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

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

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U.S. NUCLEAR REGULATORY COMMISSION
STANDARD REVIEW PLAN
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

ABSTRACT

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

The SRP addresses the long-standing health, safety, and environmental protection requirements of 10 CFR Part 70 and Part 20, as well as the amended accident safety requirements reflected in subpart H of Part 70. For example, the chapters concerning radiation safety, environmental protection, emergency management, and decommissioning contain acceptance criteria that are set primarily by regulations that have not been changed in issuing the revision to Part 70.

The new Subpart H of 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. Chapters 3 (ISA) and 11 (management measures) are the primary chapters that address the staff's review in relation to the performance requirements of Subpart H, as well as related Subpart H requirements.

(Note: This SRP focuses on safety and environmental reviews. Review criteria applicable to safeguards sections of license applications were developed earlier and are published in NUREGs 1280 and 1365.)

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EXECUTIVE SUMMARY

The *Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility* (SRP) provides U.S. Nuclear Regulatory Commission (NRC) guidance for the review and evaluation of health, safety, and environmental protection in applications for licenses to possess and use special nuclear material (SNM) to produce nuclear reactor fuel. The guidance is also applicable to the review and evaluation of proposed amendments and license renewal applications.

The principal purpose of the SRP is to ensure the quality and uniformity of staff reviews. The SRP also provides a well-defined base from which to evaluate proposed changes in the scope, level of detail, and acceptance criteria of reviews. Another important purpose of the SRP is to make information about regulatory reviews widely available and to improve communication and understanding of the staff review process. Because the SRP describes the scope, level of detail and acceptance criteria for reviewers, it serves as regulatory guidance for applicants who need to determine what information should be presented in a license application and related documents.

The SRP addresses the long-standing health, safety, and environmental protection requirements of Part 70 and 10 CFR Part 20, as well as the newer accident safety requirements reflected in Subpart H of Part 70. For example, the chapters concerning radiation safety, environmental protection, emergency management, and decommissioning contain acceptance criteria that are set primarily by regulations that have not been changed in issuing the revision to 10 CFR Part 70. (Review criteria applicable to safeguards sections of license applications were developed earlier and are published in NUREGs 1280 and 1365.)

The new Subpart H of 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. Chapters 3 (ISA) and 11 (management measures) are the primary chapters that address the staff's review in relation to the performance requirements of Subpart H, as well as related Subpart H requirements.

The requirements in Part 70 specify, in general terms, the information to be supplied in a Safety Program Description. The specific information to be submitted by an applicant and evaluated by staff is identified in this SRP. Prospective applicants should study the topic areas treated in the chapters of this document and the sections within each chapter, specifically the sections headed "Areas of Review" and "Acceptance Criteria." A license application should contain a Safety Program Description that addresses all the topics in the Table of Contents of this SRP, in the

same order as presented in this document. In addition, applicants are required to submit, in accordance with Parts 70.62 and 70.65, an ISA Summary in conjunction with the application.

In this SRP, information is provided to assist the licensing staff and the applicant in understanding the underlying objective of the regulatory requirements, the relationships among NRC requirements, the licensing process, the major guidance documents NRC staff has prepared for licensing fuel cycle facilities, and information about the staff review process set out in individual SRP sections. 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. In the case of a staff determination of inadequate description or commitments, the staff will inform the applicant of what is needed and the basis on which the determination was made.

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

The major topics addressed within the Safety Program Description of a facility license application are discussed in separate SRP chapters (general information, organization and administration, integrated safety analysis, radiation safety, nuclear criticality safety, chemical process safety, fire safety, emergency management, environmental protection, decommissioning, and management measures). Each of the chapters includes the following sections: (1) purpose of review; (2) responsibility for review; (3) areas of review; (4) acceptance criteria; (5) review procedures; (6) evaluation findings; and (7) references.

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INTRODUCTION

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

The principal purpose of the SRP is to ensure the quality and uniformity of staff reviews. The SRP also provides a well-defined base from which to evaluate proposed changes in the scope, level of detail, and acceptance criteria of reviews. Another important purpose of the SRP is to make information about regulatory reviews widely available and to improve communication and understanding of the staff review process. Because the SRP describes the scope, level of detail and acceptance criteria for reviewers, it serves as regulatory guidance for applicants who need to determine what information should be presented in a license application and related documents.

The SRP addresses the long-standing health, safety, and environmental protection requirements of Part 70 and 10 CFR Part 20, as well as the newer accident safety requirements reflected in Subpart H of Part 70. For example, the chapters concerning radiation safety, environmental protection, emergency management, and decommissioning contain acceptance criteria that are set primarily by regulations that have not been changed in issuing the revision to 10 CFR Part 70. (Review criteria applicable to safeguards sections of license applications were developed earlier and are published in NUREGs 1280 and 1365.)

The new Subpart H of 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. Chapters 3 (ISA) and 11 (management measures) are the primary chapters that address the staff's review in relation to the performance requirements of Subpart H, as well as related Subpart H requirements.

Subpart H also requires, for new facilities (that have not already been designed, built, licensed and operated), certain baseline design criteria have been specified in 10 CFR 70.64. The acceptance criteria in the SRP chapters implement the baseline design criteria in Section 70.64(a).

It is important to note that this SRP:
1) Is a guidance document;

2) Is for use during the review of license applications, license renewal applications, and amendment applications; and
3) does not prevent licensees or applicants from suggesting alternate means of demonstrating compliance.

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

An applicant submits a complete description of the safety program for the possession and use of SNM to show how compliance with the applicable requirements will be accomplished. The Safety Program Description is the principal document with which the applicant provides the information needed by staff to develop the basis for a conclusion. It must be sufficiently detailed to permit the staff to obtain reasonable assurance that the facility is designed and will be operated without undue risk to the health and safety of workers or the public. Before submitting a program description, an applicant should have analyzed the facility in sufficient detail to conclude that it is designed and can be operated safely.

The requirements in 10 CFR 70.22,10 CFR 70.23, and 10 CFR Part 70, Subpart H specify, in general terms, the information to be supplied in a Safety Program Description. This SRP supersedes and replaces draft Regulatory Guide 3.52, “Standard Format and Content for the Health and Safety Sections of License Renewal Applications for Uranium Processing and Fuel Fabrication.” The specific information to be submitted by an applicant and evaluated by staff is identified in this SRP. Prospective applicants should study the topic areas treated in the chapters of this document and the sections within each chapter, specifically the sections headed "Areas of Review" and "Acceptance Criteria." A license application should contain a Safety Program Description that addresses all the topics in the Table of Contents of this SRP, in the same order as presented in this document. The license application should be structured with chapters and chapter content as described in this SRP. Material submitted in one location in a license application may be referenced at another location, to avoid unnecessary duplication.

In addition, applicants are required to submit, in accordance with Parts 70.62 and 70.65, an ISA Summary in conjunction with the application. The ISA Summary will not be incorporated in the license or license amendment issued by the NRC.

An Appendix to this SRP provides additional guidance on filing standards for applications.

In this SRP, information is provided to assist the licensing staff and the applicant in understanding the underlying objective of the regulatory requirements, the relationships among

NRC requirements, the licensing process, the major guidance documents NRC staff has prepared for licensing fuel cycle facilities, and information about the staff review process set out in individual SRP sections. 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. In the case of a staff determination of inadequate description or commitments, the staff will inform the applicant of what is needed and the basis on which the determination was made.

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

The major topics addressed within the Safety Program Description of a facility license application are discussed in separate SRP chapters (general information, organization and administration, integrated safety analysis, radiation safety, nuclear criticality safety, chemical process safety, fire safety, emergency management, environmental protection, decommissioning, and management measures). Each of the chapters includes sections described below.

Section 1. PURPOSE OF REVIEW

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

Section 2. RESPONSIBILITY FOR REVIEW

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

Section 3. AREAS OF REVIEW

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

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

Section 4. ACCEPTANCE CRITERIA

This section contains a set of applicable NRC acceptance criteria based on regulatory requirements, and these are collectively a basis for determining the acceptability of the applicant's commitments relative to the design, programs, or functions within the scope of the particular SRP section. Technical bases consist of specific criteria such as NRC regulations, regulatory guides, NUREG reports, and industry codes and standards. The acceptance criteria present positions and approaches that are acceptable to the staff. As noted above, they are not considered the only acceptable positions or approaches, and others may be proposed by an applicant.

The NRC staff will interpret applicant commitments to follow an industry standard as a commitment to adhere to all “shall” statements in the standard. Suggestions and recommendations in the standards (so called “should” statements) will not be considered by the staff as binding commitments by the applicant, unless the applicant specifically states an intent to treat the “should” statements as binding commitments (i.e., treat as if they are “shall” statements). The applicant may make such commitments as part of the description of the safety basis for operations. 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 (RAI) on specific licensing actions. Applicants should note, however, that some industry or consensus standards specifically direct users to provide justifications for not abiding by recommendations contained in the standards. For example, ANS 8.1 on nuclear criticality safety, 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 to not abide by recommendations contained in the standards.

The SRP presents acceptance criteria for each technical function area (e.g., nuclear criticality safety, fire safety, radiation safety), and for the management measures (e.g., configuration management, maintenance, audits, and assessments), that an applicant uses to provide a level of protection commensurate with the accident risk inherent in the process activities proposed. For example, at process stations (or for an entire process or sub-process) for which the inherent risk to workers, the public, or the environment is demonstrably small, the applicant needs to provide only those design and operating controls that assure that small risk. The key

element in the staff's evaluation is the applicant's adequate demonstration of acceptable control of risk, which then supports a competent and informed review by NRC staff.

Section 5. REVIEW PROCEDURES

This section describes how the review will be performed. It generally describes procedures that the reviewer should follow to achieve an acceptable scope and depth of review and to obtain reasonable assurance that the applicant has provided appropriate commitments to ensure that it will operate the facility safely. This 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.

Section 6. EVALUATION FINDINGS

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

Staff reviews culminate in SERs that may recommend the inclusion, in the NRC issued license, of license conditions that resolve any issues not previously resolved by an applicant's commitments. Such conditions are discussed with an applicant before issuing the license (or license amendment). The license conditions become commitments to performance in addition to those commitments presented by the applicant in the license application.

Section 7. REFERENCES

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

ACRONYMS AND ABBREVIATIONS

AEGL	Acute Exposure Guideline Level
ALARA	As Low As Is Reasonably Achievable
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
BDC	Baseline Design Criteria
CAM	Continuous Air Monitor
CFR	U. S. Code of Federal Regulations
CM	Configuration Management
EA	Environmental Assessment
EIS	Environmental Impact Statement
ERPG	Emergency Response Planning Guidelines
FHA	Fire Hazards Analysis
FONSI	Finding of No Significant Impact
HS&E	Health, Safety, and Environment
IROFS	Item(s) Relied On For Safety
ISA	Integrated Safety Analysis
ISO	International Organization for Standardization
LIB	Licensing and International Safeguards Branch
MOU	Memorandum of Understanding
NCS	Nuclear Criticality Safety
NEPA	National Environmental Policy Act
NFPA	National Fire Protection Association
NRC	U. S. Nuclear Regulatory Commission
OSHA	Occupational Safety and Health Administration

PM	Preventive Maintenance
RWP	Radiation Work Permits
SECY	Office of the Secretary of the Commission
SER	Safety Evaluation Report
SNM	Special Nuclear Material
SRP	Standard Review Plan
TWA	Time-Weighted Average
QA	Quality Assurance

GLOSSARY

The following terms are defined here by the staff for the purposes of this SRP. Terms that are used in the SRP that are identical to terms listed in 10 CFR 70.4 are not defined again here, but are referenced to 10 CFR 70.4 or other regulations. Terms listed in this glossary represent the definition of the word in any chapter of this SRP. Words for which the definitions change between chapters are listed in the individual chapters.

Active engineered control	A physical device that uses active sensors, electrical components, or moving parts to maintain safe process conditions and requires no human action.
Accident sequence	An unintended sequence of events that, given the failure of certain IROFS identified in the sequence, would result in environmental contamination, a radiation exposure, a release of radioactive material, an inadvertent nuclear criticality, or an exposure to hazardous chemicals, provided the chemicals are produced from licensed radioactive material. The term "accident" may be used interchangeably with accident sequence. The accident sequences of interest in this SRP are those that would result in consequences equaling or exceeding the performance requirements of 10 CFR 70.61.
Acute	This term is defined in 10 CFR 70.4.
Administrative control	Either an augmented-administrative control or a simple-administrative control.
Augmented administrative control	A 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 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. These criteria are, in general, the acceptance criteria applicable to safety design for new facilities and new processes, described in the chapters of this SRP.
Configuration management (CM)	This term is defined in 10 CFR 70.4.
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.
Consequence	Any result of interest caused by an event or sequence of events. In this context, adverse consequence refers to the adverse health or safety effects on workers or the public, and to the adverse environmental impacts of accidents.
Critical mass of special nuclear material (SNM)	This term is defined in 10 CFR 70.4.
Double contingency protection	A characteristic or attribute of a process that has incorporated sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a nuclear criticality accident is possible.
Engineered control	Either an active engineered control or a passive engineered control
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.
Hazardous chemicals produced from licensed materials	This term is defined in 10 CFR 70.4.
Integrated safety analysis (ISA)	This term is defined in 10 CFR 70.4.
Integrated safety analysis summary	This term is defined in 10 CFR 70.4.
Items relied on for safety (IROFS)	This item is defined in 10 CFR 70.4. All safety controls, as defined in this SRP, are IROFS.
Management measures	This term is defined in 10 CFR 70.4.
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 phenomena event	Earthquakes, floods, tornadoes, tsunamis, hurricanes, and other events that occur in the natural environment and could adversely affect safety. Natural phenomena events, depending on their likelihood of occurrence, may be credible or incredible.
New processes at existing facilities	Systems-level or facility-level design changes to process equipment, process technology, facility layout, or types of licensed material possessed or used. This definition does not, generally, include component-level design changes or equipment replacement.
Passive engineered control	A device that uses only fixed physical design features to maintain safe process conditions, and requires no human action.
Preventive control	A control intended to prevent an accident (i.e., to prevent any of the radiological or chemical consequences described in 10 CFR 70.61).
Safety control	A system, device, or procedure intended to regulate a device, process, or human activity, so as to maintain a safe state. Controls may be engineered controls or administrative (procedural) controls. Controls may be preventive or mitigative.
Safe process conditions	The defined ranges or sets of acceptable values of one or more controlled parameters.
Simple administrative control	A human action that is prohibited or required to maintain safe process conditions.
Unacceptable performance deficiencies	This term is defined in 10 CFR 70.4.
Worker	This term is defined in 10 CFR 70.4.

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1.0 GENERAL INFORMATION

1.1 FACILITY AND PROCESS DESCRIPTION

1.1.1 PURPOSE OF REVIEW

The purpose of this review is to establish that an application for a new, renewed, or amended license includes an overview of the facility layout and a summary description of its manufacturing processes. This overview will be used by all reviewers, NRC managers, and the general public to understand the purpose of the facility and to obtain an overview of the design of its processes. A more detailed description of the facility and its manufacturing processes is contained in the ISA Summary.

1.1.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: None

Supporting: None

1.1.3 AREAS OF REVIEW

The staff should review the general facility description and process descriptions provided by the applicant, which should include (1) scaled drawings showing the locations of facility buildings and other major structures, hazardous materials storage areas, on-site roadways, railroad spurs or sidings, and major ingress and egress routes for the site, (2) a text index with titles that are descriptive of the purpose of each feature, (3) the interrelationships of the features, (4) the relationship of facility features to site features, (5) a narrative description of the flow of licensed material through the facility's manufacturing processes, and (6) the proximity of facility buildings to the site boundary and nearby populations. This information should be consistent with that presented in the Environmental Protection and Emergency Management chapters of this SRP.

1.1.4 ACCEPTANCE CRITERIA

1.1.4.1 Regulatory Requirements

The regulation applicable to the areas of review in this SRP is 10 CFR 70.22, "Contents of Applications", and section 70.65(b)(1), (2), and (3), "Additional content of applications."

1.1.4.2 Regulatory Guidance

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

1.1.4.3 Acceptance Criteria

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

1. The application presents information at a level of detail appropriate for general familiarization and understanding of the proposed facility and processes. This information may be less detailed than that presented in the ISA Summary.

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

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

4. The application presents a summary identification of the raw materials, by-products, wastes, and finished products of the facility. This information should include data regarding expected levels of trace impurities or contaminants, particularly fission products or transuranic elements, characterized by identity and concentration. The proposed possession at the facility of any moderator or reflector with special characteristics, such as beryllium or graphite, is identified.

1.1.5 REVIEW PROCEDURES

1.1.5.1 Acceptance Review

The staff review starts with a determination by the primary reviewer that the topics discussed in Section 1.1.3, "Areas of Review," have been included in the application.

If significant deficiencies are identified in the application, the applicant should be requested to submit additional material before the start of the safety evaluation. With the complete submittal available, the reviewer should examine the facility and process descriptions and determine their acceptability by comparison with the acceptance criteria in section 1.1.4.3 and consistency with information in the ISA summary.

1.1.5.2 Safety Evaluation

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

1.1.6 EVALUATION FINDINGS

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

The staff has reviewed the general facility description for [name of facility] according to the Standard Review Plan Section 1.1. The applicant has adequately described (1) the facility and processes so that the staff has an overall understanding of the relationships of the facility features and (2) the function of each feature. The applicant has cross-referenced its general description with the more detailed descriptions elsewhere in the application. The staff concludes that the applicant has complied with the general requirements of 10 CFR 70.22, "Contents of Applications", §70.60, “Applicability”, and with §70.65(b)(1), (2), and (3), “Additional content of applications”, as applicable to this section.

1.1.7 REFERENCES

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

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1.2 INSTITUTIONAL INFORMATION

1.2.1 PURPOSE OF REVIEW

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

1.2.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: None

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

1.2.3 AREAS OF REVIEW

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

1.2.4 ACCEPTANCE CRITERIA

1.2.4.1 Regulatory Requirements

The regulations applicable to the areas of review in this SRP are 10 CFR 70.22, "Contents of applications", §70.65(b)(1), (2), and (3), "Additional Contents of Applications," 10 CFR 70.33, "Renewal of Licenses," and 10 CFR 95, "Security Facility Approval and Safeguarding of National Security Information and Restricted Data."

1.2.4.2 Regulatory Guidance

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

1.2.4.3 Regulatory Acceptance Criteria

The application is acceptable if the following criteria are met:

1. Corporate Identity

   The applicant has furnished its full name and address. The address of the fuel cycle facility is provided if it is different from that of the applicant. If the application is for renewal, the applicant identifies the number of the license to be renewed. A full description of the plant site location (State, county, and municipality) is given. The State where the applicant is incorporated or organized and the location of the principal office are indicated. If the applicant is a corporation or other entity, the names and citizenship of its principal officers are provided. The application shall include 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.

2. Financial Qualifications

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

3. Type, Quantity, and Form of Licensed Material

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

4. Authorized Uses

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

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

5. Special Exemptions or Special Authorizations

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

6. Security of Classified Information

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

1.2.5 REVIEW PROCEDURES

1.2.5.1 Acceptance Review

The staff review starts with a determination by the primary reviewer that the is complete and addresses each issue in Subsection 1.2.3, "Areas of Review."

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

1.2.5.2 Safety Evaluation

The material to be reviewed is for the most part informational in nature, and detailed technical analysis is generally not required beyond the acceptance criterion. The reviewer requests review assistance, as needed, from the Division of Security and the Office of the General Counsel in the review of corporate and financial information.

1.2.6 EVALUATION FINDINGS

If the information provided is consistent with the guidance of this SRP, the staff will conclude that this evaluation is complete. The staff can document its review as follows:

The staff has reviewed the institutional information for [name of facility] according to Standard Review Plan Section 1.2. Based on the review, the NRC staff has determined that the applicant has adequately described and documented the corporate structure and financial information, and that the applicant is in compliance with those parts of 10 CFR 70.22 and 70.65 relating to other institutional information. In addition, in accordance with 70.22(a)(2) and (4), the applicant has adequately described the types, forms, quantities, and proposed authorized uses of licensed materials to be permitted at this facility as follows:

Material	Form	Quantity	Authorized Use(s)

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

1.2.7 REFERENCES

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

1.3 SITE DESCRIPTION

1.3.1 PURPOSE OF REVIEW

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

1.3.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

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

Supporting: Fuel Facility Inspection staff

1.3.3 AREAS OF REVIEW

The information presented by the applicant in this section is summarized from the information presented in more detail in the applicant's Environmental Report, Emergency Plan, and ISA Summary. The information NRC staff will review include the following (as appropriate for the facility being reviewed):

1. Site Geography

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

2. Demographics

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

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

3. Meteorology

a. Primary wind directions and average wind speeds.
b. Annual amount and forms of precipitation. The design basis values for accident analysis of maximum snow or ice load, probable maximum precipitation.
c. Type, frequency, and magnitude of severe weather (e.g., lightning, tornado, hurricane). Design basis event 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; potentiometric surface map.
c. Groundwater flow direction and velocity for the site.
d. Characteristics of the uppermost aquifer.
e. Design basis flood events used for accident analysis.

5. Geology

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

1.3.4 ACCEPTANCE CRITERIA

1.3.4.1 Regulatory Requirements

Regulations applicable to the areas of review in this SRP are 10 CFR 70.22, “contents of Applications.”

1.3.4.2 Regulatory Guidance

There are no regulatory guides that apply to site descriptions for a fuel cycle facility.

1.3.4.3 Regulatory Acceptance Criteria

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

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

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

3. Appropriate meteorologic data. Applicant's presentation or discussion includes a summary of design basis values for accident analysis of maximum snow or ice load, and probable maximum precipitation, as developed by 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. A summary description of the hydrology, and geology, including seismicity, for the area. Applicant cites the design basis flood event for which the plant may be safely shut down. The applicant describes the design basis earthquake magnitude, peak ground acceleration, and return period applied at an existing site. The applicant also describes the consequences of an earthquake acceleration having a likelihood of 10^{-3}/yr (see Chapter 3, ISA, Section 3.4.3.2, Item 1(c)).

Applicant's descriptions are consistent with the more detailed information presented within the ISA Summary, the Environmental Report, and the Emergency Plan, if applicable.

1.3.5 REVIEW PROCEDURES

1.3.5.1 Acceptance Review

The staff will initially determine that the application is complete and addresses all topics discussed in Section 1.3.3, "Areas of Review." The information in this section provides a general summary of the bases reported in the ISA Summary and is consistent with the applicant's environmental report and emergency plan. The applicant may include references to the more detailed data used to complete evaluations in the ISA Summary.

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

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

1.3.5.2 Safety Evaluation

The material described in this section of the SRP is informational, summarizing that contained in the ISA summary, Environmental Report, Emergency Plan and other documents referenced by the applicant. No technical analysis is required, as the primary reference for the information is the ISA Summary. This section may also need to be updated by the applicant based upon any information changes made in response to the staff's environmental, emergency management, and ISA Summary reviews.

1.3.6 EVALUATION FINDINGS

If sufficient information has been provided in the license application and is consistent with the guidance in this SRP, the staff concludes that this evaluation is complete and the applicant's site description is acceptable. The staff can document its review as follows:

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

1.3.7 REFERENCES

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

U.S. NUCLEAR REGULATORY COMMISSION
STANDARD REVIEW PLAN
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

2.0 ORGANIZATION AND ADMINISTRATION

2.1 PURPOSE OF REVIEW

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

2.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: None

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

2.3 AREAS OF REVIEW

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

For new applicants, or already licensed plants undergoing major modifications, the applicant should explain how the facility design and construction will be managed, to provide assurance that the applicant will have in place comprehensive management policies and procedures to closely monitor the engineering and construction work to ensure that all HS&E functions and standards are met.

The application should address how the management policies ensure the establishment and maintenance of design and operations. The administrative policies and management policies should describe the relationships among major plant safety functions such as the ISA, 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 for education, training, and experience for key management positions. Management positions for which such criteria should be described include the plant manager, operations manager, shift supervisor, and managers for various safety and environmental disciplines. 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 experience managing the operations of a nuclear fuel manufacturing facility."

2.4 ACCEPTANCE CRITERIA

2.4.1 Regulatory Requirements

A management system and administrative procedures for the effective implementation of HS&E functions is required by 10 CFR Part 70.22, 70.23, and 70.62(d) concerning the applicant's corporate organization, qualifications of the staff, and the adequacy of the proposed equipment, facilities, and procedures to provide adequate safety for workers, the public, and the environment.

2.4.2 Regulatory Guidance

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

2.4.3 Regulatory Acceptance Criteria

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

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

1. The applicant has identified and functionally described the specific organizational groups responsible for managing the design, construction and operation of the facility. Organizational charts are included in the application.

2. Clear, unambiguous management control and communications exist among the organizational units responsible for managing the design and construction of the facility.

3. The personnel responsible for managing the design, construction, and operation of the facility have substantive breadth and level of experience and are appropriately available. The qualifications, responsibilities, and authorities for key supervisory and management positions with HS&E responsibilities are clearly defined in position descriptions that are accessible to all affected personnel and to the NRC, upon request.

4. The applicant has described specific plans to commission the facility's startup and operation, including the transition from the startup phase to operations under the direct supervision of applicant's personnel responsible for safe operations.

Existing Facilities:

1. Applicant has identified and functionally described the specific organizational groups responsible for operating the facility, and for managing the development of design changes to the facility. Organizational charts should be included.

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. 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 must in that case approve restart of shutdown operations.

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 are investigated, assessed, and resolved promptly.

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

8. The applicant has committed to establish formal management measures required to ensure the availability and reliability of IROFS. Management measures are detailed in the SRP Chapter 11.

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

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

2.5 REVIEW PROCEDURES

2.5.1 Acceptance Review

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

2.5.2 Safety Evaluation

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, are clear with respect to assignments of primary responsibility. The primary reviewer consults with the NRC inspection staff to verify that the applicant's management positions are adequately defined in terms of both numbers of persons and their responsibilities, authorities, and required qualifications. The reviewer may visit the site, if considered necessary, to discuss and verify implementation of the acceptance criteria with plant management.

The supporting staff reviewers determine, on the basis of the foregoing, the overall acceptability of the applicant's management system, management qualifications, organizational structure, and administrative procedures. The reviewers should make a determination whether the acceptance criteria of Section 2.4 are satisfied and then prepare an SER in accordance with Section 2.6.

2.6 EVALUATION FINDINGS

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

The staff can document the evaluation as follows:

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

[For new facilities] The applicant has described (1) clear responsibilities and associated resources for the design and construction of the facility and (2) its plans for management of the project. [Insert a summary statement of what was evaluated and why the reviewer finds the

submittal acceptable.] The staff has reviewed these plans and commitments and concludes that they provide reasonable assurance that an acceptable organization, administrative policies, and sufficient competent resources have been established or are committed, to satisfy the applicant's commitments for the design and construction of the facility.

[For operating and new facilities] The applicant has described its organization and management policies for providing adequate safety management and management measures for the safe operation of the facility. [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] The staff has reviewed this information and concludes that the applicant has an acceptable organization, administrative policies, and sufficient competent 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, Title 10, Part 70, *Domestic Licensing of Special Nuclear Material,* U.S. Government Printing Office, Washington, DC.

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

3.0 INTEGRATED SAFETY ANALYSIS (ISA)

3.1 PURPOSE OF REVIEW

This chapter provides guidance for staff review of two types of information submitted by licensees or applicants:

1) Descriptions of ISA programmatic commitments or the ISA approach in a plan submitted in accordance with 10 CFR 70.62(c)(3)(i); and

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

In the case of license applications (either initial or for renewal), both types of information would be submitted. In the case of a license amendment, either or both types of information may be submitted, as needed to address the areas amended. In the case of existing licensees, 10 CFR 70.62(c)(3)(i) requires a description of the ISA approach in a plan submitted 6 months after the rule is effective. A reasonable ISA approach requires essentially the same ISA programmatic elements as a license application. Thus, a plan with an ISA approach meeting the acceptance criteria for ISA Programmatic Commitments below would be acceptable for compliance with section 70.62(c)(3)(i). The ISA Summary documenting completion of an ISA would be submitted later, in accordance with the approach and schedule in the plan.

ISA Programmatic Commitments

The purpose for the review of the ISA programmatic commitments of a license application, renewal, amendment, or ISA plan submittal is to determine that the applicant will establish and commits to an ISA organization and procedures adequate to accomplish the ISA requirements of Sec. 70.61, 70.62(c)(1) and (2), 70.64 for new facilities, and 70.72 for changes requiring ISA.

ISA Results and Summary

All the information items needed to perform, or produced from, an ISA are referred to here as "ISA results." The ISA Summary is the principal document summarizing these results that is submitted to the NRC. The purpose of the review of the ISA Summary is to establish reasonable assurance that the applicant has:

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

2. Identified and evaluated in the ISA all credible events (accident sequences) involving process deviations or other events internal to the plant (e.g., explosions, spills, and fires); and credible external events that could result in consequences to the public, worker, or the environment, of the types specified in 10 CFR 70.61. External events normally include, as a minimum:
   1) natural phenomena events such as floods, high winds, tornados, and earthquakes;
   2) fires external to the facility;
   3) transportation accidents and accidents at nearby industrial facilities.

3. Designated engineered and administrative items relied on for safety (IROFS), and correctly evaluated the set of IROFS addressing each accident sequence, as providing reasonable assurance, through preventive or mitigative IROFS and the associated management measures, that the safety performance requirements of 10 CFR 70.61 are met.

3.2 RESPONSIBILITY FOR REVIEW

Primary: Assigned staff licensing reviewer

Secondary: Technical specialists in specific areas, and Project Manager

Supporting: Fuel Facility Inspection Staff

3.3 AREAS OF REVIEW

Information about the licensee's ISA is contained in the license application, the ISA Summary, and other ISA documentation. The application and the ISA Summary are submitted to the NRC, whereas additional documentation of the ISA is available for NRC review at the facility site. The term "results of the ISA" includes all the ISA information that is submitted to the NRC plus any additional supporting information that is maintained at the site.

When a license application, renewal, amendment, or ISA plan is submitted, the NRC staff reviews the description of the applicant's ISA program and commitments. The ISA program, as referred to in this SRP, consists of: 1) the process safety information, 2) the methods used by the licensee to perform the ISA, 3) the qualifications of the team performing the ISA, 4) the methods of documenting and implementing the results of the ISA, and 5) the procedure to maintain the ISA current when changes are made to the facility. Based on the review, the staff evaluates the acceptability of the applicant's ISA program descriptions and commitments, as contained in the application, for meeting the requirements of the regulations relating to the ISA.

When an ISA Summary is submitted, the NRC staff reviews the results of the ISA, primarily as described in the ISA Summary. Review of selected additional information or review of information at the applicant's site will, in general, be necessary to attain reasonable understanding of the results and ISA Summary. The staff then evaluates whether, based on the information reviewed, there is reasonable assurance that the applicant's equipment and procedures will comply with the regulations, especially the performance requirements of 10 CFR 70.61.

3.3.1 ISA Programmatic Commitments

The staff reviews the application to determine whether the applicant's commitments to perform and maintain an ISA are adequate. In the following, the phrases, "process node" or "process", are used to refer 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 an ISA program are as follows:

1. 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, "Configuration Management").

2. The applicant's description of, and commitments to, requirements for ISA team training and qualifications (Section 11.4, "Training and Qualification").

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

   a. Hazard identification.

   b. Process hazard analysis (accident identification).

   c. Accident sequence construction and evaluation.

   d. Consequence determination and comparability to 10 CFR 70.61.

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

4. The applicant's description of, and commitments to, management procedures for conducting and maintaining the ISA. Specific review areas include the applicant's procedures for:
   (1) performance of, and updates to, the ISA;
   (2) review responsibility;
   (3) ISA documentation;
   (4) reporting of ISA Summary changes per 10 CFR 70.72(d)(1) and (3), and
   (5) maintenance of ISA records per 70.62(a)(2).

5. For existing licensees, the ISA plan describing the approach, the processes covered, the schedule for completing the ISA for each process within the time allowed by the rule, and the approach and schedule for implementing any resulting modifications. The ISAapproach is expected to include a description of those elements of the applicant's ISA organization, procedures, methods, and criteria needed to complete an ISA conforming to the rule.

3.3.2 ISA Results

The staff reviews the ISA results (primarily the ISA Summary, but may include other ISA documentation) to find reasonable assurance that the applicant has performed a systematic evaluation of the hazards and credible accident sequences; and has identified IROFS and management measures that satisfy the performance requirements of 10 CFR 70.61. The review boundary includes those 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. In addition, the staff reviews accidents involving hazardous chemicals produced from license materials. That is, 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. On the other hand, event sequences having unmitigated consequences less than those identified in 10 CFR 70.61(c), once identified as such, do not require further consideration within the ISA.

The areas of review are as follows:

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

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

3. PROCESSES: The description in the ISA Summary of each process 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. It is expected that, for certain processes, additional information or a visit to the facility will be necessary to permit staff to understand the process adequately. Reviewer visits to the facility do not obviate the need for accurate, current drawings and process descriptions that are needed to evaluate facility safety.

4. TEAM QUALIFICATIONS: The applicant's ISA Team qualifications and ISA methods as described in the ISA Summary.

5. ISA METHODS: The description of ISA methods in the ISA Summary. Additional information concerning methods provided in the application. Documentation of specific examples of the application of methods may be requested or reviewed on site to confirm understanding of specific methods.

6. CHEMICAL CONSEQUENCE STANDARDS: The applicant's quantitative standards for the chemical consequences levels specified in 10 CFR 70.61, as described in the ISA Summary.

7. LIKELIHOOD DEFINITIONS: The applicant's definitions of unlikely, highly unlikely, and credible used in §70.61 as described in the ISA Summary.

8. COMPLIANCE WITH 10 CFR 70.61: The information resulting from the ISA that demonstrates compliance with the performance criteria of 10 CFR 70.61. In addition to the information specifically required as noted in items 9 through 11 below, this information includes for each applicable process:

    a) The consequences evaluated for each postulated accident sequence; and comparison to the consequence levels identified in 10 CFR Part 70.61. Information, such as inventory, release path factors, supporting the results of the consequence evaluation.

    b) Information showing how each accident sequence has been assessed to have the likelihood required by 10 CFR 70.61.

    c) Information describing how each accident sequence, for each process, is protected sufficiently by the IROFS listed in the ISA Summary to comply with 10 CFR 70.61.

9. PROCESS HAZARDS: Information in the ISA Summary listing hazards and interactions for each process.

10. ACCIDENT SEQUENCES: Information provided in the ISA Summary that describes all accident sequences.

11. LIST OF IROFS: The list, in the ISA Summary, describing the IROFS for all accidents in each process sufficiently to understand their safety function in meeting the appropriate consequence and likelihood requirements of 10 CFR 70.61.

12. LIST OF SOLE IROFS: The list, in the ISA Summary, identifying those IROFS which are the sole item relied on in an accident sequence to assure compliance with 10 CFR 70.61.

13. CRITICALITY MONITORING: The information in the ISA Summary demonstrating compliance with the criticality monitoring requirements of 10 CFR 70.24.

14. NEW FACILITIES: The information in the ISA Summary demonstrating compliance with baseline design criteria required by 70.64(a)(1) through (5) and (7) through (10) for new facilities, or new processes at existing facilities, and required to be submitted in accordance

with 10 CFR 70.65(b)(4). Since these elements all bear on the adequacy of IROFS, it is efficient to include their review in the ISA Summary review.

It is expected that, in addition to reviewing the application and ISA Summary, the NRC staff will select subsets of certain areas for which additional information will be reviewed, in some cases at the site. The method for selecting specific processes or accidents for additional review is described in Section 3.5 of this chapter, Review Procedures.

3.4 ACCEPTANCE CRITERIA

3.4.1 Regulatory Requirements

The requirement to perform an Integrated Safety Analysis (ISA) is specified in 10 CFR 70.62. 10 CFR 70.62(c) specifies requirements for the tasks comprising the ISA and the evaluation that credible high-consequence and intermediate-consequence events meet the safety performance requirements of 70.61. 10 CFR 70.72 states requirements for keeping the ISA and its documentation current when changes are made to systems, structures, and components. 10 CFR 70.65(b) describes the contents of an ISA Summary.

3.4.2 Regulatory Guidance

Guidance applicable to performing an ISA and documenting the results is contained in NUREG-1513, "Integrated Safety Analysis Guidance Document." NUREG/CR-6410, “Nuclear Fuel Cycle Accident Analysis Handbook”, March 1998, provides guidance on acceptable methods for evaluating the chemical and radiological consequences of potential accidents.

3.4.3 Regulatory Acceptance Criteria

The acceptance criteria for an ISA are based on meeting the relevant requirements in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." The ISA will form the basis for the safety program by identifying potential accidents, designating IROFS and management measures, and evaluating the likelihood and consequences of each accident sequence for compliance with 10 CFR 70.61. Some of the acceptance criteria address the programmatic commitments made by the licensee 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 assure that the relevant accident sequences will meet the performance requirements of 10 CFR 70.61.

3.4.3.1 ISA Programmatic Commitments

10 CFR Part 70 contains a number of specific safety program requirements related to the ISA. Acceptance criteria for requirements addressed by contents of the ISA Summary appear in SRP section 3.4.3.2. These include the primary requirements that an ISA be conducted, and that it evaluate and show that the applicant’s facility complies with the performance requirements of 10 CFR 70.61. Acceptance criteria for the other ISA requirements are provided in this section (3.4.3.1) of the SRP. For each required program function there may be several

elements necessary to carry it out effectively. These elements may include: organization, assignment of responsibilities, management policies, required activities, written procedures for activities, use of industry consensus standards, and technical safety practices. The applicant's commitment to each ISA requirement of the rule is acceptable if it:

a) describes each necessary ISA program element sufficiently for the reviewer to understand how well it supports the safety program function;

b) commits to each ISA program element as described, and to maintaining written procedures on site for carrying out that function, if necessary; and

c) there is reasonable assurance that the elements, as described, would be effective in accomplishing the ISA program function.

Commitment statements in the application, to be acceptable, should be declarative sentences with main verbs such as: shall, will, is, or must. Sentences with phrases expressing optional alternatives or recommendations, such as: "should, may, will be considered, or as appropriate", may be acceptable if there are supporting statements giving the criteria for selecting the option. However, it may be acceptable for some safety elements of lesser importance not to be stated as commitments.

In citing industry consensus standards, the applicant should be clear as to whether there is a commitment to follow all recommendations ("should statements") in the standard, when applicable. If not, since the standard, by consensus, recommended these practices, the applicant should provide justifications for not committing to them.

The staff will find the commitments in the application to ISA requirements acceptable, if the following criteria are met:

1. The applicant commits to compiling and maintaining up-to-date a 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 shall include information pertaining to:

a. The hazards of all materials used or produced in the process. 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 10 CFR 1910.1200(g)] should be provided.

b. Technology of the process. Information on the process technology 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, concentration); and evaluation of the health and safety consequences of process deviations.

c. Equipment used in the process. Information of a general nature on topics such as the materials of construction; piping and instrumentation (PI&Ds); ventilation; design codes and standards employed; material and energy balances; safety systems (e.g. interlocks,

detection or suppression systems); electrical classification; and relief system design and design basis should be provided.

2. The applicant commits to keeping the ISA and ISA Summary accurate and up-to-date by means of a suitable configuration management system. The ISA must account for any changes made to the facility or its processes (e.g. changes to the site, operating procedures, control systems). Management policies, organizational responsibilities, revision time frame 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 methodology. The applicant commits to using an ISA Team for any revisions to the ISA with member qualifications similar to those used in conducting the original ISA. The applicant commits to review of any facility changes that may increase the level of risk and, if dictated by revision of the ISA, to select and implement new or additional IROFS and appropriate management measures. The applicant commits to submitting to the NRC revisions of the ISA Summary within the time frame specified in 10 CFR 70.72(d)(1).

3. The applicant commits to promptly address any safety-significant vulnerabilities or unacceptable performance deficiencies identified in the ISA. The applicant commits to taking prompt and appropriate actions to address any vulnerabilities that are identified in an update of the ISA. If a proposed change results in a new type of accident sequence (e.g. different initiating event, significant changes in the consequences) or increases the risk 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.

4. The applicant includes procedures and criteria for changing the ISA, along with its 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, and procedures and responsibilities for updating the facility ISA.

5. The applicant commits to engage personnel with appropriate experience and expertise in engineering and process operations to update and maintain the ISA. The ISA team for a process shall consist of individuals knowledgeable in the facility's ISA methodology and in the operation and hazards of the particular process.

6. 10 CFR 70.62(c) requires that an ISA of appropriate complexity be conducted for each process; and that it accomplish six results. 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-6410, item 5 of SRP section 3.4.3.2, and Appendix A of this chapter. Sufficient features, criteria, equations, and data must be provided so that the staff can evaluate how the Integrated Safety Analyses of particular processes show that the performance requirements of 10 CFR 70.61 can be met.

7. The applicant commits to implement all IROFS (if not already implemented) and to maintain them so that they are available and reliable when needed. Management measures (which are

evaluated using SRP Chapter 11) comprise the principal mechanism by which the reliability and availability of IROFS is assured.

8. For an ISA plan submitted per 10 CFR 70.62(c)(3)(i), the applicant commits to a schedule for performing an ISA for each process, and completing any needed modifications, that is consistent with the requirements of 10 CFR 70.

3.4.3.2 ISA Results including ISA Summary

The preceding section addressed commitments to ISA requirements of the safety program. This section addresses whether the results of carrying out that program, i.e., the ISA methods and results, demonstrate compliance with the performance criteria of 10 CFR 70.61. Information in the ISA Summary should provide the primary basis for drawing a conclusion that staff is reasonably assured that the identified IROFS will satisfy the performance requirements of the rule. However, the basis for the staff conclusion would not be limited to a determination that the applicant's ISA program has the capability only to identify the appropriate IROFS. Rather, the focus of the staff review would be on the sufficiency of the IROFS identified in the ISA Summary. This requires a determination of whether the identified IROFS are adequate to control the potential accidents of concern at the facility. The accidents of concern are those whose consequences would be at the high and intermediate consequence 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. This, in turn, requires staff to make a determination concerning the completeness of the accident sequences identified in the ISA Summary. To support such a review, the information in the ISA Summary needs to provide enough information concerning the accidents to which the IROFS relate to be able to assess their contributions to prevention or mitigation. The ISA Summary must contain enough information concerning the ISA procedures, methods, and human resources employed to have confidence that the potential accidents identified are reasonably complete.

The completeness and adequacy of the IROFS is not the only consideration for satisfying the performance requirements of 70.61. In addition, staff needs to determine that appropriate management measures will be in place that will ensure the availability and reliability of the identified IROFS, to the degree needed to satisfy the likelihood element of the performance requirement.

The following acceptance criteria address each of the content elements of the ISA Summary required by 10 CFR 70.65(b). For new facilities it is expected that the staff reviewing the ISA Summary will also evaluate those aspects of the design that address those baseline design criteria of 10 CFR 70.64 that apply to individual processes. Thus the content elements for which there are acceptance criteria include:

1) The site,
2) The facility,
3) The processes,
4) Team qualifications,
5) ISA methods,

6) Quantitative standards for chemical consequences,
7) Definitions of likelihood terms,
8) Information demonstrating compliance with the performance requirements,
9) Process hazards,
10) Description of accident sequences,
11) Descriptive list of all IROFS,
12) List of sole IROFS,
13) Information demonstrating compliance with the requirements for criticality monitoring,
14) Information demonstrating compliance with the requirements for new facilities.

The acceptance criteria that follow are guidance to the reviewer in determining whether the contents of the above elements are sufficient to provide reasonable assurance that the applicant's process-safety design and safety procedures meet the performance requirements of 10 CFR 70.61 and other requirements of 10 CFR Part 70.

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 from prominent natural and man-made 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 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 assess their impact on plant safety and to assess their likelihood of occurrence. At least the 100 year flood should be postulated, consistent with U.S. Army corps of Engineers flood plain maps. The applicant also describes the maximum earthquake magnitude, peak ground acceleration, and return period expected at the site, for an existing site. Also, an earthquake acceleration associated with a 10^{-3}/yr likelihood should be evaluated, to determine its resulting consequences on the structural integrity of the facility. The discussion identifies all design basis natural events for the facility and indicate which events are considered incredible and the basis for that determination. The assessment also indicates which events could occur without adversely impacting safety.

The level of detail for this material is greater than that which would be acceptable in the general information referred to in Chapter 1, because of the need to provide information needed to evaluate the ISA.

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

a. The facility location and the distance from the site boundary in all directions, including the distance to the nearest resident and distance to boundaries in the prevailing wind directions.

