5.0 INTEGRATED SAFETY ANALYSIS (ISA)

5.1 PURPOSE OF REVIEW

The types of submittals from the applicant that are addressed by this chapter are:

- The applicant's safety assessment of the design basis for the mixed oxide (MOX) fuel fabrication facility pursuant to 10 CFR 70.22(f) submitted as part of the application for construction approval; and

- The ISA for the license application, which includes:

  -- The ISA chapter of the license application, which contains the applicant's ISA programmatic commitments; and

  -- The applicant's declaration that it completed an ISA in accordance with the regulations and the ISA Summary of the processes, methods, personnel, and results of the ISA.

A. Safety Assessment of the Design Basis for the Application for Construction Approval

The purpose of this review is to establish that the application for construction approval includes a description of the plantsite and a safety assessment of the design basis that demonstrates that the applicant's principle structures, systems, and components will provide protection against natural phenomena and the consequences of other accidents in accordance with the performance requirements of proposed 10 CFR 70.61. Pursuant to §70.22(f), the application for construction approval must be approved by the Commission prior to the beginning of construction.

The safety assessment of the design basis is neither an ISA nor a substitute for the ISA that is submitted with the license application (see Item B); instead, the safety assessment of the design basis allows the staff to determine if the applicant's design basis is adequate to meet 10 CFR 70.23(b) and to determine that the applicant, by using the safety assessment of the design basis, is building a foundation for the ISA to support the license application. Moreover, the processes the applicant uses to develop the safety assessment for the design basis should be analogous to the processes that the applicant will use to develop the ISA for the license application. Therefore, the areas of review and acceptance criteria described for the safety assessment of the design basis draw upon the acceptance criteria for the ISA for the license application.

B. The ISA for the License Application

i. ISA Programmatic Commitments

The purpose of the review of the ISA chapter of a license application is to determine that the applicant established and commits to ISA organization and procedures as may be explicitly required by the regulation, or sufficient to accomplish an ISA function required by the regulation, and provides a formal system to manage changes to the ISA.

ii. ISA Results and Summary

The purpose of the review of the ISA results, primarily as described in the ISA Summary, is to establish reasonable assurance that the applicant:

a. Performed a comprehensive ISA of the MOX fuel fabrication facility and its processes using effective systematic methods and competent staff.

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

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

5.2 RESPONSIBILITY FOR REVIEW

Primary: ISA reviewer

Secondary: Reviewers in specific technical areas, including: nuclear criticality safety, fire protection, chemical safety, radiation safety, and environmental protection

Supporting: Fuel Facility Inspection Staff

5.3 AREAS OF REVIEW

The staff should review the application for construction approval, which includes the applicant's design basis, safety assessment of the design bases, and principal structures, systems and components (SSCs) of the facility. The safety assessment of the design bases is expected to consist of tasks analogous to the initial tasks in an ISA as described in Section 5.3.2. The specific areas of review for the application for construction approval are documented in Section 5.3.1.

The applicant's ISA programmatic functions and commitments should be documented in the license application. The ISA is part of the safety program and consists of the process safety information (PSI), the methods used by the licensee to perform the ISA, the qualifications of the team performing the ISA, the method of documenting and implementing the results of the ISA, and the process used to maintain the ISA current when changes are made to the facility. When

the applicant submits the license application, the staff should review the applicant's ISA programmatic functions and commitments, primarily as documented in the application. The specific areas of review are documented in Section 5.3.2(A).

The applicant's ISA Summary, and other ISA documentation, should document the methods, personnel, and ISA results. The applicant submits the ISA Summary to the NRC with the license application with additional ISA documentation available for NRC review at the facility site. The term "results of the ISA" includes all the ISA information that the applicant submits to the NRC (including the programmatic functions and commitments reviewed under Section 5.3.2(A)) plus any additional supporting information that the applicant keeps at the site. The staff should also evaluate 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 assurance of acceptability of the results for compliance with the regulations, in particular, proposed 10 CFR 70.61. The specific areas of review are documented in Section 5.3.2(B).

5.3.1 Safety Assessment of the Design Basis for the Application for Construction Approval

For the application for construction approval for the MOX facility by 10 CFR 70.22(f), the areas of review should include those items of information relating to identification of hazards; identification of potential accident sequences, frequencies and severity of natural phenomena, and SSCs; and assessment of likelihoods and consequences of accidents. These areas of review are similar to those covered under Section 5.3.2 for the ISA for the license application. Evaluation of the adequacy of methods, safety margins, and other discipline-specific safety design bases are contained in the appropriate chapters of this SRP. The areas of review should include:

A. The plantsite description related to the safety assessment of the design basis, including information needed for quantification of the likelihood and severity of the natural phenomena such as earthquakes, tornadoes, floods, natural fires, hurricanes and other wind storms.

B. The applicant's ISA elements and commitments (see Section 5.3.2(A)), including a description of how the applicant plans to incorporate the safety assessment of the design basis in the ISA performed for the license application.

C. The applicant's methods for conducting the safety assessment of the design basis, including the applicant's methods to evaluate chemical and radiological consequences and likelihood evaluation to show compliance with proposed §70.61.

