement/testing
   - surveillance/monitoring
   - pressure vessel testing
   - nonfired pressure vessel testing
   - piping integrity testing
   - containment device testing

4. Emergency Procedures

   - response to a criticality
   - hazardous process chemical releases (including uranium hexafluoride)

APPENDIX B

INCIDENT INVESTIGATION PROGRAMS AND PROCEDURES

The following eight items are good practices to incorporate in incident investigation programs or procedures or both:

(1) The investigation of an abnormal event should begin as soon as possible after the event has been brought under control.

(2) The incident investigation program contains a documented procedure for investigating an abnormal event. This procedure is separate from any required emergency plan.

(3) The program includes a description of the functions, qualifications, and responsibilities of the manager who would lead the investigative team and those of the other team members; the scope of the team's authority and responsibilities; and an assurance of management cooperation.

(4) Qualified internal or external investigators are appointed to serve on investigating teams when required. The teams should include at least one process expert and at least one team member trained in root cause analysis.

(5) The program contains guidance for personnel conducting the investigation on how to apply a reasonable, systematic, structured approach to determine the specific or generic root cause(s) and generic implications of the problem. The level of investigation should be based on a graded approach relative to the severity of the incident.

(6) The incident investigation team has assurance of the team's authority to obtain all information considered necessary and is independent from the functional area involved in the incident under investigation.

(7) The investigation process and investigating teams are independent of the line management.

(8) Auditable records and documentation related to abnormal events, investigations, and root cause analysis are maintained. For each abnormal event, the incident report should include a description, contributing factors, a root cause analysis, and findings and recommendations. Relevant findings are reviewed with all affected personnel.

APPENDIX C

RECORDS

The requirements for records management vary according to the nature of the facility and the hazards and risks it poses. Examples of the records required by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations"; 10 CFR Part 20, "Standards for Protection against Radiation"; 10 CFR Part 21, "Reporting of Defects and Noncompliance"; 10 CFR Part 25, "Access Authorization"; and 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," are listed below. The records are listed under the chapter headings of the Standard Review Plan (SRP). The list is not intended to be exhaustive or prescriptive. Different or additional records may be required in certain circumstances. The applicant may also choose to organize the records in other ways.

Examples of Records

SRP Chapter

1. General Information

    - construction records
    - facility and equipment descriptions and drawings
    - design criteria, requirements, and bases for items relied on for safety (IROFS), as specified by the facility configuration management (CM) function
    - records of facility changes and associated integrated safety analyses, as specified by the facility CM function
    - 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
    - procurement records, including specifications for IROFS

2. Organization and Administration

    - administrative procedures with safety implications

- change control records for material control and accounting program
- organization charts, position descriptions, and qualification records
- safety and health compliance records, medical records, personnel exposure records
- quality assurance records
- safety inspections, audits, assessments, and investigations
- safety statistics and trends

3. Integrated Safety Analysis

4. Radiation Safety

- bioassay data
- exposure records
- radiation protection (and contamination control) records
- radiation training records
- radiation work permits

5. 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. 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
- chemical process safety reports and analyses
- chemical process safety training

7. 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
- prefire emergency plans

8. Emergency Management

- emergency plan(s) and procedures
- comments on emergency plan from outside emergency response organizations
- emergency drill records
- memoranda 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. Environmental Protection

- environmental release and monitoring records

- environmental report and supplements to the environmental report, as applicable

10. Decommissioning

- decommissioning records
- financial assurance documents
- decommissioning cost estimates
- site characterization data
- final survey data
- decommissioning procedures

11. Management Measures

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 material control and accounting

- integrated safety analysis documents, including process descriptions, plant drawings and specifications, and purchase specifications for IROFS

- approved current operating procedures and emergency operating procedures

11.2 Maintenance

- record of IROFS failures (required by 10 CFR 70.62, “Safety Program and Integrated Safety Analysis”)

- preventive maintenance records, including trending and root cause analysis

- calibration and testing data for IROFS

- 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 and 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

12. MATERIAL CONTROL AND ACCOUNTING

12.1 Purpose of Review

The purpose of this review is to determine whether the applicant's material control and accounting (MC&A) program is adequate to detect and protect against the loss, theft, or diversion of special nuclear material (SNM) that the applicant will possess, store, and utilize at its facility, and to comply with the regulatory requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 74, "Material Control and Accounting of Special Nuclear Material," and 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

The MC&A regulations in 10 CFR Part 74 distinguishes between licensees authorized to possess different types and quantities of SNM. These designations are also used to describe the facilities at which the licensees may possess the material. The categories of licensees or facilities are:

1. Category I – Fuel facilities/licensees authorized to possess 5 formula kilograms, or more, of strategic special nuclear material (SSNM), as defined in 10 CFR 74.4, "Definitions."

2. Category II – Fuel facilities/licensees authorized to possess SNM of moderate strategic significance, as defined in 10 CFR 74.4.

3. Category III – Fuel facilities/licensees authorized to possess SNM of low strategic significance, as defined in 10 CFR 74.4. This category includes low-enriched fuel-fabrication facilities and enrichment facilities.

Correspondingly greater (graded) MC&A program capabilities are required for activities and processes involving categories of SNM of increasing strategic significance, from Category III to Category II and Category I, depending on the amounts and forms of SNM under safeguards. Therefore, this chapter will discuss the review required by safeguards category and facility type.

As indicated above, for applications regarding Category I facilities, the reviewer will need to become familiar with the terms "strategic special nuclear material," "formula kilogram," "formula quantity," and "category 1A material," each of which is defined in 10 CFR 74.4. For applications regarding Category II facilities, the reviewer will need to become familiar with the term "special nuclear material of moderate strategic significance." For applications regarding Category III facilities, the reviewer will need to become familiar with the term "special nuclear material of low strategic significance."

There are additional defined terms in part 74 that are more generally applicable. These include "special nuclear material," "low enriched uranium," "high enriched uranium," "item," "measurement," and "physical inventory."

12.2 Responsibility for Review

Primary: MC&A License Reviewer

Secondary: MC&A Technical Staff

Supporting: Licensing Project Manager

Fuel Cycle Facility MC&A Inspector

12.3 Areas of Review

As specified in 10 CFR 70.22(b), an applicant must submit a full description of its program for control and accounting of the SNM in its possession under license to demonstrate how compliance with the requirements in 10 CFR Part 74 will be accomplished. This MC&A program description is provided to the U.S. Nuclear Regulatory Commission (NRC) in the form of a Fundamental Nuclear Material Control (FNMC) plan. Guidance for the format and content of an FNMC plan is provided in the following documents, depending on the safeguards category and facility type:

1. Category I Facility – NUREG-1280, "Standard Format and Content Acceptance Criteria for the Material Control and Accounting (MC&A) Reform Amendment."