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

c. The location and arrangement of buildings on the facility site.

3. PROCESSES

The description of the processes analyzed as part of the ISA is considered acceptable if it describes the following features in sufficient detail to permit an understanding of the theory of operation, and to determine compliance with the performance requirements of the rule. A description at a systems level is acceptable provided it permits the staff to conduct adequately: 1) an evaluation of the completeness of the hazard and accident identification tasks, and 2) an evaluation of the likelihood and consequences of the accidents identified. If the information is available elsewhere in the application and is adequate to support the ISA, reference to the appropriate sections is considered acceptable. The information provides an adequate explanation of how the IROFS reliably prevent the process from exceeding safety limits for each case identified in the ISA results where they are needed.

a. Basic process function and theory. This information includes a general discussion of the basic theory of the process.

b. Major components–their function and operation. This information includes the general arrangement, function, and operation of major components in the process. It includes arrangement drawings and process schematics showing the major components and instrumentation and, if appropriate, chemical flow sheets showing compositions of the various process streams.

c. Process design and equipment. This information includes a discussion of process design, equipment, and instrumentation that is sufficiently detailed to permit an adequate understanding of the results of the ISA. It includes schematics indicating safety interrelationships of parts of the process. In particular, 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, etc..

d. Process operating ranges and limits. This information includes the operating ranges and limits for measured process variables (e.g., temperatures, pressures, flows, and compositions) that are controlled by IROFS to ensure safe operation of the process. The process operating limits and ranges are considered acceptable if they are consistent with those evaluated as adequate for safety in the ISA. One acceptable way of presenting this information is as a tabular summary of all IROFS grouped according to hazard type (i.e. nuclear criticality, radiological hazards, chemical hazards, etc.) as shown in Appendix A, Table A-7.

4. TEAM QUALIFICATIONS

The ISA teams and their qualifications as stated in the ISA Summary are acceptable if the following criteria are met:

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

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

c. The team represents a variety of process design and safety experience in those 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.

5. ISA METHODS

It is important that the reviewer determine what the methods and criteria used in the ISA are, and whether they are adequate in principle, before evaluating results for individual processes. The summary of ISA methods is considered acceptable if it describes the methods used for each ISA task. In accordance with NUREG-1513, it is expected that different specific analytical techniques will be used in different processes depending on their nature and complexity. Specific acceptance criteria for methods used in each ISA task are as follows:

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

   i. Provides 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 includes maximum intended inventory amounts and the location of the hazardous materials at the facility.[1]

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

b. Process Hazard Analysis Method. The method for performing process hazard analysis is acceptable if it consists of selecting one of the individual methods described in NUREG-1513 in accordance with the selection criteria of that document. Individual methods not described in NUREG-1513 may be acceptable provided that:

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

ii. It 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. It provides reasonable assurance that the applicant can identify all significant accident sequences (including the IROFS used to prevent or mitigate the accidents) that could result in the consequences identified in 10 CFR 70.61[2].

iv. It takes into account the interactions of identified hazards and proposed IROFS, including system interactions, to ensure that the overall level of risk at the facility is consistent with the requirements of 10 CFR 70.61.

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

vi. It addresses hazards resulting from process deviations (e.g., high temperature, high pressure); initiating events internal to the facility (e.g., fires or explosions); and hazardous credible external events (e.g., floods, high winds, and earthquakes, airplane crashes). The applicant provides justification for determinations that certain events are not credible and, therefore, not subject to the likelihood requirements of 10 CFR 70.61.

vii. It 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. It adequately considers common mode failures and system interactions in evaluating systems that are to be protected by double contingency.

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[1]At least the following hazardous materials should be included in the inventory list if present on-site: ammonia, fines (UO_2 dust, beryllium), flammable liquids and gases, fluorine, hydrofluoric acid, hydrogen, nitric acid, organic solvents, propane, uranium hexafluoride, and Zircalloy.

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

ix. The ISA Summary provides justification that the individual method would effectively accomplish ii through viii above.

3. Consequence Analysis Method. The methods used for ISA consequence evaluation, as described in the ISA Summary are acceptable if:

i. They are consistent with the approaches described in the Nuclear Fuel Cycle Facility Accident Analysis Handbook (NUREG/CR-6410, March 1998); and

ii. They are scientifically correct as a reasonable estimate; and

iii. Their use of generic assumptions and data is reasonably conservative for the types of accidents analyzed.

d. Likelihood Evaluation Method. The method for evaluation of the likelihood of accident sequences, as described in the ISA Summary, is considered acceptable if it provides reasonable assurance that the IROFS and management measures described comply with the graded performance criteria of 10 CFR 70.61; and the method is consistent with acceptable definitions of the likelihood terms in accordance with subsection 3.4.3.2, item 7, of this chapter. Specific criteria are:

i. The method includes clearly showing how each IROFS involved acts to prevent or mitigate the accident sequence being evaluated.

ii. When multiple IROFS are involved in an accident sequence, the method considers the interaction of all the IROFS involved, as in a logic diagram or tabulation, that accounts for the impact of redundancy, independence, and surveillance to correct failures 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. Such likelihood criteria should include the following when applicable: 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 grading, if any, of the management measures applied to the IROFS.

iv. Finally, the method evaluates each accident sequence as unlikely, highly unlikely, or neither, as defined by the applicant in accordance with subsection 7 of this chapter.

v. For nuclear criticality accident sequences, the method evaluates compliance with 70.61(d). That is, even in a facility with engineered measures to limit the consequences of nuclear criticalities, preventive control(s) must be in place sufficient to assure subcriticality for credible abnormal events. A moderately higher standard of likelihood may be permitted in preventing such events consistent with ANSI/ANS Standard 8.10. In particular, criticality cannot result from any single administrative error. In addition, 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 and Summary must consider and document the magnitude of those margins when they are part of the reason why exceedance of safety limits is unlikely.

One acceptable method of likelihood evaluation is described in Appendix A.

6. QUANTITATIVE STANDARDS FOR CHEMICAL CONSEQUENCES.

The applicant's description of proposed quantitative standards used to assess consequences from acute chemical exposure to licensed material or chemicals produced from licensed material is acceptable if:

a. There are unambiguous quantitative standards for each of the applicable hazardous chemicals on site corresponding to, and consistent with, the qualitative standards each of the following sections of 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 for 10 CFR 70.61(b)(4)(i) will correctly categorize as such, all exposures that could endanger the life of a worker. This language "could endanger" means that the standard should be appropriately conservative in identifying a level of exposure at which death, although not the average result, could occur in a small fraction of cases.

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

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

As indicated in the Consequence Severity Category Table of Appendix A, the staff finds the use of the ERPG and AEGL series of standards to be acceptable sets, each meeting the performance criteria of 10 CFR 70.61. However, since such standards may not cover all the appropriate chemicals, the ISA Summary to be acceptable must list the actual values selected for each chemical, and provide information or a reference justifying that they meet the acceptance criteria stated above. When the chemical is covered by ERPG or AEGL values, a reference to this fact is sufficient.

7. DEFINITIONS OF LIKELIHOOD TERMS

10 CFR 70.65 requires that the applicant's ISA Summary provide definitions of the terms unlikely, highly unlikely, and credible. The applicant's definitions of these terms is 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. In fact, it is recommended that, in any case, the reviewer focus on objective qualities and information provided concerning accident likelihoods.

Section 70.61 requires that credible high-consequence events 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 is herein synonymous with the phrase "accident sequence". This is important to recognize since there may be hundreds of potential accident sequences identified in an ISA. Thus the likelihood of each individual sequence must be quite low.

ACCEPTANCE CRITERIA FOR THE DEFINITION OF "CREDIBLE"

10 CFR 70.65 requires that the applicant define the term "credible". This term "credible" is used in 10 CFR 70.61 to state the performance requirements that all credible events be controlled to be unlikely or highly unlikely, as appropriate. Thus, to be 'not credible' could be used as a criterion for exemption from use of controls. There is a danger of circular reasoning here. In the safety program embodied in the rule, the fact that an event is 'not credible' must not depend on any plant feature that could credibly fail to function, or be rendered ineffective as a result of a change to the system. Each plant feature that is needed to assure that accident events are sufficiently unlikely is an "item relied on for safety" (IROFS). There must be high assurance, provided by management measures, 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 IROFS.

Nevertheless, there are events, including external events and some types of plant upsets, which have inherent qualities that clearly make them not credible, even in the absence of management measures. The applicant may define such events by describing what qualities they must possess to be not credible.

Three acceptable sets of qualities that define an event as not credible are:

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

2) A process deviation that consists of a sequence of many unlikely human actions or errors for which there is no reason or motive. In determining that there is no reason for such actions, consideration must have been given to a wide range of possible motives, short of intent to cause harm. Necessarily, no such sequence of events can ever have actually happened in any fuel cycle facility.

3) Process upsets for which there is a convincing argument, based on physical laws, they are not possible, or are unquestionably extremely unlikely. The validity of the argument must not be dependent on any feature of the design or materials which is not controlled by the plant's system of IROFS.

The following discusses a further consideration for evaluating the acceptability of the applicant's definition of "credible". The implication of the use of "credible" in 10 CFR 70.61 is that events which are not "credible" may be neglected. For this to be acceptable on a risk basis, unless the event is impossible, it must be of negligible likelihood. That is, "not credible" must mean impossible, practically impossible, or of negligible likelihood. Negligible likelihood means sufficiently low that, considering the consequences, the addition to total risk is small. Note that consideration must thus be given to how many such events have, in fact, been neglected. An applicant may demonstrate by quantitative reasoning, that a particular event is of negligible frequency. Such a demonstration must be convincing despite the absence of designated IROFS. Typically, this can only be achieved 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 to the extent that they are:

a) reasonably clear and based on objective criteria,

b) can reasonably be expected to consistently distinguish accidents that are highly unlikely from those that are merely unlikely.

By the phrase "objective criteria" is meant the extent to which the method relies on specific identifiable characteristics of a process design, rather than subjective judgements of adequacy. Objective criteria are needed to achieve consistency. By consistency is meant the degree to which the same results are obtained when the method is applied by different teams of analysts. This is important in order to maintain an adequate standard of safety because ISA's of future plant modifications may be performed by individuals not involved in the initial ISA.

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 is not necessarily complete, but contains many of the factors most commonly encountered. Some of these qualities relate to the characteristics of individual IROFS, such as:

1) safety margin in the controlled parameter compared to process variation and uncertainty,
2) whether the IROFS is an active engineered control, a passive engineered control, an administrative control, or an enhanced administrative control,
3) the type and grade of management measures applied to the control,
4) fail-safe, self-announcing, or surveillance measures to limit down time.
5) failure modes
6) demand rate
7) failure rate

Other reliability qualities relate characteristics of the system of IROFS protecting against the accident sequence as a whole, such as:

8) defense-in-depth,
9) degree of redundancy,
10) degree of independence,
11) diversity,
12) vulnerability to common cause failure.

Methods of likelihood evaluation, and the definitions of the rule's likelihood terms, may mix qualitative and quantitative information. Certain types of objective quantitative information may be available concerning specific processes in a plant. Some examples of such objective quantitative information are:

1) reports of failure modes of equipment or violations of procedures recorded in maintenance records or corrective actions programs,
2) the time intervals at which surveillance is conducted to detect failed conditions,
3) the time intervals at which functional tests or configuration audits are held,
4) for a fail-safe, monitored, or self-announcing IROFS, the time it takes to render the system safe;
5) demand rates, that is, how frequently process operations are conducted which place a demand on an IROFS. 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 down time 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 the multiple controls.

Acceptance Criteria for Likelihood Indexing Methods

One acceptable type of definition for the likelihood terms "unlikely" and "highly unlikely" could be based on a risk indexing method. Such a method is described in the example in Appendix A. The example described in Appendix A is intended to rely primarily on a qualitative evaluation of reliability / availability factors. In such methods, qualitative characteristics of the system of IROFS, such as those listed above, are used to set a quantitative likelihood index for each accident sequence. The definition of "unlikely" then is an acceptable limit on this likelihood index.

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:

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 addresses explicitly several reliability / availability qualities; namely:

factors of safety:	safety margins
at least two:	redundancy
unlikely:	low failure rate, low down time
concurrent:	low down time
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 with each of the applicable qualities to an appropriate degree. For example, as implied by the modifier, “at least”, sometimes more than just two-fold redundancy may be appropriate.
An 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, single high reliability IROFS, such as engineered hardware controls with high grades of applicable management measures might qualify as an acceptable definition of unlikely. Systems relying on administrative controls would normally have to make use of enhancing qualities such as large safety margins and redundancy in order to qualify as unlikely. A single simple administrative control, regularly challenged, without any special safety margin or enhancement, where a single simple error would lead to the accident, would not qualify as “unlikely” to fail.

ACCEPTANCE CRITERIA FOR QUANTITATIVE DEFINITIONS OF LIKELIHOOD

An applicant, although not required to do so, may choose to provide quantitative definitions of the terms unlikely and highly unlikely. Quantitative guidelines are developed below. These guidelines serve two purposes: 1) they can be used as acceptance criteria for quantitative definitions, if provided; and 2) they provide guidance to the reviewer when objective quantitative reliability / availability information exists. The reviewer is cautioned not to interpret these guidelines as requiring that quantitative definitions or evaluations is required.

The goals from which these quantitative guidelines were derived are for specific types of accidents. Therefore the guidelines should not be used for accidents that differ significantly from these specific types. The high consequence guideline, for example, is based on a goal of no inadvertent criticalities. Thus it is only appropriate to use this guideline for accidents whose consequences are similar to a nuclear criticality accident, that is, one where a few fatal or near fatal worker doses may occur. For substantially more severe high consequence accidents, more stringent likelihood criteria would be acceptable. For less severe high consequence accidents, less stringent criteria may be applied. It should also be noted that the quantitative guidelines are derived from goals, not limits, and have been judged to be the highest values consistent with those goals.

QUANTITATIVE GUIDELINES

The development of quantitative guidelines here does not imply that quantitative demonstration of compliance with 10 CFR 70.61 is required. As stated above, the phrase "highly unlikely" applies on a "per accident" basis. Hence, quantitative frequency guidelines for the likelihood definitions depend on how many potential accidents there are in each of the two categories. The quantitative guidelines stated below are derived from safety performance goals for the whole industry. The number of potential accidents for the whole industry will not be known until ISA results are available. For this reason, the quantitative guidelines provided below are expressed in terms of two variables, Nh and Ni. Nh is the total number of potential high-consequence accidents for the industry; and Ni is the number of intermediate-consequence accidents, as identified in the ISA's.

Since the numbers of potential accidents will not initially be known, the staff should use values of Nh = 1000 and Ni = 10 as initial estimates. If the number of accidents actually identified in industry ISAs exceeds these values significantly, they will be adjusted.

Highly Unlikely

The guideline for acceptance of the definition of "highly unlikely" has been derived as the highest acceptable frequency that is consistent with a goal of having no criticality accidents, and no accidents of similar consequences, in the industry. To within an order of magnitude, this is taken to mean a frequency limit of less than one such accident in the industry every 100 years. This has been translated below into a guideline limiting the frequency of individual accidents. The goal is to have no such accidents, thus it is reasonable to reduce accident frequencies substantially below these guidelines when feasible.

Unlikely

Intermediate consequence events include significant radiation exposures of workers, those exceeding 0.25 Sieverts (25 rem). It is taken as a goal that there be no increase in the rate of such significant exposures. This rate is currently about one exposure per 2.5 years. Since the uranium fuel cycle industry has not contributed to such exposures, an allocation of one tenth of this value, or 0.04 per year has been used as appropriate for this industry. Once adjusted to a per accident basis, this value of 0.04 per year for the industry can then be used as an appropriate guideline limiting all types of accidents with intermediate consequences, because their health consequences are all comparable. The definition and use of the term "unlikely" should be consistent with this frequency guideline.

Quantitative Guidelines for use with Acceptance Criteria

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

Likelihood term of 70.61	guideline	initial guideline value
unlikely	less than 0.04/Ni per year	< 0.004 per year
highly unlikely	less than 10^{-2}/Nh per year	< 10^{-5} per year

where:

Ni = the total number of potential intermediate-consequence accidents in regulated facilities. Although it is currently expected that Ni may be very low for the uranium fuel cycle industry, a value of at least 10 should initially be assumed.

Nh = the total number of potential high-consequence accidents in regulated facilities. Although currently not known, the value of Nh should initially be assumed to be at least 1000.

It should be noted that 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. The performance requirements of 10 CFR 70.61are limits, not goals, thus staff should use these guidelines in that sense.

The quantitative consequence categories defined in 10 CFR 70.61 are broad, especially the "high-consequence" category, which is open ended. For this reason, the meaning of "highly unlikely" for an individual accident should be graded in inverse proportion to the magnitude of consequences when these consequences are significantly greater than the lower limits defining high consequences in 10 CFR 70.61.

8. INFORMATION DEMONSTRATING COMPLIANCE WITH THE PERFORMANCE REQUIREMENTS

10 CFR 70.65(b) items 3,4,6, and 8 require certain information resulting from the ISA's performed on individual processes to be described in the ISA Summary. Section 70.65(b)(4) requires that the ISA Summary contain: "information that demonstrates 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 information needed is that which shows that all events are of appropriate consequences and likelihood. Section 70.61 effectively states that each credible accident sequence must have a likelihood corresponding to its consequences. Thus the information submitted is acceptable if it provides consequence and likelihood information for each accident showing that:

a) credible high-consequence events are highly unlikely; and

b) credible intermediate-consequence events are unlikely.

The performance requirements of 10 CFR 70.61 have three elements: 1) completeness; 2) consequences; and 3) likelihood. Completeness refers to the fact that each credible event must be addressed. Consequences refers to the magnitude of the chemical and radiological doses used by 10 CFR 70.61 in categorizing accidents as being of high or intermediate

consequences. Likelihood refers to the fact that 10 CFR 70.61 requires 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 show the basis and the 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 or tabular summaries.

Completeness is demonstrated by correctly applying an appropriate method of accident identification, as described in NUREG-1513, "ISA Guidance Document". Completeness can be effectively displayed by using an appropriate diagram or description of the accidents identified. Specific acceptance criteria for completeness are covered in item 10 below.

Specific acceptance criteria for consequence and likelihood information follow.

Consequences.
The information in the ISA Summary on consequences is acceptable for showing compliance with 10 CFR 70.61 if:

i. the information in the ISA Summary for each accident 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 summary that applies to or bounds that accident; and

ii. the consequences were calculated using a method and data consistent with NUREG-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook", March 1998 or using another method described and justified in the methods description section of the ISA Summary, and

iii. the estimates of source terms and other process specific data used are reasonably conservative for the type of accident, and

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

Unshielded criticality accidents are considered to be high consequence events, because there is a substantial likelihood that they would be. For processes with effective engineered shielding, criticalities may actually produce doses below the intermediate consequences of 10 CFR 70.61. As stated in the regulation, primary reliance must be on prevention of criticalities. This applies notwithstanding shielding or other mitigative features. Therefore, regardless of the actual consequences, shielded criticalities must meet likelihood criteria, as

described in the following section of this SRP. If needed, the Nuclear Fuel Cycle Facility Accident Analysis Handbook (NUREG/CR-6410) provides methods for estimating magnitudes of criticality events that can be applied for workers or members of the public at varying distances from the event.

Likelihood.
The information in the ISA Summary is acceptable for showing compliance with 10 CFR 70.61 if:

i. The ISA Summary contains an evaluation of the likelihood of each type of accident sequence; and

ii. These likelihood evaluations properly apply an acceptable method described in the ISA Summary's methods section; and

iii. The evaluated likelihoods comply with acceptable definitions of the terms "unlikely" and "highly unlikely" from the ISA Summary, as evaluated in this SRP chapter. Note that, 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 be a violation of the requirement, which is not the intent; and

iv. All nuclear criticality accident sequences have an evaluated likelihood of "highly unlikely", unless protected by engineered shielding and confinement; and

v. All criticality accident sequences that are protected by engineered shielding and confinement are evaluated as at least "unlikely", and none can result from a single administrative error. Preventive control(s) must be in place sufficient to assure subcriticality for credible abnormal events. A moderately higher standard of likelihood may be permitted in preventing such events consistent with ANSI/ANS Standard 8.10. In addition, 10 CFR 70.61(d) requires that the risk of criticality must be limited by an approved margin of subcriticality for safety. Validation methods to establish margins to assure that a particular parameter value is actually subcritical, are reviewed as programmatic commitments, not as part of the ISA. However, when a safety margin is part of the reason why exceedance of safety limits is unlikely, the margin should be listed in the ISA Summary description of that accident. For example, if the process is safe against double batching, the number of batches, and other conditions, required for actual criticality should be described in the ISA Summary. The likelihood of erroneously accumulating the critical number of batches should then be reflected in the evaluation of the likelihood of the accident sequence.

9. PROCESS HAZARDS

The description of process hazards provided in the ISA Summary is acceptable if it identifies, for each process, all the types of hazards relevant to determining compliance with the

performance criteria of 10 CFR 70.61. That is, the acceptance criterion is completeness. All hazards that were identified that could credibly result in the minimum consequences of section 70.61 should be listed, even if later analysis of a particular hazard shows that resulting accident sequences do not exceed these minima. Otherwise the reviewer cannot determine completeness. General exclusion of 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 minimum consequence levels of section 70.61 cannot be exceeded. In this case, the bounding inventories or conditions, if under the control of the applicant, become IROFS. The list of process hazards is acceptable if the ISA Summary provides:

1) A list of materials (radioactive, fissile, flammable, and toxic) or conditions that could result in hazardous situations. The list includes maximum intended inventory amounts and the location of the hazardous materials at the site.

2) A hazards interaction table showing potential interactions either between materials or between materials and conditions that could possibly result in hazardous situations.

10. TYPES OF ACCIDENT SEQUENCES

The general description of types of accident sequences is acceptable if it is adequate to permit the staff to determine:

a) That all accidents that could exceed the consequence criteria of 10 CFR 70.61 have been identified, and
b) How the IROFS listed in the ISA Summary protect against each type of accident.

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

For this reason, it is not, in general, acceptable to merely list the type of hazard, or just the controlled parameters, without reference to the items relied on to control that parameter or hazard. The general description of accident sequences is acceptable if it covers all types of sequences of initiating events and failures of IROFS (IROFS). Initiating events may be either failure of an IROFS or an external event. Human errors can be initiating events or failures of IROFS. The accident description is acceptable if it permits the staff to determine how each accident sequence that could exceed the minimum consequence levels in 10 CFR 70.61 is protected against by IROFS.

One acceptable way to do this is to show a fault tree where the basic events are failures of the IROFS. Another is to provide a table where each row displays the events in an accident sequence, as in Appendix A Table A-1, where, in general, each event is failure of an IROFS.

Another acceptable way is a narrative summary for each process describing the sequence of events in each type of accident.

The general description of types of accident sequences, to show completeness, must use systematic methods and consistent references. Therefore, each description is acceptable if:

a) a method of hazard identification and process hazard analysis was used in accordance with the criteria of NUREG-1513;
b) the method selected was correctly applied;
c) no hazard or accident sequence that could cause a failure to meet section 70.61 was overlooked; and
d) a method of identifying plant processes was used, so that the completeness of the analysis in covering all processes can be evaluated.

During the early phases of an ISA, accidents will be identified whose consequences may initially be unknown. These accidents will later be analyzed and may be shown to have consequences less than the levels identified in 10 CFR 70.61 which invoke requirements. The ISA Summary must show what happened to these accidents. Thus it must identify all accidents considered, and identify accidents which, although possible, were not developed due to insufficient consequences.

It is not necessary to list as a separate sequence every conceivable permutation of the accidents. Accidents having characteristics that all fall in the same categories can be grouped as a single type of accident in the table, if:

a) the initiating events have the same type of effect on the system;
b) they all consist of failure of the same IROFS;
c) they all result in violation of the safety limit on the same parameter; and
d) they all result in the same type and severity categories of consequences.

11. DESCRIPTIVE LIST OF ALL IROFS

The “list describing items relied on for safety” required by 10 CFR 70.62(c)(vi) is acceptable if:

1) It includes <u>all</u> IROFS in the identified accident sequences.

2) The <u>description</u> of the IROFS, the identification of the grade of management measures applied to them, and the associated safety limits and margins is adequate to permit a determination of compliance with 10 CFR 70.61,that is, it includes the characteristics of its preventive, mitigative, or other safety function, and the assumptions and conditions under which the item is relied upon to support compliance with the performance requirements of Sec. 70.61.

Although the regulations do not explicitly list the content and grading of management measures as a separate element of an ISA Summary, such information is required to “demonstrate compliance with the performance requirements” by the IROFS. Normally this information would

be available in the current license application. If sufficiently detailed information is not provided in the current application, submittal of additional information may be required.

The above acceptance criteria are explained in greater detail below.

1) ALL ITEMS: The primary function of the "list describing all items relied on for safety" is to document the safety basis of all processes in the facility. This list assists in assuring that the items are not degraded without a justifying safety review. Thus the key feature of this list is that all IROFS are included. To be acceptable, no item, aspect, feature, or property of the processes that is needed to show compliance with the safety performance requirements of the regulation may be left off this list. 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. 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.

2) THE DESCRIPTIONS OF ITEMS: The essential features of each item relied on for safety (IROFS) that are required to achieve adequate reliability should be described. Sufficient information should be provided about 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, the safety parameter controlled by the item, the safety limit on the parameter, and the margin to true failure should, in general, be described. 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 item must contain any information needed to identify how the management measures, such as maintenance, training, configuration management, etc. are applied to it. If a system of graded management measures is used, the grade applied to each control should be determinable from information provided. Section 70.62(d) requires that applicants "...establish management measures to provide continuing assurance of compliance with the performance requirements of Sec. 70.61". The reliability required for an IROFS is proportionate to the amount of risk reduction relied on. Thus the quality of the management measures applied to an IROFS may be graded commensurate with the reliability required. The management measures shall assure 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 assured 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 plant. In particular, the time interval between surveillance observations or

tests of the item should be stated, since restoration of a safe state can not occur until the failure is discovered.

One example of a tabular description of IROFS meeting these criteria is Table A-7 in Appendix A.

12. LIST OF SOLE ITEMS RELIED ON FOR SAFETY (IROFS)

The descriptive list that identifies all IROFS that are the sole item for preventing or mitigating an accident sequence is acceptable if it includes:

a) A descriptive title of the item;
b) Provides an unambiguous and clear reference to the process to which the item applies; and
c) Provides a clear and traceable reference to the description of the item as it appears in the full list of all items..

13. INFORMATION DEMONSTRATING COMPLIANCE WITH THE REQUIREMENTS OF 10 CFR 70.24 FOR CRITICALITY MONITORING

10 CFR 70.24 has specific sensitivity requirements for criticality monitors. To demonstrate compliance, the method for evaluating an acceptable response of at least two detectors to a criticality at any location where SNM may be handled, used, or stored should be described. Locations of all detectors relative to the potential locations of SNM should be provided as a diagram. Information supporting determination of the gamma and neutron emission characteristics of the minimum credible accident of concern capable of producing the effects specified in 10 CFR 70.24 should be provided. Actual neutron and gamma doses and dose rates at the detector locations should be given. Information showing the response characteristics of the detectors to neutron and gamma doses and rates characteristic of credible accidents should be given.

10 CFR 70.24 also requires specific emergency preparations. Information should be provided demonstrating that equipment and procedures of the applicant are adequate to assure that these requirements are met.

14. INFORMATION DEMONSTRATING COMPLIANCE WITH REQUIREMENTS OF 10 CFR 70.64 FOR NEW FACILITIES

10 CFR 70.64 specifies baseline design criteria that must be used, as applicable, for new facilities and new processes at existing facilities. If the application involves such new facilities or process, then an acceptable set of information would address each baseline design criterion listed in 10 CFR 70.64, and would show how the criterion is met. For criteria such as double contingency to which each individual process must comply, the process-specific information may be provided along with the other process information in the ISA Summary. Design basis events and safety parameter limits should be given. Methods, data, and results of analysis showing compliance with these design bases should be given for individual processes and structures.

10 CFR 70.64 states that the design process must be based on defense-in-depth principles, and must incorporate, to the extent practicable, preference for engineered controls over administrative and reduction of challenges to IROFS. Because of this regulation, new facilities with system safety designs lacking defense-in-depth, or consisting of purely administrative controls, or relying on IROFS that are frequently or continuously challenged are not acceptable unless justification is provided showing that alternatives achieving the design criteria are not feasible.

3.5 REVIEW PROCEDURES

Organization of the reviews addressed by this 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 ISA programmatic commitments there may only be a primary ISA reviewer. However, for an initial ISA Summary submittal, this primary ISA reviewer will be assisted by specialists in the various safety disciplines, including criticality safety, radiological safety, fire safety, and chemical safety. 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, there will be a primary ISA reviewer who evaluates generic methods and criteria used in the ISA and generic information about individual processes. This primary reviewer will be assisted by secondary reviewers who evaluate individual accidents, and advise on the completeness of the accident list for specific safety disciplines.

3.5.1 Acceptance Review

For an ISA programmatic application, amendment, or ISA Plan, the primary ISA reviewer will conduct a review to determine if the submittal contains appropriate information addressing each of the areas of review identified in Section 3.3.1 of this chapter. If the application does not contain sufficient information addressing the areas of review to permit a safety evaluation, then the application will not be accepted.

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 insufficient information is not present, the ISA Summary will not be accepted.

3.5.2 Safety Evaluation

3.5.2.1 Evaluation of ISA Programmatic Commitments

The staff reviews the descriptions and commitments to ISA program elements in the application or other documents in the subject areas 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 information addressing the subject areas listed in 3.3.1 may be contained in the ISA Chapter of a license application, renewal or amendment; or in the ISA approach described in an ISA Plan submitted in accordance with 70.62(c)(3)(i). Part of the information required to evaluate these areas may also be found in chapters of a license application other than the ISA chapter. ISA is

highly interrelated with all other aspects of a safety program. Hence the ISA reviewer must co-ordinate with reviews being conducted under other chapters of this SRP. Specific review steps correspond closely to the areas of review in section 3.3.1.

3.5.2.2 Evaluation of ISA Summary and Results

Evaluation of the ISA Summary to determine if the acceptance criteria of section 3.4 have been met would normally be performed by a team consisting of a primary ISA reviewer together with specialists in each category of accidents. These categories of accidents depend on the facility, but, in general, are: nuclear criticalities, 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, such as site and facility descriptions, ISA methods, criteria, and consequence and likelihood definitions. However, each specialist should also review these elements, not as an evaluation, but in support of their 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 the process descriptions in the ISA Summary should be evaluated by, and must be acceptable to, all of the team members.

Reviews of accident sequence descriptions and the likelihood and consequence information showing compliance with Section 70.61 should be done by separate specialists for each category of accidents. These accident categories are: nuclear criticalities, fires, radiological releases, and chemical accidents. As indicated in Appendix A, one acceptable format for the ISA Summary is to tabulate or give logic diagrams for accident sequences in each of these groups separately.

After a preliminary team review of the ISA Summary, a visit to the facility would normally be made for familiarization with the 3-D geometry of process equipment and other information.

Selection of specific accident sequences and IROFS for more detailed evaluation should then be made using the following approach. The staff will evaluate the risk significance of accident sequences using information supplied in the ISA Summary. The applicant's own method for evaluating compliance may provide information sufficient for this purpose. If not, the NRC staff may make an evaluation of risk significance using risk indexing, or similar qualitative screening criteria, analogous Table A-1 in Appendix A. One such procedure for evaluating risk significance is described in the last section of Appendix A. Other, more rigorous reliability or consequence analyses may be performed as judged necessary. Based on this risk screening, accident sequences will be placed in risk categories. Engineered and administrative controls appearing in those sequences in the category of highest risk significance may be selected for review in greater detail. Independent evaluation of these sequences, or site visits, will be performed, if warranted. From accident sequences categorized as of lower risk significance, staff will select a small sample of representative sequences for specific evaluation.

For the list describing the IROFS, the reviewer should categorize IROFS so that items of a similar nature, and similar risk significance, are grouped together. The reviewer should then assure that he has a full understanding of one or more prototype IROFS selected from each

category. For these selected prototypes, the reviewer may, if necessary, request additional information to reach such a full understanding particular IROFS. For complex processes, it may be necessary to visit the plant to reach an adequate understanding of how the IROFS work for the process.

3.6 EVALUATION FINDINGS

The reviewer verifies that the information submitted by the applicant is sufficiently complete so that compliance with the regulations can be evaluated. For each requirements statement in the regulation addressing ISA, the evaluation findings should include a brief statement as to why the information submitted demonstrates compliance. There should be a finding statement, following the evaluation of each area of review, stating how the information submitted in that area supports the related regulatory requirement. Specifically, the staff findings in the SER should state conclusions of the following types:

General conclusion resulting from staff evaluation of ISA Programmatic Commitments:

> The staff concludes that the applicant's safety program, if established and maintained pursuant to Sec. 70.62 of this part, is adequate to ensure that each item relied on for safety will be available and reliable to perform its intended function when needed and in the context of the performance requirements of 10 CFR 70.61.

There should be general findings, for each of the areas of review, stating how the applicant's information demonstrates compliance with the acceptance criteria of section 3.4.3.1. If staff finds that the acceptance criteria are not met, a license condition rectifying the deficiency should be recommended. If the applicant has submitted an adequate explanation of an alternative way of complying with the regulations, the staff evaluation should contain a finding that the alternative is acceptable for meeting the basic regulatory requirement addressed.

General conclusions resulting from staff evaluation of an ISA Summary:

> Many hazards and potential accidents can result in unintended exposure of persons to radiation, radioactive materials, or toxic chemicals associated with licensed materials. The staff finds that the applicant has performed an Integrated Safety Analysis (ISA) to identify and evaluate those hazards and potential accidents as required by the regulations. The staff has reviewed the ISA Summary and other information, and finds that it provides reasonable assurance that the applicant has identified items relied on for safety and established engineered and administrative controls to ensure compliance with the performance requirements of 10 CFR 70.61. Specifically, the staff finds that the ISA results, as documented in the ISA Summary, provides reasonable assurance that the IROFS, the management measures, and the programmatic commitments therein described 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 requirements statements in 10 CFR 70 that address the 14 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) for those processes to which they are applicable.

Findings may be made concerning compliance of specific processes with requirements of section 70.61 or other parts of the regulation, for those processes which receive specific detailed review. However, such findings should be limited to a finding of reasonable assurance that a process having the items relied on for safety, as described in the ISA Summary, is capable of meeting the requirements, if properly implemented, operated, and maintained.

3.7 REFERENCES

American Institute of Chemical Engineers (AIChE), “Guidelines for Hazard Evaluation Procedures, Second Edition with Worked Examples,” New York, 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.

American National Standards Institute, American Nuclear Society, "Nuclear Safety Criteria for the Design of Stationary Pressurized Water Reactor Plants," ANSI/ANS-51.1-1983, La Grange Park, IL, 1983.

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

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

U.S. Nuclear Regulatory Commission, “Integrated Safety Analysis Guidance Document,” NUREG-1513, 1995.

APPENDIX A

EXAMPLE PROCEDURE FOR RISK EVALUATION

10 CFR 70.61 defines two consequence categories, high and intermediate, by specifying quantitative radiological dose levels and qualitative chemical health effects levels. Then section 70.61 requires that intermediate consequence events be unlikely, and high consequence events be highly unlikely. These requirements are referred to as "performance requirements". The next section of the rule, 10 CFR 70.62, requires that the applicant perform an Integrated Safety Analysis (ISA) to identify all potential accident sequences, to assess their consequences, and to evaluate compliance with these consequence-likelihood performance requirements. The applicant is to convert the qualitative chemical levels into quantitative standards.

The rule language is thus quantitative concerning consequences, but qualitative ("highly unlikely") concerning likelihood. The rule does not state that the ISA's evaluation of compliance is to be quantitative. This appendix describes one method of evaluating compliance with the consequence-likelihood performance requirements of 10 CFR 70.61. The method is intended to be essentially qualitative, but it also permits quantitative information to be considered, if available. This method should not be interpreted as requiring that an applicant use quantitative evaluation. However, evaluation of a particular accident should be consistent with the any facts available, even quantitative, concerning the controls involved.

The method of this appendix describes qualitative criteria for evaluating frequency indices of safety controls. These criteria for assigning indices, particularly the descriptive criteria in Tables A-3 and A-4, are intended to be examples, not universal criteria. It is preferable that such criteria be developed by each applicant based on the particular types of controls and management measure programs in the facility evaluated. Such criteria should be modified and improved as insights are gained during performance of the ISA.

The procedure described in this appendix is one way by which the applicant may use the ISA results to demonstrate that the requirements of 10 CFR 70.61 have been met. If the licensee evaluates accidents using a different method, the method should produce similar results in terms of how accidents are categorized. This method should be regarded as a screening method, not as a definitive method of proving the adequacy or inadequacy of the controls for any particular accident. Because methods can rarely be universally valid, individual accidents for which this method does not appear applicable may be justified by an evaluation using other methods. The method does have the benefit that it evaluates, in a consistent manner, the characteristics of controls used to limit accident sequences. This will permit identification of accident sequences with defects in the combination of controls used. Such controls can then be further evaluated or improved to establish adequacy. The procedure also ensures the consistent evaluation of similar controls by different ISA teams. Sequences or controls that have risk significance, and are evaluated as marginally acceptable, are good candidates for more detailed evaluation by the applicant and the reviewer.

The tabular accident summary resulting from the ISA should identify, for each sequence, what engineered or administrative controls must fail to allow the occurrence of consequences that exceed the levels identified in 10 CFR 70.61. Chapter 3 of this SRP specifies acceptance criteria for these controls, such that the performance requirements of section 70.61 are met. These criteria require that controls 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 DETERMINING COMPLIANCE WITH GRADED PROTECTION REQUIREMENTS

Section 70.61 of 10 CFR Part 70 describes requirements for a graded system of protection sufficient to bound the risk of identified accidents by making accidents of higher potential consequences have a proportionately lower likelihood of occurrence. The regulation specifies two categories of consequences into which an accident may fall. The first category is referred to in 10 CFR 70.61 as "high consequences", and the second as "intermediate consequences". Implicitly there is a third category; namely, those accidents that produce consequences less than "intermediate". These will be referred to as "low consequence" accidents. Since the primary purpose of Process Hazard Analysis is to identify all accidents having consequences that exceed the levels in section 70.61, it will, in some cases, identify accidents that produce radioactive or chemical exposures, then subsequently determine that some of these do not exceed the threshold values for intermediate consequences. For this reason, in the method described here, the table listing accidents is intended to include such low consequence accidents in order to show that they have been considered. If they are not listed, some other demonstration of the completeness of the accident identification task should be provided in the ISA Summary.

The limits defining the three accident consequence categories are given below. Note that the categories are numbered in ascending order of the magnitude of their consequences. The usefulness of this numbering will be evident later. The symbols AEGL and ERPG refer to chemical exposure levels from accidents sufficient to produce certain effects. AEGL-3 and ERPG-3 levels are life threatening. 10 CFR 70 does not specify the use of AEGL or ERPG levels. 10 CFR 70.61(b) and (c) require applicants to propose quantitative exposure levels that they would use in the two primary consequence categories below. AEGL and ERPG levels are acceptable for those substances for which the levels have been determined by the appropriate agencies, and are described here.

Consequence Category 3- High Consequences: An accident resulting in any consequence specified in 10 CFR 70.61(b). These include acute worker exposures of 1 Sievert (100 rem)[3] or greater TEDE*, chemical exposures that could endanger the life of a worker (above AEGL-3 or ERPG-3); or acute exposures members of the public outside the controlled area to a radiation dose of 0.25 Sievert (25 rem) or greater TEDE, a 30 mg soluble uranium intake, or chemical

[3]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.

exposures that could lead to irreversible or other serious long-lasting health effects (exceeding AEGL-2 or ERPG-2).

Consequence Category 2- Intermediate Consequences: An accident resulting in any consequence specified in 10 CFR 70.61(c). These include acute exposures of workers to a radiation dose between 0.25 Sievert and 1 Sievert TEDE, or chemical exposures that could lead to irreversible or other serious long-lasting health effects (above AEGL-2 or ERPG-2); or acute exposures of members of the public outside the controlled area to a radiation dose between 0.05 and 0.25 Sievert TEDE, or chemical exposures that could cause mild transient health effects (exceeding AEGL-1 or ERPG-1); or prompt release of radiation outside the restricted area that would, if averaged over a 24 hour period, exceed 5000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20.

Consequence Category 1- Low Consequences: Any accident with potential adverse radiological or chemical consequences but at exposures less than Categories 3 and 2 above.

* TEDE is Total Effective Dose Equivalent (see 10 CFR Part 20)

This system of consequence categories is shown in the following table. In the table, D signifies the TEDE from an acute accidental radiation exposure.

Consequence Severity Categories Based on 10 CFR 70.61

	Workers	Offsite Public	Environment
Consequence Category 3: high	D>1 Sv (100 rem) >AEGL3, ERPG3	D>.25 Sv (25 rem) 30 mg sol U intake >AEGL2, ERPG2	
Consequence Category 2: intermediate	.25 Sv<D≤ 1 Sv >AEGL2, ERPG2 but <AEGL3, ERPG3	.05 Sv<D≤ .25 Sv >AEGL1, ERPG1 but <AEGL2, ERPG2	radioactive release >5000 x Table 2 App B 10 CFR 20
Consequence Category 1: low	accidents of lesser radiological and chemical exposures to workers than those above in this column	accidents of lesser radiological and chemical exposures to the public than those above in this column	radioactive releases producing effects less than those specified above in this column

Corresponding to the two consequence categories of the rule (Categories 2 and 3 above), 70.61 requires corresponding levels of graded protection, that is, engineered and administrative

controls and management measures, sufficient to ensure that the likelihood of these adverse events is correspondingly low. The two categories of likelihood thus prescribed are:

Likelihood Category 1: Consequence Category 3 accidents must be "highly unlikely", and

Likelihood Category 2: Consequence Category 2 accidents must be "unlikely."

Implicitly there is a third category into which an accident could fall, that is it could fail to be "unlikely." This category will be referred to in this document as:

Likelihood Category 3: "not unlikely."

Although this category includes unintended events that might actually be expected to happen, others might be less frequent. For this reason the term "likely" was not used for these events.

A major purpose of the ISA is to show compliance with the above system of graded protection. This can be done by using the required tabular summary of identified accident sequences. One acceptable way of doing so is for the applicant to assign two category numbers to each accident sequence, one based on its consequences and one for likelihood. The product of these two category numbers is then used as a risk index. Listing this calculated risk index in the tabular summary provides a simple method for showing that the graded protection requirements have been met for each accident sequence. A risk index value less than or equal to "4" means the sequence is acceptable. If the applicant provides this risk index in one column of the tabular summary, the reviewer can quickly scan this column to confirm that each accident conforms to the safety performance requirements of 10 CFR 70.61. This system is equivalent to assigning each accident to a cell in a 3 by 3 matrix. This conceptual matrix is shown below. The values in the matrix cells are the risk index numbers.

RISK MATRIX

	Likelihood Category 1: highly unlikely	Likelihood Category 2: unlikely	Likelihood Category 3: not unlikely
Consequence Cat. 3 High	3 acceptable	6 unacceptable	9 unacceptable
Consequence Cat. 2 Intermediate	2 acceptable	4 acceptable	6 unacceptable
Consequence Cat. 1 Low	1 acceptable	2 acceptable	3 acceptable

To demonstrate compliance with the system described above, the applicant needs to assign consequence categories to each identified accident to determine which likelihood requirement applies. Then those accident sequences identified as high or intermediate consequences must

be assigned to a likelihood category. To be acceptable, these assigned consequences and likelihoods must have a valid basis, and the applicant must demonstrate this basis in the documentation submitted in the application. The following sections describe an acceptable method for making these assignments.

A.2 CONSEQUENCE CATEGORY ASSIGNMENT

The assignment of consequence categories is based on estimated consequences of prototype accidents. Although consequences of accidents can be determined by actual calculations, it is not necessary that such a calculation be performed for each individual accident sequence listed. Accident consequences may be estimated by comparison to similar events for which reasonably bounding conservative calculations have been made. The applicant should document the bases for bounding calculations of the consequence assignment in the submittal. NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook", March 1998, describes valid methods and data that may be used by the applicant, or by the staff 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 failures at the facility or other methods that have objective validity. Because sequences leading to accidents often involve multiple failures, a combination of failure frequency and probability values determines the likelihood of the whole sequence. These values include the frequencies of initiating events and failure likelihoods of engineered and administrative controls. An acceptable method is described below by which the applicant can make an estimate of an approximate likelihood category for an accident sequence by considering all the events involved. This method makes use of the number, type, independence, and observed failure history of controls. However a correct evaluation of the appropriate likelihood of accidents using such a qualitative system depends on the informed judgement of the analyst. Engineered and administrative controls, even those of the same types, have a wide range of reliability. The ultimate criterion for acceptability, is that the frequencies of initiating events and the likelihoods of failure of controls involved are sufficiently low so that the entire accident sequence is "highly unlikely" or "unlikely" as required by 10 CFR 70.61. The virtue of the structure is that it requires explicit consideration of some of the underlying events and factors that affect the likelihood of the accident. Another virtue is that, the more explicit the criteria for assignment are, the more consistent are the results.