D. The principal SSCs of the facility.

E. The safety assessment of the design bases of the principal SSCs of the facility, including:

   i. A definition of the quantitative chemical consequence standards to be used in determining compliance with proposed §70.61;

   ii. Definition of the terms likely, unlikely, highly unlikely, and credible to be used in showing compliance with proposed §70.61;

   iii. Commitment to the methods of NUREG-1513 for hazard identification and process hazard analysis (PHA), or a description and validation of alternative methods;

   iv. A description of the design bases of the principal SSCs relied on for safety;

   v. A hazard identification for the principal SSCs relied on for safety;

   vi. A process hazard analysis identifying potential accidents; and

   vii. An assessment of the likelihoods and consequences of each general type of bounding case accident;

F. The provisions and design bases for protection against natural phenomena and the safety assessment of the design basis for natural phenomena events.

G. The design bases for protection against other accidents and the safety assessment of the design basis.

Review of the quality assurance program description required by §70.22(f) and of other non-ISA elements of the submittal are addressed by the other chapters of this SRP. In particular, the adequacy of safety management measures and generic technical aspects of methods used to analyze design bases for fire and chemical safety, radiological protection, and natural phenomena hazard estimation and evaluation of facility response, may be addressed in other chapters.

5.3.2 The ISA for the License Application

A. ISA Programmatic Commitments

   The staff should review the license application to determine whether the applicant's commitments to perform and maintain an ISA are adequate. The areas of review should include:

   i. The applicant's commitment to compile and maintain a current and accurate set of PSI including information on the hazardous materials, equipment, and technology used in each process. The applicant should explain this activity in detail in the description of its configuration management program (Section 15.2, "Configuration Management").

ii. The applicant's requirements for ISA team training and qualifications (Section 15.4, "Training and Qualification of Plant Personnel").

iii. The applicant's ISA method for each individual process node, and the applicant's justification for that methods selection. For the purposes of this review, the applicant should begin the ISA 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. The applicant should follow the hazard identification with a systematic PHA of each facility process that identifies a set of individual accident sequences or process upsets that could result from the hazards. The applicant's ISA methods address:

a. Hazard identification;
b. PHA (accident identification);
c. Accident sequence construction and evaluation;
d. Consequence determination and comparability to proposed 10 CFR 70.61; and
e. Likelihood categorization for determining compliance with proposed 10 CFR 70.61.

iv. The applicant's facility procedures for conducting and maintaining the ISA. The object of this review is to ensure the overall integrity of the ISA as a current and accurate safety basis for the facility. The applicant's facility procedures include:

a. Performing and updating the ISA;

b. Review responsibility;

c. Documentation (including provisions for updating NRC on changes to IROFS or seeking NRC approval of changes per proposed §70.72); and

d. Maintenance of ISA records per proposed §70.62(a)(2). The integrity of the ISA procedures should be controlled by the applicant's configuration management program.

B. ISA Results and Summary

The staff should review the ISA results (ISA summary and selected other ISA documentation) to find reasonable assurance that the applicant performed a systematic evaluation of the hazards and credible accident sequences and has determined that the performance objectives of proposed 10 CFR 70.61 have been satisfied. The review boundary should include those accidents that result in a release of licensed radioactive material or an inadvertent nuclear criticality event. In addition, the staff should review accidents involving hazardous chemicals when the chemicals are composed of or produced from the processing of licensed radioactive material; or if the accident has the potential to jeopardize the safety of regulated activities. The staff does not need to review event

sequences leading to consequences less than those identified in proposed 10 CFR 70.61(c) not requiring further consideration within the ISA. The areas of review should include:

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

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

iii. A description of each process analyzed as part of the ISA, including basic process function and theory, major components--their function and operation, process design and equipment, and process operating ranges and limits.

iv. The ISA results, primarily as documented in the ISA Summary, including:

    a. The list of hazardous materials and conditions resulting from the hazard identification task and a hazard interaction matrix table [see reference AIChE 1992, Section 3.3];

    b. Accident sequences identified by the ISA systematic PHA;

    c. Information demonstrating compliance with proposed 10 CFR 70.61, including:

        (1) Unmitigated and mitigated consequences of each postulated accident to facility workers or the public;

        (2) Comparisons of the consequences of each postulated accident to the consequence levels identified in proposed 10 CFR Part 70.61;

        (3) Assignment of accident sequences to likelihood categories and comparison to proposed 10 CFR 70.61 requirements.

v. The applicant's ISA team qualifications and ISA methods, including:

    a. ISA Team Qualifications: The ISA team leader(s) and team leader's(s') training and experience; team composition; and overall manager for the ISA process.

    b. ISA Methods: A descriptive summary of the methods used for each ISA task.

vi. The identification of, description of, and management measures applied to all IROFS that the applicant will use to ensure that, for each accident sequence, the performance requirements of proposed 10 CFR 70.61 are met, as interpreted in the acceptance criteria of Section 5.4. These criteria are risk informed in that IROFS applied to accident sequences having more severe consequences are to be correspondingly more reliable.

The applicant should also commit to maintain IROFS available and reliable for high and intermediate risk accident sequences.

Those management measures that are generically applied to all IROFS or to specified classes of IROFS may be described in Section 15.0, “Management Measures,” and in Chapters 6.0 through 12.0, which cover specific safety disciplines. However, since the ISA identifies the IROFS as such and provides other information needed to apply management measures in a graded manner, the staff should review information from the ISA Summary and other ISA documentation needed to implement these measures.

vii. The applicant proposes quantitative chemical standards to assess the consequences from acute chemical exposure to licensed material or chemicals produced from licensed material.

viii. The applicant provides a list of IROFS that are the sole item for preventing or mitigating an accident sequence.

ix. For accident sequences evaluated as potentially having the consequences specified in proposed §70.61, but meeting the likelihood requirements of proposed 10 CFR 70.61 without IROFS, the basis for the applicant's evaluation of the sequence as being of acceptably low likelihood. Typically, these accident sequences are initiated by very low likelihood events e.g., natural phenomena.