2. Category II Facility –There are presently no Category II facilities, and there is no guidance for a Category II facility.

3. Category III Fuel Fabrication Facility – NUREG-1065, "Acceptable Standard Format and Content for the Fundamental Nuclear Material Control (FNMC) Plan Required for Low-Enriched Uranium Facilities."

4. Category III Enrichment Facility – NUREG/CR-5734, "Recommendations to the NRC on Acceptable Standard Format and Content for the Fundamental Nuclear Material Control (FNMC) Plan Required for Low-Enriched Uranium Enrichment Facilities."

The guidance documents listed above are also used by the MC&A license reviewer to determine the acceptability of the applicant's proposed MC&A program. The specific areas of review are different depending on the type of facility and safeguards category. These areas are listed in Sections 12.3.1 through 12.3.4 below.

12.3.1 Category I Facility

For a Category I facility, the staff will review the applicant's commitments regarding the following MC&A program areas:

10. abrupt loss detection from process units (Process Monitoring)

11. timely detection of loss of items (Item Monitoring)

12. timely resolution of MC&A alarms (Alarm Resolution)

13. management structure and personnel qualification and training

14. measurements systems

15. measurement-control system

16. use of statistics to ensure requirements are met

17. conduct of periodic physical inventories and reconciliation of book records to the results of the physical inventories

18. identification and measurement of shipments and receipts

19. scrap-control program

20. independent assessment of the MC&A program

21. designation of material balance areas, item-control areas, and custodians

22. tamper-safing

23. resolving indications of loss, theft, diversion, or misuse of SNM/SSNM

24. assisting in the investigation and recovery of missing SNM/SSNM

25. recordkeeping system

12.3.2 Category II Facility

Although is no guidance for a Category II facility available at this time, if the staff were to received an application from a Category II facility, the staff will review the applicant's commitments regarding the following MC&A program areas:

1. management structure and personnel qualification and training

2. measurements systems

3. measurement-control system

4. use of statistics to ensure requirements are met

5. conduct of periodic physical inventories and reconciliation of book records to the results of the physical inventories

6. item-control system

7. shipper/receiver comparisons

8. independent assessment of the MC&A program

9. tamper-safing

10. designation of material balance areas, item-control areas, and custodians

11. resolving indications of loss, theft, diversion, or misuse of SNM

12. assisting in the investigation and recovery of missing SNM

13. recordkeeping system

12.3.3 Category III Fuel Fabrication Facility

For a Category III fuel-fabrication facility, the staff will review the applicant's commitments regarding the following MC&A program areas:

1. management structure and personnel qualification and training
2. measurements systems
3. measurement-control system
4. use of statistics to ensure requirements are met
5. conduct of periodic physical inventories and reconciliation of book records to the results of the physical inventories
6. item-control system
7. shipper/receiver comparisons
8. independent assessment of the MC&A program
9. tamper-safing
10. designation of material balance areas, item-control areas, and custodians
11. resolving indications of loss, theft, diversion, or misuse of SNM
12. assisting in the investigation and recovery of missing SNM
13. recordkeeping system

12.3.4 Category III Enrichment Facility

For a Category III enrichment facility, the staff will review the applicant's commitments regarding the following MC&A program areas:

1. management structure and personnel qualification and training
2. measurements systems
3. measurement-control system
4. use of statistics to ensure requirements are met
5. conduct of periodic physical inventories and reconciliation of book records to the results of the physical inventories
6. program for precluding and detecting unauthorized production of enriched uranium
7. item-control system
8. shipper/receiver comparisons

9. independent assessment of the MC&A program

10. tamper-safing

11. designation of material balance areas, item-control areas, and custodians

12. resolving indications of missing uranium and of unauthorized production of enriched uranium

13. assisting in the investigation and recovery of missing uranium or the investigation of unauthorized enrichment

14. recordkeeping system

Review Interfaces

In addition to the MC&A Plan, the reviewer should examine information in the following other areas to ensure that it is consistent with the information in the MC&A Plan:

- physical security plan applicable to physical protection under SRP Chapter 13

12.4 Acceptance Criteria

The acceptance criteria for an applicant's MC&A program are contained in the NUREGs listed in Section 12.3 above. Specifics for each safeguards category and facility type are described below.

12.4.1 Category I Facility

12.4.1.1 Regulatory Requirements

Regulations in Subpart B, "General Reporting and Recordkeeping Requirements," and Subpart E, "Formula Quantities of Strategic Special Nuclear Material," of 10 CFR Part 74 apply to the establishment of an MC&A program for Category I facilities. The Subpart E requirements contain the specific MC&A program capabilities needed to establish an acceptable MC&A program.

12.4.1.2 Regulatory Guidance

The NRC regulatory guidance for an acceptable MC&A program applicable to Category I facilities is NUREG-1280, "Standard Format and Content Acceptance Criteria for the Material Control and Accounting (MC&A) Reform Amendment." In addition to the specific guidance in NUREG-1280, general reporting and recordkeeping guidance for all facilities is contained in:

1. NUREG/BR-0006, "Instructions for Completing Nuclear Material Transaction Reports."

2. NUREG/BR-0007, "Instructions for the Preparation and Distribution of Material Status Reports."

3. NUREG/BR-0096, "Instructions and Guidance for Completing Physical Inventory Summary Reports."

12.4.1.3 Regulatory Acceptance Criteria

Acceptance criteria are contained in NUREG-1280. This NUREG is divided into separate chapters for each of the program areas listed in Section 12.3.1 above, and commitments and acceptance criteria are listed for each program area. The applicant's MC&A program is acceptable if the license application provides data and information that meet the commitments and acceptance criteria listed in NUREG-1280 for each of the program areas.

12.4.2 Category II Facility

12.4.2.1 Regulatory Requirements

Regulations in Subpart B and Subpart D, "Special Nuclear Material of Moderate Strategic Significance," of 10 CFR Part 74 apply to the establishment of an MC&A program for Category II facilities. The Subpart D requirements contain the specific MC&A program capabilities needed to establish an acceptable MC&A program.

12.4.2.2 Regulatory Guidance

There is currently no specific guidance for Category II facilities. General reporting and recordkeeping guidance for all facilities is contained in:

1. NUREG/BR-0006

2. NUREG/BR-0007

3. NUREG/BR-0096

12.4.2.3 Regulatory Acceptance Criteria

There are currently no specific acceptance criteria for Category II facilities.