Underlying any evaluation of an accident sequence as "unlikely" or "highly unlikely" is an implied assessment of its "likelihood" or frequency of occurrence. The structured procedure described below will indicate which likelihood category may be appropriate for an event. In order to maintain internal consistency in evaluating different control systems and accidents, it was necessary to derive this structured procedure based on the underlying frequencies of events. The following numerical guidelines were thus used to obtain consistency and to be consistent with staff safety goals.

Likelihood Category 1: highly unlikely, a frequency of less than 10^{-5} per accident per year

Likelihood Category 2: unlikely, a frequency of less than 10^{-2} per accident per year (but more frequent than 10^{-5})

Likelihood Category 3: not unlikely, more frequent than 10^{-2} per accident per year

In assessing the adequacy of engineered and administrative controls, individual accident frequencies greater than 10^{-5} per year may not be evaluated as "highly unlikely". The safety goal underlying this frequency limit is that no inadvertent nuclear criticalities occur in the industry. This goal is here interpreted as limiting the frequency of such accidents in the industry to not more than once in 100 years (0.01 per year). This is then converted to a "per accident" frequency by dividing by an estimated number of potential accidents for the whole industry. A rough estimate of 1000 accidents has been used here. Thus 0.01 per year/1000 accidents =10^{-5} per year per accident.

The value of 10^{-5} per year per accident is such that a plant with 100 potential Consequence Category 3 accidents would have a frequency of: 100 accidents times 10^{-5} per year per accident = 10^{-3} per year. These Category 3 accidents generally result in fatalities. The average statistic for all manufacturing industries is that a plant with 250 manufacturing workers would expect 10^{-2} on-the-job deaths per year (see References, "Statistical Abstract of the U.S.").

Similarly, accident sequences having frequencies more than 10^{-2} per year per accident are not considered "unlikely." Again this value should not be taken as a definitive criterion for acceptability. It is a guideline value to assure consistency. It may need to be adjusted based on the numbers and severity of accidents. The value 10^{-2} is based on a goal that the frequency of events comparable to 25 rem worker exposures not increase above its current 5 year average of 0.4 per year. Since this goal is for all NRC regulated industries, only a fraction can be allocated to the part of the industry addressed by this SRP. Again a "per accident" limit must be derived that depends on the total number of accidents in the industry. For an allocation of one-tenth and an estimate of only 4 accidents in the industry, a value of 10^{-2} per accident per year was obtained. This value is used purely as an illustration, since the actual number of accidents has not yet been determined.

The accident evaluation method described below does not preclude the need to comply with the double contingency principle for sequences leading to criticality. Although exceptions are permitted with compensatory measures, double contingency, should, in general, be applied. The reason double contingency is needed is the fact that there is usually insufficient firm data as to the reliability of the control equipment and administrative control procedures used in criticality safety. If only one item were relied on to prevent a criticality, and it proved to be less reliable than expected, then the first time it failed a criticality accident would result. For this reason, it is prudent to require two independent controls. Inadequate controls can then be determined by observing their failure, without also suffering the consequence of a criticality. Even with double contingency it is essential that each IROFS be itself sufficiently unlikely to fail. This is so that, if one of the two items that establish double contingency is actually ineffective, criticality will still be unlikely.

A.4 RISK INDEX EVALUATION SUMMARY

As previously mentioned, an acceptable way for the applicant to present the results of the ISA is a tabular summary of the identified accident sequences. Table A-1 is an acceptable format for such a table. This table lists several example accident sequences for a powder blender at a typical facility. Table A-1 summarizes two sets of information: (1) the accident sequences identified in the ISA; and (2) a risk index calculated for each sequence to show compliance with the regulation. A summary of the risk index calculation will be given below.

Accident sequences result from initiating events, followed by failure of one or more controls. Thus there are columns in Table A-1 for the initiating event and for controls. Controls may be mitigative or preventive. Mitigative controls are measures that reduce the consequences of an accident. The phrase “unmitigated consequences” describes the results when the system of preventive controls fails and mitigation also fails. Mitigated consequences result when the preventive controls fail, but mitigative measures succeed. These are abbreviated in the table as “unmit.” and “mitig.”, respectively. Index numbers are assigned to initiating events, control failure events, and mitigation failure events, based on the reliability characteristics of these items.

With redundant controls and in certain other cases, there are sequences where an initiating event occurs that places the system in a vulnerable state. While the system is in this vulnerable state, a control must fail in order for the accident to result. Thus the frequency of the accident depends on the frequency of the first event, the duration of vulnerability, and the frequency of the (second) control failure. For this reason, it is necessary to consider the duration of the vulnerable state, and to assign it a duration index. The values of all index numbers for a sequence, depending on the number of events involved, are added to obtain a total likelihood index, T. Sequences are then assigned to one of the three likelihood categories of the Risk Matrix depending on the value of this index in accordance with Table A-2.

The values of index numbers in sequences are assigned considering the criteria in Tables A-3 through A-5. Each table applies to a different type of event. Table A-3 applies to events that have frequencies of occurrence, such as initiating events and certain control failures. When failure probabilities are required for an event, Table A-4 provides the index values. Table A-5 provides index numbers for durations of failure. These are used in certain accident sequences where two controls must simultaneously be in a failed state. In this case, one of the two controlled parameters will fail first. It is then necessary to consider the duration that the system remains vulnerable to failure of the second. This period of vulnerability can be terminated in several ways. The first failure may be “fail-safe”. The first failure may be continuously monitored, thus alerting the operator when it fails so that the system may be quickly placed in a safe state. Or the controls may be subject to periodic surveillance tests for hidden failures. When hidden failures are possible, these surveillance intervals limit the duration that the system is in a vulnerable state. The reverse sequences, where the second control fails first, should be considered as a separate accident sequence. This is necessary because the duration of failure of the second control will usually differ from that of the first. The values of these duration indices are not merely judgmental. They are directly related to the time intervals used for surveillance, and the time needed to render the system safe.

As shown in Table A-5, the duration of failure is accounted for in establishing the overall likelihood that an accident sequence would continue to the defined consequence. Thus the time to discover and repair the failure is accounted for in establishing the risk of the postulated accident. Accordingly, as long as the actual undiscovered failures and repair times in service are conservatively described by applicant's chosen duration of failure index, and the defined risks (reported in the ISA Summary) associated with the consequences are acceptable pursuant to 10 CFR 70.61, then when such failures occur it does not imply a violation of the approved license.

For all these index numbers, the more negative the number is, the less likely is the failure. Accident sequences may consist of varying numbers of events, starting with an initiating event. The total likelihood index is the sum of the indices for all the events in the sequence, including those for duration.

Consequences are assigned to one of the three consequence categories of the Risk Matrix based on calculations or estimates of the actual consequences of the accident sequence. The consequences categories are based on the levels identified in 10 CFR 70.61. Multiple types of consequences can result from the same event. The consequence category is chosen for the most severe consequence.

As shown in the first row of Table A-1, the failure duration index can make a large contribution to the total likelihood index. Therefore, the reviewer should verify that there is adequate justification that the failure will be corrected in the time ascribed to the duration index. In general, duration indices with values less than minus one (-1), corresponding to 36 days, to be acceptable, should be based on the existence of intentional monitoring of the process. The duration of failure for an unmonitored process should be conservatively estimated.

Table A-1 provides two risk indices for each sequence in order to permit evaluation of the risk significance of the controls involved. To measure whether a control has high risk significance, the Table provides an "uncontrolled risk index", determined by modeling the sequence with all controls as failed (i.e., not contributing to a lower likelihood). In addition, a "controlled risk index" is also calculated, taking credit for the low likelihood and duration of control failures. When an accident sequence has an uncontrolled risk index exceeding 4, but a controlled index of less than 4, then the controls involved have a high risk significance in that they are relied on to achieve acceptable safety performance. Thus use of these indices permits evaluation of the possible benefit of improving controls, and also whether a relaxation may be acceptable.

Table A-6 provides a more detailed description of the accident sequences used in the example of Table A-1. The reviewer needs the information in Table A-6 to understand the nature of the accident sequences listed in Table A-1. Table A-1 lacks sufficient room to explain any but the simplest failure events.

Table A-7 is used to explain the controls and external initiating events that appear in the accident sequences in Table A-1. The reviewer needs the information in Table A-7 to understand why the initiating events and controls listed in Table A-1 have the low likelihood indices assigned. Thus Table A-7 needs to address such information as: 1) the margins to

safety limits, 2) the redundancy of a control, and 3) the measures taken to assure adequate reliability of a control. Table A-7 must also justify why those external events, which are not obviously extremely unlikely, have the low likelihoods which are being relied on for safety. The applicant should provide separate tables to list the controls for criticality, chemical, fire, radiological, and environmental accidents.

Table A-1: Example Accident Sequence Summary And Risk Index Assignment

Process: UO_2 Powder Preparation (PP) Unit Process: Additive Blending Node: Blender Hopper Node (PPB2)

Accident Sequence	Initiating Event (a)	Preventive Control 1 (b)	Preventive Control 2 (c)	Mitigation Control (d)	Likelihood* Index T (e) uncontrolled controlled	Likelihood Category (f)	Conse quence Evaluation Reference	Conse-quence Category (g)	Risk Indices (h=f x g) uncontrolled controlled	Comments & Recommendations
PPB2-1A (Criticality from blender leak of UO_2)	see Control 1 (note 1)	PPB2-C1: Mass Control Failure: Blender leaks UO_2 onto floor, critical mass exceeded frq1 = -1 dur1 = -4	PPB2-C2: Moderation Failure: Suffic. water for criticality introduced while UO_2 on floor frq2 = -2	N/A	unc T = -1 con T = -7	unc 3 con 1	rad 35	3 (crit: 3, rad: 0)	9 3	criticality, consequences = 3 Control 2 fails while Control 1 is in failed state. T = -1-4-2 = -7
PPB2-1B (Rad. release from blender leak of UO_2)	blender leaks UO2 frqi = -1	PPB2-C1: Mass Control success: leaked UO_2 below critical mass, OR	PPB2-C2: Moderation success: no moderator	Ventilation Failure: Ventilated blender enclosure frqm = -2	unc T = -1 con T = -3 con T = -1	unc 3 unmit. 2 mitig. 3	rad 36	unc 2 unmit. 2 mitig. 1	6 unmit. 4 mitig. 3	rad consequences, no criticality unmitigated sequence: control 1 & mitigation fail. T= -1-2 = -3 mitig.: Control 1 fails, mitig. control does not fail. T = -1
PPB2-1C	see Control 1 (note 1)	PPB2-C2: Moderation Failure: Suffic. water for criticality on floor under UO_2 blender frq1 = -2 dur1 = -3	PPB2-C1: Mass Control Failure: Blender leaks UO_2 on floor while water present frq2 = -1	N/A	unc T = -2 con T = -6	unc 2 con 1	rad 35	3 (crit: 3, rad: 0)	6 3	criticality by reverse sequence of PPB2-1A, moderation fails first. Note different likelihood T = -6
PPB2-2	Fire in Blender Room frqi = -2	Fire Suppression Failure: Fails on demand: prf1 = -1	N/A	N/A	unc T = -2 con T = -3	unc 2 con 2	rad 37	2 (rad) 1	4 2	Event sequence is just initiating event plus one control failure on demand

*Likelihood index T is a sum. uncontrolled: T=frqi or frq1; controlled: includes all indices T=a+b+c+d

Note 1: For these sequences the initiating event is failure of one of the controls, hence the frequency is assigned under that control.

Table A-2: Determination of Likelihood Category

Likelihood Category	Likelihood Index T (= sum of index numbers)
1	$T \leq -5$
2	$-5 < T \leq -2$
3	$-2 < T$

Table A-3: Failure Frequency Index Numbers

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

* Indices less than (more negative than) “-1" should not be assigned to controls unless the configuration management, auditing, and other management measures are of high quality, because, without these measures, the controls may be changed or not maintained.
** The index value assigned to a control of a given type in column 3 may be one value higher or lower than the value given in column 1. Criteria justifying assignment of the lower (more negative) value should be given in the narrative describing ISA methods. Exceptions require individual justification.

Table A-4: Failure Probability Index Numbers

Probability Index Number	Probability of Failure on Demand	Based on Type of Control	Comments
-6 *	10^{-6}		If initiating event, no controls needed
-4 or -5*	10^{-4} - 10^{-5}	Exceptionally robust passive engineered control (PEC), or an inherently safe process, or 2 redundant controls better than simple admin controls (AEC, PEC, or enhanced admin)	Rarely can be justified by evidence, since few systems are found in such large numbers . Further, most types of single control have been observed to fail.
-3 or -4*	10^{-3} - 10^{-4}	A single passive engineered ctrl. (PEC) or an active engineered control (AEC) with high availability	
-2 or -3 *	10^{-2} - 10^{-3}	A single active engineered control, or an enhanced admin control, or an admin control for routine planned operations	
-1 or -2	10^{-1} - 10^{-2}	An admin control that must be performed in response to a rare unplanned demand	

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

Table A-5: Failure Duration Index Numbers

Duration Index Number	Avg. Failure Duration	Duration in Years	Comments
1	More than 3 years	10	
0	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}	

Table A-6: Accident Sequence Descriptions

Process: UO_2 Powder Preparation (PP) Unit Process: Additive Blending
Node: Blender Hopper Node (PPB2)

Accident Sequence (see Table A-1)	Description
PPB2-1A Blender UO_2 leak criticality	The initial failure is a blender leak of UO_2 that results in a mass sufficient for criticality on the floor. (This event is not a small leak.) Before UO_2 can be removed, moderator sufficient to cause criticality is introduced. Duration of critical mass UO_2 on floor estimated to be one hour.
PPB2-1B Blender UO_2 leak, rad. release	The initial failure is a blender leak of UO_2 that results in a mass insufficient for criticality on the floor, or mass sufficient for criticality but moderation failure does not occur. Consequences are radiological, not a criticality. A ventilated enclosure should mitigate the radiological release of UO_2. If it fails during cleanup or is not working, unmitigated consequences occur.
PPB2-1C	The events of PPB2-1A occur in reverse sequence. The initial failure is introduction of water onto the floor under the blender. Duration of this flooded condition is 8 hours. During this time, blender leaks a critical mass of UO_2 onto the floor. Criticality occurs.
PPB2-2	Initiating event is a fire in the blender room. Fire is not extinguished in time. Release of UO_2 from process equipment occurs. Offsite dose estimated to exceed 100 mrem.

Table A-7: Criticality Safety Limits and Controls

Process: UO_2 Powder Preparation (PP) Unit Process: Additive Blending
Node: Blender Hopper Node (PPB2)

Safety Control Identifier	Safety Parameter and Limits	Safety Controls Description	Max Value of Other Parameters	Reliability Management Measures	QA Grade
PPB2-C1	Mass Outside Hopper: zero	Mass Outside Hopper: Hopper and outlet design prevent UO_2 leaks, double gasket at outlet.	Full Water Reflection, Enrichment 5%	Surveillance for leaked UO2 each shift	A
PPB2-C2	Moderation: in UO_2 < 1.5 wt. % External Water in area: zero	Moderation In UO_2 : Two sample measurements by two persons before transfer to hopper. External Water: Posting excluding water, double piping in room, floor drains, roof integrity	Full Water Reflection, Enrichment 5%	Drain, roof, and piping are under safety grade maintenance	A

Note: In addition to engineered controls, this table should include descriptions of external initiating events whose low likelihood is relied on to achieve acceptable risk, especially those which are assigned frequency indices lower than -4. The descriptions of these initiating events should contain information supporting the frequency index value selected by the applicant.

ACCIDENT SUMMARY AND RISK INDEX ASSIGNMENT FOR TABLE A-1

The definitions for the contents of each column in the accident summary tabulation, Table A-1, are provided below.

Accident Sequence
This column is provided to list the accident sequences identified by the applicant in the ISA Summary. It is important to the proper documentation of the ISA that the applicant subdivides the plant into a set of uniquely identified units, referred to here as "nodes". The applicant should give symbols, names, or numbers to these nodes that permit them to be uniquely identified. For example, the "Blender Hopper" node described In Table A-1 has the unique identifying symbol PPB2. Additional identifier characters have been added to form the identifier, PPB2-1, to identify the first accident sequence identified in that node. Because the applicant should list all the plant controls of significance used elsewhere in the ISA, tabulations of the unique node (and accident) identifier can be used to find the accidents that these controls have been shown to prevent. By reviewing this table, the reviewer can then evaluate (1) the adequacy of the controls for preventing accidents and (2) the bases for making the consequence and likelihood assignments in the table.

Initiating Event or Control Failure
This column is provided to list initiating events or control failures, typically identified in the Process Hazard Analysis phase of the ISA, that may lead to consequences exceeding those identified in 70.61. Initiating events are of several distinct types: (1) external events, such as hurricanes and earthquakes, (2) plant events external to the node being analyzed (e.g., fires, explosions, failures of other equipment, flooding from plant water sources), (3) deviations from normal of the process in the node (i.e., credible abnormal events), and (4) failures of controls of the node. The tabulated initiating events should only consist of those that involve an actual or threatened failure of controls, or that cause a demand requiring controls to function in order to prevent consequences exceeding 70.61 levels. The frequency index number for initiating events is referred to in the table using the symbol "frqi". Table A-3 provides criteria for assigning a value to frqi. Usually, insufficient room is present in a tabular presentation like Table A-1 to describe accurately the events indicated. Consequently, the applicant should provide supplementary narrative information to adequately describe each accident sequence of Table A-1. Cross referencing between this information and the table should be adequate, for instance, the unique symbolic accident sequence identifiers can be used. Table A-6 is an example of a list of supplementary accident sequence descriptions corresponding to Table A-1.

Preventive Control 1
This column is provided to list a control designed to prevent consequences exceeding 70.61 levels. If separate controls are used to prevent different consequences, separate rows in the table should be defined corresponding to each type of consequence. Table A-1 contains an example of a set of related sequences so separated. Sequences where two controls must simultaneously be in a failed state require assignment of three index numbers: the failure frequency of the first control, frq1, the duration of this failure, dur1, and the failure frequency of the second control, frq2. For such sequences, the initiating event is failure of the first control. In these cases, frq1 is assigned using Table A-3. The failure duration of the first control is

assigned using Table A-5. Other sequences may be more easily described as a failure of the safety controls on demand after the occurrence of an initiating event. In these cases, the failure probability index number, prf1, is assigned using Table A-4. The symbol “b” is used in the column heading for the indices associated with this control.

Preventive Control 2
This column is provided in case a second preventive control exists. The failure frequency or failure probability on demand is assigned as for Preventive Control 1. The symbol “c” is used in the column heading for the indices associated with this control.

Mitigation Control
This column is provided in case controls are available to mitigate the accident. That is, they reduce, but do not eliminate, the consequences of a sequence. A control that eliminates all adverse consequences should be considered preventive. The symbol “d” is used in the column heading for the indices associated with this control.

Likelihood Category
This column is provided to list the likelihood category number for the risk matrix, which is based on the total likelihood index for a sequence. The total likelihood index, T, is the sum of the indices for those events that comprise a sequence. These events normally consist of the initiating event, and failure of one or more controls, including any failure duration indices. However, accident sequences may consist of varying numbers and types of undesired events. Methods for deciding what frequencies and failure durations need to be considered will be described later in this appendix. Based on the sum of these indices, the likelihood category number for the risk matrix is assigned using Table A-2. The symbol “e” is used for this category number in the column heading.

Consequence Evaluation Reference
This column permits identification of the consequence calculations that relate to this accident sequence. Multiple references may be required to refer to calculations of the different types of consequences, radiological, various chemicals, etc..

Consequence Category
This column is provided to assign the consequence category numbers based on estimating the consequences of all types (i.e., radiological, criticality, chemical, and environmental) that may occur. Based on this estimate, accidents can be assigned to the categories defined in 10 CFR 70.61. The symbol “f” is used for this category number in the column heading. Sequences having controls to mitigate consequences must be divided into two cases, one where the mitigation succeeds, and one where it fails, each with different consequences. The two cases may be tabulated in one row of Table A-1, but the mitigated and unmitigated consequences should be separately indicated. Unless the mitigated case results in consequences below those levels identified in 10 CFR 70.61, both cases must satisfy the likelihood requirements as shown by the risk matrix.

Risk Index

This column is provided to list the risk index, which is calculated as the product of the likelihood category and consequence category numbers. This is shown in the column heading by the formula "g = e x f". Sequences with values of "g" less than or equal to "4" are acceptable. Another risk index can also be calculated as the product of the consequence category number times the likelihood category associated with only the failure frequency index for the initiating event. The resulting product can be referred to as the "unmitigated" risk index. It is unmitigated in the sense that no credit is taken for the functioning of any subsequent controls. For example, in the first three cases in Table A-1, the initiating event is failure of Preventive Control 1. In these cases, the failure frequency of Preventive Control 1 is used to determine the likelihood category when calculating the unmitigated risk index.

Comments and Recommendations

This column is needed to record ISA team recommendations, especially when the existing system of controls is evaluated as being deficient. This may happen because a newly identified accident sequence is not addressed by existing controls, or because a deficiency has been found in the existing controls.

DETERMINATION OF LIKELIHOOD CATEGORY IN TABLE A-2

The likelihood category is determined by calculating the likelihood index, T, then using this table. The term T is calculated as the sum of the indices for the events in the accident sequence.

DETERMINATION OF FAILURE FREQUENCY INDEX NUMBERS IN TABLE A-3

Table A-3 is used to assign frequency index numbers to plant initiating events and control system failures as found in the columns of Table A-1. The term failure must be understood to mean not merely failure of the control device or procedure, but also as violation of the safety limit by the process. In the example in Table A-1, accident sequence PPB2-1A involves loss of mass control over UO_2 in a blender. If criticality is the concern, failure does not occur unless UO_2 accumulates to a critical mass before the leak is stopped. For radiological consequences, any amount leaked may cause exposure. In assessing the frequency index, this factor should be considered because many control failures do not cause safety limits to be exceeded.

Table A-3 provides two columns with two sets of criteria for assigning an index value, one based on type of control, the other directly on observed failure frequencies. The types of controls are administrative, active engineered, passive engineered, etc. Since controls of a given type have a wide range of failure frequencies, assignment of index values based on this table should be done with caution. Due consideration should be given as to whether the control will actually achieve the corresponding failure frequency in the next column. Based on operational experience, more refined criteria for judging failure frequencies may be developed by an individual applicant. In the column labeled "Based on Type of Control", references to redundancy allow for controls that may themselves have internal redundancy to achieve a necessary level of reliability.

Another objective basis for assignment of an index value is actual observations of failure events. These actual events may have occurred in the applicant plant or in a comparable process elsewhere. Justification for specific assignments may be noted in the Comments column of Table A-1.

As previously noted, the definition of failure of a safety control to be used in assigning indices is, for non-redundant controls, a failure severe enough to cause an accident with consequences. For redundant controls, it is a failure such that, if no credit is taken for functionality of the other control, an accident with consequences would result. If most control malfunctions would qualify as such failures, then the index assignments of this table are appropriate. If true failure is substantially less frequent, then credit should be taken and adequate justification provided.

Note that indices less than (more negative than) "-1" should not be assigned to controls unless the configuration management, auditing, and other required management measures are of high quality, because, without these measures, the controls may be changed or inadequately maintained. The reviewer should be able to determine this from a tabular summary of safety controls provided in the application. This summary should include identification of the process parameters to be controlled and their safety limits, and a thorough description of the control and its applied management measures.

DETERMINATION OF FAILURE PROBABILITY INDEX NUMBERS IN TABLE A-4

Occasionally, information concerning the reliability of a safety control may be available as a probability on demand. That is, a history may exist of tests or incidents where the system in question is demanded to function. To quantify such accident sequences it is necessary then to know the demand frequency, the initiating event, and the demand failure probability of the safety control. This table provides an assignment of index numbers for such controls in a way that is consistent with Table A-3. The probability of failure on demand may be the likelihood that it is in a failed state when demanded (availability), or that it fails to remain functional for a sufficient time to complete its mission.

DETERMINING MANAGEMENT MEASURES FOR SAFETY CONTROLS

Table A-7 is an acceptable way of listing those IROFS in all the accident sequences leading to consequences exceeding those identified in 70.61. The items listed should include all safety controls and all external events whose low likelihood is relied upon to meet the performance requirements of 10 CFR 70.61. Staff reviews this list to determine whether measures have been applied to each safety control adequate to assure their continual availability and reliability in conformance to 10 CFR 70.62(d). The types of management measures include maintenance, training, configuration management, audits and assessments, quality assurance, etc. Certain criteria for management measures are indicated in the Baseline Design Criteria; others are described in greater detail in Chapters 4 through 7 and Chapter 11. IROFS meeting all the provisions of these chapters have acceptable management measures. IROFS may, with justification, have lesser management measures than those described. However, every item relied on for safety in accident sequences leading to consequence categories 2 or 3 should be

assigned at least a minimal set of management measures. Specifically, in order to defend against common mode failure of all controls on a process, this minimal set of measures must include an adequate degree of: a) configuration management, b) regular auditing for the continued effectiveness of the control, c) adequate labeling, training, or written procedures to assure the awareness of the operating staff of the safety function performed, d) surveillance and corrective maintenance, and e) preventive maintenance, if applicable.

If lesser or graded management measures are applied to some controls, Tables A-1 and A-7 and the narratives preceding them, in order to be acceptable, must identify to which controls these lesser measures are applied. In addition, information indicating that acceptable reliability can be achieved with these lesser measures must be presented. It is not necessary that the specifics of these measures, such as the surveillance interval, type of maintenance, or type of testing, be described as applied to each control. It is recognized that such specific measures must be applied differently to each control to whatever degree is necessary to achieve adequate reliability. It is the formality, documentation, and quality assurance requirements applied to these direct management measures that may be graded generically in a risk-informed manner.

The following describes the application of management measures to IROFS based on the risk importance of the item in an accident sequence, as defined by (1) the "uncontrolled" risk index shown in Appendix A to this Chapter, and (2) the failure likelihood index, "T", also described in Appendix A. In summary, items relied on to prevent or mitigate accidents with unmitigated consequences in the two highest categories identified in 70.61 should satisfy the Baseline Design Requirements of 70.64 that apply.

1. For those sequences that are reduced in risk from initially high risk (an "uncontrolled" risk index of 6 or 9) to an acceptable risk ("controlled" risk index of less than or equal to 4):

   IROFS must have satisfied all applicable Baseline Design Requirements of Section 70.64.

2. For those sequences that are initially evaluated as being in an acceptable risk category (an "uncontrolled" risk index of less than or equal to 4):

   2A. If the initiating event is <u>not</u> a control failure, then assurances for IROFS are not necessary. No additional risk reduction is required. However, for sequences claimed to be highly unlikely, the assessment that the initiating event has such a low frequency must be adequately justified in the application. Further, for accident sequences resulting in nuclear criticality, double contingency should still be achieved, thus requiring at least one more item relied on for safety, typically a control, in addition to the initiating event. This control must have satisfied all applicable Baseline Design Requirements of Section 70.64

   2B. If the initiating event <u>is</u> a control failure, and if the likelihood of that failure is taken to be at least a few times per plant lifetime (T is greater than -2), then assurances for that item relied on may be less than Baseline Design Requirements of 70.64, as defined by the applicant and approved by the NRC. Any subsequent items in the accident sequence will be unregulated.

[Rationale: Since T is greater than -2, the likelihood category is 3. Therefore the consequence category is no greater than 1, to limit the uncontrolled risk index to at most 4. Since the consequence category is low, the assurance level can be reduced]

2C. If the initiating event is a control failure, and if the likelihood of that failure is taken to be less than a few times per plant lifetime (T is less than or equal to -2), then assurance for this control must satisfy the full Baseline Design Requirements. No regulation of subsequent controls in the sequence is necessary.

[Rationale: Since T is less than or equal to -2, the likelihood category must be 1 or 2. Therefore, the consequence category must be no greater than 2, in order to limit the uncontrolled risk index to at most 4. In this case, the uncertainty in determining a low failure likelihood requires compensatory measures in the form of increased assurances (high level criteria) that the control is indeed kept at a low failure likelihood]

RISK-INFORMED REVIEW OF IROFS

NRC staff will review the IROFS failures and external events listed in Table A-7 in a risk-informed manner. Accident sequences having potential for higher risk will be subject to a more detailed review by staff to assure their adequacy.

The final results column of Table A-1 gives the risk indices for each accident sequence that was identified in the ISA. There are two indices, uncontrolled and controlled. The controlled index is a measure of risk without credit for the safety controls. If the uncontrolled risk index is a 6 or 9, while the controlled index is an acceptable value (less than 5), the set of safety controls involved are significant in achieving acceptable risk. That is, these controls have high risk significance. The uncontrolled risk index will be used by staff to identify all risk significant sets of controls. These sets of controls will be reviewed with greater scrutiny than controls established to prevent or mitigate accident sequences of low risk.

U.S. NUCLEAR REGULATORY COMMISSION
STANDARD REVIEW PLAN
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

4.0 RADIATION PROTECTION

4.1 PURPOSE OF REVIEW

The purpose of this review is to determine whether the applicant's radiation protection program is adequate to protect the radiological health and safety of workers and to comply with the regulatory requirements in 10 CFR Parts 19, 20, and 70.

The content and level of detail in this chapter are more detailed because this chapter provides acceptance criteria for evaluating compliance with Part 20, which has very specific requirements. Nevertheless the Applicant is expected and the NRC Reviewer should accept insights gained from the conduct of the ISA and information contained in the ISA summary in developing and reviewing the acceptability of the applicants radiation protection program. Review procedures and acceptance criteria for the applicant's program for protecting members of the public and the control of effluent releases are presented in Chapter 9, "Environmental Protection," of this SRP. In Chapter 3," Integrated Safety Analysis" (ISA) there are criteria for performing a comprehensive ISA at a fuel cycle facility. In performing an ISA, an applicant will evaluate and rank the radiological risks posed by potential accident sequences throughout the facility and assess the adequacy of IROFS to ensure that the radiation exposure performance criteria of 10 CFR 70.61(b) and (c) are met.

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 Parts 19, 20, and 70. Specifically, licensees must develop, document, and implement a radiation protection program in accordance with 10 CFR 20.1101. Additionally, 10 CFR 20.2102 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 review the ISA Summary to identify those facility operations, analyzed in the ISA, that have radiological consequences, and the IROFS and the management measures implemented to prevent or mitigate such radiological risks.

The staff will review an applicant's commitments, regarding the radiation protection program, in the following areas:

(1) To establish, maintain, and implement a radiation protection program;

(2) To keep occupational exposures to radiation as low as reasonably achievable (ALARA);

(3) To appoint radiological protection staff who are suitably qualified and trained in radiation protection procedures;

(4) To prepare written radiation protection procedures and Radiation Work Permits (RWPs);

(5) To 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) To design and implement programs to control airborne concentrations of radioactive material by using ventilation systems, containment systems, and respirators;

(7) To 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) To maintain additional programs including: (a) a records maintenance program; (b) a corrective actions program; and (c) a program for reporting to the NRC in accordance with requirements in Parts 20 and 70.

4.4 ACCEPTANCE CRITERIA

4.4.1 Commitment to Radiation Protection Program Implementation

4.4.1.1 Regulatory Requirements

Regulations applicable to establishment of a radiation protection program are present in 10 CFR 20.110, Subpart B, "Radiation Protection Programs."

4.4.1.2 Regulatory Guidance

NRC regulatory guides applicable to the commitment to design and implement a radiation protection program are: Regulatory Guide 8.2 "Guide for Administrative Practice in Radiation Monitoring" February 2, 1973.

4.4.1.3 Regulatory Acceptance Criteria

The applicant's radiation protection program is acceptable if the applicant provides data and information in the license application that meets each of the following commitments:

(1) To design and implement a radiation protection program that meets the regulatory requirements of Part 20 Subpart B;

(2) To outline the radiation protection program structure and define the responsibilities of key program personnel;

(3) To staff the radiation protection program with suitably trained people, to provide sufficient resources, and to implement it;

(4) To commit to the independence of the radiation protection function from the facility's operations; and

(5) To review, at least annually, the content and implementation of the radiation protection program as required by 10 CFR 20.1101(c). The review should consider facility changes, new technologies, or other process enhancements that could improve the overall program effectiveness.

4.4.2 Commitment to an ALARA Program

4.4.2.1 Regulatory Requirements

Regulations applicable to the ALARA program are present in 10 CFR 20.1101, "Radiation Protection Programs."

4.4.2.2 Regulatory Guidance

NRC regulatory guides applicable to the ALARA program are:

1.	Regulatory Guide 8.2 February 2, 1973	"Guide for Administrative Practice in Radiation Monitoring"
2.	Regulatory Guide 8.10, Rev. 1-R, May 1977	"Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable"
3.	Regulatory Guide 8.13, Rev. 3 Draft DG 8014, October 1994	"Instructions Concerning Prenatal Radiation Exposure"
4.	Regulatory Guide 8.29 February 1996	"Instructions Concerning Risks from Occupational Radiation Exposure"

4.4.2.3 Regulatory Acceptance Criteria

The applicant's ALARA program is acceptable if the applicant provides data and information, in the license application, that meet each of the following commitments:

(1) To establish a comprehensive, effective, and written ALARA program;

(2) To prepare policies and procedures to ensure occupational radiation exposures are maintained ALARA and that such exposures are consistent with the requirements of 10 CFR 20.1101;

(3) To outline specific ALARA program goals, to establish an ALARA program organization and structure, and to have written procedures for its implementation in the plant design and operations;

(4) To establish an ALARA Committee, or equivalent organization, with sufficient staff, resources, and clear responsibilities to ensure that the occupational radiation exposure dose limits of Part 20 are not exceeded under normal operations. The ALARA committee should meet at least annually and the membership should include management, radiation protection, environmental safety, industrial safety, production, etc. The ALARA committee will review the ALARA program and the review 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, etc. The review should determine if 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 if exposures, releases and contamination levels are in accordance with the ALARA concept. Recommendations of the ALARA Committee should be documented and tracked to completion;

(5) To use the ALARA program as a mechanism to facilitate interaction between radiation protection and operations personnel;

(6) To regularly review and revise, when appropriate, the ALARA program goals and objectives and to 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 applicable to the organization and qualifications of the radiological protection staff are presented in 10 CFR 70.22, "Contents of Applications."

4.4.3.2 Regulatory Guidance

NRC regulatory guides applicable to the organization and personnel qualifications of radiation protection program staff are:

1.	Regulatory Guide 8.2 February 1973	"Guide for Administrative Practice in Radiation Monitoring"
2.	Regulatory Guide 8.10, Rev. 1-R, May 1977	"Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable"

4.4.3.3 Regulatory Acceptance Criteria

The applicant's commitment to organize and staff a radiation protection program is acceptable if the applicant provides data and information in the license application that meets each of the following commitments:

(1) To appoint suitably trained radiation protection personnel and to identify their authority and responsibilities;

(2) To establish clear organizational relationships among the individual positions responsible for the radiation protection program and other line managers;

(3) To appoint a suitably trained radiation protection program director (typically referred to as the Radiation Safety Officer) who has direct access to the Plant Manager, who is skilled in the interpretation of data and regulations pertinent to radiation protection; who is familiar with the operation of the facility and radiation protection concerns of the site; who is used as a resource in radiation safety management decisions; and who will be responsible for establishing and implementing the radiation protection program;

(4) To assign responsibility to the radiation protection program staff for implementation of the radiation program functions;

(5) To describe the minimum training requirements and qualifications for the radiation protection staff.

4.4.4 Commitment to Written Procedures

4.4.4.1 Regulatory Requirements

The regulations applicable to radiation protection procedures and RWPs are presented in 10 CFR 70.22(8), "Content of Applications."

4.4.4.2 Regulatory Guidance

Regulatory guidance applicable to procedures and RWPs is Regulatory Guide 8.10, Rev., 1-R,

May 1977, “Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable.”

4.4.4.3 Regulatory Acceptance Criteria

The applicant’s commitment to prepare written radiation protection procedures and RWPs is acceptable if the applicant provides data and information in the license application that meet each of the following commitments:

(1) To prepare written, approved radiation protection procedures to carry out activities related to the radiation protection program;

(2) To specify how the radiation protection procedures will be prepared, authorized, approved, and distributed. These procedures should be reviewed and revised as necessary, to incorporate any facility or operational changes, or changes to the facility’s ISA. Approval of the procedures should be by the Radiation Safety Officer, or an individual who has the qualifications of the Radiation Safety Officer; and

(3) To 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 the record-keeping requirements for RWPs.

4.4.5 Training

An applicant’s commitments to employee training are addressed in SRP Chapters 4 and 11. Chapter 4 addresses corporate radiation protection training programs, Chapter 11 addresses training which serves as a management control, to ensure that an administrative control IROFS is available and reliable when required.

4.4.5.1 Regulatory Requirements

Regulations applicable to the radiation safety training program are the following from Title 10, CFR:

1. Section 19.12 "Instructions to workers"

2. Section 20.2110 "Form of records”

4.4.5.2 Regulatory Guidance

NRC regulatory guides and American Society for Testing and Materials (ASTM) standards pertaining to radiation protection training are:

1.	Regulatory Guide 8.10, Rev. 1-R May 1977	"Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable"
2.	Regulatory Guide 8.13, Draft DG-801 proposed R-3 October 1994	"Instructions Concerning Prenatal Radiation Exposure"
3.	Regulatory Guide 8.29, Draft DG-8012 proposed R-1 December 1994	"Instructions Concerning Risks from Occupational Radiation Exposure"
4.	ASTM C986-89 Reapproved 1995	"Developing Training Programs in the Nuclear Fuel Cycle"
5.	ASTM E1168-95	"Radiological Protection Training for Nuclear Facility Workers"

4.4.5.3 Regulatory Acceptance Criteria

The applicant's commitment to train its employees in radiation protection is acceptable if the applicant provides data and information in the license application that meets each of the following commitments:

(1) To design and implement an employee radiation protection training program that complies with the requirements of Parts 19 and 20;

(2) To provide training, to all personnel and visitors entering restricted areas, that is commensurate with the health risk to which they may be exposed, or to provide trained escorts who have received training;

(3) To provide a level of training based on the potential radiological health risks associated with that employee's work responsibilities;

(4) To incorporate, in the radiation protection training program, the provisions in 10 CFR 19.12 and topics such as:

- Correct handling of radioactive materials;
- Minimization of exposures to radiation and/or radioactive materials;
- Access and egress controls and escort procedures;
- Radiation safety principles, policies, and procedures;
- Monitoring for internal and external exposures;
- Monitoring instruments;
- Contamination control, including protective clothing

and equipment;
- ALARA and exposure limits;
- Radiation hazards and health risks; and
- Emergency response.

(5) To review the radiation protection training programs at least every 3 years and to conduct refresher training at least every 3 year to address changes in policies, procedures, requirements, and in the facility ISA; and

(6) To evaluate the effectiveness and adequacy of the training program curriculum and instructors.

4.4.6 Ventilation and Respiratory Protection Programs

4.4.6.1 Regulatory Requirements

Regulations applicable to the ventilation and respiratory protection programs are presented in part 20, Subpart H, “Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas.”

4.4.6.2 Regulatory Guidance

NRC regulatory guides, American National Standard (ANSI) standards, and a National Council on Radiation Protection and Measurements (NCRP) report applicable to the design of the ventilation and respiratory protection programs are:

1.	Regulatory Guide 8.24, Rev. 1 October 1979	"Health Physics Surveys during Enriched Uranium-235 Processing and Fuel Fabrication"
2.	ANSI N510-1980	"Testing of Nuclear Air Cleaning Systems"
3.	ERDA 76-21	“Nuclear Air Cleaning Handbook,” C. A. Burchsted, A. B. Fuller, J. E. Kahn
4.	NCRP Report No. 59 December 15, 1978	"Operational Radiation Safety Program"
5.	Regulatory Guide 8.15	“Acceptable Programs for Respiratory Protection”
6.	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 applicant provides data and information, in the license application, that meet each of the following commitments:

(1) To install appropriately sized ventilation and containment systems in areas of the plant identified in the ISA Summary as having potential airborne concentrations of radionuclides that could exceed the occupational, derived air concentration values specified in Part 20, Appendix B, during normal operations;

(2) To 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, as required in subsection (1) above;

(3) To describe the criteria for the ventilation and containment systems required in subsection (1) above, including minimum flow velocity at openings in these systems, maximum differential pressure across filters and types of filters to be used.

(4) To describe the frequency and types of tests to measure ventilation and containment systems performance, the acceptance criteria, and the actions to be taken when the acceptance criteria are not satisfied;

(5) To establish a respiratory protection program that meets the requirements of Part 20, Subpart H;

(6) To 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) To revise the written procedures for use of individual respiratory protection equipment as applicable, when processing, facility, or equipment changes are made; and

(8) To maintain records of the respiratory protection program, including training for 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 materials, 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 identified in the ISA Summary where the occupational radiation dose limits could potentially

be exceeded. Measurements of airborne radioactive material and/or bioassays are used to determine that internal occupational exposures to radiation do not exceed the dose limits specified in part 20, Subpart C.

4.4.7.1 Regulatory Requirements

NRC regulations applicable to radiation surveys and monitoring programs are the following, from Part 20:

1. Part F "Surveys and Monitoring"
2. Part C "Occupational Dose Limits"
3. Part L "Records"
4. Part M "Reports"

4.4.7.2 Regulatory Guidance

NRC regulatory guides, NUREGs, and ANSI standards applicable to radiation surveys and monitoring programs are:

1. Regulatory Guide 8.2, February 1973 — "Guide for Administrative Practice in Radiation Monitoring"
2. Regulatory Guide 8.4, February 1973 — "Direct-Reading and Indirect-Reading Pocket Dosimeters"
3. Regulatory Guide 8.7, Rev. 1, June 1992 — "Instructions for Recording and Reporting Occupational Radiation Exposure Data"
4. Regulatory Guide 8.9, Rev. 1, July 1993 — "Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program"
5. Regulatory Guide 8.24, Rev. 1, October 1979 — "Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication"
6. Regulatory Guide 8.25, Rev. 1, June 1992 — "Air Sampling in the Workplace"

7.	Regulatory Guide 8.34, July 1992	“Monitoring Criteria and Methods to Calculate Occupational Radiation Doses”
8.	NUREG-1400, September 1993	"Air Sampling in the Workplace"
9.	ANSI N13.1-1969, Reaffirmed 1993	"Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities”
10.	ANSI N328-1978	“Radiation Protection Instrumentation Test and Calibration”
11.	ANSI N13.11-1983	“Dosimetry-Personnel Dosimetry Performance-Criteria for Testing”
12.	ANSI N13.15-1985	“Radiation Detectors-Personnel Thermoluminescence Dosimetry Systems-Performance”
13.	ANSI.HPSN 13.22, 1995	“Bioassay Program for Uranium”
14.	ANSI N13.27-1981	“Performance Requirements for Pocket-Sized Alarm Dosimeters and Alarm Ratemeters”
15.	ANSI.HPSN 13.30, 1996	“Performance Criteria for Radiobioassay”
16.	ANSI N13.6-1966 Reaffirmed 1989	"Practice for Occupational Radiation Exposure Records Systems”

4.4.7.3 Regulatory Acceptance Criteria

The applicant’s commitment to implement radiation surveys and monitoring programs is acceptable if the applicant provides data and information, in the license application, that meet each of the following commitments:

(1) To have radiation surveys and monitoring programs consistent with the requirements of Part 20, Subpart F;

(2) To prepare written procedures, for the radiation survey and monitoring program, that include: an outline of the program objectives, sampling procedures, data analysis methods, types of equipment and instrumentation to be used, frequency of measurements, recordkeeping and reporting requirements, and actions to be taken when measurements exceed Part 20 occupational dose limits or administrative levels established by the applicant;

(3) To design and implement a personnel monitoring program for external occupational radiation exposures that outlines methods or procedures to:

- Identify the criteria for worker participation in the program;
- Identify the types of radiation to be monitored;
- Specify how exposures will be measured, assessed, and recorded;
- Identify the type and sensitivity of personal dosimeters to be used, when they will be used, and how they will be processed and evaluated;
- Identify the plant's administrative exposure levels or action levels at which actions are taken to investigate the cause of exposures exceeding these levels; and

(4) To design and implement a personnel monitoring program, for internal occupational radiation exposures, based on the requirements of 10 CFR 20.1201, 20.1204, and 20.1502(b), that outlines methods or procedures to:

- Identify the criteria for worker participation in the program;
- Identify the type of sampling to be used, the frequency of collection and measurement, and the minimum detection levels;
- Specify how worker intakes will be measured, assessed, and recorded;
- Specify how the data will be processed, evaluated, and interpreted;
- Identify the plant's administrative exposure levels or action levels at which actions are taken to investigate the cause of exposures exceeding these levels; and

(5) To comply with the requirements of 10 CFR 20.1202 for summation of external and internal occupational radiation exposures through the use of procedures such as those outlined in Regulatory Guide 8.7 or 8.34;

(6) To design and implement an air sampling program in areas of the plant identified as potential airborne radioactivity areas, to conduct air surveys, and to calibrate and maintain the airborne sampling equipment in accordance with the manufacturers' recommendations;

(7) To implement additional procedures, as may be required by Part 20 and the ISA Summary, to control the concentration of airborne radioactive material (e.g., control of access, limitation of exposure times to licensed materials, and use of respiratory protection equipment, etc.);

(8) To conduct a contamination survey program in areas of the plant identified in the ISA Summary to have a greater possibility of radiological contamination, which includes 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;

(9) To refer to the facility's corrective action program instances in which the results of personnel monitoring or contamination surveys exceed the applicant's administrative personnel contamination levels.