5.4 ACCEPTANCE CRITERIA

5.4.1 Regulatory Requirements

10 CFR 70.23(b) requires that an applicant to construct and operate a plutonium processing and fuel fabrication facility such as a MOX facility, obtain NRC approval prior to initiating construction. The NRC’s approval is based on information the applicant submits pursuant to 10 CFR 70.22(f), which includes the safety assessment of the design bases.

The requirement to perform an ISA is specified in proposed 10 CFR 70.62. Proposed 10 CFR 70.62(a)(2) requires that the applicant establish and maintain records of PSI, which is needed to perform and support the ISA. Proposed 10 CFR 70.62(c) specifies requirements for the tasks comprising the ISA, for the qualifications of ISA team personnel, and that the ISA must evaluate whether the applicant’s facility, with its listed IROFS, meets the safety performance requirements of proposed §70.61. Proposed 10 CFR 70.64 specifies design criteria requirements for new facilities. Proposed 10 CFR 70.72 states requirements for keeping the ISA and its documentation current when changes are made to systems, structures, and components.

5.4.2 Regulatory Guidance

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

5.4.3 Regulatory Acceptance Criteria

5.4.3.1 Safety Assessment of the Design Basis for the Application for Construction Approval

The application for construction approval includes the safety assessment of the design basis and identifies the principal SSCs that will protect against natural phenomena and other accidents. The safety assessment of the design basis is not a substitute for the ISA that is submitted with the license application (see Section 5.4.3.2); instead, the safety assessment of the design basis allows the staff to determine if the applicant's design basis is adequate to meet 10 CFR 70.23(b). However, the processes the applicant uses to develop the safety assessment for the design basis should be analogous to the processes that the applicant will use to develop the ISA for the license application. Therefore, the acceptance criteria described in this section draw upon the acceptance criteria for the ISA for the license application, as described in Section 5.4.3.2.

The staff should find the applicant's safety assessment of the design basis acceptable if the following criteria are met:

A. The applicant's plantsite description includes sufficient information to permit a safety assessment of the design basis, including a site description as defined in Section 5.4.3.2(B)(i), a facility description as described in Section 5.4.3.2(B)(ii), and a process description as defined in Section 5.4.3.2(B)(iii). The level of detail the applicant provides to meet these acceptance criteria is consistent with the level of design.

B. The applicant commits to ISA programmatic commitments for completing the ISA license application (see Section 5.4.3.2(A)). The commitments are consistent with the regulatory acceptance criteria in Section 5.4.3.2(A) considering the level of design.

C. The applicant's team qualifications for completing the safety assessment of the design basis are consistent with the acceptance criteria in Section 5.4.3.2(B)(v)(a).

D. The applicant's methods for conducting the safety assessment of the design basis are consistent with the methods the applicant will use to perform an ISA as described in Section 5.3.2(B)(v)(b). The applicant considers the level of design when it selects the methods for the safety assessment of the design basis. For example, the level of design in the application for construction may dictate that the applicant's methods for the consequence assessment are more approximate and less complete than expected for an

ISA, but should still provide reasonable estimates based on quantitative information and be consistent with valid methods.

The applicant describes how the methods used for the safety assessment of the design basis differ from the applicant's methods for the ISA (see Item B) and provides plans to transition from the design basis to the ISA.

E. The applicant describes the principal SSCs relied on for safety in sufficient detail to permit staff to evaluate the safety assessment of the design basis. In particular, the applicant describes the general features that indicate that the SSCs can be designed and constructed to meet the design basis. For natural phenomena hazards, the applicant provides the general aspects of the structures that make them resistant to failure. For internally initiated accidents, the applicant provides the general type of control(s) for parameters. For active engineered controls, the applicant states the type of sensing and the type of control device. For passive engineered controls, the applicant states the general geometry, materials, and how they prevent the accident. For administrative controls, the applicant identifies the types of human actions or prohibitions relied upon for safety.

   By definition (see the Glossary to this SRP or proposed 10 CFR 70.4) an SSC is an IROFS. Therefore, the applicant commits to evaluate any SSC identified in the design basis as part of the ISA. In addition, since the definition of IROFS includes equipment and personnel activities, where the applicant identifies administrative controls, it describes the type of human action or prohibition and flags the administrative controls for more detailed consideration in the ISA (see Section 5.4.3.2(B) and Chapter 12.0).

   The description of the principal SSCs need not be at the level of detailed engineering drawings. However, principal safety function features; devices; amounts of hazardous materials; and the principal dimensions, layout, and location relevant to safety must be given. Each general type of principal SSC or process using the same design basis must be described. However, approximate numbers of each general type of SSC or process is sufficient. It is the safety basis that is to be assessed.

F. The applicant's safety assessment of the design bases of the principal SSCs of the facility indicates the controlled parameters for safe operation, provides the limiting values of any controlled parameter, and explains and assesses the means of controlling those parameters to within those limiting values. The applicant shows that the design and design bases will result in a facility that will meet the performance requirements of proposed §70.61 and the defense-in-depth requirement of proposed §70.64(b). For processes vulnerable to criticality accidents, the applicant explains why it is expected that the given design and design bases will meet the double contingency requirement of proposed §70.64(a)(9).