12.4.3 Category III Fuel Fabrication Facility

12.4.3.1 Regulatory Requirements

Regulations in Subpart B of 10 CFR Part 74 and in 10 CFR 74.31, "Nuclear Material Control and Accounting for Special Nuclear Material of Low Strategic Significance," apply to the establishment of an MC&A program for Category III fuel fabrication facilities. The requirements in 10 CFR 74.31 cover the specific MC&A program capabilities needed to establish an acceptable MC&A program.

12.4.3.2 Regulatory Guidance

The NRC regulatory guidance for an acceptable MC&A program applicable to Category III fuel fabrication facilities is NUREG-1065, "Acceptable Standard Format and Content for the Fundamental Nuclear Material Control (FNMC) Plan Required for Low-Enriched Uranium Facilities." In addition to the specific guidance in NUREG-1065, general reporting and recordkeeping guidance for all facilities is contained in:

1. NUREG/BR-0006

2. NUREG/BR-0007

3. NUREG/BR-0096

12.4.3.3 Regulatory Acceptance Criteria

Acceptance criteria are contained in NUREG-1065. This NUREG is divided into separate chapters for each of the program areas listed in Section 12.3.3 above, and commitments and acceptance criteria are listed for each program area. The applicant's MC&A program is acceptable if the license application provides data and information that meet the commitments and acceptance criteria listed in NUREG-1065 for each of the program areas.

12.4.4 Category III Enrichment Facility

12.4.4.1 Regulatory Requirements

Regulations in Subpart B of 10 CFR Part 74 and in 10 CFR 74.33, "Nuclear Material Control and Accounting for Uranium Enrichment Facilities Authorized to Produce Special Nuclear Material of Low Strategic Significance," apply to the establishment of an MC&A program for Category III enrichment facilities. The requirements in 10 CFR 74.33 contain the specific MC&A program capabilities needed to establish an acceptable MC&A program.

12.4.4.2 Regulatory Guidance

The NRC regulatory guidance for an acceptable MC&A program applicable to Category III enrichment facilities is NUREG/CR-5734, "Recommendations to the NRC on Acceptable Standard Format and Content for the Fundamental Nuclear Material Control (FNMC) Plan Required for Low-Enriched Uranium Enrichment Facilities." In addition to the specific guidance in NUREG/CR-5734, general reporting and recordkeeping guidance for all facilities is contained in:

1. NUREG/BR-0006.

2. NUREG/BR-0007.

3. NUREG/BR-0096.

12.4.4.3 Regulatory Acceptance Criteria

Acceptance criteria are contained in NUREG/CR-5734. This NUREG is divided into separate chapters for each of the program areas listed in Section 12.3.4 above, and commitments and acceptance criteria are listed for each program area. The applicant's MC&A program is acceptable if the license application provides data and information that meet the commitments and acceptance criteria listed in NUREG/CR-5734 for each of the program areas.

12.5 Review Procedures

12.5.1 Acceptance Review

During the acceptance review of a license application, the reviewer should examine the submittals to identify major deficiencies in the information provided for each area of review specified in SRP Section 12.3. Reviewers must decide whether they have enough information to proceed with a detailed review. Less significant errors or deficiencies that can be addressed in a request for additional information should be accepted. However, before the NRC performs a detailed review, the applicant should correct major deficiencies that would require several requests for additional information to resolve.

Reviewers should record whether each area of review is adequately addressed in the application, is adequately addressed in a referenced document, is not applicable to the application, or has a major deficiency.

12.5.2 Safeguards Evaluation

During the safeguards evaluation, the reviewer determines whether the application comprehensively describes the MC&A program areas/capabilities, as identified in SRP Section 12.3, and whether the program meets the objectives and capabilities specified in 10 CFR Part 74. For deviations from the specific acceptance criteria, the staff should review the applicant's explanation of how the proposed alternatives to the SRP criteria provide an acceptable method of complying with the relevant NRC requirements identified in Section 12.4. During the initial review, the reviewer should draft the safety evaluation report (SER) described below. A request for additional information (RAI) will be prepared when clarification and additional information are needed to determine if the licensee's submittals comply with the regulations. The primary reviewer should coordinate with the licensing project manager in preparing RAIs. Additional information submitted by the applicant will be evaluated and a final SER will be provided to the licensing project manager.

For an existing facility, the reviewer may consult NRC MC&A inspectors to identify and resolve any issues related to the licensing review. For a planned facility, the reviewer may wish to consult with the facility MC&A team to gain a better understanding of the process and its MC&A program. The reviewer should coordinate these interactions through the licensing project manager.

The reviewer will prepare a safeguards evaluation report (SER) for the licensing project manager in support of the licensing action.

12.6 Evaluation Findings

The regulations in 10 CFR 70.23, "Requirements for the Approval of Applications," and 70.66, "Additional Requirements for Approval of License Application," state that an application for a license will be approved if the Commission can make the general findings listed in those sections. The basis for the general findings is an evaluation of whether the application adequately addresses all of the applicable regulatory requirements. More specifically, the staff's evaluation should determine whether the licensing submittals provide sufficient information to satisfy the regulatory requirements listed in SRP Section 12.4, and that the applicant has appropriately addressed the regulatory acceptance criteria discussed there. The SER should state how the applicable regulatory requirements have or have not been met based on the acceptance criteria. If the applicant chooses to use an alternative approach, the reviewer should

discuss in the SER whether the proposed approach satisfies the applicable regulatory requirements. The reviewers should use the following approach to document their evaluation:

1. State a specific regulatory requirement that applies to the application. Detailed acceptance criteria may be included where appropriate or necessary..

2. Identify the areas where the regulatory requirement is addressed in the application, including the areas where the specific acceptance criteria described in this SRP are addressed.

3. Describe your evaluation of the application, the basis for your conclusion, and whether regulatory requirements are met.

4. Repeat these steps for every regulatory requirement that applies to the application.

There are three possible outcomes to the staff's licensing review: (1) approval of the applicant's application or amendment request, (2) denial of the application or request, or (3) approval with conditions. If the reviewer cannot make a finding of a reasonable assurance of safety, the reviewer may consider proposing a license condition. Absent an NRC order, license conditions must be agreed upon with the licensee or applicant before becoming part of the license. A license condition should only be proposed if there is reasonable assurance that, if the licensee meets the condition, all regulatory requirements will be satisfied. Thus, license conditions should not be used to cover major deficiencies in an application. License conditions should be unambiguous, inspectable, and enforceable. They should only require those actions necessary to ensure compliance with applicable regulations. The basis for license conditions must be documented in the SER.