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(10) To refer, to the facility's corrective action program, any incident that results in airborne occupational exposures to radiation that exceed the facility's administrative limits, the dose limits in Part 20 Appendix B, or 10 CFR 70.61;

(11) To use equipment and instrumentation with sufficient sensitivity for the type(s) of radiation being measured and to calibrate and maintain equipment and instrumentation in accordance with the manufacturers' recommendations;

(12) To establish policies to ensure equipment and materials removed from restricted areas to unrestricted areas are not contaminated above the specified release levels in NRC, Branch Technical Position, "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material," April 1993;

(13) To leak- test all sealed sources in accordance with the following NRC Branch Technical Positions: (1) "License Condition for Leak- Testing Sealed Byproduct Material Sources," April 1993; (2) "License Condition for Leak- Testing Sealed Plutonium Sources," April 1993; (3) "License Condition for Plutonium Alpha Sources," April 1993; (4) "License Condition for Leak- Testing Sealed Source Which Contains Alpha and/or Beta-Gamma Emitters," April 1993; and (5) "License Condition for Leak- Testing Sealed Uranium Sources," April 1993;

(14) To establish and implement an access control program that ensures that: (a) signs, labels, and other access controls are properly posted and operative; (b) restricted areas are established to prevent the spread of contamination and are identified with appropriate signs; and (c) step-off pads, change facilities, protective clothing facilities, and personnel- monitoring instruments are provided in sufficient numbers and locations;

(15) To have a reporting program consistent with the requirements of Parts 19 & 20.

4.4.8 Additional Program Commitments

4.4.8.1 Regulatory Requirements

Regulations applicable to the additional program commitments are the following from Title 10, Part 20:

1.	Subpart L	"Records"
2.	Subpart M	"Reports"
3.	Section 70.61	"Performance Requirements"
4.	Section 70.74	"Additional Reporting Requirements"

4.4.8.2 Regulatory Guidance

There are no NRC regulatory guidelines applicable to these additional program commitments.

4.4.8.3 Acceptance Criteria

The applicant's commitment to implement additional program features is acceptable if the applicant provides data and information, in the license application, that meet each of the following commitments:

(1) To 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); and results of corrective action program referrals; RWPs; and planned special exposures;

(2) To establish a program to report to the NRC, within the timeframes specified in 10 CFR 20.2202 and 10 CFR 70.74, any event that results in an occupational exposure to radiation exceeding the dose limits in Part 20.

(3) To prepare and submit to the NRC an annual report of the results of individual monitoring, as required by 10 CFR 20.2206(b);

(4) To refer to the facility's corrective action program any incident that results in an occupational exposure to radiation that exceeds the dose limits in part 20, Appendix B, or 10 CFR 70.74, and to report to the NRC both the corrective action taken (or planned) to protect against a recurrence and the proposed schedule to achieve compliance with the applicable license condition(s).

4.5 REVIEW PROCEDURES

4.5.1 Acceptance Review

The primary reviewer should evaluate the license application to determine whether it addresses the "Areas of Review" discussed in Section 4.3. If significant deficiencies are identified, the applicant should be requested to submit additional material before the start of the safety evaluation.

4.5.2 Safety Evaluation

The primary reviewer will perform a safety evaluation with respect to the "Acceptance Criteria" in Section 4.4. For existing facilities, the reviewer will consult with the cognizant radiation protection NRC inspector to identify and resolve any issues of concern related to the licensing review. The primary reviewer will prepare an SER for the Licensing Project Manager, in support of licensing action.

4.6 EVALUATION FINDINGS

The reviewer will write an SER addressing each topic reviewed and explain why the NRC staff has reasonable assurance that the radiation protection part of the application is acceptable and that the health and safety of the workers is adequately protected. License conditions may be proposed to impose requirements where the application is deficient. The following kinds of statements and conclusions will be included in the staff's SER:

> The applicant has committed to an acceptable radiation protection program that includes: (1) an effective documented program to ensure that occupational radiological exposures are ALARA; (2) an organization with adequate qualification requirements for the radiation protection personnel; (3) approved written radiation protection procedures and RWPs for radiation protection activities; (4) radiation protection training for all personnel who have access to restricted areas; (5) a program to control airborne concentrations of radioactive material with engineering controls and respiratory protection; (6) a radiation survey and monitoring program that includes requirements for control of radiological contamination within the facility, and monitoring of external and internal radiation exposures; and (7) other programs to maintain records, to report to the NRC in accordance with Parts 20 and 70, and to correct for upsets at the facility.

The NRC staff concludes that the applicant's radiation protection program is adequate and meets the requirements of 10 CFR Parts 19, 20, and 70. Conformance to the license application and license conditions will ensure safe operation.

4.7 REFERENCES

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

U.S. Code of Federal Regulations, Title 10, Part 20, “Standards for Protection Against Radiation,” U. S. Government Printing Office, Washington, DC.

U.S. Nuclear Regulatory Commission, Branch Technical Position, "License Condition for Leak-Testing Sealed Plutonium Sources," April 1993.

U.S. Nuclear Regulatory Commission, Branch Technical Position, "License Condition for Plutonium Alpha Sources," April 1993.

U.S. Nuclear Regulatory Commission, Branch Technical Position, "License Condition for Leak-Testing Sealed Source Which Contains Alpha and/or Beta-Gamma Emitters," April 1993.

U.S. Nuclear Regulatory Commission, Branch Technical Position, "License Condition for Leak-Testing Sealed Uranium Sources," April 1993.

U.S. Nuclear Regulatory Commission, Branch Technical Position, "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material," April 1993.

5.0 NUCLEAR CRITICALITY SAFETY

5.1 PURPOSE OF REVIEW

The purpose of this review is to determine whether the applicant's Nuclear Criticality Safety (NCS) program is adequate to support safe operation of the facility, as required by Part 70. As used in this chapter, controls and barriers that are used as items relied on for safety should be IROFS in the ISA Summary. Detailed NCS information for processes should be in the criticality safety evaluation, ISA, and, in order to meet the performance requirements of the rule, in the ISA Summary.

5.2 RESPONSIBILITY FOR REVIEW

Primary: Nuclear Process Engineer (NCS Reviewer)

Secondary: None

Supporting: Project Manager and Fuel Cycle Inspector (As needed.)

5.3 AREAS OF REVIEW

The staff should review the application to determine whether: (1) the applicant has provided for the appropriate management of the NCS program; (2) the applicant has identified and committed to the responsibilities and authorities for individuals to develop and implement the NCS program; (3) the facility management measures described in 10 CFR 70.62 have been committed to and will support implementing and maintaining the NCS program; and (4) an adequate NCS program is described that includes identifying and committing to the methodologies and technical practices used to ensure the safe operation of the facility, as required by Part 70.

The specific areas for review are as follows:

5.3.1 Management of the NCS Program

The Primary Reviewer should review the application to determine whether the applicant has committed to and implemented an effective management of the NCS program. The following areas of the application related to the applicant's management of the NCS program should be reviewed:

(1) Providing the resources to develop and implement the NCS program in accordance with

the objectives of an effective NCS program which should include:

a. Preventing an inadvertent nuclear criticality;

b. Protecting against the occurrence of an identified accident sequence in the ISA Summary that could lead to an inadvertent nuclear criticality;

c. Complying with the NCS performance requirements of 10 CFR 70.61;

d. Establishing and maintaining NCS safety parameters and procedures;

e. Establishing and maintaining NCS safety limits and NCS operating limits for IROFS;
f. Developing NCS determinations to assure that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety;

g. Establishing and maintaining NCS IROFS, based on current NCS determinations;

h. Providing training in emergency procedures in response to an inadvertent criticality;

i. Complying with NCS baseline design criteria requirements in 10 CFR 70.64(a);

j. Complying with the NCS ISA Summary requirements in 10 CFR 70.65(b); and

k. Complying with the NCS ISA Summary change process requirements in 10 CFR 70.72.

5.3.2 Organization and Administration

The Primary Reviewer should review the application to determine whether the applicant has identified and committed to the responsibilities and authorities for individuals to develop and implement the NCS program, including the responsibilities and authorities for the organization and administration of the NCS program. The following areas of the application related to the applicant's organization and administration should be reviewed:

1. For familiarity, the general organization and administration methods used by the applicant (see SRP Chapter 2.0); and

2. The areas of review listed in SRP Section 2.3, as they relate to NCS, including the experience, educational requirements, responsibilities, and authorities of NCS management and staff.

5.3.3 Management Measures

The Primary Reviewer should review the application to determine whether the applicant has

committed to the facility management measures in 10 CFR 70.62 and whether the commitments demonstrate the applicant's ability to implement and maintain the NCS program. The following areas of the application related to the applicant's management measures should be reviewed:

1. For familiarity, the general configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance elements used by the applicant (see SRP Sections 11.3.1 through 11.3.9); and

2. The NCS program should provide for the following elements of management measures:

   a. Training and qualifications of NCS management and staff;

   b. Auditing, assessing, and upgrading the NCS program;

   c. Revising the ISA Summary, as they relate to NCS;

   d. Recommending modifications to operating and maintenance procedures, to reduce the likelihood of occurrence of an inadvertent nuclear criticality;

   e. Designing and installing a criticality accident alarm system (CAAS) to provide immediate detection and annunciation of an inadvertent nuclear criticality;

   f. Referring to the corrective action function any unacceptable performance deficiencies that might result in an inadvertent nuclear criticality;

   g. Referring to the corrective action function any unacceptable performance deficiencies that did result in an inadvertent nuclear criticality; and

   h. Retaining records of the NCS program, including documentation of corrective actions taken.

5.3.4 Methodologies and Technical Practices

The Primary Reviewer should review the application to determine whether the applicant has implemented NCS methodologies and NCS technical practices used to make NCS determinations to ensure the safe operation of the facility as required by 10 CFR 70.24 "Criticality Accident Requirements" for criticality accident alarm systems, 10 CFR 70.61(d) "Performance Requirements" for under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety, 10 CFR 70.64(a) "Requirements for New Facilities or New Processes at Existing Facilities" for baseline design criteria, and 10 CFR 70.65(b) "Additional Content of Applications" for ISA Summary. The following areas of the application related to the applicant's NCS methodologies and NCS technical practices should be reviewed:

1. The commitment to use the NCS methodologies identified by the applicant's

NCS program;

2. The commitment to use the NCS technical practices identified by the applicant's NCS program;

3. The commitment to fulfill the requirements of 10 CFR 70.24 and to have a CAAS that has been incorporated into the facility management measures;

4. The commitment to detect an inadvertent nuclear criticality and promptly notify personnel, which should ensure that the radiation exposure to workers will be minimized;

5. The commitment to the requirements of 10 CFR 70.61(d);

6. The commitment to the requirements in 10 CFR 70.64, as they relate to NCS;

7. The areas of review listed in SRP Section 3.3, as they relate to NCS, including accident sequences, consequences, likelihoods, risks, and IROFS; and

8. Identification and use of appropriate NCS methodologies and NCS technical practices.

5.4 ACCEPTANCE CRITERIA

To provide for NCS, the applicant should provide both commitments and descriptions on how the commitments will be met. Individual commitments and descriptions are expected only when the acceptance criteria are relevant to the operations and materials to be licensed. In addition, the applicant's use of standards should be considered acceptable if the applicant has met the following acceptance criteria:

If an applicant intends to conduct activities where a standard applies and the standard has been endorsed by an NRC Regulatory Guide, then a commitment to comply with all the requirements (i.e., "shalls") of the standard is necessary but may not be sufficient to meet the acceptance criteria. Notwithstanding such a general commitment to a standard, the applicant should clarify its intended compliance with those requirements in the standard that are expressed only in terms of general principles by more specific commitments and descriptions in the application. Any variations from the requirements of the standard should be identified and justified in the application. The commitments and descriptions should be considered acceptable if the applicant has met the acceptance criteria as described below.

5.4.1 Regulatory Requirements

The regulatory basis for the review should be the general and additional contents of an application, as required by 10 CFR 70.22 and 70.65, respectively. In addition, the NCS review should be conducted to ensure compliance with 10 CFR 70.24, 70.61, 70.62, 70.64, 70.72, and Appendix A of 10 CFR Part 70.

5.4.2 Regulatory Guidance

NRC Regulatory Guide 3.71, "Nuclear Criticality Safety Standards for Fuels and Materials Facilities," August 1998, endorses the American National Standards Institute (ANSI)/American Nuclear Society (ANS)-8 national standards listed below in part or in full.

1. ANSI/ANS-8.1, "Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors," 1983 (Reaffirmed in 1988).

2. ANSI/ANS-8.3, "Criticality Accident Alarm System," 1997.

3. ANSI/ANS-8.5, "Use of Borosilicate-Glass Raschig Rings as a Neutron Absorber in Solutions of Fissile Material," 1996.

4. ANSI/ANS-8.6, "Safety in Conducting Subcritical Neutron-Multiplication Measurements In Situ," 1983 (Reaffirmed in 1995).

5. ANSI/ANS-8.7, "Guide for Nuclear Criticality Safety in the Storage of Fissile Materials," 1975 (Reaffirmed in 1987).

6. ANSI/ANS-8.9, "Nuclear Criticality Safety Criteria for Steel-Pipe Intersections Containing Aqueous Solutions of Fissile Materials," 1987 (Reaffirmed in 1995).

7. ANSI/ANS-8.10, "Criteria for Nuclear Criticality Safety Controls in Operations With Shielding and Confinement," 1983 (Reaffirmed in 1988).

8. ANSI/ANS-8.12, "Nuclear Criticality Control and Safety of Plutonium-Uranium Fuel Mixtures Outside Reactors," 1987 (Reaffirmed in 1993).

9. ANSI/ANS-8.15, "Nuclear Criticality Control of Special Actinide Elements," 1981 (Reaffirmed in 1995).

10. ANSI/ANS-8.17, "Criticality Safety Criteria for the Handling, Storage, and Transportation of LWR Fuel Outside Reactors," 1984 (Reaffirmed in 1997).

11. ANSI/ANS-8.19, "Administrative Practices for Nuclear Criticality Safety," 1996.

12. ANSI/ANS-8.20, "Nuclear Criticality Safety Training," 1991.

13. ANSI/ANS-8.21, "Use of Fixed Neutron Absorbers in Nuclear Facilities Outside Reactors," 1995.

14. ANSI/ANS-8.22, "Nuclear Criticality Safety Based on Limiting and Controlling Moderators," 1997.

15. ANSI/ANS-8.23, "Nuclear Criticality Accident Emergency Planning and Response," 1997.

NRC endorsement of these standards means that they provides procedures and methodology generally acceptable to NRC staff for the prevention and mitigation of nuclear criticality accidents. However, application of a standard is not a substitute for detailed nuclear criticality safety analyses for specific operations. Reference in this chapter to a specific version of a standard should not be construed as discouraging an applicant from using the most recent version of a standard. However, if an applicant commits to an unendorsed standard, then the applicant needs to demonstrate in the application why the unendorsed standard should be acceptable to NRC.

5.4.3 Regulatory Acceptance Criteria

5.4.3.1 Management of the NCS Program

To provide for NCS, the applicant's management of the NCS program should be considered acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

1. The applicant commits to develop, implement, and maintain an NCS program to meet the regulatory requirements of Part 70;

2. The applicant states the NCS program objectives, which should include those objectives listed in SRP Section 5.3.1;

3. The applicant establishes NCS safety parameters and procedures;

4. The applicant outlines an NCS program structure and defines the responsibilities and authorities of key program personnel;

5. The applicant commits to maintain and update the NCS methodologies and NCS technical practices to current configuration, by means of the configuration management function;

6. The applicant commits to use the NCS program to establish and maintain NCS safety limits and NCS operating limits for IROFS in nuclear processes and to maintain the adequacy of management measures, to ensure their availability and reliability;

7. The applicant commits to preparation of NCS postings, to NCS training, and to NCS emergency procedure training;

8. The applicant commits to adhere to the NCS baseline design criteria requirements in 10 CFR 70.64(a) for new facilities and new processes at existing facilities that require a license amendment under 10 CFR 70.72; and

9. The applicant commits to use the NCS program to evaluate modifications to operations, to recommend process parameter changes to maintain the safe operation of the facility, and to select appropriate IROFS and management measures.

5.4.3.2 Organization and Administration

Information related to NCS organization and administration acceptance criteria may be located in the organization and administration part of the application. To provide for NCS, the applicant's organization and administration should be considered acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

1. The applicant meets the acceptance criteria in SRP Section 2.4, as they relate to NCS, including organizational positions, functional responsibilities, experience, and qualifications of personnel responsible for NCS;

2. The applicant commits to both ANSI/ANS-8.1-1983 and ANSI/ANS-8.19-1996, as they relate to organization and administration;

3. The applicant commits to the intent of Section 4.11 of ANSI/ANS-8.1-1983, which is the following: The applicant shall commit to the use of personnel, skilled in the interpretation of data pertinent to NCS and familiar with the operation of the facility, as a resource in NCS management decisions. These specialists should be independent of operations supervision;

4. The applicant commits to provide NCS postings in areas, operations, work stations, and storage locations, in order to provide operators a reference for ensuring conformance and safe operation;

5. The applicant commits to the following policy: Personnel shall report defective NCS conditions to the NCS function and perform actions only in accordance with written, approved procedures. Unless there is a specific procedure that deals with an situation, personnel shall report defective NCS conditions to the NCS function and take no action until the NCS function has evaluated the situation and provided recovery procedures;

6. The applicant commits to describe organizational positions, experience of personnel, qualifications of personnel, and functional responsibilities, and commits also to outline organizational relations amongst the individual positions;

7. The applicant commits to designate an NCS program director who will be responsible for implementation of the NCS program; and

8. The applicant commits to staff the NCS program with suitably trained personnel and to provide sufficient resources for its operation.

5.4.3.3 Management Measures

Information related to NCS management measures acceptance criteria may be located in the management measures part of the application. To provide for NCS, the applicant's management measures required by 10 CFR 70.62 should be considered acceptable if the

applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

1. Training (see SRP Section 11.4.3.3):

   a. The applicant commits to both ANSI/ANS-8.19-1996 and ANSI/ANS-8.20-1991, as they relate to training;

   b. The applicant commits to provide training to all personnel to recognize the CAAS signal and to evacuate promptly to a safe area; and

   c. The applicant commits to provide instruction training regarding the policy in SRP section 5.4.3.2(5).

2. Procedures (see SRP Section 11.4.3.4):

   a. The applicant commits to ANSI/ANS-8.19-1996, as it relates to procedures; including the following policy: No single, inadvertent departure from a procedure could cause an inadvertent nuclear criticality.

3. Audits and assessments (see SRP Section 11.4.3.5):

   a. The applicant commits to ANSI/ANS-8.19-1996, as it relates to audits and assessments;

   b. The applicant commits to conducting and documenting weekly NCS walkthroughs (e.g., checklists) of all operating SNM process areas such that all operating SNM process areas should be reviewed at least every 2 weeks. Identified weaknesses should be incorporated into the facility corrective action function and should be promptly and effectively resolved. A graded approach may be used to justify an alternate NCS walkthrough schedule based on the ISA and included in the ISA Summary; and

   c. The applicant commits to conducting and documenting quarterly NCS audits such that all NCS aspects of management measures (see SRP Chapter 11.0) should be audited at least every 2 years. A graded approach may be used to justify an alternate NCS audit schedule based on the ISA and included in the ISA Summary.

5.4.3.4 Methodologies and Technical Practices

To provide for NCS, the applicant's methodologies and technical practices should be considered acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

1. NCS controlled parameters will be appropriately applied; and

2. NCS limits on IROFS will be appropriately determined.

5.4.3.4.1 Methodologies

To provide for NCS, the applicant's commitment to NCS methodologies should be considered acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

1. NCS determinations will be performed using acceptable methodologies;

2. NCS limits on controls and controlled parameters will be established to ensure an adequate margin of subcriticality for safety;

3. Methods used to develop NCS limits will be validated, including ensuring that they are used within acceptable ranges, with appropriate assumptions, and with acceptable computer codes;

4. An inadvertent nuclear criticality will be detected promptly to ensure that radiation exposures to workers are minimized;

5. The applicant commits to ANSI/ANS-8.1-1983, as it relates to methodologies;

6. The applicant commits to the intent of the validation report statement in NRC Regulatory Guide 3.71, August 1998, which is: The applicant should demonstrate: (1) the adequacy of the margin of safety for subcriticality by assuring that the margin is large compared to the uncertainty in the calculated value of k-eff, (2) that the calculation of k-eff is based on a set of variables whose values lie in a range for which the methodology used to determine k-eff has been validated, and (3) that trends in the bias support the extension of the methodology to areas outside the area(s) of applicability;

7. The applicant includes a reference to (including date and revision number) and summary description of either a manual or a documented, reviewed, and approved validation report (by NCS function and management) for each methodology that will be used to make an NCS determination (e.g., experimental data, reference books, hand calculations, deterministic computer codes, probabilistic computer codes, consensus standards). When there are changes to either a reference manual or validation report, the change should be reported to NRC by letter. After reviewing the change notification letter, NRC will determine if a review of a reference manual or validation report is necessary. The summary description of a reference manual or validation report should have:

    a. A summary of the theory of the methodology in sufficient detail, clarity, and lack of ambiguity that allows understanding of the methodology;

    b. A summary of the results of the reference manual or validation report that shows the area(s) of applicability;

    c. A commitment to apply the methodology only in the area(s) of applicability or provide justifications for applying the methodology outside the area(s) of applicability;

d. A commitment to use pertinent computer codes, assumptions, and techniques in the methodology;

e. A commitment to use proper functioning of the mathematical operations in the methodology;

f. A commitment to use data consistent with reliable experimental measurements;

g. A commitment to use plant-specific benchmark experiments and data derived therefrom that will be used to validate the methodology;

h. A commitment to determine the bias, uncertainty in the bias, uncertainty in the methodology, uncertainty in the data, uncertainty in the benchmark experiments, and margin of subcriticality for safety, when using the methodology;

i. A commitment to use controlled software and hardware, when using the methodology; and

j. A commitment to use a verification process when using the methodology.

8. The applicant commits to have, at the facility, the reference manual or documented, reviewed, and approved validation report (by NCS function and management) for each methodology used to make an NCS determination. The manual or validation report should have:

a. A description of the theory of the methodology in sufficient detail, clarity, and lack of ambiguity that allows understanding of the methodology and independent duplication of results;

b. A description of the area(s) of applicability that identifies the range of values for which valid results have been obtained for the parameters used in the methodology. In accordance with the provisions in ANSI/ANS-8.1-1983, any extrapolation beyond the area(s) of applicability should be supported by an established mathematical methodology;

c. A description of the use of pertinent computer codes, assumptions, and techniques in the methodology;

d. A description of the proper functioning of the mathematical operations in the methodology (e.g., mathematical testing);

e. A description of the data used in the methodology, consistent with reliable experimental measurements;

f. A description of the plant-specific benchmark experiments and data derived therefrom that were used for validating the methodology;

g. A description of the bias, uncertainty in the bias, uncertainty in the methodology, uncertainty in the data, uncertainty in the benchmark experiments, and margin of subcriticality for safety, as well as the basis for these items, as used in the methodology. If the bias is determined to be advantageous to the applicant, the applicant shall use a bias of 0.0 (e.g., in a critical experiment where the k-eff is known to be 1.00 and the code calculates 1.02, the applicant cannot use a bias of 0.02 to allow calculations to be made above the value of 1.00);

h. A description of the software and hardware that will use the methodology; and

i. A description of the verification process and results.

9. The applicant commits to incorporate each reference manual or documented, reviewed, and approved validation report (by NCS function and management) for a methodology, as well as assumptions used, into the facility configuration management program;

10. The applicant commits to performing NCS determinations in accordance with specified methods incorporated in the facility's management measures and in accordance with the following principles:

a. NCS safety limits, NCS operating limits, and limits on NCS controlled parameters will be established assuming credible optimum conditions (i.e., most reactive conditions physically possible or limited by written commitments to regulatory agencies) unless specified controls are implemented to control the limit to a certain range of values;

b. NCS safety limits, NCS operating limits, and limits on NCS controlled parameters will be derived from the NCS determinations;

c. NCS safety limits, NCS operating limits, and limits on NCS controlled parameters will be based on application of the NCS methodology appropriate to the process under study;

d. NCS operating limits will be derived from NCS safety limits by taking into consideration changes in operating parameters to ensure processes will remain subcritical under both normal and credible abnormal conditions;

e. NCS operating limits will establish sufficient margins of safety for processes and take into consideration the variability and uncertainty in a process and the NCS subcritical limit;

f. NCS safety limits will establish sufficient margins of safety for processes and take into consideration the variability and uncertainty in a process and the NCS operating limit;

g. The margin of subcriticality for safety for a process should be relative compared to the calculated value of k-eff; and

h. K-eff is calculated from a set of variables whose values lie in a range for which the validity of the NCS methodology has been demonstrated.

5.4.3.4.2 Technical Practices

Controlled parameters available for NCS control include the following: mass, geometry, density, enrichment, reflection, moderation, concentration, interaction, neutron absorption, and volume. To provide for NCS, the applicant's commitment to NCS technical practices should be considered acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

1. Although the applicant may use a single NCS control to maintain the values of two or more controlled parameters, this use constitutes only one component necessary to meet double contingency protection;

2. Based on 10 CFR 70.61, the applicant commits to the following policy: No single credible event or failure can result in a criticality accident;

3. The applicant commits to the preferred use of passive engineered controls to ensure NCS. The applicant should commit to the following preference, in general, for controls to ensure NCS: (1) passive engineered; (2) active engineered; (3) augmented administrative; and (4) simple administrative. When using a control, the choice of the type and manner should be justified;
4. When evaluating a controlled parameter, heterogeneous effects are considered. Heterogeneous effects are particularly relevant for low-enriched uranium processes, where, when all other parameters are equal, heterogeneous systems are more reactive than homogeneous systems;

5. The applicant commits to perform an evaluation, for all controlled parameters, that shows that during both normal and credible abnormal conditions, the controlled parameter will be maintained;

6. When controlled parameters are controlled by measurement, reliable methods and instruments should be used. Where there is significant susceptibility to human error, it is acceptable if the applicant commits to representative sampling, reliable measurement instruments and methods, and dual independent measurements;

7. The use of mass as a controlled parameter should be considered acceptable if:

   a. When a given mass of material has been determined, a percentage factor is used to determine the mass percentage of SNM in that material;

   b. When fixed geometric devices are used to limit the mass of SNM, a conservative process density is used;

   c. When physical measurement of the mass is needed, the measurement is obtained by using instrumentation;

d. When using double-batching of SNM as a single parameter limit control from experimental data, and double-batching of SNM is possible, the mass of SNM is limited to no more than 45 percent of the minimum critical mass, based on spherical geometry; and

e. When using double-batching of SNM as a single parameter limit control from experimental data and double-batching of SNM is not possible, the mass of SNM is limited to no more than 75 percent of the critical mass, based on spherical geometry.

9. The use of geometry as a controlled parameter should be considered acceptable if:

a. Before beginning operations, all dimensions and nuclear properties that use geometry control are verified. The facility configuration management program should be used to maintain these dimensions and nuclear properties; and

b. When using large single units as a single parameter control from experimental data, the margins of safety are 90 percent of the minimum critical cylinder diameter, 85 percent of the minimum critical slab thickness, and 75 percent of the minimum critical sphere volume.

10. The use of density as a controlled parameter should be considered acceptable if:

a. When process variables can affect the density, the process variables are shown in the ISA Summary to be controlled by IROFS; and

b. When physical measurement of the density is needed, the measurement is obtained by using instrumentation.

11. The use of enrichment as a controlled parameter should be considered acceptable if:

a. A method of segregating enrichments is used to ensure differing enrichments will be not interchanged, or else the most limiting enrichment is applied to all material; and

b. When physical measurement of the enrichment is needed, the measurement is obtained by using instrumentation.

12. The use of reflection as a controlled parameter should be considered acceptable if:

a. When investigating an individual unit, the wall thickness of the unit and all reflecting adjacent materials of the unit are considered. The adjacent materials should be farther than 30.48 cm (12 inches) away from the unit; and

b. After identifying potential reflectors, the controls to prevent the presence of the potential reflectors are identified as IROFS in the ISA Summary.

13. The use of moderation (e.g., exclusion of moderators) as a controlled parameter should be considered acceptable if:

    a. When using moderation, the applicant commits to ANSI/ANS-8.22-1997;

    b. When process variables can affect the moderation, the process variables are shown in the ISA Summary to be controlled by IROFS;

    c. When physical measurement of the moderation is needed, the measurement is obtained by using instrumentation;

    d. When designing physical structures, the design precludes the ingress of moderation;

    e. When sampling of the moderation is needed, the sampling program uses dual independent sampling methods;

    f. When developing firefighting procedures for use in a moderation controlled area, restrictions are placed on the use of moderator material; and

    g. After evaluating all credible sources of moderation for the potential for intrusion into a moderation controlled area, the ingress of moderation is precluded or controlled.

14. The use of concentration as a controlled parameter should be considered acceptable if:

    a. When process variables can affect the concentration, the process variables are shown in the ISA Summary to be controlled by IROFS;

    b. High concentrations of SNM in a process are precluded unless the process is analyzed to be safe at any credible concentration;

    c. When using a tank containing concentration controlled solution, the tank is normally closed;

    d. When sampling of the concentration is needed, the sampling program uses dual independent sampling methods; and

    e. After identifying possible precipitating agents, precautions are taken to ensure that such agents will not be inadvertently introduced.

15. The use of interaction as a controlled parameter should be considered acceptable if:

    a. When maintaining a physical separation between units, engineered controls with a minimum spacing or augmented-administrative controls are used. The structural integrity of the spacers or racks should be sufficient for normal and credible abnormal conditions.

16. The use of neutron absorption as a controlled parameter should be considered acceptable if:

    a. When using borosilicate-glass raschig rings, the applicant commits to ANSI/ANS-8.5-1996;

    b. When using fixed neutron absorbers, the applicant commits to ANSI/ANS-8.21-1995; and

    c. When evaluating absorber effectiveness, neutron spectra are considered (e.g., cadmium is an effective absorber for thermal neutrons, but ineffective for fast neutrons).

17. The use of volume as a controlled parameter should be considered acceptable if:

    a. When using volume control, fixed geometry are used to restrict the volume of SNM and engineered devices should limit the accumulation of SNM; and

    b. When physical measurement of the volume is needed, the measurement is obtained by using instrumentation.

5.4.3.4.3 Requirements in 10 CFR 70.24

To provide for NCS, the applicant's commitment to the CAAS requirements in 10 CFR 70.24 should be considered acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

1. The applicant documents that the facility CAAS meets 10 CFR 70.24;

2. The applicant commits to ANSI/ANS-8.3-1997, as modified by Regulatory Guide 3.71, August 1998;

    a. At or above the 10 CFR 70.24 mass limits, CAAS coverage shall be required in each area in which SNM is handled, stored, or used;

    b. 10 CFR 70.24 requires that each area that needs CAAS coverage be covered by two detectors; and

    c. 10 CFR 70.24 requires that a CAAS be capable of detecting a nuclear criticality that produces an absorbed dose in soft tissue of 20 rads of combined neutron and gamma radiation at an unshielded distance of 2 meters from the reacting material within 1 minute.

3. The applicant commits to having a CAAS that is uniform throughout the facility for the type of radiation detected, the mode of detection, the alarm signal, and the system dependability;

4. The applicant commits to having a CAAS that is designed to remain operational during credible events such as a seismic shock equivalent to the site-specific design-basis earthquake or the equivalent value specified by the Uniform Building Code;

5. The applicant commits to having a CAAS that is designed to remain operational during credible events such as a fire, an explosion, a corrosive atmosphere, and other credible conditions;

6. The applicant commits to having a CAAS alarm that is clearly audible in areas that must be evacuated or provides alternate notification methods that are documented to be effective in notifying personnel that evacuation is necessary;

7. The applicant commits to rendering operations safe, by shutdown and quarantine if necessary, in any area where CAAS coverage has been lost and not restored within a specified number of hours. The number of hours should be determined on a process-by-process basis, because shutting down certain processes, even to make them safe, may carry a larger risk, than being without a CAAS for a short time. The applicant should commit to compensatory measures (e.g., limit access, halt SNM movement) when the CAAS system is not functional; and

8. Emergency management (see SRP Chapter 8.0):

   a. The applicant commits to the requirements in ANSI/ANS-8.23-1997, as they relate to NCS;

   b. The applicant either has an emergency plan or satisfies the alternate requirements in 10 CFR 70.22.(h)(1)(i);

   c. The applicant commits to provide fixed and personnel accident dosimeters in areas that require a CAAS. These dosimeters should be readily available to personnel responding to an emergency and there should be a method for prompt onsite dosimeter readouts; and

   d. The applicant commits to provide emergency power for the CAAS or provide justification for the use of continuous monitoring with portable instruments.

5.4.3.4.4 Requirements in 10 CFR 70.61(d)

To provide for NCS, the applicant's commitment to the requirements in 10 CFR 70.61(d) that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety should be considered acceptable if the

applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

1. The applicant commits to the use of NCS controls and controlled parameters to assure that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety;

2. As stated in ANSI/ANS-8.1-1983, the applicant commits to the following policy: Process specifications shall incorporate margins to protect against uncertainties in process variables and against a limit being accidentally exceeded;

3. The applicant commits to the following national standards, as they relate to these requirements: ANSI/ANS-8.7-1975, ANSI/ANS-8.9-1987, ANSI/ANS-8.10-1983, ANSI/ANS-8.12-1987, ANSI/ANS-8.15-1981, and ANSI/ANS-8.17-1984;

4. If the applicant intends to use administrative k-eff margins for normal and credible abnormal conditions, the applicant commits to NRC pre-approval of the administrative margins;

5. The applicant commits to determining subcritical limits for k-eff calculations such that : k-subcritical = 1.0 - bias-margin, where margin includes adequate allowance for uncertainty in the methodology, data, and bias, to assure subcriticality;

6. The applicant commits to performing studies to correlate the change in a value of a controlled parameter and its k-eff value. The studies should also include changing the value of one controlled parameter and determining its effect on another controlled parameter and k-eff; and

7. The applicant commits to implement an NCS program that ensures double contingency protection, when practicable. When evaluating double contingency protection, the following should be considered with respect to both ANSI/ANS-8.1-1983 and the likelihood in the SRP Chapter 3.0:

    a. Adherence to double contingency protection: Each process that could have an inadvertent nuclear criticality should have double contingency protection. Double contingency protection may be provided by either: (i) at least two-parameter control: the control of at least two independent process parameters or (ii) single-parameter control: a system of multiple independent controls on a single process parameter. The first method is the preferred approach because of the difficulty of preventing common-mode failure when controlling only one parameter;

    b. As used in double contingency protection, the term “concurrent” means that the effect of the first process change persists until a second change occurs, at which point the process could have an inadvertent nuclear criticality. It does not mean that the two events initiating the change must occur simultaneously. The possibility of an inadvertent nuclear criticality can be markedly reduced if failures of NCS controls are rapidly detected and the processes rendered safe. If not, processes can remain vulnerable to a second failure for extended periods of time and;

c. Exceptions to double contingency protection: There may be processes where double contingency protection is not practicable. In those processes, the facility should implement sufficient redundancy and diversity in controlled parameters such that at least two unlikely and concurrent events, errors, accidents, or equipment malfunctions are necessary before an inadvertent nuclear criticality is possible. The applicant should commit in the license application, to identify and provide justification, in the ISA.

1. The applicant meets the acceptance criteria in SRP Section 3.4, as they relate to subcriticality of operations and margin of subcriticality for safety.

   Note: This is the acceptance criterion to review the high-risk accident sequences and a selected sampling of other than high-risk accident sequences.

5.4.3.4.5 Requirements in 10 CFR 70.64(a)

To provide for NCS, the applicant's commitment to the baseline design criteria requirements in 10 CFR 70.64(a) should be considered acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

1. The applicant commits to the double contingency principle in determining NCS controls and IROFS in the design of new facilities or new processes at existing facilities that require a license amendment under 10 CFR 70.72; and

2. The applicant commits to double contingency protection as discussed in SRP Section 5.4.3.4.4(9).

5.4.3.4.6 Requirements in 10 CFR 70.65(b) (ISA Summary)

The applicant is required to meet the performance requirements in 10 CFR 70.61(b) and (c), as well as the performance requirements in 10 CFR 70.61(d), which include the requirement to limit the risk of an inadvertent nuclear criticality by assuring that all nuclear processes remain subcritical. The applicant’s evaluation of NCS accident sequences should be performed in a manner consistent with the applicant’s evaluation of non-NCS accident sequences used to meet 10 CFR 70.61(b) and (c); however 10 CFR 70.61(d) requires the applicant to use prevention methods as the primary means to meet the performance requirements of 10 CFR 70.61(b) and (c).

To provide for NCS, the applicant's commitment to the requirements in 10 CFR 70.65(b) should be considered acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

1. The applicant meets the acceptance criteria in SRP Section 3.4, as they relate to the following: identification of NCS accident sequences, consequences for NCS accident sequences, likelihoods for NCS accident sequences, risks for NCS accident sequences, and IROFS for NCS accident sequences;

2. The applicant commits to use Appendix A of ANSI/ANS-8.1-1983, in determining NCS accident sequences; and

3. The applicant commits to ANSI/ANS-8.10-1983, as modified by Regulatory Guide 3.71, August 1998, in determining consequences for NCS accident sequences.

5.4.3.4.7 Additional NCS Program Commitments

The applicant's description of additional commitments regarding the NCS program should be considered acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

1. The applicant commits to use the NCS program to promptly detect any NCS deficiencies by means of operational inspections, audits, or investigations, and to refer to the facility's corrective action function any unacceptable performance deficiencies in IROFS, NCS function, or management measures, so as to prevent recurrence;

2. The applicant commits to support the facility change mechanism process by performing NCS determinations to evaluate changes to processes, operating procedures, IROFS, and management measures;

3. The applicant commits to upgrade the NCS program to reflect changes in the ISA or new NCS methodologies, and to modify operating and maintenance procedures in ways that could reduce the likelihood of occurrence of an inadvertent nuclear criticality;

4. The applicant commits to retain records of NCS programs and to document any corrective actions taken;

5. The applicant commits to use the NCS methodologies and technical practices in SRP Section 5.4.3.4 to evaluate NCS accident sequences in operations and processes;

6. The applicant's description of measures to implement the facility change process requirements in 10 CFR 70.72 should be considered acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

    a. The applicant commits to a change control process that is sufficient to ensure that the safety basis of the facility will be maintained during the lifetime of the facility. The change process should be documented in written procedures and shall ensure that:

        i. All potentially affected SNM processes are evaluated to determine the effect of the change on the safety basis of the process, including the effect on bounding process assumptions, on the reliability and availability of NCS controls, and on the NCS of connected processes. The change control process shall have procedures for the review and approval of facility changes by the NCS function to determine the potential effects on NCS.

b. The change control process shall be connected to the facility's configuration management system to ensure that changes to the NCS basis are incorporated into procedures, evaluations, postings, drawings, other safety basis documentation, and the ISA Summary; and

c. The applicant commits to a program to determine whether facility changes require NRC approval in accordance with the 10 CFR 70.72(c). This program shall be documented in written procedures and must involve individuals qualified to determine the incremental effect of changes to the safety basis as documented in the ISA Summary; the change shall be compared to the baseline, approved version of the ISA Summary.

7. The applicant's description of measures to implement the reporting requirements in 10 CFR 70 Appendix A should be considered acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative in the application:

1. The applicant has a program for evaluating the criticality significance of NCS events and an apparatus in place for making the required notification to the NRC Operations Center. The determination of significance shall be made by qualified individuals. The determination of loss or degradation of double contingency protection should be made against the application and Appendix A;

2. The applicant incorporates the reporting criteria of Appendix A and the report content requirements of 10 CFR 70.50 into the facility emergency procedures;

3. The applicant commits to issue the necessary report based on whether the IROFS credited were lost, irrespective of whether the safety limits of the associated parameters were actually exceeded; and

4. The applicant commits to the following: If it cannot be determined within one hour of whether the criteria of 10 CFR 70 Appendix A Paragraph (a) or (b) apply, the event shall be treated as a one-hour report.

5.5 REVIEW PROCEDURES

The reviewer should use the regulatory guidance of this chapter; references in this chapter; and the applicant's reports to the NRC (e.g., NRC Bulletin 91-01, 10 CFR 70.50, and 70.74).

5.5.1 Acceptance Review

The Primary Reviewer should review the applicant's NCS information for completeness with respect to the requirements in 10 CFR 70.22, 70.24, 70.61, 70.62, 70.64, 70.65 and the acceptance criteria in Section 5.4. According to NRC fuel facility licensing guidance, if deficiencies are identified, then either the applicant should be requested to submit additional material before the start of the safety evaluation or the application should be denied.

5.5.2 Safety Evaluation

When an acceptable application is received from the applicant, the Primary Reviewer for SRP Chapter 5.0 will conduct a complete review of the application and determine its acceptability, consulting with the supporting reviewers to identify and resolve any issues of concern related to the licensing review. The Primary Reviewer of Chapter 5.0 (i.e., NCS reviewer acting as a Secondary Reviewer or Supporting Reviewer) should also coordinate with other reviewers, concerning NCS, regarding the following:

1. In support of the Primary Reviewer for SRP Chapter 2.0, the NCS reviewer should determine whether the acceptance criteria in Chapter 2.0 have been met, as they relate to NCS;

2. In support of the Primary Reviewer for SRP Chapter 11.0, the NCS reviewer should determine whether the acceptance criteria in SRP Chapter 11.0 have been met, as they relate to NCS;

3. In support of the Primary Reviewer for Chapter 3.0, the NCS reviewer should determine whether the acceptance criteria in Chapter 3.0 have been met, as they relate to NCS; and

4. In support of the Primary Reviewer for Chapter 8.0, the NCS reviewer should determine whether the acceptance criteria in Chapter 8.0 have been met, as they relate to NCS.

The Primary Reviewer for Chapter 5.0 should determine whether the acceptance criteria in SRP Section 5.4 have been met and should prepare the SER NCS Chapter in accordance with SRP Section 5.6.

5.6 EVALUATION FINDINGS

Note: The evaluation finding for the ISA Summary requirements for 10 CFR 70.65 should be in SRP Section 3.6.

If the staff's review verifies that sufficient information has been provided in the safety program description to satisfy the acceptance criteria in SRP Section 5.4, the staff should document its review as follows:

The staff has reviewed the Nuclear Criticality Safety (NCS) program for *[name of facility*] according to SRP Chapter 5.0. The staff has reasonable assurance that:

1. The applicant will have in place a staff of managers, supervisors, engineers, process operators, and other support personnel who are qualified to develop, implement, and maintain the NCS program in accordance with the facility organization and administration and management measures;

2. The applicant's conduct of operations will be based on NCS methodologies and NCS technical practices, which will ensure that the fissile material will be possessed, stored, and used safely according to the requirements in Part 70;

3. The applicant will develop, implement, and maintain a criticality accident alarm system in accordance with both the requirements in 10 CFR 70.24 and the facility emergency management program;

4. The applicant will have in place an NCS program in accordance with the subcriticality of operations and margin of subcriticality for safety requirements in 10 CFR 70.61(d) and baseline design criteria requirements in 10 CFR 70.64(a); and

5. Based on this review, the staff concludes that the applicant's NCS program meets the requirements of Part 70 and provides reasonable assurance for the protection of public health and safety, including workers and the environment.