   The applicant completes the safety assessment of the design bases by following steps analogous to the steps necessary to perform an ISA. However, the level of detail obtained at each step is correlated to the level of design. The applicant's safety assessment of the design basis addresses:

i. Hazard identification

The applicant identifies the approximate location and quantities of SNM and other hazardous materials (see Section 5.4.3.2(B)(ii)).

ii. Process hazard analysis and accident sequence identification

The applicant identifies the principal ways the hazards identified in Item i could impact the workers, public, or the environment, including:

a. Mechanisms to release hazardous materials;
b. Failures to control criticality parameters; and
c. Other potential initiating events for accidents;

As discussed in Item E, the accident severity will depend on the types of features, structures, control devices, or procedures the applicant will use to mitigate or prevent the accident consequences. The applicant compares the consequences of the accident with SSCs to the unmitigated accident consequences.

iii. Consequence Assessment

The applicant's consequence assessment is sufficiently quantitative to compare the consequence estimates against the performance requirements of proposed 10 CFR 70.61. The applicant does not determine the consequences for all accidents and all SSCs individually; however, the applicant demonstrates that the consequence assessment is bounding through the applicant's analysis of representative processes sufficient to cover all principal types of hazardous materials.

iv. Likelihood assessment

The applicant's safety assessment of the design basis with respect to likelihood provides reasonable assurance that the likelihood requirements of proposed §70.61 will be met by the final design. The applicant defines likely, unlikely, highly unlikely, and credible to evaluate the performance requirements for the safety assessment of the design basis and commits to use equivalent or refined definitions in the ISA for the license application. In addition, the applicant describes the likelihood evaluation method to be used in the ISA. The applicant makes these methods and definitions part of the design bases. The applicant's methods and definitions of likelihood terms are acceptable if they meet the same criteria as for ISA (see Section 5.4.3.2).

G. The applicant's safety assessment of the design basis for internal accidents provides reasonable assurance that the applicant will be able to meet the likelihood requirements of proposed §70.61. The applicant's safety assessment need not use the applicant's specified likelihood evaluation methods in detail, but it should be consistent with them. The applicant's safety assessment is consistent with the definitions of the likelihood terms. The applicant's safety assessment of the design basis includes:

i. The number and types of the principal SSCs;

ii. The functional relationship of each SSC to the top level safety function for a process, for example, by a fault tree;

a. For each SSC, the design basis parameters that will be specified or controlled for safety;

iii. The ranges and values of those parameters that constitute the design bases. The applicant demonstrates that these values are correct and incorporates sufficient safety margins to account for uncertainties. The applicant uses large safety margins when manual operations depend on operator actions as administrative controls.

H. The applicant's safety assessment of the design basis considers design basis events and shows that the likelihood for accidents resulting from natural phenomena will meet the performance requirements of proposed §70.61. The applicant's safety assessment of the design basis for natural phenomena:

i. Provides the frequency of occurrence of severity levels of the phenomena; and

ii. Demonstrates the ability of the SSC to withstand specified severity levels.

The applicant provides quantitative information that indicates that the frequencies of accidents are in accordance with the quantitative acceptance criteria for likelihood definitions given in Section 5.4.3.2(B). The acceptance criteria for assessment of the chemical and radiological consequences of accidents caused by natural phenomena are the same as described in Item G.

The applicant may demonstrate the frequencies of natural phenomena and assess the likelihood that the safety functions of the SSCs will not fail when subject to natural phenomena by reference to accepted standards rather than by individual analyses.

A discussion of what tasks constitute a safety assessment of design bases for protection against natural phenomena is found in Appendix B of this SRP. Accepted standards for natural phenomena assessment are referenced therein.

5.4.3.2 The ISA for the License Application

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 of each accident sequence for compliance with proposed §70.61. The acceptance criteria in Section 5.4.3.2(A) address the programmatic commitments made by the applicant to perform and maintain an ISA. The acceptance criteria

in Section 5.4.3.2(B) address the ISA results and whether those results demonstrate the ability of the applicant to meet the performance requirements of proposed §70.61.

A. ISA Programmatic Commitments

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, documented procedures for activities, use of industry consensus standards, and technical safety practices. The applicant's commitment to each ISA requirement of the rule should be acceptable if it:

i. Describes each necessary safety program element sufficiently to understand how well it supports the safety program function;

ii. Commits to each safety program element as described, and to maintaining on-site written procedures for carrying out that function, if necessary; and

iii. There is reasonable assurance that the elements, as described, would be effective in accomplishing the safety 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. If no selection criteria are given, then phrases stating recommendations or options are not commitments. However, it may be acceptable for some safety elements of lesser importance not to be stated as commitments.