The SER should include a summary statement of what the NRC staff evaluated and the basis for the reviewer's conclusions similar to the following (this is an example for a Category III facility):

> The staff has evaluated the application using the criteria listed previously. Based on the review of the license application, the NRC staff concludes that the applicant provided an acceptable FNMC plan for the proposed facility, and that the 10 CFR 70.23(a)(6) requirement for approving applications has therefore been met. The FNMC plan describes acceptable methods for achieving the performance objectives in 10 CFR 74.31(a) and the system capabilities of 10 CFR 74.31(c). As a result, the staff has determined that the applicant meets the MC&A requirements in 10 CFR Part 74. The staff therefore finds there is reasonable assurance that the MC&A program will detect and protect against the loss, theft, or diversion of SNM that the applicant will possess, store, and utilize at its facility.
>
> In accordance with 10 CFR 70.32(c), each license authorizing the use of uranium source material at a uranium enrichment facility, or authorizing the use of special nuclear material in a quantity exceeding one effective kilogram, must contain a license condition to ensure that such material is adequately controlled and accounted for within the licensed facility. The license will therefore contain the following license condition:
>
> "The licensee shall follow its FNMC plan with respect to all activities involving special nuclear material. The approved plan consists of [identify revision], or as it may be further revised pursuant to 10 CFR 70.32(c).

12.7 References

U.S. Code of Federal Regulations, "Domestic Licensing of Special Nuclear Material," Part 70, Chapter I, Title 10, "Energy."

U.S. Code of Federal Regulations, "Material Control and Accounting of Special Nuclear Material," Part 74, Chapter I, Title 10, "Energy."

U.S. Nuclear Regulatory Commission, "Instructions for Completing Nuclear Material Transaction Reports," NUREG/BR-0006.

U.S. Nuclear Regulatory Commission, "Instructions for the Preparation and Distribution of Material Status Reports," NUREG/BR-0007.

U.S. Nuclear Regulatory Commission, "Instructions and Guidance for Completing Physical Inventory Summary Reports," NUREG/BR-0096.

U.S. Nuclear Regulatory Commission, "Acceptable Standard Format and Content for the Fundamental Nuclear Material Control (FNMC) Plan Required for Low-Enriched Uranium Facilities," NUREG-1065.

U.S. Nuclear Regulatory Commission, "Standard Format and Content Acceptance Criteria for the Material Control and Accounting (MC&A) Reform Amendment," NUREG-1280.

U.S. Nuclear Regulatory Commission, "Recommendations to the NRC on Acceptable Standard Format and Content for the Fundamental Nuclear Material Control (FNMC) Plan Required for Low-Enriched Uranium Enrichment Facilities," NUREG/CR-5734.

13. PHYSICAL PROTECTION

13.1 Purpose of Review

The purpose of this review is to determine if the applicant has committed to establish and maintain a physical protection system, as required by Title 10, "Energy," of the *Code of Federal Regulations* (10 CFR) Part 73, "Physical Protection of Plants and Materials," and 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." The review should establish that the applicant's physical protection system provides reasonable assurance that its activities involving the protection of special nuclear material (SNM) are not inimical to the common defense and security and do not constitute an unreasonable risk to the public health and safety. Certain 10 CFR Part 73 requirements, such as the 10 CFR 73.20(a) general performance objectives, require "high assurance" that licensed activities involving formula quantities of strategic special nuclear material (SSNM) are not inimical to the common defense and security and do not constitute an unreasonable risk to the public health and safety.

13.2 Responsibility for Review

Primary: Physical Protection Specialist

Secondary: Licensing Project Manager

Supporting: Regional Physical Protection Inspector

The licensing project manager will receive information from the applicant and coordinate the review by the various technical disciplines involved. The physical protection specialist is responsible for reviewing all materials submitted in response to 10 CFR Part 73 requirements and determining the adequacy of the proposed physical protection system.

13.3 Areas of Review

As specified in 10 CFR 70.22, "Contents of Application," an applicant may need to submit one or more plans to demonstrate compliance with physical security requirements. The specific physical security requirements for the contents of applications for facilities regulated under 10 CFR Part 70 include the following:

- 10 CFR 70.22(g)—Physical Protection of SNM in Transit
- 10 CFR 70.22(h)—Physical Security Plan for Formula Quantities
- 10 CFR 70.22(j)—Safeguards Contingency Plan for Formula Quantities
- 10 CFR 70.22(k)—Physical Security Plan for SNM of Moderate Strategic Significance and Low Strategic Significance

Each of the requirements listed above references more detailed requirements in 10 CFR Part 11, "Criteria and Procedures for Determining Eligibility for Access to or Control over Special Nuclear Material," and 10 CFR Part 73 regarding the physical security of SNM at fixed sites and in transit. The application must contain or reference the plans which demonstrate compliance with all of the requirements that apply to the authorization being requested in the license application.

Table 13.1 Categories of Materials

Material	Isotopic Composition	**Category I** Formula Quantities	**Category II** Moderate Strategic Significance	**Category III** Low Strategic Significance
Plutonium	All plutonium (element)	2,000 grams or more	Less than 2,000 grams, but more than 500 grams	500 grams or less, but more than 15 grams
Uranium-233	All U-233 enrichments	2,000 grams or more	Less than 2,000 grams, but more than 500 grams	500 grams or less, but more than 15 grams
Uranium-235	Uranium enriched to 20% or more in isotope U-235	5,000 grams or more	Less than 5,000 grams, but more than 1,000 grams	1,000 grams or less, but more than 15 grams
	Uranium enriched to 10%, but less than 20%, in isotope U-235	N/A	10,000 grams or more	Less than 10,000 grams, but more than 1,000 grams
	Uranium enriched above 0.711%, but less than 10%, in isotope U-235	N/A	N/A	10,000 grams or more

13.3.1 Formula Quantity of Strategic Special Nuclear Material

For a Category I facility, the staff will review the applicant's physical protection plan in accordance with the applicable regulations. The applicant may choose to have one physical protection plan addressing all the applicable requirements or have separate plans for each specific area described in the regulations. When applicable, the reviewer will review the applicant's commitments regarding the following physical protection program areas:

1. Plan for Protection of Formula Quantities in Transit—The license application includes a plan addressing the detailed requirements in 10 CFR Part 73 (including those in 10 CFR 73.1, "Purpose and Scope"; 73.20, "General Performance Objective and Requirements"; 73.25, "Performance Capabilities for Physical Protection of Strategic Special Nuclear Material in Transit"; and 73.26, "Transportation Physical Protection Systems, Subsystems, Components, and Procedures"). Note that 10 CFR 73.6(d) exempts licensees from transportation security requirements if the SNM is transported by the United States Department of Energy (DOE) transport system. Most high enriched uranium is moved by the DOE system. If the application states that the DOE transport system is used, no transportation security plan is required.