5.7 REFERENCES

H. K. Clark, Du Pont de Nemours and Co. DP-1014, "Maximum Safe Limits for Slightly Enriched Uranium and Uranium Oxide," Aiken, SC, 1966.

R. A. Knief, "Nuclear Criticality Safety --Theory and Practice," American Nuclear Society, La Grange Park, IL, 1985.

H. C. Paxton and N. L. Pruvost, LA-10860-MS, "Critical Dimensions of Systems Containing ^{235}U, ^{239}Pu, and ^{233}U," Los Alamos National Laboratory, Los Alamos, NM, 1987.

N. L. Pruvost and H. C. Paxton, LA-12808/UC-714, "Nuclear Criticality Safety Guide," Los Alamos National Laboratory, Los Alamos, NM, 1996.

W. R. Stratton (D. R. Smith Revisor), DOE/NCT-04, "A Review of Criticality Accidents," U.S. Department of Energy, March 1989.

U.S. Code of Federal Regulations, Title 10, "Energy," Part 70, 'Domestic Licensing of Special Nuclear Material,' U.S. Government Printing Office, Washington, DC., January 1, 1999.

U.S. Department of Energy, DOE Order 420.1 (Change 2), "Facility Safety," October 24, 1996.

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6.0 CHEMICAL PROCESS SAFETY

6.1 PURPOSE OF REVIEW

The primary purpose of the review is to determine with reasonable assurance that the applicant has designed a facility that will provide adequate protection against chemical hazards related to the storage, handling, and processing of licensed materials. The facility design must adequately protect the health and safety of workers and the public during normal operations and during credible accident conditions from chemical risks produced by licensed material and hazardous chemicals produced from licensed material. It must also protect against plant conditions that could affect the safety of licensed materials and thus present an increased radiation risk (e.g., release of a chemical that could incapacitate operators and preclude their entry to an area of the plant handling licensed materials).

Chemical safety issues are initially evaluated as part of the applicant's "ISA Summary." The ISA Summary must evaluate credible accident sequences at the facility; identify 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. Before assessing the applicant's facility design to protect against chemical hazards, the reviewer should first review the license application, "Facility and Process Description" (SRP Chapter 1.1), and the "ISA Summary" (Chapter 3), to gain familiarity with:

- Process information and accident sequences leading to conditions that could pose chemical hazards;
- Specific IROFS, to prevent or mitigate such chemical hazards; and
- Management measures recommended, ensuring 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 Part 20 uranium and transuranic toxicity issues)
Primary Reviewers of Chapters 1.0, 3.0, 8.0, and Chapter 11.0

6.3 AREAS OF REVIEW

10 CFR 70.62(a), requires 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. The staff recommends that a separate chapter describing the

chemical process safety function be provided. Note: This does not necessarily require the establishment of a separate chemical process safety program, but the applicant must demonstrate that chemical hazards and accident sequences that affect licensed materials be considered and adequately prevented or mitigated. Applicants are required to conduct an ISA and provide an ISA Summary that meets the requirements of section 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 3.0) and the corresponding "Management Measures" (SRP Chapter 11.0) to confirm that 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 produced from plant conditions that affect the safety of licensed materials. The review will verify that any grading of IROFS or management measures proposed by the applicant in accordance with 10 CFR 70.62(a) is commensurate with the accident risk that the IROFS are designed to reduce.

The NRC-Occupational Safety and Health Administration (OSHA) Memorandum of Understanding (MOU) directs the NRC to oversee chemical safety issues related to: (a) radiation risk produced by licensed materials; (b) chemical risk produced by licensed materials; and (c) plant conditions that affect or may affect the safety of licensed materials and thus present an increased radiation risk to workers, the public, and the environment. The NRC does not oversee plant conditions that absolutely do not affect or involve the safety of licensed materials.

Specific areas to be reviewed by the staff include:

1. Chemical Process Description – including process chemistry, flow diagrams, major process steps, and major pieces of equipment. The narrative description of the site, facility, and processes with respect to chemical safety for normal operations.

2. Chemical Accident Sequences – including unmitigated accident sequences involving hazardous chemicals and licensed materials, and interpretation of the quantitative chemical risk levels.

3. Chemical Accident Consequences – including interpretation of the qualitative chemical risk levels, assumptions, bases, and methods used to forecast the consequences of accidents for workers and the public, identified in the ISA Summary, that involve hazardous chemicals and licensed materials.

4. Chemical Process IROFS – including identification and description of the adequacy of items relied on for (chemical) safety.

5. Chemical Process Management Measures – including management measures to assure the reliability and availability of IROFS (chemical process safety).

6. Safety Grading – including, if applicable, grading of IROFS and their associated management measures.

7. Verify, with the reviewer of Chapter 8.0, the coordination of chemical process safety and emergency management.

8. The applicant's commitment to retain records for chemical process safety compliance and reporting commitments for chemical releases.

9. The applicant's commitment to adhere to the 10 CFR 70.64 chemical baseline design criteria for new facilities or new processes at existing facilities that require a license amendment under 10 CFR 70.72 (as applicable).

10. The applicant's commitment to refer, to the facility's corrective action function, any unacceptable performance deficiency.

6.4 ACCEPTANCE CRITERIA

6.4.1 Regulatory Requirements

The regulatory basis for the review should be the general and additional contents of an application for chemical process safety, as required by 10 CFR 70.22, and 70.65. In addition, the chemical process safety review should be conducted to provide reasonable assurance of compliance with 10 CFR 70.61, 70.62, and 10 CFR 70.64, for new facilities or new processes, at existing facilities, that requires a license amendment under 10 CFR 70.72.

6.4.2 Regulatory Guidance

Relevant regulatory guidance for chemical process safety includes:

1. NUREG-1513, "Integrated Safety Analysis Guidance Document," latest revision.

2. NUREG-1601, "Chemical Process Safety at Fuel Cycle Facilities," 1997.

3. NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook," 1998.

6.4.3 Regulatory Acceptance Criteria

The reviewer should find the applicant's chemical process safety information acceptable if it provides reasonable assurance that the following acceptance criteria are adequately addressed and satisfied. The applicant may elect to incorporate some or all the requested chemical process information in the "Facility and Process Description" (SRP Chapter 1.1), or ISA Summary, rather than in this section. Either approach is acceptable, so long as the information is adequately cross-referenced.

Also, the applicant should describe commitments to maintain chemical process safety records, and describe applicable commitments for "Audits and Assessments" and "Incident Investigation" for detection and correction of any unacceptable performance deficiencies in accordance with the section on "Management Measures" (SRP Chapter 11.0).

6.4.3.1 Process Chemical Risk and Accident Sequences

The applicant's descriptions of facility processes and chemical accident sequences are acceptable if they contain the following information:

(a) Process descriptions of sufficient detail are provided to support an understanding of chemical process hazards (including radiological hazards caused by or involving chemical accidents) and to allow development of potential accident sequences.

(b) The applicant provides an adequate list of the consequences and likelihoods of accident sequences, identified in the ISA Summary, involving hazardous chemicals produced from licensed material, and chemical risks produced by plant conditions that affect the safety of licensed materials. Each accident sequence should include the chemical hazard evaluation that identifies potential interactions of process chemicals with associated confinement vessels, process equipment, and plant personnel. The hazard evaluation should use appropriate, accepted methods. The applicant provides reasonable assurance that applicable accident sequences identified in the ISA Summary are consistent with actions provided in "Emergency Management" (SRP Chapter 8.0).

(c) The applicant identifies and uses appropriate techniques and valid assumptions in estimating the concentrations or in predicting the "toxic" footprint for releases of hazardous chemicals produced from licensed material, or from abnormal plant conditions, that could affect the safety of licensed materials. The applicant uses "Performance Requirements," criteria as described in 10 CFR 70.61(b) and 70.61(c).

(d) Source-term and vapor-dispersion models used to calculate the concentration of uranium hexafluoride (UF_6) and its reaction products conform to guidance on the applicability of models provided in NUREG/CR-6481, "Review of Models Used for Determining Consequences of UF_6 Release."

(e) If dispersion models are used to determine whether a release of chemicals might affect worker or public health and safety, the applicant provides evidence that the models used are appropriate to the application and that the assumed input data lead to a conservative estimate of potential consequences. Consequence analyses conform to the guidance on atmospheric and consequence modeling found in NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook," 1998.

(f) The applicant has proposed appropriate chemical exposure standards to assess chemical consequences. Acceptable exposure standards include, but are not limited to: Emergency Response Planning Guidelines (ERPGs) established by the American Industrial Hygiene Association; Acute Exposure Guideline Levels (AEGLs), established by the National Advisory Committee for Acute Guideline Levels for Hazardous Substances; exposure limits established by OSHA; or exposure limits contained in International Standards Organization (ISO) standards. If the applicant does not use a published exposure standard, or if a chemical has an unknown exposure standard, the applicant may propose an alternate exposure standard accompanied by supporting documentation to justify selection of such an alternative. Note: 10 CFR 70.61, "Performance Requirements," are for "acute chemical exposures," and OSHA permissible exposure limits (PELS) are typically time-weighted average (TWA) values. Consequently, for ISA purposes only, acute chemical release limits may not be adjusted, using the TWA calculation, where concentration and time of exposure are used, unless a rational basis is provided in the ISA Summary.

6.4.3.2 IROFS and Management Measures

The license application should identify the design basis that provides chemical process safety for normal operations. A description could include specified features such as materials of construction, sizing, system fabrication, and process control schemes. Based on a comparison of the unmitigated chemical consequences determined in Section 6.4.3.1, with the performance criteria of 10 CFR 70.61, the applicant should identify (in the ISA Summary) chemical process safety controls (i.e., IROFS) suitable to prevent or mitigate potential accidents. IROFS also should be identified for those accident sequences containing a chemical system/process failure that may ultimately lead to radiological consequences that exceed the performance requirements. If the applicant has elected to apply a graded approach to safety in accordance with 10 CFR 70.62(a), the reviewer should establish that the grading of IROFS is appropriate and sufficient to protect against chemical process risks. For example, the applicant should consider reliance on passive controls over active systems and consider defense-in-depth in accordance with 10 CFR 70.64(b). To reduce common mode failures, the applicant should favor design features that use independent sources of motive force for items such as control actuators, jet pumps, eductors, and ejectors. Fail-safe controls are preferred unless safety concerns preclude this approach.

Management measures to assure the availability and reliability of such IROFS, when they are required to perform their safety functions, must also be described. Management measures may be graded commensurate with risk.

The applicant must also address the following:

(a) The application should describe the engineering approach, basis, or schemes employed for maintaining safety in normal operations.

(b) The ISA Summary includes the following information: identification of the administrative and engineered controls to prevent or mitigate chemical process risks, the hazard being mitigated, and the risk category. The applicant should also explain how the controls and management measures have been graded commensurate with the reduction in risk that the controls are designed to achieve.

(c) The application should describe the management measures proposed to assure IROFS are available and reliable when required by satisfying the following criteria:

    (i) Engineered Controls: procedures to ensure the reliable operation of engineered controls should be briefly described (e.g., inspection and testing procedures and frequencies, calibration programs, functional tests, corrective and preventive maintenance programs, criteria for acceptable test results, etc.).

    (ii) Administrative Controls: procedures to ensure that administrative controls will be correctly implemented, when required, should be briefly described (e.g., employee training and qualification in operating

procedures, refresher training, safe work practices, development of standard operating procedures, training program evaluation, etc.).

6.4.3.3 Requirements for New Facilities or New Processes at Existing Facilities

The application should address the baseline design criteria (BDC) for new facilities or new processes at existing facilities that require a license amendment under 10 CFR 70.72. NUREG-1601, Section 2.4, "Design Basis," contains a list of items that should be considered in an adequate facility design. With respect to chemical process safety, the application should be considered acceptable if it includes information listed below (or references other sections of the application):

(a) A brief description of 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 chemical process safety design would be those that support hierarchy of controls with preference for prevention, mitigation, and operator intervention (in that order). For example, limiting inventory of on-site chemicals would be a preferential, preventive practice for limiting chemical safety-related accidents.

(b) The descriptions of proposed facility-specific or process-specific relaxations or additions to BDC, along with justifications for relaxations.

(c) In the ISA Summary, a description of how the chemical safety BDC were applied in establishing the design principles, features, and control systems of the new process.

6.5 PROCEDURES FOR REVIEW

6.5.1 Acceptance Review

The Primary Reviewer should evaluate the application to determine whether it addresses the topics in Section 6.3, "Areas of Review." If significant deficiencies are identified, the applicant should be requested to submit additional material before the start of the safety evaluation.

6.5.2 Safety Evaluation

After determining that the application is acceptable for review in accordance with Section 6.5.1, the primary reviewer will perform a safety evaluation against the "Acceptance Criteria" described in Section 6.4. If, during the course of the safety evaluation, the primary reviewer determines a need for additional information, the primary reviewer coordinates a request for additional information with the licensing project manager. The reviewer should ascertain that the chemical process safety approach is consistent with other sections of the application, including the ISA Summary (SRP Chapter 3); "Radiation Safety" (SRP Chapter 4); "Emergency Management" (SRP Chapter 8); and "Management Measures" (SRP Chapter 11.0). For example, the reviewer should determine that the chemical safety program will not have unacceptable or adverse impacts on the radiological safety at the facility.

For an existing facility the reviewer may consult cognizant NRC inspectors to identify and resolve any issue of concern 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.

The Primary Reviewer will prepare a Safety Evaluation Report (SER) for the Licensing Project Manager in support of the licensing action.

6.5.2.1 Process Chemical Risks and Accident Sequences

The results of the ISA form the basis for the chemical process safety evaluation. The reviewer should review the chemical risks identified in the ISA Summary and ensure that the level of safety is reflected in the design and operational plans for the facility. The reviewer should establish that the applicant's facility design, operations, and IROFS pertaining to chemical safety provide reasonable assurance that they will function as intended and provide for the safe handling of licensed material at the facility. The reviewer should review the mechanisms that will allow the applicant to identify and correct potential problems.

The reviewer will make an independent judgment of the comparative risks assigned by the applicant to accident sequences identified in the ISA Summary, based on risk relative to other sequences (competing risks); the complexity of the sequence; plant operating history; and general industry performance. The review may encompass examination of a selected number of lower-risk chemical safety-related accident sequences not contained in the ISA Summary, to validate the risk threshold criteria used by the applicant in reporting sequences in the ISA Summary.

6.5.2.2 IROFS and Management Measures

The staff reviews the chemical process safety 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 grading of IROFS or "Management Measures," is appropriate and sufficient to protect against chemical process risks.

6.5.2.3 Requirements for New Facilities or New Processes at Existing Facilities

The staff reviews the applicant's commitments to adhere to the BDC, in 10 CFR 70.64(a), for the design of new facilities or new processes, at existing facilities, that require a license amendment under 10 CFR 70.72.

6.6 EVALUATION FINDINGS

The reviewer writes an SER addressing each topic reviewed and explains why the NRC staff has reasonable assurance that the chemical safety part of the application is acceptable. License conditions may be proposed to impose requirements where the application is deficient. In cases where the SER is drafted in advance of resolving all outstanding chemical process

safety issues, the reviewer documents the review as described below and includes a list of open issues that require resolution before the staff finding of reasonable assurance. For partial reviews, revisions, and process changes, the reviewer will use applicable sections of the acceptance criteria, and the SER will be written to reflect what portions were not reviewed and the chemical process safety significance, if any. On completion of the review, NRC staff may impose temporary or limited time license conditions to authorize short-duration activities. For certain functions and requirements that concern safety or regulatory issues, a license condition may be imposed and remain in effect until removed by an amendment or license renewal.

The SER should include a summary statement of what was evaluated and the basis for the reviewer's conclusions. The following kinds of statements and conclusions will be included in the staff SER:

> The staff has evaluated the licensee's application using criteria listed previously. Based on the review of the license application, the NRC staff concluded that the applicant has adequately described and assessed accident consequences having potentially significant chemical consequences and effects that could result from the handling, storage, or processing of licensed materials. A hazard analysis has been conducted that identified and evaluated those chemical process hazards and potential accidents, and established safety controls that provide reasonable assurance for safe facility operation. To ensure that the performance requirements in Part 70 are met, the applicant will provide reasonable assurance that controls are maintained available and reliable when required to perform their safety functions. The staff has reviewed these safety controls and the applicant's plan for managing chemical process safety and finds them acceptable.
>
> The staff concludes that the applicant's plan for managing chemical process safety and the chemical process safety controls meet the requirements of Part 70, and provides reasonable assurance that the health and safety of the public will be protected.

6.7 REFERENCES

Center for Chemical Process Safety, "Guidelines for the Technical Management of Chemical Process Safety," American Institute of Chemical Engineers, New York, 1989, Chapter 11, as revised.

Chemical Manufacturers Association, "Responsible Care®, Process Safety Code of Management Practices," Washington, 1990.

U.S. Code of Federal Regulations, Title 10, Part 70, "Domestic Licensing of Special Nuclear Material," U.S. Government Printing Office, Washington, D.C., as revised.

U.S. Code of Federal Regulations, Title 29, Part 1910.119, "Process Safety Management of Highly Hazardous Chemicals," U.S. Government Printing Office, Washington, D.C., as revised.

U.S. Nuclear Regulatory Commission, Manual Chapter 2603, “Inspection of the Nuclear Chemical Process Safety Program at Fuel Cycle Facilities,” as revised.

U.S. Nuclear Regulatory Commission/Occupational Safety and Health Administration, “Memorandum of Understanding between the Nuclear Regulatory Commission and the Occupational Safety and Health Administration, ‘Worker Protection at NRC-Licensed Facilities,’” Federal Register No. 53, October 31, 1988.

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

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

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

U.S. Nuclear Regulatory Commission, “Review of Models Used for Determining Consequences of UF_6 Release,” NUREG/CR-6481, as revised.

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7.0 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 for adequate protection against fires and explosions that could affect the safety of licensed materials and thus present an increased radiological risk. The review should also establish that the radiological consequences from fires have been considered and that suitable safety controls will be instituted to protect the workers, the public and the environment.

7.2 RESPONSIBILITY FOR REVIEW

Primary: Fire Safety Specialist

Secondary: Criticality Safety Specialist
Environmental Specialist
Chemical Safety Specialist
Physical Security Specialist

Supporting: Regional, Resident, and Fuel Cycle Inspection Staff

7.3 AREAS OF REVIEW

The regulation, 10 CFR 70.62(a), requires a licensee to develop, implement, and maintain a safety program that will provide reasonable assurance of public health and safety and of the environment from the fire and explosive hazards of processing, handling, and storage of licensed material during normal operations, anticipated operational occurrences and credible accidents. The reviewer should first consult the “ISA Summary” (SRP Chapter 3) to identify those operations analyzed in the ISA that have a fire or explosion potential and gain familiarity with the IROFS (and complementary management measures) that are proposed to prevent or mitigate any resulting chemical or radiological risks. The fire protection program must address these process-specific risks as well as general fire prevention, protection, and management issues. Although Part 70 does not require a separate fire safety program, an applicant should provide commitments pertaining to fire safety in the following areas:

- Fire Safety Management: This includes safety organization; engineering review; fire prevention; inspection, testing, and maintenance; pre-fire plans; and personnel qualifications, drills, and training.

- Fire Risk Identification: This includes Fire Hazards Analysis (FHA) and ISA Summary.

- Facility Design: This includes information on building construction; fire areas; life safety; ventilation; and electrical system design. Consideration of competing requirements among fire safety and security, criticality, and environmental concerns should be included.

- Process Fire Safety: This involves design consideration to prevent an accident or mitigate the consequences from using process chemicals; combustible metals; flammable and combustible liquids and gasses; high-temperature equipment; hot cells and glove boxes; and laboratories.

- Fire Protection Systems: This includes fire detection, alarm, and suppression systems; portable extinguishers; water supply; and emergency response organizations.

7.4 ACCEPTANCE CRITERIA

An applicant that has met the following acceptance criteria, or has provided an acceptable alternative, should be considered to have an acceptable fire safety program.

7.4.1 Regulatory Requirements

The regulatory basis for the review should be the general and additional contents of an application as required by 10 CFR 70.22 and 70.65. In addition, the fire safety review should be conducted to provide reasonable assurance of compliance with 10 CFR 70.61, 70.62, and 70.64.

7.4.2 Regulatory Guidance

Relevant regulatory guidance for fire safety includes:

National Fire Protection Association, NFPA Standard 801, “Standards for Facilities Handling Radioactive Material,” latest edition.

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

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

7.4.3 Regulatory Acceptance Criteria

The acceptability of the application and the "ISA Summary" will be based on the NRC staff's review of the applicant's commitments to control and mitigate fire hazards. The staff will focus on an application that is risk-informed, has addressed maintaining an acceptable level of fire safety, and demonstrates that an applicant is prepared to react quickly and safely to extinguish fires. An applicant may use a graded approach for defining fire safety, but sufficient documentation and commitments must be made to assure the protection of workers, the public, and the environment from fire events.

These acceptance criteria may be incorporated in the information supplied to satisfy SRP Section 3.0 (ISA) or other SRP sections with references provided (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, wherever the information appears.

Nationally recognized codes and standards are used by the reviewer to measure reasonable assurance of fire safety. These include, but are not limited to, the National Fire Protection Association (NFPA) National Fire Codes; Factory Mutual (FM) Data Sheets and Approval Guide; Underwriters Laboratories (UL) Standards and Building Material Directory; ANSI Standards; and ASTM Standards. Commitments to specified standards will normally be considered an acceptable means of meeting the acceptance criteria.

The NRC staff will review the application regarding the following acceptance criteria:

7.4.3.1 Fire Safety Management Measures

An adequate application documents how fire safety is administered and assured at the licensed facility. The application should reflect a commitment to assure that the IROFS, as identified in the "ISA Summary," are available and reliable; fire safety awareness among employees is maintained; transient ignition sources and combustibles are controlled; and the facility maintains a readiness to extinguish or limit the consequences of fire. These measures are unique to fire safety and are therefore not included in the acceptance criteria for SRP Section 11, "Management Measures."

An adequate application identifies a senior level manager who has the authority and staff to assure that fire safety receives appropriate priority. A Plant or Fire Safety Review Committee staffed by different discipline managers should integrate plant modifications. The Plant Safety Committee can do the work of a Fire Safety Review Committee. Day-to-day supervision of fire safety should be by an individual with sufficient practical fire safety experience (that is described in the application) in nuclear facilities.

The Standard for Fire Protection for Facilities Handling Radioactive Materials, NFPA 801, specifies the following fire safety management measures: fire prevention; inspection, testing, and maintenance of fire protection systems; emergency response organization qualifications,

drills, and training; and pre-fire plans. An adequate application documents the fire safety management measures in sufficient detail to identify their relationship to, and functions for, normal operations; anticipated (off-normal) events; and accident safety (i.e., IROFS). The staff recognizes NFPA 801 as one acceptable standard for fire safety management measures. The licensee may use other nationally recognized codes and standards if appropriate. The staff's fire safety specialist will review the application's fire safety management measures for adequacy.

7.4.3.2 Fire Hazards Analysis

Knowing the fire risk allows a licensee to apply the appropriate level of fire protection to assure the safety of workers, the public and the environment from fire induced radiological 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 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, then assess the consequences of an unmitigated fire. The staff recognizes NFPA 801 as one standard that provides guidance for conducting FHAs. The licensee 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, the consequences, and a description of the mitigative controls.

The FHA is used to inform the ISA team of possible fire initiators and accident sequences leading to radiological consequences or toxic chemical consequences resulting from interaction with SNM. The ISA team, in developing accident sequences that will be reported in the ISA summary, will consider the FHA results and assign likelihoods of the various events in the accident sequences. With respect to fire safety, the ISA summary is acceptable if the credible fire hazards (e.g., from the FHA) are identified for each process fire area; and information is provided detailing how that fire hazard was considered and addressed (i.e., the management measures and/or IROFS) for each process such that the performance requirements in 10 CFR 70.61 are satisfied with respect to the fire hazards. Thus, while ultimate conclusions are based on the ISA Summary, the FHA is a fundamental tool in evaluating fire hazards as input to the ISA evaluation. The staff's fire safety specialist will review the fire safety aspects of the "ISA Summary" for adequacy.

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. An adequate application documents the fire safety considerations used in the general design of the facilities containing radiological material or facilities that impose an exposure threat to radiological facilities. The staff recognizes NFPA 801 as one standard that specifies acceptable facility fire safety design criteria. The licensee may use other nationally recognized codes and standards if appropriate. The staff's fire safety specialist will review the facility's fire safety design for adequacy.

The following are other specific areas of concern:

Criticality: Criticality concerns may exclude water extinguishing systems from process areas. However, during major fire events, the fire may easily overcome the extinguishing capability of portable extinguishers, and hose lines may be needed to extinguish the fire. Consideration should be given to total flooding gaseous systems in water-exclusion areas with significant fire risks. An adequate application should address the methodology used for extinguishing fires in water-exclusion areas. The staff's fire safety and criticality specialist will review for adequacy.

Environmental Concerns: There is a potential for thousands of gallons of fire water to be contaminated with nuclear material during a fire event. 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 for control of fire water runoff. The staff's fire safety and environmental specialists will review for adequacy.

Physical Security Concerns: Buildings and facilities should be designed to provide safe egress in case of fire or chemical events that could lead to radiological emergencies. Physical security requirements for SNM may inadvertently delay worker egress and fire fighter access. Physical security procedures should allow off-site 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. The licensee may use other nationally recognized codes and standards if appropriate. The staff's fire safety and physical security specialists will review for adequacy.

Design of New Facilities: New facilities should be designed and constructed in accordance with: (a) the BDC specified in 10 CFR 70.64(a); (b) the defense-in-depth requirements of 10 CFR 70.64(b); and (c) consistent with the guidance provided in NFPA 801 or other appropriate nationally recognized fire protection codes and standards. The staff's fire safety specialist will review the fire safety design of new facilities for adequacy.

7.4.3.4 Process Fire Safety

Many hazardous chemicals and processes used by fuel cycle facilities contribute to the fire hazards affecting radiological areas. In fire areas that have fire hazards that may threaten radiological material, the application should identify the hazardous chemicals, processes, and design standards used to assure 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/or glove boxes. The licensee may use other nationally recognized codes and standards if appropriate. The staff's fire safety and chemical safety specialists will review the application for adequacy.

The following are a few of the more common hazardous materials used at fuel cycle facilities:

Anhydrous Ammonia: Explosive, flammable, and toxic gas used to make hydrogen.
Fluorine: Reacts violently with organic material or metal powders and water vapor.
Hydrogen: Explosive and flammable gas used in reduction processes.
Hydrogen Peroxide: Off-gases hydrogen and oxygen, incompatible with some extinguishers.
Nitric Acid: Nitrates organic material, lowering the ignition temperature of combustibles.
Sulfuric Acid: Absorbs water from organic material in an exothermic reaction, causing ignition.
Zirconium: Combustible metal that burns at elevated temperatures.

7.4.3.5 Fire Protection and Emergency Response

The application should document the fire protection systems and fire emergency response organizations provided for licensed facilities. The "ISA Summary" (see SRP Section 3.0) should identify the fire protection IROFS. An adequate application describes the fire protection provided for radiological areas and fire areas that may cause an exposure fire hazard to radiological areas. The application should describe which standards the fire protection systems and equipment meet. The staff recognizes NFPA National Fire Codes as acceptable standards for the design, installation, testing, and maintenance of the fire protection systems and equipment. The licensee may use other nationally recognized codes and standards if appropriate.

Facilities with significant fire risks may need a fire emergency response team. One acceptable standard is NFPA 600, "Industrial Fire Brigades." The licensee may use other nationally recognized codes and standards if appropriate. If off-site fire departments are needed for plant fire safety, periodic training with the fire departments is necessary to become familiar with facility access procedures, plant layout, and pre-fire plans. A memorandum of understanding (MOU) between the applicant and the fire departments may be necessary to define the protection required. The staff's fire safety specialist will review the fire protection and emergency response commitments for adequacy.

7.5 REVIEW PROCEDURES

7.5.1 Acceptance Review

During the acceptance review, the primary reviewer evaluates the application for completeness as required by Part 70 and whether the necessary criteria discussed in Section 7.3, "Areas of Review," have been addressed. If significant deficiencies in the application are identified, the application should be returned or additional information requested before the start of the safety evaluation.

7.5.2 Safety Evaluation

During the Safety Evaluation, the primary and secondary reviewers evaluate the adequacy of the application to comprehensively describe the fire safety of the licensed activity as covered in Section 7.3, "Areas of Review," and the commitments made to the criteria specified in

Section 7.4, “Acceptance Criteria.” The staff may request the applicant or licensee to provide additional information or modify the submittal to meet the acceptance criteria.

Reviewers should note that NFPA 801 uses "administrative control" in a different sense than Part 70 and elsewhere in this SRP. In Part 70 an administrative control is a subset of IROFS and is the human action necessary to meet safety performance requirements. It is supported by management measures (training, quality assurance, procedures, etc.) that assure the action will be taken if needed. In NFPA 801, administrative controls are the training, qualifications, procedures, etc., behind the human action. These elements are "Management Measures," in Part 70.

7.6 EVALUATION FINDINGS

The staff’s review should verify: (a) that sufficient information has been provided, in the license application, to satisfy the intent of Part 70 requirements relating to the overall safety program; and (b) that it is consistent with the fire safety criteria in this SRP. On the basis of this information, the staff should be able to evaluate the application’s ability to meet the appropriate criteria. As an example, the staff might document in an SER the fire safety review in the following manner:

The applicant has established a Fire Protection function meeting the acceptance criteria in the Fuel Cycle SRP, Chapter 7. The function includes a Plant 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 plant personnel are in accordance with applicable NFPA codes and standards. (Note: fire protection training requirements are described in SER Section 11.3)

The applicant has conducted risk analysis in accordance with NFPA 801, “Standard for Fire Protection for Facilities Handling Radioactive Material.” 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, “Industrial Fire Brigades.” An MOU with the fire department documents the assistance required 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 staff concludes that the applicant’s capabilities meet and exceed the criteria in Chapter 7 of the SRP. The staff concludes that the applicant’s proposed equipment, facilities and procedures provide a reasonable level of assurance that adequate fire protection will be provided and maintained for those IROFS, to meet the safety performance requirements and BDC of Part 70.

7.7 REFERENCES

National Fire Protection Association, “National Fire Codes,” latest edition.

U.S. Nuclear Regulatory Commission, Information Notice No. 92-14, ”Uranium Oxide Fires at Fuel Cycle Facilities,” February 21, 1992.

U.S. NUCLEAR REGULATORY COMMISSION
STANDARD REVIEW PLAN
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

8.0 EMERGENCY MANAGEMENT

8.1 PURPOSE OF REVIEW

The review should determine if the applicant has established, before the start of operations, adequate emergency management facilities and procedures to protect the public, the workers, and the environment. The Applicant may use either this SRP or Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," in preparing its emergency plan. Information requested for the Emergency plan may be provided once and cross referenced in other sections.

Licensed facilities requiring an Emergency Management Plan are those authorized to possess: (a) enriched uranium or plutonium for which a criticality accident alarm system is required; (b) uranium hexafluoride in excess of 50 kg (110 lb.) in a single container or (c) 1000 kg (2200 lb.) total; or in excess of 2 Ci of plutonium in unsealed form or on foils or plated sources and when an evaluation(the ISA Summary may be referenced in lieu of the evaluation) shows that the maximum dose to a member of the public off-site from a release of radioactive materials would exceed 0.01 Sv (1 rem) effective dose equivalent or an intake of 2 milligrams of soluble uranium.

Emergency capability is incorporated into the baseline design criteria (BDC) of Part 70, as revised, and is intended to ensure control of licensed material, evacuation of personnel, and availability of emergency facilities.

8.2 RESPONSIBILITY FOR REVIEW

Primary: Assigned LIB staff

Secondary: Licensing Project Manager

Supporting: Regional Emergency Preparedness Inspector
ISA Reviewer
Fuel Facility Inspection staff

8.3 AREAS OF REVIEW

The NRC staff should review the applicant's submittal for an acceptable level of evidence of planning for emergency preparedness directed at situations involving real or potential radiological hazards. The review should address those design features, facilities, functions, and equipment that may affect some aspect of emergency planning or the capability of an applicant to cope with plant emergencies. In addition, the review should address coordination with off-site emergency response organizations. The staff should either review the emergency plan made in accordance with 10 CFR 70.22(i)(1)(ii) and with the guidance contained in the

acceptance criteria below, or review the applicant's evaluation(the applicant may reference the ISA Summary in lieu of providing the evaluation.) that an emergency plan is not needed in accordance with 10 CFR 70.22(i)(1)(i).

The NRC staff reviewer should address the material presented, as described below.

8.3.1 Evaluation That No Emergency Plan is Required

If the applicant submits an evaluation, or references the ISA Summary to demonstrate that an emergency plan is not required, the staff should review the information against 10 CFR 70.22(i)(1)(i), and NUREG-1140, "A Regulatory Analysis of Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees." NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook," also contains useful information. Areas to be evaluated should include the following:

1. A description of the facility;
2. Types of materials used, including both radioactive material and hazardous chemicals;
3. Types of accidents;
4. Detection of accidents;
5. Site specific information used to support the evaluation; and
6. An evaluation of the consequences.

8.3.2 Emergency Plan

If the applicant submits an emergency plan, the staff should evaluate the emergency plan against 10 CFR 70.22(i)(1)(ii) and Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," which provides a standard format and content for an emergency plan. Elements in the emergency plan to be reviewed should include the following:

1. Facility description (including both on-site and off-site emergency facilities);
2. Types of accidents;
3. Classification of accidents;
4. Detection of accidents;
5. Mitigation of consequences (and safe shutdown);
6. Assessment of releases;
7. Responsibilities of licensee;
8. Notification and coordination;
9. Information to be communicated and parties to be contacted;
10. Training;
11. Safe shutdown (recovery and plant restoration);
12. Exercises and drills;
13. Hazardous chemicals inventories and locations; and
14. Responsibilities for developing and maintaining the emergency program and its procedures.

8.4 ACCEPTANCE CRITERIA

8.4.1 Regulatory Requirements

10 Part 70.22(i)(1)(i) specifies when an emergency plan does not have to be submitted to the NRC and, if an emergency plan is required to be submitted, 10 CFR 70.22(i)(3) contains the information that must be included in the emergency plan.

10 CFR 70.64(a)(6) requires that applicants address the control of licensed material, evacuation of personnel, and availability of emergency facilities for the design of new facilities.

8.4.2 Regulatory Guidance

Regulatory guidance for preparing an emergency plan includes:

U.S. Nuclear Regulatory Commission Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," January 1992.

U.S. Nuclear Regulatory Commission NUREG-1140, “A Regulatory Analysis of Emergency Preparedness for Fuel Cycle and Other Radioactive Materials,” January 1988.

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

8.4.3 Regulatory Acceptance Criteria

8.4.3.1 Evaluation That No Emergency Plan Is Required

The adequacy of the evaluation or the referenced ISA Summary that no emergency plan is required should be reviewed by the staff against the requirements in 10 CFR 70.22(i)(2), and the specific criteria given in the following sections of the SRP. This evaluation should be acceptable if the regulatory requirements and the following criteria are met:

8.4.3.1.1 Facility Description

The evaluation includes a description of the facility and site, the area near the site, and the licensed activities conducted at the facility sufficient to support the evaluation. The description includes the following:

1. A detailed drawing of the site showing: (1) on-site and near off-site, within 1.61 Km (1 mile) structures, with building numbers and labels; (2) roads and parking lots on-site and main roads near the site; (3) site boundaries, showing fences and gates; (4) major site features; (5) water bodies within approximately 1.61Km (1 mile); and (6) the location(s) of nearest residents.

2. The stack heights, typical stack flow rates, and the efficiencies of any emission - control devices.

3. A general description of licensed and other major activities conducted at the facility, and the type, form, and quantities of radioactive material used.

8.4.3.1.2 Types of Accidents

The evaluation describes or refers to each type of accident identified by the ISA Summary that has the maximum off-site consequences exceeding the limit of 10 CFR 70.22(i)(1)(i), and the following information is available for review:

1. The process and physical location where it could occur;

2. Complicating factors and off-site consequences including non-radioactive hazardous chemicals incident to the process that are released; and

3. The accident sequence that has the potential for the greatest radiological or non-radioactive hazardous chemicals incident to the process impact.

8.4.3.1.3 Detection of Accidents

The evaluation described, for each type of accident identified, the following:

1. The means of detecting the accident;

2. The means of detecting any release of radioactive or non-radioactive hazardous chemicals incident to the process that are released;

3. The means of alerting the operating staff; and

4. The anticipated response of the operating staff.

8.4.3.1.4 Evaluation of Maximum Public Exposure

To demonstrate that no emergency plan is required, an applicant may either;
(1) request that its total possession limit for radioactive material be reduced below the emergency plan threshold in 10 CFR 70.22(i)(1); or (2) perform a site-specific evaluation(or refer to the ISA Summary as appropriate) that demonstrates maximum public exposure is less than the limits in 10CFR 70.22(i)(1)(i).

The evaluation should make available the following information sufficient to allow for independent verification:

1. Type of accident (e.g., fire, exposure, non-radioactive hazardous chemicals incident to the process that are released; and, nuclear criticality);
2. Location of accident;
3. Maximum source term;
4. Solubility of material;
5. Facility design or IROFS and the proposed release fraction;
6. Location and distance of nearest member of the public to the facility;

7. Dose model used and the process used to verify the reliability of the model and validity of the assumptions;
8. Assumed worst case weather condition; and
9. Maximum calculated exposure to a member of the public at the facility boundary.

The evaluation should include a list and a description of the factors in 10 CFR 70.22(i)(2) considered in evaluating maximum dose to members of the public. The applicant should demonstrate why the factors used in the evaluation are appropriate when compared with the factors in NUREG-1140. If the factors and evaluation show that the maximum dose to a member of the public off-site from a release of radioactive materials, could not exceed 0.01 Sv (1 rem) effective dose equivalent or the intake of soluble uranium of 2 milligrams, no emergency plan is required, in accordance with 10 CFR 70.22(i)(1)(i).

8.4.3.2 Emergency Plan

The adequacy of the proposed emergency plan should be evaluated by the reviewer against the requirements in 10 CFR 70.22(i)(3), and the specific criteria given in the following sections of the SRP. The applicant's emergency plan should be acceptable, if the regulatory requirements and the following criteria are met:

8.4.3.2.1 Facility Description

8.4.3.2.1.1 Operational Facilities

The emergency plan should include a description of the facility and site, the area near the site, and the licensed activities. The description should include the following:

1. A detailed drawing of the site showing:

    a. On-site and near off-site within 1.61 km (1mile) structures with building numbers and labels;
    b. Roads and parking lots on-site and main roads near the site;
    c. Site boundaries, showing fences and gates;
    d. Major site features; and
    e. Water bodies within approximately 1.61 km (1 mile).

2. A general area map (approximately 16.1 km [10-mile] radius); a United States Geological Survey topographical quadrangle (7 ½ minute series; including the adjacent quadrangle(s) if site is located less than 1.61 km (1 mile) from the edge of the quadrangle); and a map or aerial photograph indicating on-site structures and near-site structures (about 1.61 km [1-mile] radius). The map should include the location of sensitive facilities near the site such as hospitals, schools, nursing homes, nearest residents, fire department, prisons, and environmental sampling locations, and other structures and facilities important to emergency management;

3. The stack heights, typical stack flow rates, and the efficiencies of any emission-control devices;

4. A general description of licensed and other major activities conducted at the facility, and the type, form, and quantities of radioactive and other hazardous materials normally on-site, by location (use and storage) and building, and hazardous characteristics (exposure rates, pH, temperature, and other characteristics) important to emergency management; and

5. Certification by the Plant Manager or the individual authorized be the applicant, that the applicant has met responsibilities under Emergency Planning and Community Right To Know Act of 1986, Title III, Public Law 99-499, in accordance with 10 CFR 70.22(i)(3)(xiii).

8.4.3.2.2 On-site and Off-site Emergency Facilities

The emergency plan should include a list and description of on-site and off-site facilities that could be relied on in case of an emergency. The description should include the following:

1. A list and description of both on-site and off-site emergency facilities, by location and purpose of the facility;

2. A description of emergency monitoring equipment that is available for personnel and area monitoring, as well as that for assessing the release of radioactive or hazardous chemicals incident to the process to the environment;

3. A description of the on-site and off-site services that support emergency response operations. The following are included:

   a. Decontamination facilities;
   b. Medical treatment facilities;
   c. First aid personnel;
   d. Fire fighters;
   e. Law enforcement assistance; and
   f. Ambulance services.

4. In addition, the applicant should commit to the following:

   a. Facilities of adequate size and appropriate location that are designated, equipped, and ready for emergency use;

   b. Adequate backup facilities required by the emergency plan and supporting documents that are available and ready for use;

   c. Appropriate equipment and supplies necessary to support emergency response activities, that are accessible during accident conditions;

   d. Emergency equipment that is inventoried, tested, and serviced on a periodic basis, to ensure accountability and reliability;

e. Sufficient reliable primary and backup communications channels that are available to accommodate emergency needs;

f. Off-site emergency resources and services that are identified, and are ready, to ensure their timely mobilization and use;

g. Operational engineering information, such as current as-built drawings and procedures, that are readily available in the emergency facilities;

h. Sufficient equipment for personnel protection and monitoring; and

i. Systems in place to alert on-site and off-site personnel in case of an emergency.

8.4.3.2.3 Types of Accidents

The emergency plan should include a description for each generic- type accident, identified in the ISA Summary, for which protective actions may be needed. The description should include:

1. The process and physical location(s) where the accidents could occur;

2. Complicating factors and possible on-site and off-site consequences, including nonradioactive hazardous chemicals incident to the process releases that could impact emergency response efforts;

3. The accident sequence that has the potential for the greatest radiological and/or nonradioactive hazardous chemicals incident to the process impact; and

4. Figure(s) projecting doses and chemicals substance concentrations as a function of distance and time for various meteorological stability classes, including a description of how such doses/ concentrations were projected(e.g., computer models, assumptions, etc.)

8.4.3.2.4 Classification of Accidents

1. The emergency plan classification system should include the following two classifications:

   - "Alert": Events that may occur, are in progress, or have occurred, that could lead to a release of radioactive material or hazardous chemicals, incident to the process however, the release is not expected to require a response by an off-site response organization, to protect persons off-site; and

   - "Site area emergency": Events that may occur, are in progress, or have occurred, that could lead to a significant release of radioactive material or hazardous chemicals, incident to the process, that could require a response by off-site emergency response organizations to protect persons off-site.

2. For each accident in the emergency plan, the classification (alert or site area emergency) that is expected for each accident is identified;

3. The emergency plan should specify emergency action levels (EALs) at which an alert or site area emergency will be declared. EALs are specific conditions that require emergency response measures to be performed. The applicant's EALs should be consistent with Appendix A of Regulatory Guide 3.67 and should be comparable with the U.S. Environmental Protection Agency's Protective Action Guides (EPA 400-R-92-001, May 1992, Revision). Transportation accidents more than 1.61Km (1 mile) from the facility should not classified.

4. The emergency plan should designate the personnel positions and alternates with the responsibility for accident classification during normal operations and back shifts.

8.4.3.2.5 Detection of Accidents

The emergency plan should describe, for each type of accident identified, the following:

1. The means of detecting the accident;

2. The means of detecting any release of radioactive material or hazardous chemicals, incident to the process ;

3. The means of alerting the operating staff; and

4. The anticipated response of the operating staff.

8.4.3.2.6 Mitigation of Consequences

The emergency plan should briefly describe, for each accident identified in the ISA Summary, measures and equipment used for a safe shutdown and for mitigating the consequences to workers on-site and off-site, as well as to the public, off-site.

8.4.3.2.7 Assessment of Releases

1. The emergency plan should describe the applicant's procedures to be used to promptly and effectively assess the release of radioactive material or hazardous chemicals, incident to the process . The description includes:

   a. The procedures for estimating or measuring the release rate or source term;

   b. Valid computer codes used to project doses or concentrations to the public or environment and associated assumptions, along with adequate justifications to show the validity of the assumptions;

   c. The types, methods, frequencies, implementation time, and other details of on-site and off-site sampling and monitoring that will be performed to assess a release of radioactive materials or hazardous chemicals, incident to the process; and

d. Method for assessing collateral damage to the facility, especially IROFS.