The staff should find the applicant's ISA programmatic commitments acceptable if the following criteria are met:

iv. The applicant commits to compiling and maintaining current a database of PSI. As part of this commitment, the applicant will use the written PSI to update the ISA and to identify and understand the hazards associated with the processes. The applicant's compilation of written PSI includes:

a. The hazards of all materials used or produced in the process, including information on chemical and physical properties such as toxicity, acute exposure limits, reactivity, chemical and thermal stability or other applicable information as is typically included on Material Safety Data Sheets (meeting the requirements of 10 CFR 1910.1200(g)).

b. Equipment used in the process, including information of a general nature on topics such as the materials of construction; piping and instrumentation diagrams (P&IDs); 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 the design basis.

c. Technology of the process, including block flow diagrams or simplified process flow diagrams, a brief outline of the process chemistry, safe upper and lower limits for controlled parameters (e.g., temperature, pressure, flow, concentration) and an evaluation of the health and safety consequences of process deviations.

v. The applicant commits to engage personnel with appropriate experience and expertise in engineering and process operations to update and maintain current 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.

vi. The applicant commits to those aspects of the methods for each task of the ISA, as described in the ISA Summary, that are essential to assuring that Integrated Safety Analyses of particular processes will continue to correctly evaluate compliance with the performance requirements of proposed §70.61. The applicant's description of methods may be at a somewhat more generic level than in the ISA Summary in order to permit certain methodology changes without license amendment.

vii. The applicant includes procedures and criteria for changing the ISA either in the ISA commitments or in the commitment to design and implement a facility change mechanism that meets the requirements of proposed 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.

viii. The applicant commits to keeping the ISA and ISA Summary accurate and up-to-date by means of a suitable configuration management system. The applicant's ISA accounts for any changes made to the facility or its processes (e.g., changes to the site, operating procedures, control systems). The applicant succinctly outlines its management policies, organizational responsibilities, revision time frame, and procedures to perform and approve revisions to the ISA. 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 with similar qualifications to that used in conducting the original ISA for any modifications and revisions that the applicant deems necessary. 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 proposed 10 CFR 70.72(d)(1).

ix. The applicant commits to promptly address any safety-significant vulnerabilities or unacceptable performance deficiencies identified in the ISA. Whenever an update of the ISA is conducted, the applicant commits to taking prompt and appropriate actions to address any vulnerabilities that may have been identified. If a proposed change results

in a new type of accident sequence (e.g., different initiating event, changes in the consequences as defined in proposed 10 CFR 70.61) or increases the risk of a previously analyzed accident sequence to an unacceptable level, the applicant commits to promptly evaluating the adequacy of existing IROFS and associated management measures and to making necessary changes, if required.

x. The applicant commits to installation of IROFS (including administrative controls) and maintaining them in a functional state so that they are available and reliable when needed. Management measures (which are evaluated in Chapter 15.0) comprise the principal mechanism by which the reliability and availability of IROFS is assured.

B. ISA Results and Summary

In principle, if the applicant performs an acceptable ISA, the applicant's results could show that the applicant's processes do not comply with the performance criteria of proposed §70.61. Thus it is necessary for staff to review the ISA to verify that the applicant's ISA results demonstrate compliance with proposed 10 CFR 70.61. The staff should use the ISA Summary as the primary source of information for making this compliance determination. However, it may be necessary for the staff to request additional information or make site visits in order to reach an adequate understanding of the characteristics of selected individual processes. The review is not merely an acceptance review of ISA Summary contents, but of whether those contents demonstrate that the applicant's processes and procedures comply with proposed §70.61. It is a review to determine that the process designs, IROFS, and specific management measures applied to each process are sufficient.

The following acceptance criteria address, in the order given in proposed §70.65(b), each of the required content elements of the ISA Summary; namely descriptions of: the site, the facility, each process, process hazards, types of accident sequences, information demonstrating compliance with performance requirements, team qualifications, ISA methods, list of IROFS, quantitative chemical consequence standards, list of IROFS that are the sole items preventing or mitigating an accident sequence, and definitions of likelihood terms. The acceptance criteria are not simply that the ISA Summary elements are described in the document submitted, but rather that the information submitted is sufficient to demonstrate that the applicant's process safety design and safety procedures meet the performance requirements of proposed §70.61 and other ISA requirements of proposed 10 CFR Part 70. Thus the staff will accept the applicant's ISA results if the staff finds that the following criteria are met:

i. Site Description

The applicant's site description includes or references the following safety-related information with emphasis on those factors that could affect safety:

a. The site geography, including the site location and the location of other prominent natural and man-made features such as mountains, rivers, airports, population

centers, possibly hazardous commercial and manufacturing facilities, etc. adequate to permit evaluation of:

(1) The likelihoods of accidents caused by external factors; and
(2) 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 the public consequences listed in proposed 10 CFR 70.61.

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

The level of detail for this material is greater than that which would be acceptable in the general information contained in Chapter 1.0 because the information is needed to evaluate the ISA.

ii. Facility Description

The applicant's facility description identifies and describes the general facility features that are relied on or required for safety and adequately supports an overall understanding of the facility structure and its general arrangement as it pertains to the ISA. As a minimum, the applicant 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 proposed §70.61.