2. Plan for Protection of Formula Quantities at Fixed Sites—The license application includes a plan addressing the detailed access authorization requirements in 10 CFR Part 11 (including those in 10 CFR 11.11, "General Requirements"; and 11.15, "Application for Special Nuclear Material Access Authorization") and the applicable 10 CFR Part 73 requirements (including those in 10 CFR 73.1; 73.20; 73.45, "Performance Capabilities for Fixed Site Physical Protection Systems"; and 73.46, "Fixed Site Physical Protection Systems, Subsystems, Components, and Procedures").

3. Security Training and Qualification Plan—The license application includes a plan addressing the detailed training and qualification requirements in Part 73 for security personnel (see Appendix B, "General Criteria for Security Personnel," to Part 73). Applicants often address these requirements in a separate training and qualification plan.

4. Safeguards Contingency Plan—The application must include a plan addressing how the licensee will engage and impede adversaries. Such plans are subject to the requirements in Appendix C, "Nuclear Power Plant Safeguards Contingency Plans," to Part 73, unless 10 CFR 73.55 ("Requirements for Physical Protection of Licensed Activities in Nuclear Power Reactors against Radiological Sabotage") is applicable, in which case those requirements are applicable.

Associated guidance and reference documents are listed in SRP Section 13.4.

13.3.2 Moderate Strategic or Low Strategic Special Nuclear Material

For Category II and Category III facilities, the staff will review the applicant's physical-protection plan in accordance with the applicable regulations and will review the applicant's physical protection program commitments associated with moderate strategic or low strategic SNM.

Review Interfaces

The reviewer should examine information in the following other areas to ensure that it is consistent with the information provided for physical protection:

- Coordinate with the reviewer of the Material Control and Accounting plan applicable to physical protection under SRP Chapter 12.

- Proposed quantities of SNM to be possessed, used or produced by the applicant as stated in the Part 70 application or existing license.

13.4 Acceptance Criteria

Acceptance criteria for an applicant's physical security plan are based on meeting the relevant requirements of the regulations described in this section. Separate NUREGs have been developed for each facility type.

13.4.1 Formula Quantity of Strategic Special Nuclear Material

13.4.1.1 Regulatory Requirements

Acceptance criteria are based on meeting the relevant physical protection requirements of the following regulations:

1. 10 CFR 73.1 defines the design basis threat a safeguards system must be designed to protect against.

2. 10 CFR 73.20 defines the general performance objective and requirements for fixed-site physical protection systems.

3. 10 CFR 73.45 defines the performance capabilities for fixed-site physical protection systems.

4. 10 CFR 73.46 describes the specific measures for fixed-site physical protection systems, subsystems, components, and procedures.

5. Appendices B; C; G, “Reportable Safeguards Events”; and H, “Weapons Qualification Criteria,” to Part 73 provide additional requirements applicable to applicants possessing formula quantities of SSNM.

6. 10 CFR 73.1; 73.20; 73.25; 73.26; and 73.70, “Records,” describe in detail the requirements for transportation of formula quantities of SSNM.

13.4.1.2 Regulatory Guidance

The following documents contain some of the regulatory guidance that is relevant to physical protection of formula quantities of SSNM:

1. International Atomic Energy Agency (IAEA), “The Physical Protection of Nuclear Material and Nuclear Facilities,” Information Circular 225, Rev. 5 (corrected), Vienna, Austria, June 1999.

2. U.S. Nuclear Regulatory Commission, “User's Guide to Physical Protection Documents Published by the NRC,” NUREG/BR-0252, November 1998.

3. U.S. Nuclear Regulatory Commission, “Standard Review Plan for Training and Qualifications Plans for Security Personnel at Category I Fuel Facilities,” NUREG/CR-6668, May 2000.

4. U.S. Nuclear Regulatory Commission, " Safeguards Contingency Response Standard Review Plan,” May, 2000.

5. U.S. Nuclear Regulatory Commission, “Training, Equipping, and Qualifying of Guards and Watchmen,” Regulatory Guide (RG) 5.20, September 2011.

6. U.S. Nuclear Regulatory Commission, “Perimeter Intrusion Alarm Systems,” RG 5.44, October 1997.

7. U.S. Nuclear Regulatory Commission, “Standard Format and Content of a Licensee Physical Protection Plan for Strategic Special Nuclear Material at Fixed Sites (Other than Nuclear Power Plants),” RG 5.52, Rev. 3, December 1994.

8. U.S. Nuclear Regulatory Commission, “Standard Format and Content of Safeguards Contingency Plans for Fuel Cycle Facilities (for Comment),” RG 5.55, March 1978.

9. U.S. Nuclear Regulatory Commission, “Standard Format and Content of Safeguards Contingency Plans for Transportation (for Comment),” RG 5.56, March 1978.

10. U.S. Nuclear Regulatory Commission, “Shipping and Receiving Control of Strategic Special Nuclear Material,” RG 5.57, June 1980.

11. U.S. Nuclear Regulatory Commission, “Standard Format and Content of a Licensee Physical Protection Plan for SSNM in Transit,” RG 5.60, September 2011.

13.4.1.3 Regulatory Acceptance Criteria

The primary reviewer will find the applicant's physical protection system acceptable if the applicant’s commitments are consistent with the regulations identified above and with security orders issued by the Commission. With respect to any physical-protection plan regarding formula quantities of SSNM, the primary reviewer will confirm that such a plan contains inspectable commitments.

13.4.2 Moderate Strategic or Low Strategic Special Nuclear Material

13.4.2.1 Regulatory Requirements

Acceptance criteria for possession, use, or transport of moderate strategic or low strategic SNM are based on meeting the relevant requirements of the following regulations:

1. 10 CFR 73.67(a) contains the general performance objectives that are applicable to applicants who plan to possess, use, or transport SNM of moderate or low strategic significance.

2. 10 CFR 73.67(c)(1) requires a licensee who possess, uses, trasponrts, or delivers to a carrier for transport SNM of moderate strategic significance or low strategic significance to submit a security plan addressin the applicable requirements contained in 10 CFR 73.67.

3. 10 CFR 73.67(d) and (e) contain the fixed-site and in-transit requirements applicable to SNM of moderate or low strategic significance.

4. 10 CFR 73.67(f) and (g) contain the fixed-site and in-transit requirements applicable to SNM of low strategic significance.

5. Compliance with Commission-issued orders, if applicable.

13.4.2.2 Regulatory Guidance

The following documents contain some of the regulatory guidance that is relevant to physical protection of moderate- or low-significance SSNM:

1. IAEA, “The Physical Protection of Nuclear Material and Nuclear Facilities,” Information Circular 225, Rev. 5 (corrected), Vienna, Austria, June 1999.