2. 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 process.

8.4.3.2.8 Responsibilities

The emergency plan should describe the emergency response organization and administration that ensure effective planning, implementation, and control of emergency preparedness activities.

In addition the applicant should make the following commitments.

1. The organizational structure and chain of command will be clearly defined in procedures;

2. Staffing and resources will be sufficient to accomplish all assigned tasks;

3. Responsibilities and authority for each management, supervisory, and professional position will be clearly defined in procedures. Responsibility is assigned for the coordination of on-site and off-site emergency response preparedness;

4. Interfaces with supporting groups, both on-site and off-site, will be clearly defined in procedures;

5. Mutual cooperation agreements exist with local agencies such as fire, police, ambulance/rescue, and medical units;

6. Plant management measures will be in place by procedures to audit and assess of emergency preparedness to ensure site readiness to handle emergencies and to identify and correct problems;

7. The on-site emergency response organization will provide effective command and control of the site during the assessment, mitigation, and recovery phase of an accident;

8. The emergency public information system will provides advance and ongoing information to the media and public on subjects that would be discussed during an emergency, such as radiation hazards, chemical hazards, site operation, and site emergency plans; and

9. The schedule of emergency preparedness procedure will provide for availability of procedures to support startup and operation of new processes/ facilities on-site.

8.4.3.2.9 Notification and Coordination

1. The emergency plan should provide reasonable assurance that emergency notification procedures will enable the emergency organization to correctly classify emergencies,

notify emergency response personnel, and initiate or recommend appropriate actions in a timely manner, based on the following:

a. Classification of emergency events are based on the current emergency plan;

b. Notification procedures minimize distractions of shift operating personnel and include concise, preformatted messages. Appropriate follow-up messages to off-site authorities are issued in a timely manner;

c. Information on the nature and magnitude of the hazards is made available to appropriate emergency response personnel;

d. Radiological and chemical source term data are available to the command post, technical support center, emergency operation center, and appropriate State personnel, in cooperation with the NRC;

e. When available, off-site field monitoring data are logged, compared with source term data, and used in the protective action recommendation process;

f. Protective Action Guides are available and used by appropriate personnel in a timely manner;

g. The emergency public information program ensures timely dissemination of accurate, reliable, and understandable information;

h. Systems are in place, if required, to alert, notify, and mobilize on-site and off-site response personnel in case of an emergency;

i. Notification and coordination with responsible parties when some personnel, equipment, and facility components are not available.

2. The emergency plan should describe how and by whom the following actions will promptly and effectively be taken:

a. Decision to declare an alert or site area emergency;

b. Activation of on-site emergency response organization during all shifts;

c. Prompt notification of off-site response authorities that an alert or site area emergency has been declared, including the licensee's initial recommendation for off-site protective actions (normally within 15 minutes of classification);

d. Notification to the NRC Operations Center (as soon as possible and, in any case, no later than one hour after a declared emergency);

e. Decision on what on-site protective actions to initiate;

f. Decision on what off-site protective actions to recommend;

g. Decision to request support from off-site organizations; and

h. Decision to terminate the emergency or enter recovery mode.

8.4.3.2.10 Information To Be Communicated

The emergency plan should describe the information to be communicated during an emergency, including the following:

1. A standard reporting checklist to facilitate timely notification;

2. The types of information to be provided concerning facility status, radioactive releases or hazardous chemicals, incident to the process, and protective action recommendations,

3. A description of preplanned protective action recommendations to be made to each appropriate off-site organization;
4. The off-site officials to be notified, as a function of the classification of the event; and

5. The recommended actions to be implemented by off-site organizations for each accident treated in the emergency plan.

8.4.3.2.11 Training

The emergency plan should include a description of the frequency and performance objective and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical, and other non-licensees emergency personnel to ensure knowledge of the emergency plan, assigned duties, and effective response to an actual emergency. The following should be included:

1. The topics and general content of training programs used for training the on-site and off-site licensee's emergency response personnel to satisfy the objectives described above;

2. The administration of the training program, including responsibility for training, the positions to be trained, the schedules for training, the frequency of retraining, use of team training, and the estimated number of hours of initial training and retraining;

3. The training to be provided on the use of protective equipment such as respirators, protective clothing, monitoring devices, and other equipment used in emergency response;

4. The training program for on-site personnel who are not members of the emergency response staff; and

5. Any special instructions and orientation tours the licensee would offer to fire, police, medical, and other non- licensee's personnel, who may be required to respond to an emergency.

8.4.3.2.12 Safe Shutdown (Recovery and Plant Restoration)

The emergency plan should describe the plans for adequately restoring the facility to a safe status after an accident and recovery after an emergency. The description should include:

1. The methods and responsibilities for assessing the damage to and the status of the facility's capabilities to safely control radioactive material or hazardous chemicals associated with the process;

2. The procedures for promptly determining the actions necessary to reduce any ongoing releases of radioactive material or hazardous chemicals, incident to the process, and to prevent further incidents;

3. The provisions for promptly and effectively accomplishing required restoration action; and

4 key positions in the recovery organization.

8.4.3.2.13 Exercises and Drills

The emergency plan should commit to conducting exercises and drills in a manner that demonstrates the capability of the organization to plan and perform an effective response to an emergency. An adequate plan should demonstrate the following:

1. Task-related knowledge is demonstrated through periodic participation by all qualified individuals for each position in the emergency response organization;

2. Drill performance is assessed against specific scenario objectives, using postulated accidents, that adequately test personnel, equipment, and resources, including previously identified weaknesses;

3. Effective player, controller, evaluator, and observer pre-drill briefings are conducted;

4. Scenario data and exercise messages provided by the controllers effectively maintain the time line and do not interfere with the emergency organization's response to exercise scenario events, except where safety considerations are involved;

5. Trained evaluators are used to identify and record participant performance, scenario strengths and deficiencies, and equipment problems;

6. Prestaging of equipment and personnel is minimized to realistically test the activation and staffing of emergency facilities;

7. Critiques are conducted in a timely manner and include a follow-up plan for correcting identified weaknesses and improving training effectiveness;

8. Emergency drills demonstrate that resources are effectively used to control the site, to mitigate further damage, and to control radiological releases, to perform required on-site activities, under simulated radiation/airborne and other emergency conditions, to provide accurate assessments and status during an accident, and to initiate recovery;

9. Emergency drills demonstrate personnel protection measures, including controlling and minimizing hazards to individuals during events such as fires, medical emergencies, mitigation activities, search and rescue, and other similar events;

10. The emergency drill demonstrates that on-site communications effectively support emergency response activities;

11. The emergency drill demonstrates that the emergency public information organization disseminates accurate, reliable, timely, and understandable information;

12. Provisions are made for conducting quarterly communications checks with off-site response organizations; and

13. Off-site organizations are invited to participate in the biennial on-site exercise that tests the major elements of the emergency plan and response organizations.

8.4.3.2.14 Responsibilities for Developing and Maintaining Current, the Emergency Program and Its Procedures

The emergency plan should describe the responsibilities for developing and maintaining the emergency program and its procedures. The description should include:

1. The means for ensuring that the revisions to the emergency plan and the procedures that implement the emergency plan are adequately prepared, kept up to date normally (within 30 days of any changes), and distributed to all affected parties, including the NRC; and

2. The provisions for approval of the implementing emergency procedures, making and distributing changes to the procedures, and ensuring that each person responsible for an emergency response function has immediate access to a current copy of emergency procedures. Provisions for approval of changes to the emergency plan and the procedures and those individuals authorized to make these changes are clearly stated;

3. Procedures for allowing off-site response organizations 60 days to comment on any new emergency plan or significantly updated emergency plans. Amendments to emergency plans that do not affect an organization or those changes allowed by 10 CFR 70.32(i))need not be provided to offsite organizations prior to submitting it to the NRC.

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 provides copies of the changes to the NRC and appropriate organizations within 6 months of the changes in accordance with 10 CFR 70.32(i). Proposed changes that decrease the effectiveness of the emergency plan may not be implemented without prior application to and prior approval of the NRC.

8.6 REVIEW PROCEDURES

8.6.1 Acceptance Review

The primary reviewer should evaluate the application to determine whether it addresses the "Areas of Review" discussed in Section 8.3, above. If significant deficiencies are identified, the applicant should be requested to submit additional material before the start of the safety evaluation.

8.6.2 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. If, during the course of the safety evaluation, the primary reviewer determines the need for additional information, the primary reviewer should coordinate a request for additional information with the licensing project manager.

8.6.2.1 Evaluation That No Emergency Plan Is Required

The primary reviewer should verify that the evaluation is consistent with the potential accident sequences described in the ISA Summary. The ISA reviewer and the primary reviewer should coordinate to assure the resolution of any issues concerning the evaluation relative to ISA information. The final step for the primary reviewer should be to prepare a SER in accordance with Section 8.7 that either agrees with the applicant's conclusion that no emergency plan is required or indicates that the staff does not accept the applicant's evaluation and recommends that an emergency plan be required by the applicant.

8.6.2.2 Emergency Plan

After an acceptable application has been received from the applicant, the primary reviewer should conduct a complete review and determine its acceptability in accordance with Section 8.4.3.2. The reviewer should verify that emergency planning is consistent with the potential accident sequences described in the ISA Summary. The ISA reviewer and emergency plan reviewer should coordinate to assure the resolution of any issues concerning the emergency plan relative to ISA Summary information.

Although the bulk of this information should be found in the Emergency Management program section of the licensee's submittal, the primary and secondary reviewers should gain familiarity

with the site, including the demography, land use, plant design and layout, and major accidents postulated by the applicant presented in relevant sections of the application. The primary and secondary reviewers should also gain familiarity with proposed radiation protection activities and other operational matters that interface with emergency plans, particularly the functions reviewed using SRP Chapters 4 and 11. Draft and final environmental statements for the proposed facility should be consulted. This information may be supplemented by a personal visit to the site by the reviewer and meetings with the applicant.

The final step for the primary reviewer should be to prepare an SER in accordance with Section 8.7, "Evaluation Findings."

8.7 EVALUATION FINDINGS

The primary reviewer writes an SER section addressing each topic reviewed under this SRP Chapter and explains why the NRC staff has reasonable assurance that the emergency management part of the application is acceptable. License conditions may be proposed to impose requirements where the application is deficient. The report includes a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.

The staff can document the evaluation as follows:

The staff has evaluated [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] In accordance with 10 CFR 70.22(i), the licensee commits to maintaining and executing an emergency plan for responding to the radiological hazards resulting from a release of radioactive material or hazardous chemicals, incident to the process. The NRC staff reviewed the emergency plan with respect to 10 CFR 70.22(i) and the acceptance criteria in 8.4.3 of the SRP. NRC staff determined that the applicant's emergency plan is adequate to demonstrate compliance with 10 CFR 70.22(i), including: (1) the plant is properly configured to limit releases of radioactive materials in the event of an accident; (2) a capability exists for measuring and assessing the significance of accidental releases of radioactive materials; (3) appropriate emergency equipment and procedures are provided on-site to protect workers against radiation and other chemical hazards that might be encountered after an accident; (4) a notification system has been established for notifying Federal, State, and local government agencies and recommending appropriate protective actions to protect members of the public; and (5) necessary recovery actions are established for returning the plant to a safe condition after an accident.

The requirements of the emergency plan are implemented through approved written procedures. Changes that decrease the effectiveness of the emergency plan may not be made without NRC approval. The NRC will be notified of other changes which do not decrease the effectiveness of the emergency plan within 6 months of the changes.

8.8 REFERENCES

1. U.S. Nuclear Regulatory Commission, "Part 30 Statements of Consideration and Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees," Federal Register 54, 14051, 1989.

2. U.S. Nuclear Regulatory Commission, NUREG/CR-6410, Nuclear Fuel Cycle Accident Analysis Handbook, 1998.

3. U.S. Nuclear Regulatory Commission, NUREG/BR-0150, Vol. 1, Rev. 4, RTM-96 Response Technical Manual, 1996.

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

U.S. NUCLEAR REGULATORY COMMISSION
STANDARD REVIEW PLAN
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

9.0 ENVIRONMENTAL PROTECTION

9.1 PURPOSE OF REVIEW

The purpose of this review is to determine whether the applicant's proposed environmental protection measures are adequate to protect public health and the environment and comply with the regulatory requirements imposed by the Commission in 10 CFR Parts 20, 51, and 70. In addition, the staff will determine if the applicant has submitted an environmental report that is adequate for staff use in preparation of an Environmental Assessment (EA) and Finding of No Significant Impact (FONSI), or an Environmental Impact Statement (EIS), pursuant to Part 51.

Staff should coordinate the preparation of an EA and FONSI, or EIS, with the Environmental Review Team in the Division of Waste Management. Staff coordination is described in Section 9.6.2 of this chapter.

9.2 RESPONSIBILITY FOR REVIEW

Primary: Environmental Engineer/Scientist

Secondary: Licensing Project Manager

Supporting: Fuel Cycle Facility Inspector
Radiation Safety Reviewer
ISA Lead Reviewer

9.3 AREAS OF REVIEW

There are two distinct components of the application that require an environmental review. These are: (1) the environmental report; and (2) the description of environmental protection measures. The review of environmental protection measures includes a review of the applicant's ISA. The following subsections identify the areas of review for each of these components. Greater detail on each component is provided in Section 9.4, which specifies the review acceptance criteria.

9.3.1 Environmental Report

The regulatory requirements for the environmental report are contained in Part 51. These regulations were promulgated by the Commission to implement the National Environmental Policy Act (NEPA) of 1969, which requires an assessment of the environmental impacts for all major Federal actions. The NRC staff conducts an independent assessment for all licensing actions that may have a significant effect on the environment, based on the information

provided by the applicant in the environmental report. This assessment is documented in an EA or EIS. The Commission has determined that actions listed in 10 CFR 51.22(c) have insignificant environmental impacts and are categorically excluded from the requirement for an EA and an environmental report. However, the applicant may be required to submit information to the NRC to justify the applicability of the categorical exclusion. In accordance with 10 CFR 51.21, the Commission may, in special circumstances, prepare an EA on an action covered by a categorical exclusion.

The areas of review for the environmental report correspond to the content specified in 10 CFR 51.45:

- Date of Application;
- Environmental Considerations;
  - ➛Description of the proposed action;
  - ➛Purpose of the proposed action;
  - ➛Description of the affected environment;
  - ➛Discussion of considerations (including environmental impacts and alternatives to the proposed action);
- Analysis;
- Status of Compliance; and
- Adverse Information.

The environmental report may include, reference, or supplement information submitted to the NRC for prior licensing actions.

9.3.2 Environmental Protection Measures

The regulatory requirements for environmental protection are contained in Parts 20, 51, and 70. The NRC staff environmental review is focused on that part of the applicant's plant-wide safety program that is established to control and assess the level of radioactive and nonradioactive releases (gaseous, liquid, and solid) to the environment. Therefore, the effluent control portion of the applicant's radiation protection program, as well as effluent and monitoring practices, are reviewed.

To receive authorization to possess a critical quantity of SNM, as defined in 10 CFR 70.4, an applicant must also perform an ISA and an ISA Summary in accordance with Subpart H of Part 70. Guidance on the ISA is covered in Chapter 3 of this SRP. The environmental safety review of the ISA Summary will include a review of the identified potential accident sequences that result in radiological and nonradiological releases to the environment; the IROFS that are specified by the applicant to reduce the risk of those accidents; and the associated management measures that provide reasonable assurance that the IROFS will perform their designated safety functions.

Thus, environmental protection includes three main components: (1) the radiation protection

program; (2) effluent and environmental monitoring; and (3) the ISA Summary and other ISA documentation, as necessary. The areas of review include:

9.3.2.1 Radiation Protection

- ALARA goals for effluent control;
- Effluent controls to maintain public doses ALARA;
- ALARA reviews and reports to management; and
- Waste-minimization practices and for new operations, design plans for waste-minimization.

9.3.2.2 Effluent and Environmental Monitoring

- In-place filter-testing procedures for air-cleaning systems;
- Known or expected concentrations of radionuclides in effluents;
- Physical and chemical characteristics of radionuclides in discharges;
- Discharge locations;
- Environmental media to be monitored and the sample locations;
- Sampling collection and analysis procedures, including the minimum detectable concentrations of radionuclides;
- Action levels and actions to be taken when the levels are exceeded;
- Permits, including air discharge and National Pollutant Discharge and Elimination System permits;
- Leak-detection systems for ponds, lagoons, and tanks;
- Pathways analysis methods to estimate public doses;
- Recording and reporting procedures; and
- Solid waste handling and disposal programs.

9.3.2.3 ISA Summary

- Accident sequences (and associated facility processes) which, if unmitigated, result in releases to the environment;
- Likelihood and environmental consequences of these accident sequences;
- Controls relied on to reduce the unmitigated risk from “high” risk to an acceptable level; and
- Availability and reliability of controls.

9.4 ACCEPTANCE CRITERIA

Acceptance criteria for the environmental report and for the environmental protection measures are described in Sections 9.4.1 and 9.4.2, respectively.

9.4.1 Regulatory Requirements

1) Part 20, specifically the effluent control and treatment measures necessary to meet the dose limits and dose constraints for members of the public specified in Subparts B, D,

and F; the survey requirements specified in Subpart F; the waste disposal requirements in Subpart K; the records requirements of Subpart L; and the reporting requirements of Subpart M.

2) Part 51, specifically the applicant must establish effluent and environmental monitoring systems to provide the information required by 10 CFR 51.60(a).

3) Part 51, specifically the applicant must submit an environmental report, as required by 10 CFR 51.60(b), or support a categorical exclusion as described in 10 CFR 51.22(c).

4) Part 70, specifically the applicant must demonstrate that proposed facilities and equipment, including measuring and monitoring instruments and devices for the disposal of radioactive effluents and wastes, are adequate to protect public health and the environment as specified in 10 CFR 70.22(a)(7).

5) Part 70, specifically the applicant for a facility as described in 10 CFR 70.4, must submit a safety assessment of the design basis of the principal structure, systems, and components of the plant, including provisions for protection against natural phenomena, as specified in 10 CFR 70.22(f).

6) Part 70, specifically an application for a facility must contain 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 outlines the radiological effluent monitoring reporting requirements for a Part 70 licensee.

9.4.2 Regulatory Guidance

The regulatory guidance for environmental protection is contained in:

(1) NRC Regulatory Guide 4.5, “Measurements of Radionuclides in the Environment Sampling and Analysis of Plutonium in Soil.”

(2) NRC Regulatory Guide 4.15, “Quality Assurance for Radionuclide Monitoring Programs (Normal Operations) - Effluent Streams and the Environment.”

(3) 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.”

(4) NRC Regulatory Guide 4.20, “Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other than Power Reactors.”

(5) NRC Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities."

(6) NRC Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised Part 20," January 28, 1994.

(7) NRC Information Notice 94-23, "Guidance to Hazardous, Radioactive and Mixed Waste Generators on the Elements of a Waste Minimization Program," March 1994.

(8) ANSI N13.1-1982, "Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities."

(9) ANSI N42.18-1980, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents."

(10) NCRP Report No. 123, "Screening Models for Releases of Radionuclides to Atmosphere, Surface Water, and Ground," January 1996.

(11) Draft Environmental Standard Review Plan, 2000.

9.4.3 Regulatory Acceptance Criteria

9.4.3.1 Environmental Report (or Categorical Exclusion Information)

An environmental report is required for actions listed in 10 CFR 51.60(b). The acceptance criteria for the environmental report are discussed in Section 9.4.3.1.1.

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). However, if pursuant to 10 CFR 51.23(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 justify that the action will not result in significant effects on the environment. The acceptance criteria for this categorical exclusion are given in Section 9.4.3.1.2.

9.4.3.1.1 Environmental Report

(1) Date of Application

The date of an application for a license to possess and use SNM for processing and fuel fabrication, scrap recovery, conversion of uranium hexafluoride, or for the conduct of any other activity, that the NRC has determined pursuant to 10 CFR 51 Subpart A will significantly affect the quality of the environment, is acceptable if the application is submitted at least 9 months before construction begins, as required by 10 CFR 70.21(f). However, an EIS is generally estimated to take 2 years to complete.

(2) Environmental Considerations

An adequate environmental report addresses the requirements of 10 CFR 51.45(b), as described below.

1. Description of the proposed action

The description of the proposed action includes a brief summary of the significant characteristics of the proposed facility, including the major site features and the major plant design and operating parameters. The description includes a complete discussion about how SNM will be processed at the facility. If future construction is proposed, the description includes a proposed project schedule showing the dates for initiation of site preparation, plant construction, and operation.

B. Purpose of the proposed action

The statement of purpose demonstrates a need for the proposed project. This demonstration provides at least the following information: (a) the quantities of SNM used for domestic benefit; (b) a projection of national and foreign requirements for the services; and (c) alternative sources of supply for the proposed facility's services. If delay of the proposed project would have effects on the Nation's energy program, or on the applicant's business (such as loss of contracts, jobs, or future business), these effects are discussed.

C. Description of the affected environment

The description of the affected environment includes:

i. Site location (including longitude and latitude) and facility layout;
ii. Regional demography and land use;
iii. Socioeconomic information, including low-income and minority populations within a 50 mile radius;
iv. Regional historic, archaeological, architectural, scenic, cultural, and natural landmarks;
v. Local meteorology and air quality;
vi. Local surface water and groundwater hydrology;
vii. Regional geology and seismology; and
viii. Local terrestrial and aquatic ecology.

To the extent possible, this information is current, and affects observations and measurements made over a period of years, especially for conditions that are expected to vary seasonally (e.g., precipitations, wind speed and direction, and groundwater levels).

D. Discussion of considerations

The reviewer should find the discussion of considerations acceptable if it includes:

i. Impact of the proposed action on the environment

- Effects of site preparation and construction on land use and water use;
- Effects of plant operation on the human population (including consideration of occupational and public radiation exposure) and important biota;
- Any irreversible commitments of resources because of site preparation and plant construction and operation, such as destruction of wildlife habitat, removal of land from agricultural use, and diversion of electrical power;
- Plans and policies regarding decommissioning and dismantling at the end of the plant's useful life;
- Environmental effects of the transportation of radioactive materials to and from the site;
- Environmental effects of accidents;
- Impacts on air and water quality; and
- Impacts on cultural and historic resources.

This section of the environmental report discusses the impacts on the environment in proportion to their significance, and considers the cumulative impacts of the proposed action. In addition, accident analyses provided in the report are consistent with the applicant's ISA.

ii. Adverse environmental effects

The information submitted describes any adverse environmental effects that cannot be avoided should the proposal be implemented. This description is presented in quantitative terms to the maximum extent possible. This discussion makes clear which of these effects are unavoidable and subject to later amelioration and which are unavoidable and irreversible. The description includes specific measures that the applicant could take or plan to take to mitigate adverse effects.

iii. Alternatives to the proposed action

The discussion of alternatives to the proposed action is sufficiently complete to aid the NRC in developing and exploring, pursuant to Section 102(2)(E) of the NEPA, "appropriate alternatives to recommended courses of action in any proposal which involves unresolved conflicts concerning alternative uses of available resources." To the extent practicable, the environmental impacts of the proposal and the alternatives are presented in comparative form.

The discussion of alternatives includes siting alternatives and design alternatives. Comparable levels of information on each site need not be presented as long as the

applicant presents sufficient information to facilitate a fair and reasonable comparison. The following factors are considered when comparing alternative sites:

- Physical characteristics of the area, including demographic, geological, hydrological, meteorological, and seismological conditions of the site and surrounding area;
- Location of power sources and transmission lines;
- Location of the major product market;
- Location of raw materials, components, and sources of supply;
- Availability of air, rail, roads, and water for transport of raw materials and supplies, finished products, and solid wastes;
- Commitment of natural resources for site preparation and plant construction, including but not limited to the destruction or diminution of wildlife habitats, flora, woodlands, and marshlands;
- Commitment of capital for site preparation and plant construction;
- Cost of operation, including consideration of labor supply, prevailing wage rates, and other recurring or nonrecurring costs;
- Availability of municipal services and facilities or, conversely, the cost of providing services such as water and sewage treatment;
- Requirements for relocating homes and families; and
- Existing and projected land use and economic status of the community (e.g., urban, industrial, stable).

iv. Relationship between short-term uses and long-term productivity

The relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity is discussed. Short-term uses are considered to be those that occur during the active life of the facility. Long-term productivity represents the use of the environment beyond decommissioning of the facility.

v. Irreversible and irretrievable commitments of resources

Any irreversible environmental commitments and irretrievable material resources that would be involved in the proposed action are discussed.

3. Analysis of Environmental Effects of Proposed Action and Alternatives

An adequate environmental report analyzes the environmental effects of the proposed action and alternatives. In accordance with 10 CFR 51.45(c), the analysis considers and balances the environmental effects of the proposed action and the alternatives available for reducing or avoiding adverse environmental effects, as well as the environmental, economic, social, and other benefits of the proposed action.

This analysis quantifies, to the fullest extent practicable, the various factors considered. If the application involves renewal or amendment of a current license, environmental impacts are quantified using environmental monitoring data collected by the licensee. To the extent that there are important qualitative considerations or factors that cannot be quantified, the analysis discusses those considerations and factors in qualitative terms. The analysis contains sufficient data to aid the staff in its development of an independent analysis.

4. Status of Compliance

As required by 10 CFR 51.45(d), the applicant should list all Federal permits, licenses, approvals, and other entitlements, that must be obtained in connection with the proposed action. The list is acceptable if it is complete and current as of the application date.

In addition, 10 CFR 51.45(d) requires that the environmental report include a discussion of the status of compliance with applicable environmental quality standards and requirements including, but not limited to, applicable zoning and land-use regulations, and thermal and other water pollution limitations or requirements that have been imposed by Federal, State, regional, and local agencies having responsibility for environmental protection. The discussion is acceptable if it includes a discussion of whether each alternative will comply with such applicable environmental quality standards and requirements. The discussion includes, but is not limited to, the following Federal laws:

- The National Historic Preservation Act of 1966;
- The Fish and Wildlife Coordination Act of 1966;
- The Wild and Scenic Rivers Act of 1968;
- The Endangered Species Act Amendments of 1978; and
- The Coastal Zone Management and Improvement Act of 1990.

5. Adverse Information

In accordance with 10 CFR 51.45(e), the preceding discussions and analyses are acceptable if they include information that is adverse to the proposed actions, as well as information supporting the proposed action.

9.4.3.1.2 Categorical Exclusion

An environmental report is not required for actions, identified in 10 CFR 51.60(b)(1), that involve an amendment to licenses for fuel cycle plants, radioactive waste disposal sites, and other materials licenses, which are not expected to result in significant environmental impacts. However, when amendments involve changes in process operations or equipment as defined in 10 CFR 51.22(c)(11), the applicant needs to justify that the changes will not result in significant

environmental effects.

The information provided by the applicant to justify the categorical exclusion determination is acceptable if it demonstrates the following, as specified in 10 CFR 51.22(c)(11):

- There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite;
- There is no significant increase in individual or cumulative occupational radiation exposure;
- There is no significant construction impact; and
- There is no significant increase in the potential for or consequences from radiological accidents.

9.4.3.2 Environmental Protection Measures

An applicant's proposed actions for environmental protection are acceptable if they provide for qualified and trained staff, effluent control, and effluent and environmental monitoring, in accordance with NRC requirements. Using the acceptance criteria provided in Chapter 11 of this SRP, the NRC staff will review the training and qualifications for plant personnel associated with environmental protection, as described in the license application. This will include the training and qualification of managers, supervisors, technical staff, operators, technicians, and maintenance personnel whose levels of knowledge are important to maintain protection of public health and the environment. Managers and staff will be expected to have levels of education and experience commensurate with the responsibilities of their positions.

9.4.3.2.1 Radiation Safety

In accordance with 10 CFR 20.1101, each licensee must implement a radiation protection program, which is discussed in detail in Chapter 4.0 of this SRP. The environmental review of the radiation protection program focuses on the applicant's methods to maintain *public* doses ALARA in accordance with 10 CFR 20.1101. NRC guidance on compliance with these regulations can be found in Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," July 1993.

Specifically, 10 CFR 20.1101(d) requires the applicant to establish a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its decay products, such that the individual member of the public likely to receive the highest dose will not be expected to receive a TEDE in excess of 0.1 mSv (10 mrem) per year from these emissions. The applicant must have procedures to report, when this dose constraint is exceeded, to the NRC, in accordance with 10 CFR 20.2203, and take prompt appropriate corrective action to ensure against recurrence. NRC guidance on compliance with this regulation can be found in Regulatory Guide 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," December 1996.

The environmental review of the radiation protection program also focuses on the applicant's waste minimization practices. Applicants for new licenses are required to comply with 10 CFR 20.1406, which states that the applicant must describe how facility design procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste. 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 20.1101 [62 FR 39082].

Guidance for waste minimization programs can be found in NRC Information Notice No. 94-23: "Guidance to Hazardous, Radioactive and Mixed Waste Generators on the Elements of a Waste Minimization Program," March 25, 1994. More information on compliance with the decommissioning aspects of the waste minimization regulations can be found in Chapter 10.0 of this SRP.

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 Appendix B, Table 2, Columns 1 and 2 and Table 3 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, through a calculation of the total effective dose equivalent (TEDE) to the individual likely to receive the highest dose.

   An applicant's constraint approach is acceptable if it is consistent with guidance found in Regulatory Guide 4.20, and the applicant's description of the constraint approach provides sufficient detail to demonstrate specific application of the guidance to proposed routine operations and non-routine operations, including anticipated events.

2. Effluent Controls to Maintain Public Doses ALARA

   The applicant describes and commits to using 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 the storage of materials for radioactive decay. Practices for large, diffuse sources such as contaminated soils or surfaces include covers, wetting during operations, and the application of stabilizers. The applicant demonstrates a commitment to reducing unnecessary exposure to members of the public and releases to the environment.

Engineering options that do not result in a substantial reduction in collective dose and require unreasonable costs are not required. Reasonableness can be based on a qualitative or quantitative cost/benefit analysis. Quantitative analyses may use a $2000 per person-cSv (man-rem) value, as discussed in NUREG-1530, "Reassessment of the NRC's Dollar per Person-Rem Conversion Factor Policy."

3. ALARA Reviews and Reports to Management

The applicant commits to annual review of the content and implementation of the radiation protection program, which includes the ALARA effluent control program. This review includes analysis of trends in release concentrations, environmental monitoring data, and radionuclide usage; determines whether operational changes are needed to achieve the ALARA effluent goals; and evaluates all designs for system installations or modifications. The applicant also includes a commitment to report the results to senior management, along with recommendations for changes in facilities or procedures that are necessary to achieve ALARA goals.

4. Waste minimization

To comply with 10 CFR 20.1406, applications for new licenses are acceptable if they contain a description of how facility design procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, and minimize, to the extent practicable, the generation of radioactive waste. Waste-minimizations programs proposed by applicants for both new and existing licenses are acceptable if the programs include:

- Top management support;
- Methods to characterize waste generation, including types and amounts, and waste management costs, including costs of regulatory compliance, paperwork, transportation, treatment, storage, disposal, etc.;
- Periodic waste minimization assessments to identify waste minimization opportunities and solicit employee or external recommendations;
- Provisions for technology transfer to seek and exchange technical information on waste minimization; and
- Methods for implementation and evaluation of waste minimization recommendations.

9.4.3.2.2 Effluent and Environmental Controls and Monitoring

A. Effluent Monitoring

The reviewer should find that the applicant's effluent monitoring is acceptable if it meets the following criteria:

1. The known or expected concentrations of radioactive materials in airborne and liquid

effluents are below the limits in Part 20, Appendix B, Table 2, or below site-specific limits established in accordance with 10 CFR 20.1302(c), and are ALARA.

If, in accordance with 10 CFR 20.1302(c), the applicant proposes to adjust the effluent concentrations in Appendix B to Part 20, to take into account the actual physical and chemical characteristics of the effluents, the applicant provides information related to aerosol-size distributions, solubility, density, radioactive-decay equilibrium, and chemical form. This information is complete and accurate for the radioactive materials, to justify the derivation and application of the alternative concentration limits.

2. If the licensee proposes to demonstrate compliance with 10 CFR 20.1301 through a calculation of the TEDE to the individual likely to receive the highest dose in accordance with 10 CFR 20.1302(b)(1), calculation of the TEDE by pathway analyses uses appropriate models and codes and assumptions that accurately represent the facility, the site, and the surrounding area; assumptions are reasonable; input data are accurate; all applicable pathways are considered; and the results are interpreted correctly.

   NCRP Report No. 123, "Screening Models for Releases of Radionuclides to Atmosphere, Surface Water, and Ground," January 1996, provides acceptable methods for calculating the dose from radioactive effluents. Computer codes are acceptable tools for pathway analyses if the applicant is able to demonstrate that the code has undergone validation and verification to demonstrate the validity of estimates developed using the code for established input sets. Dose-conversion factors used in the pathway analyses are acceptable if they are based on the methodology described in ICRP 30, "Limits for Intakes of Radionuclides by Workers" as reflected in Federal Guidance Report 11. Such methods are acceptable for determining the dose to the maximally exposed individual during normal facility operations and anticipated events.

3. All liquid and airborne effluent discharge locations are identified and monitored. Monitoring locations are identified, and 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. Airborne effluents from all routine operations, and non-routine operations, as well as anticipated events associated with the plant, including effluents from areas not used for processing SNM such as laboratories, experimental areas, storage areas, and fuel element assembly areas, are continuously sampled.

   Effluents are sampled unless the applicant has established, by periodic sampling or other means, that radioactivity in the effluent is insignificant and will remain so. In such cases, the effluent is sampled at least quarterly to confirm that effluents are not significant. For the purposes of this SRP, 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 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 representative samples are obtained by use of appropriate sampling equipment and sample collection and storage procedures. For liquid effluents, representative samples are taken at each release point for the determination of concentrations and quantities of radionuclides released to an unrestricted area, including discharges to sewage systems. For continuous releases, samples are continuously collected at each release point. For batch releases, a representative sample of each batch is collected. If periodic sampling is used in lieu of continual sampling, the applicant shows that the samples are representative of actual releases. Monitoring instruments are calibrated at least annually, or more frequently if suggested by the manufacturer.

6. Radionuclide specific analyses are performed on selected composited samples unless either:

   1. The gross alpha and gross beta activities are so low that individual radionuclides could not be present in concentrations greater than 10 percent of the concentrations specified in Table 2 or 3 of Appendix B to Part 20, or

   2. The radionuclide composition of the sample is known through operational data, such as the composition of the feed material.

   Monitoring reports in which estimates of quantities of individual radionuclides are based on methods other than direct measurement include an explanation and justification of how the results were obtained.

   Examples of cases in which operational data may not be adequate for the determination of radionuclide concentration are: (1) plants processing uranium in which extraction, ammonium diuranate precipitation, ion exchange, or other separation processes could result in concentration of thorium isotopes (principally Th-234); (2) plants in which uranium of varying enrichments is processed; and (3) plants processing plutonium in which significant variation in the Pu-238/Pu-239 ratio among batches and the continuous in-growth of Am-241 would preclude the use of feed material data to determine the radionuclide composition of effluents.

   Radionuclide analyses are performed more frequently than usual under three circumstances: (1) at the beginning of the monitoring program until a predictable and consistent radionuclide composition in effluents is established; (2) whenever there is a significant unexplained increase in gross radioactivity in effluents; or (3) whenever a process change or other circumstance might cause a significant variation in the radionuclide composition.

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 Part 20. If the actual concentrations of radionuclides in samples are known to be higher than 5 percent of the Part 20 limits, the analysis methods need only be adequate to measure the actual concentration. However, in such cases, the MDC is low enough to accommodate fluctuations in the concentrations of the effluent and the uncertainty of the MDC.

8. The laboratory quality control (QC) procedures are adequate to support the validity of the analytical results. These QC procedures include the use of established standards such as those provided by the National Institute of Standards and Technology (NIST), as well as standard analytical procedures, such as those established by the National Environmental Laboratory Accreditation Conference.

9. The 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 assure and control effluents. A slightly higher than normal concentration of a radionuclide in effluent triggers an investigation into the cause of the increase. An action level is specified that will result in the shutdown of an operation if this level is exceeded. These action levels are selected based on the likelihood that a measured increase in concentration could indicate potential violation of the effluent limits.

10. The descriptions of applicable Federal and/or State standards for discharges and any permits issued by local, State, or Federal governments for gaseous and liquid effluents are complete and accurate.

11. The systems for the detection of leakage from ponds, lagoons, and tanks are adequate to detect and assure against any unplanned releases to groundwater, surface water, or soil.

12. Releases to sewer systems are controlled and maintained to meet the requirements of 10 CFR 20.2003, including (i) the material is water soluble; (ii) known or expected discharges meet the effluent limits of Part 20 Appendix B, Table 3; and (iii) the known or expected total quantity of radioactive material released into the sewer system in a year does not exceed 5 Ci (185 GBq) of ^{3}H, 1 Ci (37 GBq) of ^{14}C, and 1 Ci (37 GBq) of all other radioactive materials combined. Solubility is determined in accordance with the procedure described in NRC Information Notice 94-07.

13. Reporting procedures comply with the requirements of 10 CFR 70.59 and the guidance specified in Regulatory Guide 4.16. Reports of the concentrations of principal radionuclides released to unrestricted areas in liquid and gaseous effluents are provided and include the MDC for the analysis and the error for each data point.

14. The applicant's procedures and facilities for solid and liquid waste handling, storage, and monitoring result in safe storage of the material and timely disposition.

B. Environmental Monitoring

The scope of the applicant's environmental monitoring is acceptable if it is commensurate with the scope of activities at the facility and the expected impacts from operations as identified in the environmental report and meets the following criteria:

1. Background and baseline concentrations of radionuclides in environmental media have been established through sampling and analysis.

2. Monitoring includes sampling and analyses for monitoring of air, surface water, groundwater, soil, sediments, and vegetation, as appropriate.

3. The description of monitoring identifies adequate and appropriate sampling locations and frequencies for each environmental medium, the frequency of sampling, and the analyses to be performed on each medium.

4. Monitoring procedures employ acceptable analytical methods and instrumentation to be used. The applicant commits to a program of instrument maintenance and calibration appropriate to the instrumentation. If the applicant proposes to use its own analytical laboratory for the analysis of environmental samples, the applicant commits to provide third-party verification of the laboratory's methods such as may be 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 based on a pathway analysis that demonstrates that below those concentrations, doses to the public will be below the limits in Part 20, Subpart B, and are ALARA. The action levels specify the concentrations at which an investigation would be performed and levels at which process operations would be shut down.

6. MDCs are specified for sample analyses, and are at least as low as those selected for effluent monitoring in air and water. MDCs for sediment, soil, and vegetation are selected based on the action levels, to ensure that sampling and analytical methods are sensitive and reliable enough to support application of theaction levels.

7. Data analysis methods and criteria to be used for evaluating and reporting the environmental sampling results are appropriate and will indicate when an action level is being approached in time to take corrective actions.

8. The description of the status of all licenses, permits, and other approvals of plant operations required by Federal, State, and local authorities is complete and accurate.

9. Environmental monitoring is adequate to assess impacts to the environment from potential radioactive and nonradioactive releases, as identified in high and medium risk accident sequences in the ISA.

9.4.2.3 Integrated Safety Analysis

In accordance with 10 CFR 70.60, applicants requesting a critical mass of SNM are required to perform an ISA. The applicant's treatment of environmental protection in the ISA is acceptable if it fulfills the following criteria:

- The ISA provides a complete list of accident sequences that result in radiological and nonradiological releases to the environment;
- The ISA provides a reasonable estimate for the likelihood and consequences of each accident sequence identified;
- Adequate controls are identified for each accident sequence of environmental significance. The controls (engineering or administrative) will prevent or mitigate "high" risk sequences to an acceptable level. (Definitions of risk categories are given in Chapter 3 of this SRP.) Controls provide the indicated level of protection;
- Adequate levels of assurance are afforded to the controls to ensure that IROFS will satisfactorily perform their safety functions. This may be accomplished through configuration management, training, and maintenance activities; and
- The ISA uses acceptable methods for estimating environmental effects from accident sequences.

9.5 REVIEW PROCEDURES

The staff will review the environmental report and the environmental protection measures to verify that each meets the acceptance criteria in Section 9.4. If the applicant has not provided sufficient information to make these determinations, then a request for additional information (RAI) should be made in coordination with the facility project manager. The format for an RAI is specified in Chapter 4 of the Fuel Cycle Licensing Branch "Materials Licensing Procedures Manual." Additional review procedures are provided in Sections 9.5.1 to 9.5.3.

9.5.1 Environmental Report

Review of the environmental report or information presented to support a categorical exclusion includes review of occupational exposure information. This review should be coordinated with the radiation safety reviewer to assess the adequacy of the information provided by the applicant.

9.5.2 Environmental Protection

For renewal and amendment applications, an environmental specialist review of environmental protection will include coordination with the fuel cycle facility inspector responsible for environmental protection. Any comments or concerns that the inspector identifies will be addressed and resolved, and the SER (described in Section 9.6.1) for the licensing action will contain a statement indicating if the inspection staff has any objections to approval of the proposed licensing action. In addition, the review of applications will include review of inspection reports and semi-annual effluent reports submitted in accordance with 10 CFR 70.59, to assure licensee performance in environmental protection.

As part of the environmental protection review, the environmental specialist will review the ISA Summary. All accident sequences identified in the ISA Summary that can have significant environmental consequences will be reviewed to determine that the list of potential accidents is complete and properly identified. This review will be coordinated with the ISA reviewer. Detailed review will only be conducted of the accident sequences which, when left unmitigated, are rated as "high risk" by the applicant, as well as approximately 10 percent of the "medium" risk sequences, and a smaller number of the "low" risk sequences. However, additional "medium" and "low" risk sequences may be evaluated based on the results of the initial review.

Evaluation of the ISA Summary requires coordination with other technical reviewers. The environmental review of the controls will be coordinated with the reviewers for the specific assurance functions, such as training and maintenance.

Finally, review of the ISA may require examination of detailed supporting documents that have not been submitted for the public record and are instead located at the facility. The reviewer should decide, as a result of these reviews, what supporting documents need to be forwarded to the NRC for inclusion in the public record of the application. As a general rule, material that directly supports a licensing decision of reasonable assurance of safety should be a matter of public record. Whether the material is placed in the public record or only available at the facility, the reviewer will clearly cite in the SER what materials were examined, and what descriptions and commitments were considered and relied on, or the basis for the staff's safety decision.

9.6 EVALUATION FINDINGS

9.6.1 Introduction

Documentation of the evaluation findings for the environmental protection review is contained in two types of products. An SER documents the technical review of the application including, the review of the environmental protection program and the ISA Summary. The EA or EIS documents the staff's independent assessment of the environmental impacts of the proposed action.

The staff reviewers will verify that the information submitted by the applicant is in accordance

with Parts 20, 51, and 70, and that this information is consistent with the guidance in this SRP as it applies to environmental protection. In the input to the SER, the primary reviewer documents the bases for determining the adequacy of the application with respect to environmental protection, and should recommend additional license conditions in areas where the license application is not adequate. The primary reviewer also describes the applicant's approach to ensuring the quality and reliability of the controls required for environmental protection.

Often, environmental protection is reviewed and evaluated in conjunction with the environmental report, and the environmental protection function is summarized in the EA or EIS. However, the EA or EIS does not become part of the license. Issues identified during the review should be discussed briefly in the SER, and any recommended license conditions based on the analysis in the EA or EIS should be added to the license.

If an EA and EIS were prepared for the licensing action, the date the documents were issued should be reported in the environmental safety section of the SER. If the EA resulted in a FONSI, the FONSI's publication date in the Federal Register should be included in the SER. If an EIS is prepared, the SER would include the Federal Register publication date for the Record of Decision. When applicable, the SER also documents the determination that an action meets a categorical exclusion.

9.6.2 NEPA Documentation and Coordination

Before taking a licensing action, including issuance, renewal, or amendment, the appropriate NRC Branch Chief will determine whether the proposed action qualifies for a categorical exclusion under 10 CFR 51.22, or whether an EA should be prepared, or whether conditions warrant staff going directly to an EIS, and then initiate the appropriate coordination with the Division of Waste Management.

1. An EIS will be prepared if the action meets the criteria in 10 CFR 51.20. An EA is not necessary if it is determined that an EIS will be prepared. The NRC Branch Chief should initiate coordination with the Division of Waste Management to prepare the EIS.