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

If the applicant provides facility description information in the license application, the applicant may provide a reference to the appropriate section.

iii. Processes

The applicant's description of the processes analyzed as part of the ISA provides sufficient detail to provide staff with an understanding of the theory of operation and to

allow the staff to determine compliance with the performance requirements of proposed 10 CFR 70.61. The applicant may provide a description at the systems level if it permits the staff to conduct: (1) an evaluation of the completeness of the hazard and accident identification tasks (see Item B(iv)(a)) and (2) an evaluation of the likelihood and consequences of the accidents identified (see Item B(iv)(c)). Where the applicant identified a need for IROFS in the ISA results (as identified in the ISA Summary, see Item B(iv)), the applicant provides an adequate explanation of how the IROFS reliably prevent the process from exceeding safety limits for each case identified in the ISA results.

a. Basic process function and theory, including a general discussion of the basic theory of the process;

b. Major components--their function and operation, including the general arrangement, function, and operation of major components in the process; process schematics showing the major components and instrumentation; and, if appropriate, chemical flow sheets showing the compositions of the various process streams.

c. Process design and equipment, including a discussion of the process design, equipment, and instrumentation that is sufficiently detailed to permit an adequate understanding of the results of the ISA. The applicant's discussion includes schematics indicating safety interrelationships of parts of the process. In particular, the applicant either provides schematics or descriptions that indicate the location and geometry of special nuclear material (SNM), moderators, and other materials in the process that are sufficient for the staff to understand the adequacy of controls on mass, geometry, moderation, reflection, and other criticality parameters affected by geometry (see Chapter 6.0 for more information on nuclear criticality safety).

d. Process operating ranges and limits, including 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 consistent with those the applicant evaluated as adequate for safety in the ISA. The applicant may elect to present this information 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 to this SRP.

If the applicant provides facility description information in the license application, the applicant may provide a reference to the appropriate section.

iv. The ISA Results As Documented in the ISA Summary

The staff should not use the regulatory acceptance criteria for the applicant's ISA results merely to confirm that the applicant conducted an ISA; instead the staff should use the regulatory acceptance criteria to determine that the applicant will be in compliance with proposed §70.61. Proposed §70.61 effectively states that each of the applicant's

credible accident sequences must be correspondingly unlikely. High consequence events must be highly unlikely; and intermediate consequence events must be unlikely. The performance criteria of proposed §70.61 have three elements: (1) completeness, (2) consequences, and (3) likelihood. Completeness refers to the fact that the applicant must address each credible event. Consequences refers to the magnitude of the chemical and radiological doses used by the applicant to categorize accidents as being of high or intermediate consequences. Likelihood refers to the fact that proposed §70.61 requires that the applicant must demonstrate that intermediate consequence events will be unlikely, and high consequence events will be highly unlikely.

The applicant provides two types of information for each of the three elements: (1) the methods used and (2) the results of applying these methods to each process. That is, the applicant's information demonstrates compliance if it describes methods and criteria that should, if properly applied, provide reasonable assurance that the applicant will meet the performance criteria. In each case, the applicant's resulting accident sequences, consequences, and likelihoods for each process demonstrate that the applicant properly applied the methods. The staff should refer to Section 5.4.3.2(B)(v) for the regulatory acceptance criteria for the applicant's ISA methods.

a. Hazards

The applicant's process hazards, as provided in the ISA Summary, identify hazards of all types specific to each process relevant to determining compliance with the performance criteria of proposed §70.61. The applicant should list hazards even if no accident exists that could exceed the minimum consequences of proposed §70.61. The applicant's hazard identification:

(1) Provides 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) Provides a hazards interaction table showing potential interactions between materials including conditions that could possibly result in hazardous situations.

(3) Is complete. To satisfy the criteria of completeness the applicant:

(a) Uses a systematic method of hazard identification in accordance with the regulatory acceptance criteria for ISA methods (see Section 5.4.3.2(B)(v));

(b) Correctly applied the method (see Section 5.4.3.2(B)(v));

(c) Did not overlook a hazard. If the staff can identify a hazard not identified, then this criterion is not met.

b. Accident Sequences

The applicant's accident sequences, as determined by a systematic PHA, permit the staff to determine that the IROFS, as described in the ISA Summary, address each type of accident sufficiently to show that the applicant will meet the performance requirements of proposed §70.61. For this reason, the applicant should not, in general, merely state that a criticality, radiological accident, or chemical release is possible. These items are merely the hazards required by Section 5.4.3.2(B)(iv)(a). Nor should the applicant, in general, merely list controlled parameters without reference to the items relied on to control that parameter.

(1) The applicant's general description of accident sequences:

(a) Covers all types of sequences of failures of IROFS. The applicant's description permits the staff to determine that all accident sequences that could exceed the minimum consequence levels in proposed §70.61 are protected against by IROFS.

(b) Clearly shows the consequences and likelihood assigned to each type of accident sequence, and includes the results of any intermediate data or analysis that led to the consequence and likelihood assignments.

(c) Shows that each such type of accident is adequately addressed by IROFS and lists the specific IROFS that must fail for the type of accident to occur. The applicant's level of detail for each accident sequence is correlated to the number of combinations of failures of IROFS that lead to consequences referred to in proposed §70.61.

(2) The applicant's completeness for accident sequences

When the applicant identifies accident sequences through the PHA, the applicant may identify accidents whose consequences may initially be unknown, then later are analyzed and shown to be below the consequence levels identified in proposed §70.61. The applicant's ISA Summary must either list all the accidents identified or state that certain accidents are possible, but were not listed due to insufficient consequences. However, the applicant need not list every conceivable permutation of accidents as a separate accident sequence. The applicant may group accidents having characteristics that all fall in the same category as a single type of accident, 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. A primary purpose of showing completeness is to assure that existing IROFS are adequate. Once the applicant demonstrates that a type of accident has the same characteristics, it is not necessary for the applicant to distinguish among

the different events within the type. On the other hand, if a different initiating event poses a different type of challenge to a control, then the applicant should address that initiating event separately, because it may reveal a weakness of the control.