2. U.S. Nuclear Regulatory Commission, “User's Guide to Physical Protection Documents Published by the NRC,” NUREG/BR-0252, November 1998.

3. U.S. Nuclear Regulatory Commission, “Standard Format and Content for a Licensee Physical Security Plan for the Protection of Special Nuclear Material of Moderate or Low Strategic Significance,” RG 5.59, Rev. 1, February 1983.

13.4.2.3 Regulatory Acceptance Criteria

The reviewer will find the applicant's physical protection system acceptable if the physical protection plan meets the requirements of 10 CFR 73.67, “Licensee Fixed Site and In-Transit Requirements for the Physical Protection of Special Nuclear Material of Moderate and Low Strategic Significance,” as well as the requirements of any Commission security orders. The physical protection plan for applicants possessing moderate- or low-significance quantities of SNM should contain inspectable commitments that shall be the basis for the NRC physical-protection inspection program. Therefore, it is imperative that commitments be expressed in unambiguous terms. Specific topics required by regulation are delineated in more detail in the current version of Regulatory Guide 5.59.

13.5 Review Procedures

13.5.1 Acceptance Review

The applicant is expected to provide one or more plans to demonstrate compliance with the physical-security requirements specified in 10 CFR 70.22, “Contents of Applications.” During the acceptance review of a license application, the reviewer should examine the submittals to identify major deficiencies in the information provided for each area of review specified in SRP Section 13.3. Reviewers must decide whether they have enough information to proceed with a detailed review. Less significant errors or deficiencies that can be addressed in a single request for additional information should be accepted. However, before the NRC performs a detailed review, the applicant should correct major deficiencies that would require several requests for additional information to resolve.

Reviewers should record whether each area of review is adequately addressed in the application, is adequately addressed in a referenced document, is not applicable to the application, or has a major deficiency.

13.5.2 Safety Evaluation

During the safety evaluation, the reviewer determines whether the physical security plan (or “plans” if the applicant chose to separate them) included in the application establishes physical protection systems meeting the objectives and capabilities specified in 10 CFR 70.22, 10 CFR Part 73, and applicable security orders. The primary reviewer will perform a safety evaluation with respect to the acceptance criteria in Section 13.4. During the initial review, the reviewer should draft the safety evaluation report (SER) described below. A request for additional

information (RAI) will be prepared when clarification and additional information are needed to determine whether the licensee's submittals comply with the regulations. The primary reviewer should coordinate with the licensing project manager in preparing RAIs. Additional information submitted by the applicant will be evaluated and a final SER will be provided to the licensing project manager.

13.6 Evaluation Findings

The regulations in 10 CFR 70.23, "Requirements for the Approval of Applications," and 70.66, "Additional Requirements for Approval of License Application," state that an application for a license will be approved if the Commission can make the general findings listed in those sections. The basis for the general findings is an evaluation of whether the application adequately addresses all of the applicable regulatory requirements. More specifically, the staff's evaluation should determine whether the licensing submittals provide sufficient information to satisfy the regulatory requirements referenced in this SRP Chapter. The SER should state how the applicable regulatory requirements have or have not been met based on the acceptance criteria described in this chapter of the SRP. If the applicant chooses to use an alternative approach, the reviewer should discuss in the SER whether the proposed approach satisfies the applicable regulatory requirements. The reviewers should use the following approach to document their evaluation:

1. State a specific regulatory requirement that applies to the application. Detailed acceptance criteria may be included where appropriate or necessary.

2. Identify the areas where the regulatory requirement is addressed in the application, including the areas where the specific acceptance criteria described in this SRP are addressed.

3. Describe your evaluation of the application, the basis for your conclusion, and whether regulatory requirements are met.

4. Repeat these steps for every regulatory requirement that applies to the application.

There are three possible outcomes to the staff's licensing review: (1) approval of the applicant's application or amendment request, (2) denial of the application or request, or (3) approval with conditions. If the reviewer cannot make a finding of a reasonable assurance of safety, the reviewer may consider proposing a license condition. Absent an NRC order, license conditions must be agreed upon with the licensee or applicant before becoming part of the license. A license condition should only be proposed if there is reasonable assurance that, if the licensee meets the condition, all regulatory requirements will be satisfied. Thus, license conditions should not be used to cover major deficiencies in an application. License conditions should be unambiguous, inspectable, and enforceable. They should only require those actions necessary to ensure compliance with applicable regulations. The basis for license conditions must be documented in the SER.

If the submittal is acceptable, the final SER security input should conclude with a statement similar to the following:

> Based on the evaluation described above, the NRC staff finds that the plan(s) for physical protection of SNM provide reasonable assurance [or "high assurance" if the application pertains to formula quantities of strategic SNM] that the licensee

will provide adequate protection during the term of the license. The staff concludes that the applicant provided an acceptable physical protection plan for the proposed facility that will meet the applicable requirements specified in 10 CFR Part 73.

13.7 References

U.S. Code of Federal Regulations, “Criteria and Procedures for Determining Eligibility for Access to or Control over Special Nuclear Material,” Part 11, Chapter I, Title 10, “Energy.”

U.S. Code of Federal Regulations, “Access Authorization for Licensee Personnel,” Part 25, Chapter I, Title 10, “Energy.”

U.S. Code of Federal Regulations, “Physical Protection of Plants and Materials,” Part 73, Chapter I, Title 10, “Energy.”

U.S. Code of Federal Regulations, “Security Facility Approval and Safeguarding of National Security Information and Restricted Data,” Part 95, Chapter I, Title 10, “Energy.”

U.S. Nuclear Regulatory Commission, “Entry/Exit Control for Protected Areas, Vital Areas, and Material Access Areas,” Regulatory Guide (RG) 5.7, Rev. 1, May 1980.

U.S. Nuclear Regulatory Commission, “Perimeter Intrusion Alarm Systems,” RG 5.44, Rev. 3, October 1997.

U.S. Nuclear Regulatory Commission, “Standard Format and Content of a Licensee Physical Protection Plan for Strategic Special Nuclear Material at Fixed Sites (Other than Nuclear Power Plants),” RG 5.52, Rev. 3, December 1994.

U.S. Nuclear Regulatory Commission, "Standard Format and Content of Safeguards Contingency Plans for Fuel Cycle Facilities," RG 5.55, March 1978.

14. GLOSSARY

This glossary defines technical/industry terms that are used consistently throughout this standard review plan (SRP) or references the related definitions in either Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1003 or 10 CFR 70.4, both titled "Definitions." This glossary does not define terms that may have different connotations in different contexts; such terms are defined in the various chapters of this SRP.