2. An EA will be prepared if the action meets the criteria in 10 CFR 51.21. If the EA results in a FONSI, no further environmental review is necessary unless significant new information comes to light or the licensee changes its plan. Review of the EAs by the Environmental Review Team is required and the EA should be sent to the team for review prior to its finalization. If the EA does not result in a FONSI, then an EIS must be prepared.

3. A categorical exclusion will suffice if the action meets the criteria for categorical exclusions as defined in 10 CFR 51.22(c). (An action that qualifies for a categorical exclusion is usually identified at the start of the licensing review, and an environmental report is not required.) No coordination with the Division of Waste Management is

required.

Requirements for the preparation of an EIS, EA, or FONSI are described in detail in Part 51. Documents prepared in accordance with NEPA will follow pertinent NMSS procedures, including consultation with States (Policy & Procedures Letter 1-48), evaluation of environmental justice (Policy & Procedures Letter 1-50 Revision 2), and Chapter 6 of the NRC Division of Fuel Cycle Safety and Safeguards, Fuel Cycle Licensing Branch Manual. Sections 9.6.2.1 and 9.6.2.2 contain an overview of the regulatory requirements for an EA, FONSI, EIS and Record of Decision specified in Part 51. However, this discussion is not intended to be all-inclusive.

9.6.2.1 Environmental Assessment (EA)

The staff will prepare an EA using information contained in the license application and a separate submittal, the environmental report submitted by the licensee, in accordance with 10 CFR 51.45. The EA that is prepared identifies the proposed action and includes the following, in accordance with 10 CFR 51.30:

1. A brief discussion of:
   a. The need for the proposed action
   b. Alternatives to the proposed action as required by Section 102(2)(E) of the NEPA
   c. The environmental impacts of the proposed action and alternatives, as appropriate
   d. As required for special case EAs, as defined by NMSS Policy and Procedures letter 1-50, Revision 2, September 7,1999, disproportionately high and adverse human health or environmental effects on low-income and minority populations

2. A list of agencies and persons consulted and identification of sources used. During preparation of an EA, the staff will consult with affected States, the Fish and Wildlife Service, State HIstoric Preservation Officer, and Tribal Officer (as necessary), on environmental issues and will document such contacts in the EA. This documentation will include the following information identified in NMSS Policy and Procedures Letter 1-48, January 1995:

   a. The name of each State, agency (including contacted individual's name), or person consulted
   b. Date of consultation(s)
   c. Purpose for the consultation
   d. Brief summary of the views or comments expressed by the consulted party and the staff's resolution
   e. Reference to publicly available documents containing additional information, if applicable

Much of the information used to prepare the EA is provided by the applicant in the environmental report. However, the staff will perform independent analyses of the

environmental impacts of the proposed action and will discuss the conclusions of these analyses in the EA. The EA should focus on the impacts of the proposed action and should be no more than 15 pages, unless more are necessary to explain any complicated environmental issues associated with the proposed action.

On completion, the EA should be forwarded to the Environmental Review Team for review. The Environmental Review Team reviews the EA to ensure consistency among all EAs prepared by NMSS. When the Environmental Review Team completes its review, the appropriate NRC Branch Chief will determine whether to prepare an EIS or a FONSI on the proposed action. As discussed in Section 9.6.2.2 and provided in 10 CFR 51.33, a determination to prepare a draft FONSI may be made. As provided in 10 CFR 51.25, an EA is not necessary if it is determined that an EIS will be prepared.

9.6.2.2 FONSI

When the staff makes a final finding that there are no significant environmental impacts from the proposed action, a final FONSI will be published in the Federal Register. The Commission will not take the proposed action, including license issuance, renewal, or amendment, until after the FONSI has been published. Requirements for the preparation of a FONSI for materials licensing actions are contained in 10 CFR 51.32 to 51.35. A FONSI will include the following:

1. Identification of the proposed action
2. Statement that the Commission has determined not to prepare an EIS for the proposed action
3. Brief presentation of the reasons why the proposed action will not have a significant impact on the quality of the human environment
4. The EA or a summary of the EA
5. A note of any other related environmental documents
6. A statement that the finding and any related environmental documents are available for public inspection and where the documents may be inspected.

NRC may make a determination to prepare and issue a draft FONSI for public review and comment before making a final determination on whether to prepare an EIS or a final FONSI on the proposed action. A draft FONSI may be prepared if a FONSI appears warranted, but the proposed action is similar to one that normally requires an EIS, or is without precedent.

The draft FONSI will be identified as a "draft" and will contain the information specified above for a final FONSI. The draft FONSI will be accompanied by or will include a request for comments on the proposed action and the draft findings within 30 days, or a longer period, as may be specified in the notice of the draft findings. This draft FONSI will be published in the Federal Register, distributed as provided in 10 CFR 51.74(a), and made available in accordance with 10 CFR 51.123.

When a draft FONSI is issued, a final determination to prepare an EIS or final FONSI will not be made until the last day of the public comment period has expired.

9.6.2.3 EIS

When the appropriate NRC Branch Chief determines that an EIS will be prepared for the licensing action the NRC Branch Chief should initiate coordination with the Environmental Review Team. The Environmental Review Team will prepare the EIS. The project manager should coordinate with Environmental Review Team to: 1) ensure that there is consistency between the environmental review and the preparation of the EIS; and 2) ensure that the results of the NEPA analysis are appropriately incorporated into the SER and license.

9.6.3 Sample Safety Evaluation Report

The following language would be appropriate for a licensing action that required an EIS in accordance with 10 CFR 51.20.

> *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 public health and the environment and comply with the regulatory requirements imposed by the Commission in Parts 20, 51, and 70. The bases for these conclusions are:*
>
> *[State the bases for the conclusion, including any recommended license conditions.]*
>
> *The NRC staff prepared an environmental impact statement (EIS) [publication date] for this licensing action as required by 10 CFR 51.20. Based on the EIS, the NRC stated in its Record of Decision [publication date in the Federal Register] that the preferred option was [state preferred option here].*

9.7 REFERENCES

American National Standards Institute, N13.1-1982, "Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities."

American National Standards Institute, N42.18-1980, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents."

National Council on Radiation Protection and Measurements, NCRP Reports No. 123 I & II, "Screening Models for Releases of Radionuclides to Atmosphere, Surface Water, and Ground," January 1996.

U.S. Nuclear Regulatory Commission Information Notice No. 94-23: "Guidance to Hazardous, Radioactive and Mixed Waste Generators on the Elements of a Waste Minimization Program," March 25, 1994.

U.S. Nuclear Regulatory Commission Information Notice 94-07, "Solubility Criteria for Liquid

Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20," January 28, 1994.

U.S. Nuclear Regulatory Commission, NMSS/FCSS/Fuel Cycle Licensing Branch, Rev. 5, "Materials Licensing Procedures Manual," September 1996.

U.S. Nuclear Regulatory Commission, Regulatory Guide 4.15, Rev. 2, "Quality Assurance for Radiological Monitoring Programs (Normal Operations)–Effluent Streams and the Environment," February 1979.

U.S. Nuclear Regulatory Commission, Regulatory Guide 4.16, Rev. 2, "Monitoring and Reporting Radioactivity in Releases of Radioactive Materials in Liquid and Gaseous Effluents from Nuclear Fuel Processing and Fabrication Plants and Uranium Hexafluoride Production Plants," December 1985.

U.S. Nuclear Regulatory Commission, Regulatory Guide 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees other Than Power Reactors," December 1996.

U.S. Nuclear Regulatory Commission, Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities", July 1993.

DRAFT

U.S. NUCLEAR REGULATORY COMMISSION
STANDARD REVIEW PLAN
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

10.0 DECOMMISSIONING

10.1 PURPOSE OF REVIEW

The purpose of the review of the applicant's plans for decommissioning is to determine with reasonable assurance that the applicant will be able to decommission the facility safely and in accordance with NRC requirements.

At the time of the initial license application, and on license renewal, the applicant/licensee may be required to submit a decommissioning funding plan (DFP). The purpose of NRC evaluation of the DFP is to determine that the applicant/licensee has considered decommissioning actions that may be needed in the future; has performed a credible site-specific cost estimate for those actions; and has presented the NRC with financial assurance to cover the cost of these actions in the future. The DFP, therefore, should contain an overview of the proposed decommissioning actions; the methods used to determine the cost estimate; and the financial assurance mechanism. These must be in sufficient detail to allow the reviewer to determine that the decommissioning cost used in the DFP is reasonably accurate.

Before the initiation of decommissioning actions, the licensee must submit, to the NRC, for approval a Decommissioning Plan (DP) if required by §70.38(g). The DP details the specific decommissioning activities to be performed; describes radiation protection procedures to protect workers, the public and the environment during decommissioning. It must provide sufficient information to allow the reviewer to assess the appropriateness of the decommissioning activities, and the adequacy of the actions to protect health and safety and the environment. It must also update the cost estimate originally presented in the DFP to undertake the facility decommissioning. Approval of a DP is often obtained through application for a license amendment. The reviewer must ascertain that the applicant understands decommissioning requirements and procedures, and commits to the protection of the health and safety of workers, the public and the environment during decommissioning.

10.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: Environmental Reviewer
Technical and financial specialists in the Division of Waste Management

Supporting: Fuel facility inspection staff

10.3 AREAS OF REVIEW

The reviewer will evaluate the applicant's DFP or DP in accordance with the "NMSS Decommissioning Program Standard Review Plan" currently under development in the Division of Waste Management.

Before starting the DFP or DP review, the reviewer should first review the applicant's proposed "Environmental Protection Measures" (SRP Chapter 9), and specifically the commitments to waste minimization applicable to decommissioning, and the "Radiation Protection Program" (SRP Chapter 4) as it applies to radiological decontamination and management of radiological effluents.

10.4 ACCEPTANCE CRITERIA

10.4.1 Regulatory Requirements

Decommissioning planning, financial assurance for decommissioning, recordkeeping for decommissioning, and waste and contamination minimization are required by the following NRC regulations:

7.	10 CFR 70.22(a)(9)	"Decommissioning Funding Plan";
2.	10 CFR 70.25	"Financial Assurance and Recordkeeping for Decommissioning";
3.	10 CFR 70.38	"Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas"; and
4.	10 CFR 20.1401-1406	"Radiological Criteria for License Termination" (Subpart E).

10.4.2 Regulatory Guidance

Relevant regulatory guidance and the appropriate acceptance criteria for DPs and DFPs contained in license applications and/or amendment requests are included in the "NMSS Decommissioning Program Standard Review Plan" currently under development.

10.5 REVIEW PROCEDURES

The primary reviewer will evaluate the application against NRC requirements and acceptance criteria identified in "NMSS Decommissioning Program SRP." This review will be supplemented as appropriate by detailed review of any contamination and waste-minimization plans submitted

by the applicant in response to 10 CFR 20.1406. The reviewer will also coordinate with the principal reviewers for environmental protection listed in Chapter 9.0, to confirm review of a new applicant's descriptions of plans for waste minimization, as well as plans for existing licensees to minimize contamination and reduce exposures and effluents as part of the radiation protection established under Part 20. The purpose of this coordination is to ensure that any issues that are relevant to the environmental review are properly conveyed to the lead reviewers, for these sections, for consideration and resolution. Similarly, any decommissioning issues that arise in the environmental review that are most suited for review using guidance in Chapter 10.0 are conveyed to the primary reviewer for consideration and resolution.

If the review identifies the need for the applicant to submit information that has not already been included in the application, the reviewer will document these additional information needs in a Request for Additional Information (RAI). The RAI will be transmitted to the applicant with a request for the information in a reasonable amount of time (e.g., 30 to 60 days). Failure of the applicant to provide the information by the requested date, or on an alternative schedule that is mutually agreeable, could be grounds for terminating or suspending the application review.

In accordance with the Fuel Cycle and International Safeguards Branch licensing manual, the lead reviewer will coordinate with the Division of Waste Management for appropriate technical assistance reviewing proposed DPs and financial assurance. The lead reviewer will coordinate the evaluation of the application with reviewers assigned by the Division of Waste Management and will incorporate, as appropriate, RAIs and review findings in licensing correspondence and SERs related to decommissioning.

10.5.2 Safety Review

The reviewer should perform a safety analysis against the acceptance criteria in the "NMSS Decommissioning Program Standard Review Plan," to ensure that the proposed decommissioning methodology, principal remediation activities, and worker and environmental radiation protection programs are acceptable.

10.6 EVALUATION FINDINGS

If sufficient information has been provided in the application to satisfy the acceptance criteria and requirements identified in Section 10.4, the staff will concluded that the DFP or DP evaluation is complete and satisfactory. The primary reviewer will prepare a Safety Evaluation Report (SER) for the Licensing Project Manager, in support of the licensing action. The SER should address each topic area reviewed and explain why the NRC has reasonable assurance that the DFP or DP should be acceptable. License conditions may be imposed where the application is deficient. The SER should include a summary statement of what was evaluated and the bases for the reviewers' conclusions. The staff will document its evaluation as follows:

> The NRC staff has evaluated the applicant's/licensee's plans for decommissioning and financial assurance for decommissioning in accordance with the NMSS

Decommissioning Program Standard Review Plan. Based on this evaluation, the NRC staff has determined that the applicant's/licensee's plans for decommissioning and financial assurance for decommissioning provide reasonable assurance of protection for members of the public and the environment and comply with the NRC's regulations.

10.7 REFERENCES

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

Orlando, D. A., *et al*. *NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees*, U.S. Nuclear Regulatory Commission, NUREG/BR-0241, 1997.

U.S. Nuclear Regulatory Commission, *NMSS Decommissioning Program Standard Review Plan*, NUREG-XXX, date to de determined.

11.0 MANAGEMENT MEASURES

11.1 PURPOSE OF REVIEW

Management measures are functions, performed by a licensee, generally on a continuing basis, that are applied to items relied on for safety, to provide reasonable assurance that the items are available and able to perform their functions, when needed. The phrase "available and reliable," as used in this rule, means that, based on the analyzed, credible conditions in the ISA, items relied on for safety will perform their intended safety functions when needed to prevent accidents or mitigate the consequences of accidents. Management measures are implemented to provide reasonable assurance of compliance with the performance requirements, considering factors such as necessary maintenance, operating limits, common-cause failures, and the likelihood and consequences of failure or degradation of the items and the measures. The following discussion addresses each of the management measures included in the Part 70 definition of management measures, i.e., configuration management (CM); maintenance; training and qualifications; procedures; audits and assessments; and other QA elements. The degree to which measures are applied to the items is a function of the item's importance in terms of meeting the performance requirements as evaluated in the ISA.

The purpose of this review is to enable the staff to conclude, with reasonable assurance, that the management measures applied to items relied on for safety (IROFS), as documented in the ISA Summary, provide reasonable assurance that the items will be available and able to perform their functions, when needed, consistent with the performance requirements of 10 CFR 70.61. If a graded approach is used, the review should also determine whether the measures are applied to the IROFS commensurate with the IROFS' importance to safety.

11.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary:

Configuration Management: Primary ISA Reviewer, QA and Records Management Reviewers
Maintenance: Criticality, Chemical, Fire, Radiation Protection, and Environmental Reviewers
Training and Qualification: Training Specialist, QA Reviewer
Procedures: Radiation Protection, Criticality and Fire Protection Engineers, Fuel Cycle Facility Inspector
Audits and Assessments: QA Reviewer
Incident Investigations: Inspection Specialist

Records Management: QA Reviewer
QA: Quality Assurance Engineer
Supporting: Technical Discipline Engineers, Fuel Cycle Facility Inspectors, Resident Inspectors

11.3 AREAS OF REVIEW

11.3.1 Configuration Management (CM)

This review should provide reasonable assurance that the applicant has committed to develop and implement a CM function that is consistent with the requirements of 10 CFR 70.72(a). The review should determine, with reasonable assurance, that the applicant has described and committed to a CM function that assures consistency among the facility design and operational requirements, the physical configuration, and the facility documentation. The review should also determine that the applicant's CM function captures formal documentation governing the design and continued modification of the site structures, processes, systems, equipment, components, computer programs, personnel activities, and supporting management measures, as identified and described in the ISA. The review should assure that the CM function is adequately coordinated and integrated with the other management measures.

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 review should focus on the applicant's CM measures that provide reasonable assurance of the disciplined documentation of: engineering, installation, and operation of modifications; the training and qualification of affected staff; the revision and distribution of operating, test, calibration, surveillance, and maintenance procedures and drawings; post-modification testing; and readiness review.

The NRC staff should review the following:

1. CM Policy

   The review should cover the applicant's description of overall CM functions, including at least the following topics: (a) the scope of the IROFS to be included in the CM function; (b) objectives of each CM activity; (c) a description of each CM activity; and (d) the organizational structure and staffing interfaces.

   The review should examine the applicant's establishment of a CM policy applicable to all operations, in accordance with 10 CFR 70.72.

2. Design Requirements

   The reviewer should examine the applicant's descriptions concerning how design requirements and associated design bases have been established and are maintained. The

applicant's CM controls on the design requirements and the ISA Summary should be evaluated. the review should be coordinated with the primary reviewer of the ISA Summary.

3. Document Control

The reviewer should examine the applicant's description of its methods used to establish and control documents within the CM function.

4. Change Control

The review should examine the applicant's commitments to provide reasonable assurance that the CM function maintains consistency among the design requirements, the physical configuration, and the facility documentation, in accordance with 10 CFR 70.72, "Facility changes and change process." An important component of this review is the applicant's process, within the CM function, for ensuring that the ISA and ISA Summary will be systematically reviewed and modified (as appropriate) to reflect design or operational changes from an established safety basis, and that all documents that are affected by safety basis changes will be properly modified, authoritatively approved, and made available to personnel.

5. Assessments

The review should examine the applicant's commitments to conduct initial and periodic assessments of the CM function, to determine the function's effectiveness, and to correct deficiencies, consistent with the acceptance criteria for "Audits and Assessments."

8. Design Reconstitution

The review should examine the applicant's discussion of design reconstitution of the current design basis that has been done for the purpose of the application, and how that reconstitution was translated into a fixed baseline design basis from which subsequent changes will be measured.

11.3.2 Maintenance

The NRC staff will evaluate the applicant's description of its maintenance function. The reviewer will examine the applicant's commitments to inspect, calibrate, test and maintain IROFS to a level commensurate with the items' importance to risk reduction, to provide reasonable assurance of their ability to perform their safety functions when required. The applicant identifies these IROFS in the ISA summary. The staff will review the applicant's description of how each of the following functions is implemented within the site organization. Note that not every aspect of each of the four maintenance functions is necessarily required; the applicant is expected to identify the IROFS in the ISA Summary and would justify assigning differing degrees of maintenance to individual IROFS, based on the item's contribution to the reduction of risk.

1. Corrective maintenance

   a. A commitment to promptly perform corrective actions to remediate IROFS unacceptable performance deficiencies; and

   b. A description of the approach and methods for planning and implementing repairs to IROFS with the objective of eliminating or minimizing the recurrence of unacceptable performance deficiencies.

2. Preventive maintenance (PM)

   a. A commitment to conduct preplanned and scheduled periodic refurbishing and/or overhauls of IROFS; and

   b. A description of PM activities including, for example, instrumentation calibration and testing, and the methods used to establish the frequency of PM activities.

3. Surveillance/monitoring

   a. A commitment to design and implement a program to survey and monitor the performance of IROFS; and

   b. A description of the components of the surveillance and monitoring program including methods used to establish the frequency of such inspections for IROFS having different degrees of safety importance.

4. Functional testing

   a. A commitment to perform the appropriate post-maintenance functional testing to provide reasonable assurance that the maintenance activity did not adversely affect the reliability of the control; and

   b. A general description of functional testing, and the test results documentation.

11.3.3 Training and Qualifications

Part 70 requires that personnel who perform activities relied on for safety be trained and tested, as necessary to provide reasonable assurance that they understand, recognize the importance of, and are qualified to perform these activities in a manner that adequately protects: (1) the health and safety of the public and workers; and (2) the environment. As appropriate for their authority and responsibilities these personnel should have the knowledge and skills necessary to design, operate, and maintain the facility in a safe manner. Therefore, the training, testing, and qualification of these personnel should be described in the application and should be reviewed by the staff. This should include the training, testing, and qualification of all personnel who perform activities relied on for safety. The review should examine the applicant's training and qualifications based on the adequacy to fulfill the objectives for the training identified by the licensee, especially when human factors are relied on for safety. The review of the training and qualification should address the following training areas:

1. Organization and management of the training function;
2. Analysis and identification of functional areas requiring training;
3. Position training requirements
4. Development of the basis for training, including objectives;
5. Organization of instruction, using lesson plans and other training guides;
6. Evaluation of trainee learning;
7. Conduct of on-the-job training;
8. Evaluation of training effectiveness;
9. Personnel qualification; and
10. Applicant's provisions for continuing assurance, including the needs for retraining or reevaluation of qualification.

11.3.4 Procedures

The review should examine the applicant's process for the preparation, use, and management control of written procedures. This should include the basic elements of identification; development; verification; review and comment resolution; approval; validation; issuance; change control; and periodic review. The applicant should prepare two general types of procedures for use at the facility:

1. Procedures used to directly control process operations, commonly called "operating procedures." These are procedures for workstation operators and should include directions for normal operations as well as off-normal events caused by human error or failure of an IROFS. Procedures of this type include required actions to provide reasonable assurance of nuclear criticality safety; chemical safety; fire protection; emergency planning; and environmental protection; and,

2. Procedures used for activities that support the process operations, which are commonly referred to as "management control procedures." These are procedures used to manage the conduct of activities such as CM; radiation safety; maintenance; human-systems interface; QA; training and qualification; audits and assessments; incident investigations; record-keeping; and reporting.

The actual operating procedures are not part of the license and would not normally be reviewed for technical adequacy for low-risk processes, since this aspect is addressed by the inspection function. For new licenses or processes, especially those that involve high-risk operations, such as some highly enriched uranium liquid processes or some mixed-oxide processes, the licensing review may include a site visit, to make an adequate safety determination, at which time some procedures may be reviewed.

The NRC staff should review the commitments in the application to provide reasonable assurance that the applicant's program adequately addresses the following:

1. The method for identification of the procedures that are needed plant-wide. The ISA Summary identifies IROFS where human actions are important. Procedures should be provided for all necessary steps or operations that are conducted at the facility. Procedures should be provided for every element of management control that is discussed in the SRP sections;

2. Essential elements that are generic to all procedures including: criticality; chemical process and fire safety; warning notes; reminders or pertinent information regarding specific hazards or concerns which include station limits; Materials Safety Data Sheet availability; special precautions; radiation and explosive hazards; and special personal protective equipment;

3. The method for creating and controlling procedures within plant management control systems. This includes how procedures are managed within the plant CM function;

4. Method for verifying and validating procedures before use. During procedure development, workers and operators review procedures to ensure they are usable and accurate.

5. The method and schedule for periodically reverifying and revalidating procedures; and

6. The method for ensuring that current procedures are available to personnel and that personnel are qualified to use the latest procedures.

11.3.5 Audits and Assessments

The applicant should describe a system of audits and assessments that consists of two distinct levels of activities: an audit activity structured to monitor compliance with regulatory requirements and license commitments, and an assessment activity oriented to determining the effectiveness of the activities in achieving applicant-specified objectives that provide reasonable assurance of the continued availability and reliability of IROFS. An applicant may describe a "corrective actions program" which includes the functions of both audits and assessment and incident investigations (see following section 11.3.6). This approach is acceptable and the reviewer should, in that case, review applicant's description and commitments with regard to the acceptance criteria in this SRP chapter for both audits and assessments and incident investigations.

The reviewer should examine the applicant's presentation with respect to:

1. The commitments to audit and assessment activities;

2. The use of qualified and independent audit and assessment personnel;

3. The general structure of typical audits and assessments;

4. The facility procedures to be used to direct and control the audit and assessment activities;

5. The planned use of the results of the audit and assessment activities;

6. The documentation to record and distribute the findings and recommendations of these audits and assessments; and

7. The planning and implementation of corrective actions based on the findings and recommendations.

11.3.6 Incident Investigations

The NRC staff should review the applicant's policy, 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 procedures for tracking and completing corrective actions and for documenting the process for the purpose of applying the "lessons learned" to other operations. An applicant may describe a “corrective actions program” which includes the functions of both audits and assessment and incident investigations. This approach is acceptable and the reviewer should, in that case, review applicant’s description and commitments with regard to the acceptance criteria in this SRP chapter for both audits and assessments and incident investigations.

11.3.7 Records Management

The requirements for the management of records vary according to the nature of the facility and the hazards and risks posed by it. The staff should review areas related to the handling and storing of health and safety records and the records generated or needed in the design, construction, operation, and decommissioning phases of the facility. The staff should review the following:

1. The process whereby records - training records; dosimetry records; effluents records; records of classified information; records concerning facility IROFS; and records of their failure - are created; selected; verified; categorized; indexed; inventoried; protected; stored; maintained; distributed; deleted; or preserved. The review should provide reasonable assurance that the records management function is adequately coordinated and integrated with other management measures.

2. The handling and control of various kinds of records and the methods of recording media that comprise the records (including contaminated and classified records); and

3. The physical characteristics of the records storage area(s) with respect to the preservation and protection of the records for their designated lifetimes.

11.3.8 Other QA Elements

The application must address the Part 70 requirements with respect to management measures, to include other QA elements. 10 CFR 70.62(d) requires that each applicant or licensee shall establish management measures to provide continuing assurance of compliance with the performance requirements of 10 CFR 70.61.

The review should determine that a complete description of the applicant’s application of QA elements to IROFS is included in the application. The review objective is to obtain reasonable assurance of the implementation of accepted QA principles in the design, construction, operation, maintenance, and modification phases of a facility's life. Fundamental to this effort is the applicant's application of QA elements to the identified IROFS resulting from the ISA and identified in the ISA summary. QA elements would also be applicable, as appropriate, to the hazards analysis process in the applicant’s ISA.

The application defines the QA elements and the levels to be applied to IROFS identified by the ISA (SRP Section 3.0). Further, the relationship between QA and other management measures should be described. The applicant determines the relative risk, or relative safety importance, of the various IROFS, to determine the QA elements and their levels to be applied to individual IROFS.

The review should recognize that facility safety may not be the only area requiring QA elements at a fuel cycle facility. The applicant's customers and the NRC, under Part 50, may impose product-related QA criteria. The focus of the review of QA measures per this SRP is limited 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). The review should provide reasonable assurance that the QA function is adequately coordinated and integrated with other management measures.

Since many QA elements may be described in other sections of the application, the reviewer should determine the applicant's commitment to overall QA, the selection of quality criteria and quality level, and the proposed method for implementation. The applicant may reference other areas of the application that present information relevant to QA. The reviewer should focus on the management measures applied to criticality, containment of licensed materials, personnel protection, and environmental safety. With the 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.

11.4 ACCEPTANCE CRITERIA

The reviewer should find the applicant’s information acceptable if it provides reasonable assurance that the following acceptance criteria are satisfactorily addressed.

11.4.1 Regulatory Requirements

The requirements for fuel cycle facility management measures are specified in Part 70, “Domestic Licensing of Special Nuclear Material," as revised.

10 CFR 70.4 states that management measures include CM; maintenance; training and qualifications; procedures; audits and assessments; incident investigations; records management; and other QA elements.

10 CFR 70.62(a)(3) states that failure records must be kept for all IROFS failures, describes required data to be reported, and sets time requirements for updating the records.

10 CFR 70.62(d) requires an applicant to establish management measures, for application to engineered and administrative controls and control systems that are identified as IROFS, pursuant to 10 CFR 70.61(e) so they are available and reliable to perform their functions when needed.

A regulation specifically applicable to personnel training and qualification is 10 CFR Part 19, “Notices, Instructions and Reports to Workers: Inspection and Investigations,” specifically Section 19.12, "Instructions to Workers."

The regulatory requirement for procedures that protect health and minimize danger to life is specified in 10 CFR 70.22(a)(8).

Facility change processes are required to conform with 10 CFR 70.72.

Incident investigation and reporting are required by 10 CFR 70.74(a) and (b).

11.4.2 Regulatory Guidance

1. American Society of Mechanical Engineers standard, “Quality Assurance Requirements for Nuclear Facility Applications,” ANSI/ASME NQA -1, 1994

2. American National Standards Institute standards for quality management, ANSI/ISO/ASQ 9000 series;

3. International Atomic Energy Agency Safety Guide, “Establishing and Implementing a Quality Assurance Program,” Safety Guide 50-SG-Q1, 1995;

4. U.S. Department of Energy, Draft, “Implementation Guide for use with 10 CFR Part 830.120 and DOE Order 5700.6C, September 1997;

5. U.S. Nuclear Regulatory Commission, “Guidance on Management Controls/Quality Assurance, Requirements for Operation, Chemical Safety, and Fire Protection for Fuel Cycle Facilities”, Federal Register 54 (No. 53), 11590–11598, March 21, 1989.

6. U.S. Nuclear Regulatory Commission, “Training Review Criteria and Procedures,” NUREG-1220, Revision 1, January 1993.

11.4.3 Regulatory Acceptance Criteria

11.4.3.1 Configuration Management (CM)

1. CM Policy

   The applicant's description of overall CM functions describes at least the following topics: (a) the scope of the IROFS and management measures to be included in the CM function (coordinate with the Section 3, ISA, reviewer for the application), (b) the objectives of each

CM activity, (c) a description of each CM activity, and (d) the organizational structure and staffing interfaces. The functional interfaces with maintenance and training and qualification are of particular importance and should be addressed individually. The IROFS under CM should include all those IROFS as defined by the ISA Summary.

An important element of an applicant's overall CM policy is the establishment of a baseline CM policy applicable to all new facilities or new processes at existing facilities, in accordance with 10 CFR 70.64. That baseline initially includes all the CM functions described in this SRP Chapter. After an ISA is completed and IROFS are identified that may not be associated with high-risk accident sequences, as defined by the ISA Summary or the ISA, the applicant may choose to reduce or eliminate certain features of the CM function as applied to those lesser-risk design or operational features. In that case, the applicant then, in its description of CM policy, defines the specific attributes of a reduced level or levels of CM that would be applied to selected IROFS, and in the ISA identifies those items that will be assigned the lesser category of CM.

The design process leading to drawings and other statements of requirements proceeds logically from the design basis. IROFS to be listed under CM are clearly defined in the ISA Summary, along with the assignment of any grades or quality levels. The applicant should have indicated in the ISA Summary what level of CM attributes is applied to a particular item. However, in the ISA Summary, this indication may only consist of an index or category designation. The definition of the multiple CM levels, if used, should be in the CM description within the application.

2. Design Requirements

The applicant describes how design requirements and associated design bases are established and are maintained through control of the design process. Technical management review and approval functions are described.

3. Document Control

The applicant describes an acceptable method to establish and control documents within the CM function, including cataloging the document data base, the information content of the document data base, maintaining and distributing documents, document retention policies, and document retrieval policies. The applicant describes how CM will capture documents that are relevant and relied on for safety. This includes design requirements; the ISA; as-built drawings; specifications; all operating procedures relied on for safety; procedures involving training; QA; maintenance; audits and assessments; emergency operating procedures; emergency response plans; system modification documents; assessment reports; and others that the applicant may deem part of CM. The document database is used to control documents and track document change status.

4. Change Control

The applicant describes how the CM function will maintain strict consistency among the design requirements, the physical configuration, and the facility documentation. The

applicant commits to an acceptable process for identifying and authorizing proposed changes; for performing appropriate technical, management, and safety reviews of proposed changes in configurations relied on for safety; for approving changes; for tracking and implementing changes; and for documenting changes (including placement of documentation in a document control center and dissemination to affected functions such as training, engineering, operations, maintenance, and QA). The applicant also describes an acceptable process, within the CM function, 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. When a change is made in accordance with 10 CFR 70.72, the affected on-site documentation must be made within five working days [10 CFR 70.72(e) states "promptly"].

5. Assessments

   The applicant confirms that initial and periodic assessments of the CM function are conducted to determine the program's effectiveness and to correct deficiencies. Both document assessments and physical assessments (system walkdowns) will be conducted periodically to check the adequacy of the CM function. All assessments and follow-ups are documented. These reports can provide a basis for future changes. The applicant indicates that such assessments are systematically planned and conducted in accordance with an overall facility audit and assessment function (see sections in Chapter 11 for details on audits and assessments) .

6. Design Reconstitution [Existing Facilities Only]

   The applicant describes whatever design reconstitution has been done for the purpose of the application. Because this information may duplicate the plant design bases information described elsewhere to support the ISA, this information may be included by reference to other parts of the application. The applicant has available current design bases, including design requirements, supporting analyses, and documentation supporting all IROFS. A verification process, including walk-downs, is complete and has verified that the configuration is consistent with as-built facility documentation.

11.4.3.2 Maintenance

The reviewers should find the applicant's submittal acceptable if the application includes the following:

1. Surveillance / monitoring

   For IROFS identified in the ISA summary, the applicant describes the surveillance function and its commitment to the organization and conduct of surveillance at a specified frequency. The surveillance activity should support the determination of performance trends for IROFS, thus providing data useful in determining PM frequencies. Applicant describes how results from incident investigations, review of the failure log 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 from recurring. Records showing the current surveillance schedule, performance criteria, and test results for all IROFS are maintained by the applicant. For surveillance tests that can only be done while IROFS are out of service, proper compensatory measures are prescribed for the continued normal operation of a process.

2. Corrective maintenance

   Applicant provides the documented approach used to perform corrective actions or repairs on IROFS. 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. After conducting corrective maintenance and before returning an IROFS to operational status, if necessary, a functional test is conducted to provide reasonable assurance that the safety control performs as designed and provides the safety action expected.

3. PM

   Applicant provides a description of the PM function that demonstrates a commitment to conduct preplanned and scheduled periodic refurbishing, or partial or complete overhaul, for the purpose of ensuring that unanticipated loss of IROFS do not occur. This activity includes using the results of the surveillance component of maintenance and the failure log required by 70.62(a)(3). Instrumentation calibration and testing are addressed by the applicant as part of this component. The applicant describes how the function will be designed to ensure that the objective of preventing failures through maintenance is appropriately balanced against the objective of minimizing unavailability of IROFS because of monitoring or PM. After conducting PM and before returning a safety control to operational status, if necessary, a functional test is conducted to ensure that an IROFS performs as designed and provides the safety action expected. The methodology or basis used to determine PM frequency is described. Applicant describes how results from incident investigations and identified root causes are used to modify the affected maintenance function and eliminate or minimize the root cause from recurring. Feedback from PM, corrective maintenance, and incident investigations is used as appropriate to modify frequency or scope of the PM activity. A rationale for deviation from industry standards or from vendor recommendations for PM is provided. Records showing the PM schedule, and results, for all IROFS subject to this maintenance component, are maintained by the applicant.

4. Functional testing

   Applicant includes a general description of the methods used and the commitment to perform functional testing, as needed, of IROFS, after PM or corrective maintenance. These tests should be conducted using applicant-approved procedures and should include compensatory measures while the test is being conducted. Applicant designs the functional test to include all operational aspects of the IROFS that are important to safety.

For illustrative purposes only, the following scenario is provided:

> A level controller, identified as an IROFS, is used to actuate a three-way valve and divert flow to an alternate tank. The level monitor sending unit and the valve, power supplies, utility services, and any corresponding local or control room displays should be tested at the same time during the functional test. The objective should be to simulate actual upset conditions and demonstrate that the IROFS is available and reliable and will function in the field as intended.

As necessary, during start-up of new process equipment, functional tests are conducted, documented, and maintained, for NRC review. Records showing the functional test schedule, and results, for all IROFS subject to this maintenance component, are maintained by the applicant.

Administrative controls are often identified as IROFS. The applicant should provide a general discussion about how these IROFS are assured to be available and reliable to perform their intended safety function over extended periods of operation. Specific management measures and how they are applied should be described.

A general acceptance criterion applicable to all maintenance functions is an adequate description of work-control methods. Listed below are methods or practices that should be applied to the corrective, preventive and functional test maintenance elements, and for which the applicant should commit to prepare written procedures. These include, as applicable: a) authorized work instructions with detailed steps and a reminder of the importance of the IROFS identified in the ISA summary; b) parts lists; c) as-built or redlined drawings; d) a notification step to the operations function before conducting repairs and removing an IROFS from service; e) radiation work permits; f) replacement with like-kind parts and the control of new or replacement parts to ensure compliance with 10 CFR Part 21; g) compensatory measures while performing work on IROFS; h) procedural control of removal of components from service for maintenance and for return to service; i) ensuring safe operations during the removal of IROFS from service; and j) notification to operations personnel that repairs have been completed. Written procedures for the performance of maintenance include steps a) through j). The details of maintenance procedure acceptance criteria are addressed in Section 11.4.3.2 of this SRP. All work requests and maintenance procedures include technical and safety discipline reviews and approval.

As applicable, contractors that work on or near IROFS identified in the ISA Summary should be required, by the applicant, to follow the same maintenance guidelines described for the corrective, preventive, functional, or surveillance/monitoring activities listed above for the maintenance function.

The four maintenance elements described above are covered by elements of the management measures discussed in SRP Section 11.0. The applicant should include a discussion of or provide references to how the maintenance function uses, interfaces with, or is linked to the various management measures. As an example, since maintenance workers are trained and qualified to perform their duties, a description of the link between maintenance and the training and qualification function should be described.

11.4.3.3 Training and Qualification

The applicant's submittal regarding personnel training and qualification should be acceptable if it satisfies the following criteria. In addition to the regulatory acceptance criteria given below, SRP section 4.4.5.3 provides specific criteria for training and qualification for radiation safety personnel. Similarly, some of the information specified below may be found in other sections of the SRP and incorporated by reference.

1. Organization and Management of Training - The organization and management of training are acceptable if the design, operation, and maintenance of the facility are organized, staffed, and managed to facilitate planning, directing, evaluating, and controlling a training process that fulfills the objectives for the training as identified by the licensee, especially where human factors are relied on for safety. Formal training should be provided for each position or activity for which the required performance is relied on for safety. Training may be either or both classroom or on-the-job training. The application should state what training will be conducted and which personnel will be provided with this training.

The following commitments should be in the application regarding organization and management of training:

1. Line management is responsible for the content and effective conduct of the training.
2. The job function, responsibility, authority, and accountability of personnel involved in managing, supervising, and implementing training is clearly defined.
3. Performance-based training is used as the primary management tool for analyzing, designing, developing, conducting, and evaluating training.
4. Procedures are documented and implemented to provide reasonable assurance that all phases of training are conducted reliably and consistently.
5. Training documents are linked to the CM system to provide reasonable assurance that design changes and modification are accounted for in the training.
6. Exemptions from training are granted to trainees and incumbents only when justified, documented, and approved by management.
7. Both programmatic and individual training records are maintained. These records, support management information needs and provide required data on each individual's training, job performance, and qualification.

2. Analysis and Identification of Activities Requiring Training - analysis and identification of activities requiring training is acceptable if the activities required for competent and safe job performance are identified, documented, and addressed by the training.

Design, construction, operations, training, and other subject matter experts, as appropriate, should conduct an analysis to identify activities requiring training. The activities treated in this manner should include - as a minimum - those for managing, supervising, performing, and verifying the activities relied on for safety specified in the ISA Summary as preventing or mitigating accident sequences. Each activity selected for training (initial or continuing) from the facility-specific activities should be matrixed to supporting procedures and training materials. The facility-specific activities selected for training and the comparison with training materials should be reviewed on an established schedule and updated as necessitated by changes in procedures, facility systems/equipment, or job scope.

3. Position Training Requirements - position training requirements are acceptable if minimum requirements for positions are specified for candidates whose activities are relied on for safety or who perform actions that prevent/mitigate accident sequences described in the ISA Summary. Trainees should meet entry-level criteria defined for the position, including minimum educational, technical, experience, and physical fitness (if necessary) requirements.

4. Development of the Basis for Training Including Objectives - The development of the basis for training including the objectives is acceptable if the basis identifies training content, defines satisfactory trainee performance and identifies objectives from the analysis of activiesand performance requirements. Objectives should state the knowledge, skills, and abilities the trainee should demonstrate; the conditions under which required actions will take place; and the standards of performance the trainee should achieve on completion of the training activity.

5. Organization of Instruction Using Lesson Plans and Other Training Guides - Lesson plans and other training guides should provide guidance to assure the consistent conduct of training activities, and should be based on required learning objectives derived from specific job performance requirements. Plans/guides should be used for in-class training and on-the-job training and should include standards for evaluating proper trainee performance. Review and approval requirements should be established for all plans/guides and other training materials before their issue and use.

6. Evaluation of Trainee Accomplishment of Learning Objectives - The evaluation of trainee accomplishment of learning objectives is acceptable if trainees are evaluated 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.

7. Conduct of On-the-Job Training - The conduct of on-the-job training is acceptable if on-the-job training used for activities required by the ISA are fully described. On-the-job training should be conducted using well-organized and current training materials. On-the-job training should be conducted by designated personnel who are competent in the program standards and methods of conducting the training. Completion of on-the-job training should be by actual task performance. When the actual task cannot be performed and is therefore “walked-down,” the conditions of task performance, references, tools, and equipment should reflect the actual task to the extent possible.

8. Evaluation of Training Effectiveness - 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. A comprehensive evaluation of individual training should be conducted periodically by qualified individuals to identify strengths and weaknesses. Feedback from trainee performance during training and from former trainees and their supervisors should be used to evaluate and refine the training. Change actions (for example procedure changes, equipment changes, facility modifications) should be monitored and evaluated for their impact on the development or modification of initial and continuing training and should be incorporated in a timely manner. This should be accomplished with document control through the CM function. Improvements and changes to initial and continuing training should be initiated, evaluated, tracked, and incorporated to correct training deficiencies and performance problems.

9. Personnel Qualification - Commitments should be provided regarding personnel minimum qualifications for personnel required to meet NRC regulations Minimum qualifications should be commensurate with the assigned functional responsibility and authority of the respective personnel. Such commitments should be in the application regarding personnel qualification for managers, supervisors, designers, technical staff, construction personnel, plant operators, technicians, maintenance personnel, and other staff required to meet NRC regulations:

1. Managers should have a minimum of a B.S./B.A. or equivalent. Each manager should have either management experience or technical experience in facilities similar to the facility identified in the application.
2. Supervisors should have at least the qualifications required of personnel being supervised, plus, either one additional year of experience supervising the technical area at a similar facility, or, completion of a supervisor training course.
3. Technical professional staff identified in the ISA Summary whose actions or judgments are critical to satisfy the performance requirements identified in 10 CFR Part 70 (i.e. related to an IROFS) should have a B.S. in the appropriate technical field and 3 years of experience. Other technical professional staff should have a B.S. in the appropriate technical field and one year of experience.
4. Construction personnel, plant operators, technicians, maintenance personnel, and other staff whose actions are required to comply with NRC regulations should have completed the applicant's training process or have equivalent experience or training.
5. Candidates for process operators should be required to meet minimum qualifications described in the application. Candidates for job functions other than process operators should also be required to meet minimum qualifications, but these minimum qualifications need not be described in the application.

10. Applicant's Provisions for Continuing Assurance - The applicant's provisions for continuing assurance of personnel training and qualification are acceptable if the submittal addresses periodic requalification of personnel, as necessary, by training and/or testing, to provide reasonable assurance that they continue to understand, recognize the importance of, and are qualified to perform their activities that are relied on for safety.

11.4.3.4 Procedures Development and Implementation

The reviewer should determine that the applicant's process for developing and implementing procedures is acceptable if it satisfies the following:

1. Procedures are written or planned for the operation of IROFS and for all management measures supporting those controls.

2. Operating procedures contain the following elements: (a) purpose of the activity; (b) regulations, polices, and guidelines governing the procedure; (c) type of procedure; (d) steps for each operating process phase; (e) initial start-up; (f) normal operations; (g) temporary operations; (h) emergency shutdown; (I) emergency operations; (j) normal shutdown; (k) start-up following an emergency or extended downtime; (l) hazards and safety considerations; (m) operating limits; (n) precautions necessary to prevent exposure to hazardous chemicals (resulting from operations with SNM) or to licensed SNM; (o) measures to be taken if contact or exposure occurs; (p) IROFS associated with the process and their functions; and (q) the time frame for which the procedure is

valid. It is particularly important that safety limits and controls (such as mass limits, moderator exclusion, independent sampling requirements, etc.) be clearly identified as such in the procedure for the operators.

3. Procedures reflect the important elements of the functions described in the applicable chapters of this SRP. Procedures exist to direct the following activities: a) design; b) CM; c) procurement; d) construction; e) radiation safety; f) maintenance; g) QA elements; h) training and qualification; i) audits and assessments; j) incident investigations; k) records management; l) criticality safety; m) fire safety; n) chemical process safety; and o) reporting requirements.