In particular, the applicant's accident sequences are complete if the applicant:

(a) Uses a systematic method to identify accident sequences, e.g., a PHA, in accordance with the regulatory acceptance criteria for ISA methods (see Section 5.4.3.2(B)(v));

(b) Correctly applied the method (see Section 5.4.3.2(B)(v));

(c) Did not overlook an accident sequence. If the staff can identify an accident sequence not identified, then this criterion is not met.

(d) Indicates and explains why the applicant evaluated certain accidents as incredible events.

(e) Provides accident sequences. For processes having few IROFS, the applicant may use a numbered list of accident sequences. For processes with many accidents resulting from multiple combinations of IROFS failures, the applicant provides a logic diagram, such as a fault tree, that describes all accident sequences in a succinct explicit format. Appendix A to this SRP shows a third acceptable way of providing a general description of accident sequences; namely, in a tabular format. The applicant provides:

    (i) A tabular summary description of the accident sequences identified in the PHA. The tabular description consists of one row for each accident sequence. The applicant summarizes accident sequences initiated by the same type of event, consisting of the same sequence of control failures, and resulting in the same consequence category as a single row. This row lists the initiating event, the IROFS that must fail in order for the accident to occur, and the level of unmitigated consequences, if all IROFS fail. The tabular summary identifies the severity level of each type of consequence (radiological, criticality, chemical, environmental) according to the values defined in proposed 10 CFR 70.61. The applicant tabulates information sufficient for staff evaluation of compliance with the likelihood requirements of proposed 10 CFR 70.61, such as likelihood indices. Appendix A to this SRP provides an acceptable way of presenting this information; or

    (ii) A set of logic diagrams, such as fault trees or event trees for each process, presenting the same information as in Item (i); or

(iii) A numbered list of narrative summaries describing each type of accident sequence for the process and containing the same information as the tabular summary of Item (i).

c. Information Demonstrating Compliance with Proposed 10 CFR 70.61

The third required item in the ISA Summary is "information that demonstrates compliance with the performance criteria of §70.61" which addresses the consequences and likelihoods of the accident sequences.

(1) Consequences: The applicant's consequences demonstrate compliance with proposed 10 CFR 70.61 if:

(a) The applicant's ISA Summary includes, for each accident, an estimate of its quantitative consequences (doses, chemical exposures, criticality) in a form that can be directly compared to the consequence levels in proposed 10 CFR 70.61, or includes a reference to a value documented elsewhere in the ISA Summary that applies to or bounds that accident;

(b) The applicant calculated the consequences in accordance with the regulatory acceptance criteria for ISA methods (see Section 5.4.3.2(B(v));

(c) The applicant used reasonably conservative estimates for source terms and other process specific data used for the type of accident and provided intermediate data. For example, for consequence analysis the applicant would provide intermediate data such as the inventory of hazardous material and the facts about the accident that result in release path reduction factors;

(d) The applicant's ISA Summary correctly assigns each type of accident to one of the consequence categories of proposed §70.61; and

(e) The applicant assigns criticality accidents as high consequence events. For processes with effective engineered shielding, criticalities may produce doses below the intermediate consequences of proposed §70.61. As stated in the regulation, notwithstanding shielding or other mitigative features, the applicant must place primary reliance on the prevention of criticalities. When the applicant uses shielding, the applicant may use preventive measures of lower reliability. That is, shielded criticality events need not be highly unlikely.

(2) Likelihood: The applicant's likelihoods demonstrate compliance with proposed 10 CFR 70.61 if:

(a) The applicant provides an evaluation of the likelihood of each type of accident sequence in the ISA Summary;

(b) The applicant provides information that allows the staff to assess whether the applicant correctly assigned likelihoods as shown in the tabular method in Appendix A to this SRP. The applicant's information includes intermediate data such as whether an IROFS is active or passive, the degree of redundancy, information on independence, and methods and time intervals for surveillance of IROFS to limit the duration that they may be in a failed state. Much of the applicant's information relevant to likelihood of failure of individual IROFS is provided in the descriptive list of IROFS, a required item in the ISA Summary (see Section 5.4.3.2(B)(vi)). However, the applicant should show redundancy and independence among multiple IROFS used for a single type of accident through a method such as fault trees or the tabular format of Appendix A to this SRP.

(c) The applicant evaluated likelihoods in accordance with the regulatory acceptance criteria for ISA methods (see Section 5.4.3.2(B)(v));

(d) The applicant's evaluated likelihoods comply with acceptable definitions of the terms "unlikely" and "highly unlikely" for use with proposed §70.61 as evaluated in Section 5.4.3.2(B)(ix) of this SRP;

(e) The applicant evaluated unshielded nuclear criticality accident sequences with a likelihood of "highly unlikely" and, in general, possesses double contingency protection; and

(f) The applicant evaluated shielded nuclear criticality accident sequences, regardless of estimated radiation doses, as not substantially less unlikely than "highly unlikely," but may not possess double contingency protection.

v. ISA Team Qualifications and ISA Methods

a. ISA Team Qualifications: The applicant's ISA teams and team qualifications, as stated in the ISA Summary, include:

(1) 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, although the team leader need not be the cognizant engineer or expert for that process, the team leader can demonstrate an adequate understanding of all process operations and hazards under evaluation.

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

(3) 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.