Many of these definitions state that they are specifically relevant to nuclear criticality safety.

Abnormal condition	When applied to nuclear criticality safety, an event or condition not intended as a desirable or regularly occurring condition in the facility or process design, but which is anticipated as a contingency in criticality safety evaluations. A condition that is reached by exceeding the safety limit(s) of one or more controlled parameters.
Accident sequence	An unintended sequence of events that, given the failure of certain items relied on for safety identified in the sequence, would result in environmental contamination, radiation exposure, release of radioactive material, inadvertent nuclear criticality, or exposure to hazardous chemicals (provided that the chemicals are produced from licensed radioactive material). The term "accident" may be used interchangeably with "accident sequence."
Active engineered control	A physical device that uses active sensors, electrical components, or moving parts to maintain safe process conditions without any required human action.
Acute	(This term is defined in 10 CFR 70.4.)
Administrative control	Either an augmented administrative control or a simple administrative control, as defined herein. When applied to nuclear criticality safety, a human action [comprising either simple or augmented administrative controls, as defined herein], whether required or prohibited, relied on to prevent or mitigate a specific accident sequence or to maintain subcriticality, and established in formal plant procedures.
Analytical limit	(See "safety limit").

Area(s) of applicability	When applied to nuclear criticality safety, the range of physical parameters (isotopic abundance, moderation, neutron energy, absorbers, etc.) that (1) characterizes a fissile material system over which a given calculational method has been validated; (2) is covered by the chosen benchmark experiments, and (3) for which a bias has been determined.
Augmented administrative control	A procedurally required or prohibited human action, combined with a physical device that alerts the operator that the action is needed to maintain safe process conditions or that otherwise adds substantial assurance of the required human performance.
Available and reliable to perform their function when needed	(This term is defined in 10 CFR 70.4.)
Baseline design criteria	A set of criteria specifying design features and management measures that are required and acceptable under certain conditions for new processes or facilities specified in 10 CFR 70.64, "Requirements for New Facilities or New Processes at Existing Facilities." In general, these criteria are the acceptance criteria that apply to safety design for new facilities and new processes, as described in this SRP.
Benchmark	When applied to nuclear criticality safety, a critical experiment which is widely accepted and whose physical characteristics and their uncertainties have been well-characterized, so that it is suitable for validation.
Bias	The numerical difference between the calculated and experimental values of k_{eff} for a set of benchmark experiments covering a particular area of applicability (often expressed as a function of system parameters).
Concurrent	When applied to nuclear criticality safety and in the context of double contingency, two changes in process conditions are *concurrent* if the effect of the first change persists until the second change occurs. This does not mean simultaneous (where both upsets occur at the same time), but rather that the system is affected by both changes during some time interval.
Configuration management	(This term is defined in 10 CFR 70.4.)

Consequence	Any result of interest caused by an event or sequence of events. In this context, “adverse consequence” refers to adverse health or safety effects on workers, the public, or the environment. When applied to nuclear criticality safety, (1) Occurrence of an accidental criticality; (2) the energy released in an accidental criticality, normally expressed in terms of the number of fissions or dose to workers.
Contingency	In the context of double contingency, a change in process conditions or loss of a criticality control that could result in one or more parameters exceeding their safety limits.
Controlled area	(This term is defined in 10 CFR 20.1003.)
Controlled parameter	A measurable parameter that is maintained within a specified range by one or more specific controls to ensure the safety of an operation. When applied to nuclear criticality safety, is a parameter of a system that is maintained within a specified range to ensure subcriticality.
Credible abnormal condition	As used in meeting the requirements of 10 CFR 70.61(d), one of the spectrum of abnormal conditions resulting from credible single failures and related sequences of events, up to those that must be considered in the context of demonstrating compliance with the double-contingency principle (see Appendix 5-A for more information).
Critical	(1) Having an actual k_{eff} value ≥ 1; (2) Having a calculated k_{eff} value ≥ the Upper Subcritical Limit.
Critical mass	A quantity of fissionable material capable of supporting a self-sustained nuclear chain reaction; sometimes, the minimum quantity of such material given spherical geometry, optimum moderation, and full water reflection (also referred to as the *minimum critical mass*).
Critical mass of special nuclear material	(This term is defined in 10 CFR 70.4.)
Criticality control	When applied to nuclear criticality safety, a control used to ensure subcriticality.

Criticality safety evaluation	When applied to nuclear criticality safety, a structured analysis demonstrating criticality safety for a given process, including a demonstration that processes will be subcritical under normal and credible abnormal conditions, and the specification of controls and limits to achieve that goal (also often referred to as a *nuclear criticality safety evaluation*, *analysis*, *assessment*, etc.).
Degraded	When applied to nuclear criticality safety, a control, control system, or controlled parameter is considered to be *degraded* when the parameter is kept within its safety limits but its reliability and availability has been reduced in such a way that it is no longer unlikely that those limits will be exceeded.
Double-contingency principle	When applied to nuclear criticality safety , process designs should 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 characteristic or attribute of a process that has incorporated sufficient safety factors so that at least two unlikely, independent, and concurrent changes in process conditions are required before a nuclear criticality accident is possible. The condition of requiring at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.
Engineered control	(See “active engineered control” and “passive engineered control.”)
Event	(1) A change in process conditions that has the potential to adversely affect safety; (2) one of several occurrences that constitute an accident sequence.
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.
Favorable geometry	Characteristic of structures, systems, devices, or equipment such that fissile material maintained within specified dimensions will be subcritical under the most reactive credible conditions (defined for a given isotopic composition and physicochemical form).
Hazardous chemicals produced from licensed materials	(This term is defined in 10 CFR 70.4.)

Independent	In the context of double contingency, two changes in process conditions are considered *independent* if the occurrence of one does not cause, or affect the probability of occurrence of, the other, so that the probability that both occur is independent of the order in which they occur(i.e., there are no identifiable common-mode failures that can lead to criticality).
Integrated safety analysis	(This term is defined in 10 CFR 70.4.)
Integrated safety analysis summary	(This term is defined in 10 CFR 70.4.)
Isolated	Describes (1) the condition whereby the flow of matter and energy between a system and surrounding systems can be neglected for the purpose of performing a safety analysis or (2) the condition of being separated by a sufficient distance from other systems or materials that their presence has a negligible effect on the system's k_{eff}.
Items relied on for safety	This item is defined in 10 CFR 70.4
k_{eff}	The effective neutron multiplication factor of a nuclear fission reaction; that is, the average number of neutrons from each fission that cause another fission.
Lost	When applied to nuclear criticality safety, a control, control system, or controlled parameter is considered to be *lost* when the measures that keep the parameters within their safety limits cease to function as designed, or cannot be verified to function as designed, whether or not the affected parameters actually exceed their safety limits.
Management measures	(This term is defined in 10 CFR 70.4.)
Margin of safety	When applied to nuclear criticality safety, the difference between the actual value of a parameter and the value of the parameter at which the system is expected to be critical (taking bias and bias uncertainty into account).
Margin of subcriticality	(1) The difference between the actual value of k_{eff} and the value at which the system is expected to be critical (taking bias and bias uncertainty into account); (2) the difference between the calculated value of k_{eff} (including uncertainties) and the value at which the system is expected to be critical (taking bias and bias uncertainty into account), plus any margin in k_{eff} resulting from conservative modeling of system parameters.