4. The applicant describes the method for identifying, developing, approving, implementing, and controlling operating procedures. Identifying needed procedures includes consideration of ISA results. The method includes, as a minimum, that: (a) operating limits and controls are specified in the procedure; (b) procedures include required actions for off-normal conditions of operation, as well as normal operations; (c) if needed, safety checkpoints are identified at appropriate steps in the procedure; (d) procedures are validated through field tests; (e) procedures are approved by management personnel responsible and accountable for the operation; (f) a mechanism is specified for revising and reissuing procedures in a controlled manner; (g) the QA elements and CM functions at the plant provide reasonable assurance that current procedures are available and used at all work locations; and (h) the plant training program trains the required persons in the use of the latest procedures available.

5. The applicant includes the following commitment regarding procedure adherence: “Activities involving licensed special nuclear material and/or IROFS will be conducted in accordance with approved procedures.”

6. The applicant describes the types of procedures used during facility operation. These will typically include management control, operating, maintenance, and emergency procedures. The applicant provides information regarding the procedure categories used at the facility. The applicant develops procedures for site-wide safe work practices to provide for the control of processes and operations with licensed SNM and/or IROFS and/or hazardous chemicals produced from licensed materials. These safe work practices apply to workers, visitors, contractors, and vendors. An acceptable identification discussion clearly states areas for which a procedure is required. Procedures are required for operator actions that are necessary to prevent or mitigate accidents identified in the ISA ISA Summary. The applicant provides a listing (in an appendix) of the types of activities that are covered by written procedures. The listing includes the topics of administrative procedures; system procedures that address start-up, operation, and shutdown; abnormal operation/alarm response; maintenance activities that address system repair, calibration, inspection, and testing; and emergency procedures. Appendix A to this chapter provides an acceptable listing of the items to be included under each topic.

7. 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.

8. Applicant ensures technical accuracy of procedures and that they can be performed as written. The discussion identifies who is responsible for verification. The verification process ensures that the technical information is included and correct, including formulas, set points, and acceptance criteria, and includes either a walk-down of the procedure in the field, or a table-top walk-through. The review process includes technical, cross-discipline reviews by affected organizations. This process includes both new procedures and procedure changes. The review ensures that the operating limits and controls identified in the ISA Summary are specified in the procedures and that QA requirements are identified and included in operating procedures. The applicant describes who can approve procedures and includes the approval level for each procedure type. At a minimum, responsible management, along with the safety disciplines, approves new procedures and changes to existing procedures.

9. Documents are distributed in accordance with applicable distribution lists. A process is used to limit the use of outdated procedures. Copies are available to appropriate personnel. Issuance and distribution of procedures are documented and refer to the Records Management function.

10. The applicant has formal requirements governing temporary changes. Temporary changes do not involve a change to the ISA. The review and approval process is documented. Temporary procedures may be issued only when permanent procedures do not exist to: a) direct operations during testing, maintenance, and modifications; b) provide guidance in unusual situations not within the scope of permanent procedures; and, c) ensure orderly and uniform operations for short periods when the plant, a system, or component of a system is performing in a manner not covered by existing permanent procedures, or has been modified or extended in such a manner that portions of existing procedures do not apply. The discussion includes establishment of a timeframe for use of the temporary procedure and includes the same level of review and approval as that for permanent procedures.

11. Maintenance procedures involving IROFS commit to the topics listed below for corrective, preventive, functional testing after maintenance, and surveillance maintenance activities:

    a. Pre-maintenance activity requires reviews of the work to be performed, including procedure reviews for accuracy and completeness;

    b. Steps that require notification of all affected parties (operators and supervisors) before performing work and on completion of maintenance work. The discussion includes potential degradation of IROFS during the planned maintenance;

    c. Control of work by comprehensive procedures to be followed by maintenance technicians. Maintenance procedures are reviewed by the various safety disciplines including criticality, fire, radiation, industrial, and chemical process safety. The procedures describe, as a minimum the following:

        i. Qualifications of personnel authorized to perform the maintenance or surveillance;

ii. Controls on and specification of any replacement components or materials to be used (this should be controlled by the CM function, to ensure like-kind replacement and adherence to Part 21;

iii. Post-maintenance testing to verify operability of the equipment;

iv. Tracking and records management of maintenance activities;

v. Safe work practices (e.g., lockout/tagout; confined space entry; moderation control or exclusion area; radiation or hot work permits; and criticality, fire, chemical, environmental or human-systems interface issues).

12. Applicant conducts periodic reviews of procedures to ensure their continued accuracy and usefulness and establishes the timeframe for reviews of the various types of procedures. At a minimum all operating procedures are reviewed every 5 years and emergency procedures are reviewed every year. The applicant describes the use and control of procedures. Provisions allow for operations to stop and place the process in a safe condition if a step of a procedure cannot be performed as written. Guidance identifies the manner in which procedures are to be implemented. Routine procedural actions that are frequently repeated might not require the procedure to be present. Procedures for complex jobs or dealing with numerous sequences where memory cannot be trusted may require valve alignment check sheets, approved operator aids, or in-hand procedures that are referenced directly, when the job is conducted.

11.4.3.5 Audits and Assessments

The NRC reviewers should find the applicant's submittal regarding audits and assessments provides reasonable assurance that the regulatory review criteria below are adequately addressed and satisfied.

1. The applicant should describe policy directives covering the audit and assessment function (i.e., at a minimum, 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 applicant has committed to conduct internal audits and independent assessments of activities significant to plant safety and environmental protection;

3. Audits will be conducted to verify that operations are being conducted in accordance with regulatory requirements and commitments in the license application;

4. Independent assessments will be conducted by off-site groups or individuals not involved in the licensed activity, to verify that the health, safety, and environmental compliance functions are effectively achieving their designed purposes;

5. 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; and

6. Qualified personnel without direct responsibility for the function and area being audited or assessed will be used. The staff positions and committees responsible for audits and assessments are specified. The levels of management to which results are reported, and the systems to ensure that corrective actions are taken, are also described.

11.4.3.6 Incident Investigations

The applicant's description and commitments in the application will be acceptable if the reviewer finds reasonable assurance of the following:

1. The applicant will establish a process to investigate abnormal events that may occur during operation of the facility, to determine their specific or generic root cause(s) and generic implications, to recommend corrective actions, and to report to the NRC as required by 10 CFR 70.50 and 70.74. The investigation process should include a prompt risk-based evaluation and, depending on the complexity and severity of the event, an individual may be all that is required to conduct the evaluation. The investigator(s) will be independent from the line function(s) involved with the incident under investigation. Investigations will begin within 48 hours of the abnormal event, or sooner, depending on the safety significance of the event. The failure log required for IROFS should be reviewed as part of the investigation.

2. The applicant will monitor and document corrective actions, through completion; and

3. The applicant will maintain documentation so that "lessons learned" may be applied to future operations of the facility. Details of the event sequence will be compared with accident sequences already considered in the ISA, and actions will be taken to ensure that the ISA Summary includes the evaluation of the risk associated with accidents of the type actually experienced.

The applicant has a formal policy or procedure in place for conducting an incident investigation, and the policy or procedures contain the following elements:

1. A documented plan for investigating an abnormal event. This plan is separate from any required Emergency Plan. The investigation of an abnormal event should begin as soon as possible, commensurate with the safety of the investigative team, after the event has been brought under control;

2. A description of the functions, qualifications, and responsibilities of the management person who would lead the investigative team and those of the other team members; the scope of the team's authority and responsibilities; and assurance of cooperation of management;

3. Assurance of the team's authority to obtain all the information considered necessary, and independence from responsibility for or to the functional area involved in the incident under investigation;

4. Procedures requiring maintenance of all documentation relating to abnormal events for 2 years or for the life of the operation, whichever is longer;

5. Guidance for personnel conducting the investigation on how to apply a reasonable, systematic, structured approach to determine the root cause(s) of the problem. The level of investigation should be based on a graded approach relative to the severity of the incident;

6. Requirements to make available, to the NRC, original investigation reports on request; and

7. A system for monitoring to ensure completion of appropriate corrective actions.

The assessment of the adequacy of the applicant's commitments to establish and use a plan for the investigation of abnormal events will also be based on the following acceptance criteria:

1. The licensee has described the overall plan and method for investigating abnormal events;

2. The functions, responsibilities, and scope of authority of investigators and/or teams are documented in the plan;

3. Qualified internal or external investigators are appointed to serve on investigating teams when required. The teams will include at least one process expert and at least one team member will be trained in root-cause analysis;

4. The applicant commits to prompt investigation of any abnormal events, and precursors to abnormal events (such as undetected failure of controls);

5. The investigation process and investigating team are independent of the line management, and participants are assured of no retribution from participating in investigations;

6. A reasonable, systematic, structured approach is used to determine the root cause(s) of abnormal events;

7. 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, root-cause analysis, and findings and recommendations. Relevant findings are reviewed with all affected personnel, and

8. Documented corrective actions are taken within a reasonable period to resolve findings from abnormal event investigations.

11.4.3.7 Records Management

The reviewer will find the applicant's records management system for records acceptable if it satisfies the following criteria:

1. Records are specified, prepared, verified, characterized, and maintained;

2. Records are legible, identifiable, and retrievable for their designated lifetimes;

3. Records are protected against tampering, theft, loss, unauthorized access, damage, or deterioration for the time they are in storage;

4. Procedures are established and documented specifying the requirements and responsibilities for record selection; verification; protection; transmittal; distribution; retention; maintenance; and disposition; and

5. The organization and procedures are in place to promptly detect and correct any deficiencies in the records management system or its implementation.

   Examples of records that should be included in the system are listed in Appendix B to Chapter 11. Records are categorized by relative safety importance to identify record protection and storage needs and to designate the retention period for individual kinds of records. The procedures should: a) assign responsibilities for records management; b) specify the authority needed for records retention or disposal; c) specify which records must have controlled access and provide the controls needed; d) provide for the protection of records from loss, damage, tampering, or theft or during an emergency; and e) specify procedures for ensuring that the records management system remains effective.

   For computer codes/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/data as computing technology changes. This could include transcribing the older forms of information (e.g., punched cards or paper tapes) and codes for older computing equipment to contemporary computing media and equipment. Records of IROFS failures must be kept and updated in accordance with 10 CFR 70.62(a)(3). Record revisions necessitated by post-failure investigation conclusions should be made within five working days [10 CFR 70.62(a)(3) states "promptly"].

11.4.3.8 Other QA Elements

To be acceptable, the applicant's QA elements should be structured to apply appropriate measures and controls to IROFS, which may include site design features. QA elements may be applied in proportion to the importance of the item to the achievement of safety (graded approach). Applicants'/licensees' QA elements are expected to differ based on the purpose and complexity of the facility and processes to be controlled.

The ISA summary should identify the IROFS, the degree of their importance to safety, and their related activities that are required for safety. The applicant's selection of QA elements to be applied to an IROFS, and the applicant's grading and level of the QA elements may be proportional to the importance to safety of the IROFS. An applicant may choose to apply all QA elements and the highest level to all IROFS, or may grade the application in proportion to the importance of the item to the achievement of safety.

All IROFS should have all appropriate QA elements applied. If the applicant grades the application of QA elements, the relative risk importance ranking of IROFS, as established within the maintenance function, should parallel those used in for QA elements.

A checklist for evaluating the application of QA elements is given below. If the application of QA is graded, the attributes described for each element listed below are applied for accident sequences based on the highest level of risk. The application of QA elements may be reduced by modifying or eliminating either the number of elements or the attributes within each element, based on evaluations performed and documented in the ISA. Attributes of QA elements are as follows:

1. The applicant describes the: a) organizational structure; b) functional responsibilities; and c) charts of the lines, interrelationships, and areas of responsibility and authority for all organizations performing activities relied on for safety, including the organization of the applicant and, as applicable, its principal contractors (architect/engineer, constructor, construction manager, and operator). Persons or organizations responsible for ensuring that appropriate QA has been established and for verifying that activities affecting quality have been correctly performed have sufficient authority, access to work areas, and organizational independence to carry out their responsibilities;

2. The applicant may describe its application of QA elements in the form of a QA program, in which the applicant commits to meet the applicable requirements of applicable industry standards. The commitment may describe the applicant's graded approach to QA, describing controls implemented consistent with an item's importance to safety, or the commitment may describe a QA program applied to all IROFS. The application of QA elements should be well-documented, planned, implemented, and maintained to provide reasonable assurance that, together with the other management measures, IROFS will be available and reliable when needed. It should be functional before performing the ISA required by Part 70. See references in Section 11.7 (e.g., ANSI/ASME NQA-1).

3. A design control function is established that includes design inputs, process, analyses, verification, interfaces, changes, and design documentation and records (see Sections 11.3.1, 11.4.3.1, 11.5.2.1, and 11.6.1 for details on CM);

4. Applicable design bases and other requirements necessary to provide reasonable assurance of quality are included or referenced in documents for procurement of items or service for IROFS. To the extent necessary, suppliers are required to have QA consistent with the quality level of the item or service to be procured;

5. Activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate for the circumstances (see Sections 11.3.4, 11.4.3.4, 11.5.2.4, and 11.6.4 for details on procedures);

6. The preparation, issuance, and changes of documents that specify quality requirements or prescribe activities affecting quality are controlled to provide reasonable assurance that the appropriate documents are in use. Document changes are reviewed for adequacy and approved for implementation by authorized personnel (see Sections 11.3.1, 11.4.3.1, 11.5.2.1, and 11.6.1 for details on CM and sections 11.3.4, 11.4.3.4, 11.5.2.4, and 11.6.4 for details on procedures);

7. Purchased items and services for IROFS are controlled to provide reasonable assurance of conformance with specified requirements;

8. Provisions are made to identify and control IROFS and to provide reasonable assurance that incorrect or defective items are not use;.

9. Controls are established to ensure the acceptability of special processes used in the course of construction, maintenance, modifications, and testing activities, such as welding, heat treating, nondestructive testing, and chemical cleaning and that they are performed by qualified personnel using qualified procedures and equipment;

10. Inspection required to verify conformance of IROFS with requirements is planned and executed. Inspection requirements are specified in written procedures with provisions included for documenting and evaluating inspection results (see Sections 11.3.4, 11.4.3.4, 11.5.2.4, and 11.6.4 for details on procedures). Personnel qualification programs are established for inspection test personnel (see Sections 11.3.3, 11.4.3.3, 11.5.2.3, and 11.6.3 for details on training and qualifications);

11. Tests are conducted to verify that IROFS conform to specified requirements and will perform satisfactorily in service. Test requirements are specified in written procedures with provisions included for documenting and evaluating test results (see Sections 11.3.4, 11.4.3.4, 11.5.2.4, and 11.6.4 for details on procedures). Personnel qualification programs are established for test personnel (see Sections 11.3.3, 11.4.3.3, 11.5.3, and 11.6.3 for details on training and qualifications);

12. Provisions are made to provide reasonable assurance that tools, gauges, instruments, and other measuring and testing devices are properly identified, controlled, calibrated, and adjusted at specified intervals, to maintain performance within required limits;

13. Provisions are made to control the handling, storage, shipping, cleaning, and preservation of IROFS, in accordance with work and inspection instructions, to prevent damage, loss, and deterioration caused by environmental conditions such as temperature or humidity;

14. Provisions are made to control the inspection, test, and operating status of IROFS to prevent inadvertent use of nonconforming items or bypassing of inspections and tests;

15. Provisions are made to control the identification, segregation, disposition, and prevention of installation or use of nonconforming IROFS;

16. Provisions are made to provide reasonable assurance that conditions adverse to safety are promptly identified and corrected and that measures are taken to preclude repetition. These actions should be documented and reported to appropriate levels of management (see Sections 11.3.6, 11.4.3.6, 11.5.2.6, and 11.6.6 for details on incident investigations, and Sections 11.3.5, 11.4.3.5, 11.5.2.5, and 11.6.5 for details on audits and assessments);

17. Provisions are made for the identification, retention, retrieval, and maintenance of records that furnish evidence of the control of quality for IROFS (see Sections 11.3.7, 11.4.3.7, 11.5.2.7, and 11.6.7 for details on records management);

18. Provisions are made for planning and scheduling assessments and audits to verify compliance with and to determine the effectiveness of QA; responsibilities and procedures are identified for assessing, auditing, documenting, and reviewing results and for designating management levels to review assessment and audit results; and provisions are made for incorporating the status of findings and recommendations in management reports (see Sections 11.3.5, 11.4.3.5, 11.5.2.5, and 11.6.5 for details on audits and assessments);

19. The applicant's provisions for continuing QA address reviews and updates of QA documents based on reorganizations, revised activities, lessons learned, changes to applicable regulations, and other QA program changes.

11.5 REVIEW PROCEDURES

11.5.1 Acceptance Review

The primary reviewer should evaluate the application to determine whether it addresses the "Areas of Review" discussed in Section 11.3, above. If significant deficiencies are identified, the applicant should be requested to submit additional material before the start of the safety evaluation review.

11.5.2 Safety Evaluation

After the primary reviewer determines that the application is acceptable for review in accordance with Section 11.5.1, above, the primary and secondary reviewers should perform a safety evaluation review against the acceptance criteria described in Section 11.4. Review procedures for each criterion are discussed in the sections below. If deficiencies are identified, the applicant should be requested to submit additional information or modify the submittal to meet the acceptance criteria in Section 11.4 of this SRP.

11.5.2.1 CM

1. CM Policy Management

   The primary reviewer should consider whether the CM plan acceptably states management commitments, gives the policy directive, and defines key responsibilities, terminology, and equipment scope. The secondary reviewers should examine the ISA Summary and the ISA, as needed, to assure that identified IROFS will be subject to the CM function. Appropriate interfaces both within the CM function and with external organizations and functions should be examined. In particular, the functional interfaces with QA, maintenance, and training (including qualification) should be examined. The reviewers should look for the applicant's identification of required databases and the rules for their maintenance. The reviewers should examine implementing procedures for the CM function.

2. Design Requirements

   The primary reviewer should confirm that the design process leading to drawings and other statements of requirements proceeds logically from the design basis. The design basis is a set of facts, about the systems covered by CM, that has been reviewed and approved by appropriate authority within the organization. The reviewers should verify that specific personnel are assigned the responsibility for maintaining the design bases and requirements. The reviewers should verify that the IROFS to be listed under CM will be clearly defined in the requirements documents, along with the assignment of any grades or quality levels. This part of the review should be coordinated with the ISA primary reviewer. The ISA Summary should specify all IROFS, and the applicant should have indicated in the ISA Summary, what level of CM attributes is applied to a particular item. However, in the ISA Summary this indication may consist of only an index or category designation. The definition of the individual content of multiple CM levels, if used, should be in the CM Chapter of the application. The primary reviewer for the CM Chapter is responsible to determine if the reduced levels the applicant would apply to safety items for lesser risk accident sequences are adequate.

3. Document Control

   The primary reviewer should evaluate the applicant's material showing that the CM system will capture documents that are relevant and important to safety. The documents should include design requirements; the ISA; the ISA Summary; as-built drawings; specifications; all safety-important operating procedures; procedures involving training, maintenance, audits and assessments; emergency operating procedures; emergency response plans; system modification documents; assessment reports; and others, as necessary, that the applicant may deem part of the CM function. The primary reviewer should determine whether a controlled document database is used to control documents and track document change status. Rules of storage for originals or master copies of documents within the CM function follow the guidance of “Records Management.”

4. Change Control

The primary reviewer should be able to find that the description of change control within the CM function commits to acceptable methods in place for: (a) the identification of changes in configurations relied on for safety; (b) technical and management review of changes; and (c) tracking and implementing changes, including placement of documentation in a document control center and dissemination to affected functions such as training, engineering, operations, maintenance, and other QA elements.

5. Assessments

The primary reviewer should be able to find that both document assessments and physical assessments (system walkdowns) will be conducted periodically, to check the adequacy of the CM function. The primary reviewer should be able to find that all assessments and follow-ups will be documented. These reports can provide a supporting basis for future changes.

6. Design Reconstitution (Existing Facilities Only)

Design reconstitution may be necessary for existing facilities if current design information is not adequate. The primary reviewer examines the applicant's description of work to establish, organize, and document design requirements and design bases for items for which design information was not available before the application was submitted. Of particular importance are the methods used to evaluate, verify, and validate reconstituted design data for IROFS. For existing facilities, the design requirements and physical configuration may have greatly changed according to the demands of a changed mission. If documentation has not kept pace, it will be necessary for the applicant to walk down systems, update drawings and specifications, perform new calculations and analyses, and otherwise rebuild the design bases. The reviewer will seek evidence that the need for design bases reconstitution was investigated, that reconstitution was accomplished as necessary, and that new or revised documentation was properly incorporated into the CM function. On the basis of its review, the staff may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria in Section 11.4 of this SRP.

When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the CM input for the Safety Evaluation Report (SER) as described in SRP Section 11.6, using the regulatory acceptance criteria from SRP Section 11.4.3.1.

11.5.2.2 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 the supporting reviewers to identify any common weaknesses in the applicant’s approach and consider these during the review.

An acceptable maintenance function includes descriptions and applicant's commitments regarding corrective maintenance, preventive maintenance, surveillance/monitoring, and functional testing.

When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the maintenance input for the SER as described in SRP Section 11.6 using the regulatory acceptance criteria from SRP Section 11.4.3.2.

11.5.2.3 Training and Qualification

The primary reviewer performs a safety evaluation against the acceptance criteria described in Section 11.4, recognizing that thetraining objectives and methods and the required personnel qualification may be graded to correspond to the hazard potential of the facility, and the IROFS, and to the complexity of the training needed. The review should evaluate the adequacy of training and qualification on the basis of how well it fulfills the objectives for the training as identified by the applicant, especially when human factors are relied on for safety. The review should determine whether the applicant has adequately planned for the training and personnel qualification to be accomplished and whether necessary policies, procedures, and instructions will be in place and appropriate training and qualification will be accomplished before personnel begin activities relied on for safety. The reviewers should focus on the training and qualification of personnel who will perform activities relied on for safety.

The secondary reviewer should confirm that the applicant's personnel training and qualification commitments are consistent with other sections of the submittal.

The supporting reviewer should become familiar with the applicant's personnel training and qualification commitments and determine whether ongoing activities are in agreement with them.

The review should result in a determination that there is reasonable assurance that the applicant's personnel training and qualification will ensure that only properly trained and qualified personnel will perform activities relied on for safety.

When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the personnel training and qualification input for the SER as described in Section 11.6, using the acceptance criteria from Section 11.4.3.3.

11.5.2.4 Procedures

On acceptance of the application for review, the secondary reviewer will evaluate whether the applicant has adequately addressed the acceptance criteria listed in Section 11.4. The secondary reviewer will document in an SER that the applicant has committed to the following:

1. Controls identified in the ISA Summary are highlighted in safety procedures (i.e., procedures that constitute administrative controls for safety). There may be several

levels of requirements within procedures for diagnosing and correcting process upsets, dealing with abnormal situations, or other matters. There is a clear hierarchy of requirements within procedures. Cautions and notes appearing in procedures precede the steps to which they apply. Rules for entering and leaving a procedure are clear.

2. Procedures important to safety are independently verified and validated before use, and this is documented in a policy on procedures.

3. Policy and administrative procedures, non-crucial operating procedures, and other non-operational procedures that do not impact IROFS or other environmental, safety, and health concerns need not be controlled with the stringency applied to operating procedures or management control procedures associated with controls specified by the ISA Summary. The applicability of less stringent procedure control should be specified to avoid misunderstandings in implementation.

4. Changes to operating, management control, or maintenance procedures are reviewed and approved by an independent multi-disciplinary safety review team and controlled by the CM function.

5. The applicant includes a statement to follow approved procedures while processing licensed SNM.
6. Procedures exist for the notification of operations personnel before and after maintenance is performed on IROFS and activities are controlled by procedures.

When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the procedures input for the SER, as described in Section 11.6, using the acceptance criteria from Section 11.4.3.4.

11.5.2.5 Audits and Assessments

After determining that the application is acceptable for review in accordance with Section 11.5.1, above, the secondary reviewer will perform a safety evaluation against the acceptance criteria described in Section 11.4. The review should determine whether the applicant has adequately planned for audits and assessments to be accomplished and whether necessary policies, personnel, procedures, and instructions will be in place to begin audits and assessments early, that is, during the design of IROFS.

If the applicant references other sections of the application when describing its audits and assessments, the primary reviewer should review these other sections of the application to determine the applicant's commitment to overall audits and assessments and the proposed method for implementation. The reviewers should focus on audits and assessments of IROFS.

The secondary reviewer should confirm that the applicant’s audit and assessment commitments are consistent with other sections of the submittal. The secondary reviewer is also responsible for integrating the audit and assessment input into the SER.

The supporting reviewer should become familiar with the applicant's audit and assessment commitments and determine whether ongoing audits and assessments of the applicant and the applicant's principal contractors are in agreement with them.

The review should result in a determination that there is reasonable assurance that the audits and assessments of the applicant and the applicant's principal contractors will provide additional assurance that IROFS will perform satisfactorily in service and that activities relied on for safety will be performed satisfactorily.

When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the audits and assessments input for the SER, as described in Section 11.6, using the acceptance criteria from Section 11.4.3.5.

11.5.2.6 Incident Investigations

The primary 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 presented in Section 11.4 of this SRP.

During the review, the primary reviewer will consult with the NRC inspection staff and review any historical information regarding the adequacy of the applicant's incident investigation process. On the basis of its review, the staff may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria in Section 3.7.4 of this SRP.

When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the incident investigation input for the SER as described in Section 11.6, using the acceptance criteria from Section 11.4.3.6.

11.5.2.7 Records Management

The reviewer will review the applicant's records management system to determine the adequacy of the policies, procedures, and practices. The reviewer should coordinate this review with the person reviewing the CM function.

For fuel cycle facilities that are parts of larger organizations, certain documents may be retained or stored at a site other than the plant site. For example, master drawings for structures might be kept in the engineering department of the headquarters of the parent company. The reviewer may choose to review the physical characteristics of these offsite record storage areas, as well, particularly for records for controls or high-risk accident sequences.

When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the records management input for the SER, as described in Section 11.6, using the acceptance criteria from Section 11.4.3.7.

11.5.2.8 Other QA Elements

After the primary reviewer has determined that the application is acceptable for review in accordance with Section 11.5.1, above, the primary reviewer should confirm that the applicant's (and the applicant's principal contractors') QA element commitments are consistent with other sections of the submittal. The secondary reviewer should review the QA elements information with respect to the acceptance criteria in Section 11.4. The secondary staff reviewer should determine whether the applicant has adequately planned the work to be accomplished and whether necessary policies, procedures, and instructions either are in place or will be in place before work starts. The review is based on an assessment of the material presented. It should provide reasonable assurance that the applicant's QA elements, maintenance, and CM are coordinated and that the QA elements are an integral part of everyday work activities. The review should provide reasonable assurance that the applicant will be able to monitor the effectiveness of the implementation of QA elements and will make needed adjustments on a timely basis. The staff is to look for and measure the effectiveness of the QA elements design, not just the existence of appropriate elements.

The secondary reviewer should also determine that the applicant has specified the QA elements criteria and the basis on which the criteria were selected and how they are apportioned within the sections of the application as well as the proposed method for implementation. If the applicant references other sections of the application when describing its QA elements, the reviewer should review these other sections of the application to determine the applicant's commitment to the QA elements and the proposed method for implementation.

The supporting reviewers should become familiar with the applicant's (and principal contractors') QA elements commitments and determine whether ongoing activities are in agreement with them.

Staff Reviewers of SRP Chapters 3 through 15 should determine whether IROFS within their areas of review are specified to be within the appropriate QA elements and level.

The review should result in a determination that there is reasonable assurance that the applicant's (and the applicant's principal contractors') QA elements will provide reasonable assurance that IROFS will perform their safety functions in a satisfactory manner.

When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the QA input for the SER, as described in SRP Section 11.6, using the acceptance criteria from SRP Section 11.4.3.8.

11.6 EVALUATION FINDINGS

The staff's evaluation should verify that the license application provides sufficient information to satisfy the regulatory requirements of Section 11.4.1 and that the regulatory

acceptance criteria in Section 11.4.3 have been appropriately considered in satisfying the requirements. On the basis of this information, the staff should conclude that this evaluation is complete. The reviewers should write material suitable for inclusion in the SER prepared for the entire application. The SER should include a summary statement of what was evaluated and the basis for the reviewers' conclusions.

In cases where the SER is drafted in advance of resolving all open issues, the reviewer should document the review as described below and include a list of open issues that require resolution before the staff can reach a reasonable-assurance-of-safety conclusion. For partial reviews, revisions, and process changes, the reviewer should use applicable sections of the acceptance criteria and the SER should be written to reflect what portions were not reviewed and the safety significance, if any.

The staff can document the evaluation as follows:

11.6.1 CM

The staff has reviewed the CM function for (name of facility) according to Section 11 of the SRP. [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.]

The applicant has suitably and acceptably described its commitment to a proposed CM system, including the method for managing changes in procedures, facilities, activities, and equipment for systems important to safety. Management-level policies and procedures, including an analysis and independent safety review of any proposed activity involving systems important to safety, are described that will provide reasonable assurance that the relationship between design requirements, physical configuration, and facility documentation is maintained as part of a new activity or change in an existing activity involving licensed material. The management measures will include (or do include) the following elements of CM:

1. CM Management

   The organizational structure, procedures, and responsibilities necessary to implement CM are in place or committed to.

2. Design Requirements

   The design requirements and bases are documented and supported by analyses, and the documentation is maintained current.

3. Document Control

   Documents, including drawings, are appropriately stored and accessible. Drawings and related documents captured by the systme are those necessary and sufficient to adequately describe systems important to safety.

4. Change Control

Responsibilities and procedures adequately describe how the applicant will achieve and maintain strict consistency among the design requirements, the physical configuration, and the facility documentation. Methods are in place for suitable analysis, review, approval, and implementation of identified changes to systems important to safety. This includes appropriate CM controls to assure configuration verification, functional tests, and accurate documentation for equipment or procedures that have been modified.

11.6.2 Maintenance

The applicant has committed to maintenance of IROFS. The applicant's maintenance commitments contain the basic elements to ensure availability and reliability: corrective maintenance, preventive maintenance, 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/monitoring, PM and functional testing activities described in the license application provide reasonable assurance that 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 at what level; (4) justifies the PM intervals in the terms of equipment reliability goals; (5) provides for training that emphasizes the importance of ISA or ISA Summary identified controls, regulations, codes, and personal 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 Part 70, and provide reasonable assurance that the health and safety of the worker and the public are provided for.

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 has concluded that the applicant has adequately described and assessed its personnel training and qualification in a manner that (1) satisfies regulatory requirements; (2) is consistent with the guidance in this SRP; and (3) is acceptable.

There is reasonable assurance that implementation of the described training and qualification will result in personnel who are qualified and competent to design, construct, start-up, operate, maintain, modify, and decommission the facility safely. The staff

concludes that the applicant's plan for personnel training and qualification meet the requirements of Part 70.

11.6.4 Procedures

The application has described a suitably detailed process for the development, approval, and implementation of procedures. IROFS have been addressed, as well as items important to the health of plant 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 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 has concluded that the applicant has adequately described its audits and assessments. The staff has reviewed the applicant's plan for audits and assessments and finds them acceptable.

The staff concludes that the applicant's plan for audits and assessments meets the requirements of Part 70 and provides reasonable assurance of protection of: (1) the health and safety of the public and workers, and (2) 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) of the event; and (3) recommending corrective actions for ensuring a safe facility and safe facility operations, in accordance with the acceptance criteria of Subsection 11.4 of the SRP.

The applicant has committed to monitoring and documenting of corrective actions, through 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 SRP's acceptance criteria and concluded that the system: (1) will be effective in collecting, verifying, protecting, and storing information about the facility and its design, operations and maintenance 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 in a timely manner.

11.6.8 Other QA Elements

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 review record should demonstrate the adequacy of the applicant's application of other QA elements, as applied to IROFS, for design, construction, and operations] the NRC staff has concluded that the applicant has adequately described the application of other QA elements (and the applicable QA elements of its principal contractors). The staff concludes further that:

1. The applicant has established and documented a commitment for an organization responsible for developing, implementing, and assessing the management measures for providing reasonable assurance of safe facility operations in accordance with the criteria in Section 11.4 of this SRP;

2. The applicant has established and documented a commitment for QA elements, and the administrative controls for staffing, performance, assessing findings, and implementing corrective actions are in place;

3. The applicant has developed a process for preparation and control of written administrative plant procedures, including procedures for evaluating changes to procedures, items, tests, and processes relied on for safety. A process for review, approval, and documentation of procedures will be implemented and maintained;

4. The applicant has established and documented surveillances, tests, and inspections to provide reasonable assurance of satisfactory in-service performance of IROFS. Specified standards or criteria and testing steps have been provided;

5. 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;

6. Training requirements have been established and documented to provide employees with the skills to perform their jobs safely. Management measures have been provided for evaluation of the effectiveness of training against predetermined objectives and criteria;

7. 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;

8. QA elements cover the IROFS, as identified in the ISA summary, and controls are established to prevent hazards from becoming pathways to higher risks and accidents.

Accordingly, the staff concludes that the applicant's application of other QA elements (and the applicable QA elements of its principal contractors) meets the requirements of Part 70 and provide reasonable assurance of protection of public health and safety and of the environment.

11.7 REFERENCES

1. American National Standards Institute/American Society of Mechanical Engineers Standard, "Quality Assurance Requirements for Nuclear Facility Applications," ANSI/ASME NQA-1-1994.

2. International Atomic Energy Agency, "Establishing and implementing a Quality Assurance Program," Safety Guide 50-SG-Q1, 1995.

3. International Standards Organization, ISO 9000 series of quality management standards.

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

5. U.S. Code of Federal Regulations, Title 10, Part 21, "Reporting of Defects and Noncompliance," U.S. Government Printing Office, Washington D.C., as revised.

6. U.S. Code of Federal Regulations, Title 29, Chapter XVII, Section 1910.119, "Process Safety Management of Highly Hazardous Chemicals," U.S. Government Printing Office, Washington D.C., as revised.

7. U.S. Code of Federal Regulations, Title 40, Part 68, "Risk Management Program for Chemical Accidental Release Prevention," U.S. Government Printing Office, Washington D.C., as revised.

8. U.S. Department of Energy,"DOE Standard: Guide for Operational CM Function," Parts I and II, DOE-STD-1073-93

9. U.S. Department of Energy, Draft, "Implementation Guide for Use with 10 CFR Part 830.120 and DOE Order 5700.6C," September 1997.

10. U.S. Nuclear Regulatory Commission, "A Systematic Approach to Repetitive Failures," NUREG/CR-5665, February 1991.

11. U.S. Nuclear Regulatory Commission, "Guidance on Management Controls/Quality Assurance, Requirements for Operation, Chemical Safety, and Fire Protection for Fuel Cycle Facilities," Federal Register 54 (No. 53), 11590–11598, March 21, 1989.

12. U.S. Nuclear Regulatory Commission, “Guide to NRC Reporting and Recordkeeping Requirements,” NUREG-1460, Rev. 1, July 1994.

13. U.S. Nuclear Regulatory Commission, “Maintenance and Inspection,” Inspection Procedure 88062, January 16, 1996.

14. U.S. Nuclear Regulatory Commission, “Maintenance and Surveillance Testing,” Inspection Procedure 88025, May 23, 1984.

15. U.S. Nuclear Regulatory Commission, “Proposed Method for Regulating Major Materials Licensees,” Section 3.2.6, ‘Configuration Management,’ NUREG-1324, 1992.

16. U.S. Nuclear Regulatory Commission, “Proposed Revision to Code of Federal Regulations, Title 10, Part 70, ‘Domestic Licensing of Special Nuclear Material,’ as revised.

17. U.S. Nuclear Regulatory Commission, “Root Causes of Component Failures Program: Methods and Applications,” NUREG/CR-4616, December 1986.

18. U.S. Nuclear Regulatory Commission, “Suggested Guidance Relating to Development and Implementation of Corrective Action,” Information Notice 96-28, May 1966.

19. U.S. Nuclear Regulatory Commission, ”Training Review Criteria and Procedures,” NUREG 1220, Rev. 1, January 1993.

APPENDIX A

CHECKLIST FOR PROCEDURES

All activities listed below are covered by written procedures. The list is not intended to be all-inclusive nor is it intended to imply that procedures be developed with the same titles as those on the list. This listing is divided into four categories and provides guidance on topics to be covered.

1. Management Control Procedures:

   Training
   Audits and Assessments
   Incident Investigation
   Records Management
   Configuration Management
   Quality Assurance
   Equipment control (lockout/tagout)
   Shift turnover
   Work Control
   Procedure management
   Nuclear criticality safety
   Fire protection
   Radiation protection
   Radioactive waste management
   Maintenance
   Environmental protection
   Chemical process safety
   Operations
   Calibration control
   Preventive maintenance

2. Operating Procedures:

   a. System Procedures That Address Startup, Operation, Shutdown, Control of Process Operations, and Recovery after a Process Upset

      Ventilation
      Criticality alarms
      Shift routines, shift turnover, and operating practices
      Decontamination operations
      Uranium recovery
      Plant Utilities (air, other gases, cooling water, fire water, steam)
      Temporary changes in operating procedures

b. Abnormal Operation/Alarm Response

Loss of cooling water
Loss of instrument air
Loss of electrical power
Loss of criticality alarm system
Fires
Chemical process releases

3. Maintenance Activities Tthat 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 (HEPA) filter maintenance
Functional testing of IROFS
Relief valve replacement/testing
Surveillance/monitoring
Pressure vessel testing
Non-fired pressure vessel testing
Piping integrity testing
Containment device testing

4. Emergency Procedures:

Response to a criticality
Hazardous process chemical releases (including uranium hexafluoride)

APPENDIX B

RECORDS

The requirements for records management vary according to the nature of the facility and the hazards and risks posed by it. Examples of the records required by 10 CFR Parts 19, 20, 21, 25, and 70 are presented below. These listings are organized under the chapter headings of the Standard Review Plan (SRP). Although they indicate the kinds of records to be found in these chapters of the SRP, the listing is not intended to be exhaustive or prescriptive in format. For example, in particular instances, different or additional records might fall within these groupings. Further, the applicant may choose to organize the records in ways other than shown here.

Examples of Records

SRP Chapter

1.0 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 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

2.0 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, etc.

QA records

Safety inspections, audits, assessments, and investigations

Safety statistics and trends

3.0 Integrated Safety Analysis

4.0 Radiation Safety

Bioassay data

Exposure records

Radiation protection (and contamination control) records

Radiation training records

Radiation work permits

5.0 Nuclear Criticality Safety

Nuclear criticality control written procedures and statistics

Nuclear criticality safety analyses

Records pertaining to nuclear criticality inspections, audits, investigations, and assessments

Records pertaining to nuclear criticality incidents, unusual occurrences, or accidents

Records pertaining to nuclear criticality safety analyses

6.0 Chemical Safety

Chemical process safety procedures and plans

Records pertaining to chemical process inspections, audits, investigations, and assessments

Diagrams, charts, and drawings

Records pertaining to chemical process incidents, unusual occurrences, or accidents

Chemical process safety reports and analyses

Chemical process safety training

7.0 Fire Safety

Fire Hazard Analysis

Fire prevention measures, including hot-work permits and fire-watch records

Records pertaining to inspection, maintenance, and testing of fire protection equipment

Records pertaining to fire protection training and retraining of response teams

Pre-fire emergency plans

8.0 Emergency Management

Emergency plan(s) and procedures

Comments on emergency plan from outside emergency response organizations

Emergency drill records

Memorandum of understanding with outside emergency response organizations

Records of actual events

Records pertaining to the training and retraining of personnel involved in emergency preparedness functions

Records pertaining to the inspection and maintenance of emergency response equipment and supplies

9.0 Environmental Protection

Environmental release and monitoring records

Environmental Report and supplements to the Environmental Report, as applicable

10. 0 Decommissioning

Decommissioning records

Financial assurance documents

Decommissioning cost estimates

Site characterization data

Final survey data

Decommissioning procedures

11.0 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 (ISA) documents, including process descriptions, plant drawings and specifications, purchase specifications for IROFS
- Approved, current operating procedures and emergency operating procedures

11.2 Maintenance

- Failure log (required by 10 CFR 70.62)
- PM 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, how and when implemented
- Summary of reportable events for the term of the license
- Incident investigation policy

11.7 Records Management

- Policy
- Material storage records
- Records of receipt, transfer and disposal of radioactive material

11. 8 Other Quality Assurance Elements

- Inspection records
- Test records
- Corrective action records

APPENDIX - FILING STANDARDS FOR SUBMITTALS

The requirements of 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," specifies that applications for a license for a fuel cycle facility should be filed in accordance with the general information in Sections 70.5 “Communications” and 70.21 “Filing”. This Appendix has been prepared to provide more specific guidance for staff reviewers regarding acceptable and preferred format for license and amendment applications.

Use of a standard submittal format for new and renewal applications facilitates a uniform and clear presentation by fuel cycle facility applicants. Such clarity and uniformity will facilitate a timely and uniform review by the NRC staff, and a clear and cogent presentation for understanding by parties other than the NRC and applicant who may have a legitimate interest in the application. Information contained in previous submittals, statements, or reports filed with the NRC with respect to an existing license may be incorporated by reference provided such references are clear and specific. The information called for in this SRP that is incorporated by reference to a previous application should be summarized.

Proprietary Information

Proprietary information should be submitted separately. When submitted, it should be clearly identified and accompanied by the applicant's justifications for requesting its being withheld from public disclosure, as specified by § 2.790, "Public Inspections, Exemptions, Requests for Withholding," of 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings." The NRC staff's review of the safety analysis should depend as much as possible on nonproprietary information to ensure that the public is properly apprised of the reasons for and effects of licensing actions.

Classified Information

Classified information should be submitted separately. When submitted, it should be clearly identified and accompanied by the applicant’s justifications for requesting its being withheld from public disclosure, as specified by applicable classification regulations. The NRC staff’s review of the safety analysis should depend as much as possible on unclassified information to ensure that the public is properly apprised of the reasons for and effects of licensing actions.

Style and Composition

Applications should clearly and concisely present the information to demonstrate compliance with NRC requirements.

Where numerical values are stated, the number of significant figures given should reflect the accuracy or precision to which the number is known. Where appropriate, estimated limits of errors or uncertainty should be given.

Abbreviations should be consistent throughout the application and should be consistent with generally accepted usage. Any abbreviations, symbols, or special terms not in general usage or unique to the plant should be defined when they first appear in the application or should be presented in a separate "Glossary" of terms and definitions.

Text pages should be single spaced, with a type face and style suitable for microfilming or reproduction by image-copying equipment.

Pages should be numbered with the digits corresponding to the chapter followed by a hyphen and a sequential number, e.g., the third page of Chapter 4 should be number 4–3. Sequential numbers for the entire report should not be used.

A table of contents should be included in each volume of the renewal application.

Graphical Presentations

Graphical presentations such as drawings, maps, diagrams, sketches, and tables should be employed where the information may be presented more adequately or conveniently by such means. Due concern should be taken to ensure that all information so presented is legible, that symbols are defined, and that scales are not reduced to the extent that visual aids are necessary to interpret pertinent items of information. These graphical presentations should be located in the section where they are primarily referenced.

Physical Specifications

Paper size: Text pages should be 8 1/2 × 11 inches; drawings and graphics should also be 8 1/2 × 11 inches; however, a larger size is acceptable provided the finished copy when folded does not exceed 8 1/2 × 11 inches.

Paper stock and ink:

The paper stock and ink should be of suitable quality in substance, paper color, and ink density for handling and reproduction by microfilming or image-copying equipment.

Page margins:

A margin of no less than 1 inch should be maintained on the top, bottom, and binding side of all pages submitted.

Printing: The material may be mechanically or photographically reproduced. All pages of text should be printed on both sides and the image printed head-to-head. Pages should be punched and mounted in 3-hole ring binders.

Submittal to NRC

In addition to paper copies of the applications submitted in accordance with 10 CFR 70.5 and 70.21, submittals to NRC should include a reproducible copy on electronic media in Corel WordPerfect version 8.0 or other word processing format that converts accurately to the Corel WordPerfect format.

Procedures for Updating or Revising Pages

Data and text should be updated or revised by replacing pages. The changed or revised portion on each page should be highlighted by a "change indicator" mark consisting of a bold vertical line drawn in the margin opposite the binding margin. The line should be of the same length as the portion actually changed. All pages submitted to update, revise, or add pages to the report should show the date of change and a revision or amendment number. A guide page listing the pages to be inserted and the pages to be removed should accompany the revised pages. Where major changes or additions are made, a revised table of contents should be provided.