[Approved] margin of subcriticality for safety	The minimum allowable value of the margin of subcriticality, including the minimum margin of subcriticality and any margin resulting from conservative modeling practices.
Minimum margin of subcriticality	Margin in k_{eff} beyond the bias and uncertainty in the bias, to allow for any unknown or difficult-to-quantify uncertainties in calculating k_{eff} (frequently referred to as the *arbitrary margin* or *administrative margin*).
Mitigative control	A control intended to reduce the consequences of an accident sequence, not to prevent it. When a mitigative control works as intended, the results of the sequence are called the mitigated consequences.
Natural-phenomenon events	Earthquakes, floods, tornadoes, tsunamis, hurricanes, and other events that occur in the natural environment and could adversely affect safety. Natural-phenomenon events may be credible or incredible, depending on their likelihood of occurrence.
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. Generally, this definition does not include component-level design changes or equipment replacement.
Normal condition	A condition specifically anticipated or allowed for as part of the normal operation of the facility. A condition in which all controlled parameters are within their safety limits.
Nuclear criticality safety	An approach to a facility's design, operation, and other activities that is chiefly concerned with preventing the occurrence of events involving an inadvertent and self-sustaining nuclear chain reaction.
Operating limit	A limiting value (or range of values) for a process parameter at which the plant operators normally operate the facility.
Optimum	When applied to nuclear criticality safety, the value of a parameter that produces the highest k_{eff}.
Parameter	When applied to nuclear criticality safety, a measurable or observable characteristic of a system that affects the value of k_{eff}. The parameters normally are mass, geometry, density, enrichment/isotopics, reflection, moderation, concentration, interaction, absorption, volume, heterogeneity, physicochemical form, and process variables.

Passive engineered control	A device that uses only fixed physical design features to maintain safe process conditions without any required human action.
Preventive control	A control intended to prevent an accident (i.e., any of the radiological or chemical consequences described in 10 CFR 70.61, “Performance Requirements”).
Process condition	In the context of double contingency, the set of all characteristics or attributes of a process important to safety (a change in the value of a parameter, or loss or degradation of a control affecting the ability to maintain a parameter, etc.).
Reactivity	Loosely used synonymously with k_{eff}. The adjective form *reactive* is used most frequently in the phrase *most reactive credible* to mean the physical conditions that produce the highest credible value of k_{eff}.
Safe mass	The quantity of fissile material that is safely subcritical under the most reactive credible conditions (defined for a given isotopic composition and physicochemical form), including allowance for overbatching.
Safe process conditions	The defined ranges or sets of acceptable values of one or more controlled parameters.
Safety control	A system, device, or procedure that is intended to regulate a device, process, or human activity in order to maintain a safe state. Controls may be engineered controls or administrative (procedural) controls, and they may be either preventive or mitigative, as defined herein.
Safety limit	A limit chosen to maintain the integrity of physical barriers that protect against exceeding the performance requirements of 10 CFR 70.61. When applied to nuclear criticality safety, the *safety limit* is the value of a controlled parameter established by a criticality safety evaluation to which the process will be controlled. This can be equal to the subcritical limit, but can include additional margin because of uncertainty and variability in the process (also referred to as the “analytical limit”).
Safety margin	Same as *margin of safety*.
Setpoint	A predetermined value for actuation of the final setpoint device to initiate a protective action.

Simple administrative control	A procedural human action that is prohibited or required to maintain safe process conditions.
Subcritical	Demonstrated not to be critical; having a value of k_{eff} no greater than the upper subcritical limit.
Subcritical limit	(1) The bounding value of a controlled parameter that has been demonstrated to maintain a system subcritical in plant criticality safety evaluations; (2) the upper subcritical limit.
Subcritical margin	Same as *margin of subcriticality*.
System	When applied to nuclear criticality safety, discrete part of a fissile material operation that can be separated from other systems for the purpose of conducting a safety analysis, and that is the subject of a criticality safety evaluation.
Unacceptable performance deficiencies	(This term is defined in 10 CFR 70.4.)
Upper subcritical limit	The maximum value of k_{eff} that is considered to be subcritical with an acceptable degree of confidence (taking bias and bias uncertainty into account, and including a minimum margin of subcriticality).
Validation (criticality code)	The process of quantifying the suitability of a computer code system (or other methodology) for use in nuclear criticality safety analyses.
Verification (criticality code)	The process of confirming that the computer code system correctly performs intended numerical calculations.
Worker	(This term is defined in 10 CFR 70.4.)

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11. ABSTRACT (200 words or less)
This "Standard Review Plan (SRP) for Fuel Cycle Facilities License Applications" (NUREG-1520), provides guidance to the staff reviewers in the U.S. Nuclear Regulatory Commission's (NRC's) Office of Nuclear Material Safety and Safeguards who perform safety and environmental impact reviews of applications to construct or modify and operate nuclear fuel cycle facilities. This SRP addresses the longstanding health, safety, and environmental protection requirements of Title 10, "Energy," of the Code of Federal Regulations (10 CFR) Part 20, "Standards for Protection against Radiation," and 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," as well as the accident safety requirements reflected in Subpart H, "Additional Requirements for Certain Licensees Authorized To Possess a Critical Mass of Special Nuclear Material," of 10 CFR Part 70. The SRP is intended to be a comprehensive and integrated document that provides the reviewer with guidance that describes methods or approaches that the staff has found acceptable for meeting NRC requirements. Each SRP section addresses the responsibilities of the staff reviewers, the matters that they review, the Commission's regulations pertinent to specific technical matters, the acceptance criteria used by the staff, the process and procedures used to accomplish the review, and the conclusions that are appropriate to summarize the review. This SRP is not a substitute for NRC regulations and compliance is not required. The approaches and methods in this report are provided for information only. Methods and solutions different from those described in this report will be acceptable if they provide a basis for the staff to make the determination needed to issue or continue a license.

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