(4) A manager provides overall administrative and technical direction for the ISA.

b. ISA Methods: The applicant's descriptive summary of the ISA methods describes the methods used for each ISA task (e.g., see Section 5.3.2(A)(iii)), and the applicant's basis for selecting each method, so that the adequacy of the method is clear and appropriate according to the criteria described in this SRP and NUREG-1513. Or, if in any case, the applicant selects an alternative method, the applicant justifies the proper selection of that method in the ISA programmatic commitments (see Section 5.4.3.2(A)) and meets any additional regulatory acceptance criteria specified in Items (1)-(4). Specific acceptance criteria for the ISA methods for each task are:

(1) Hazard Identification Method: The applicant's hazard identification method leads to a hazard identification that satisfies the regulatory acceptance criteria specified in Section 5.4.3.2(B)(iv)(a).

(2) PHA Method: To perform the PHA, the applicant selects one of the individual methods described in NUREG-1513 in accordance with the selection criteria of that document. The applicant may use individual PHA methods not described in NUREG-1513, provided that:

(a) The applicant uses criteria for an individual PHA process that are consistent with the principles of the PHA selection criteria in NUREG-1513;

(b) The applicant's PHA method adequately addresses all the hazards identified in the hazard identification task. The method justifies any hazards eliminated from further consideration.

(c) The applicant's PHA method provides reasonable assurance that the applicant identifies all significant accident sequences (including the IROFS used to prevent or mitigate the accidents) that could result in the consequences identified in proposed §70.61[1].

(d) The applicant's PHA method accounts for 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 proposed §70.61 and appropriately limited.

(e) The applicant's PHA method addresses all modes of operation including startup, normal operation, shutdown, and maintenance.

[1]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.

(f) The applicant's PHA method addresses hazards resulting from process deviations (e.g., high temperature, high pressure), initiating events internal to the facility (e.g., fires or explosions), and credible hazardous external events (e.g., floods, high winds, and earthquakes, airplane crashes). The applicant provides justification for the determination that certain events are incredible and, therefore, not subject to analysis in the ISA.

(g) The applicant's PHA method considers initiation of, or contribution to, accident sequences by human error through the use of human-systems interface analysis or other appropriate methods.

(h) The applicant's PHA method considers common mode failures and system interactions in evaluating systems that are to be protected by double contingency.

(i) The applicant provides justification, in the ISA Summary, that the individual method would effectively accomplish Items (a) through (h) above.

(3) Consequence Analysis Method. The applicant's method for ISA consequence evaluation, as described in the ISA Summary:

(a) Consists of or is consistent with, the approaches described in NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook," March 1998. (NUREG/CR-6410 also provides methods for estimating magnitudes of criticality events.) Or, if the applicant used an alternative method, the applicant described and justified in the alternative in the methods section of the ISA Summary (see Section 5.4.3.2(B)(vi)).

(b) Provides a scientifically correct and reasonable estimate of the consequences; and

(c) Uses reasonably generic assumptions and data for the types of accidents analyzed.

(4) Likelihood Evaluation Method. The applicant's evaluation method for likelihood, as described in the ISA Summary, demonstrates compliance with the graded protection criteria of proposed 10 CFR 70.61 consistent with the guidance in the Appendix A to this SRP. Or, for individual accident sequences not conforming to the guidance in Appendix A, specific and adequate justification showing conformance to proposed 10 CFR 70.61 is provided.

vi. List of IROFS

The primary function of the "list describing all items relied on for safety" is to document the safety basis of all processes in the facility to assist in assuring that these items are not degraded or removed without a justifying safety review. One example of a tabular

description of IROFS meeting these criteria is Table A-7 in Appendix A to this SRP. The applicant's "list describing items relied on for safety" required by proposed 10 CFR 70.62(c)(vi):

a. Includes all IROFS in the identified accident sequences. 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 include both engineered controls and administrative controls. All such items must be listed, no matter how low their safety significance, if they are relied on to demonstrate compliance with the safety performance requirements of proposed §70.61. Such items may assure compliance by making the accident unlikely or by mitigating its consequences.

   For example, if a process upset is required before an accident may occur and in showing compliance with proposed §70.61, the applicant places reliance on the fact that this process upset is an unlikely event, then those features of the process that assure that the upset is of low frequency are IROFS. Similarly, if the dimension or the material composition of a piece of process equipment is essential to preventing an accident, then that dimension or material is an IROFS. In such cases, only those dimensions, features, or properties of the process that are essential to the safety function are IROFS. It is essential that the applicant identify such process features so that a description of their safety function is available to safety staff for change control.

b. A subset of the complete list of all IROFS that identifies the IROFS that are the sole item for preventing or mitigating an accident sequence. The subset includes a descriptive title of the item, provides an unambiguous and clear reference to the process to which the item applies, and provides a clear and traceable reference to the description of the item as it appears in the list of all IROFS described in Item a.

c. Describes the IROFS, management measures, and the associated safety limits and margins to permit a determination of compliance with proposed 10 CFR 70.62(c)(vi). The applicant describes the essential features of each IROFS, including hardware controls, that are required to achieve adequate reliability. If the IROFS is an administrative control, the applicant describes the nature of the action or prohibition involved sufficiently to permit an understanding that, in principle, adherence to it should be reliable. The description of each IROFS contains any information needed to identify how the management measures, such as maintenance, training, configuration management, etc. of proposed 10 CFR 70.62(d) are applied to it.

d. Provides information concerning the assignment of management measures to engineered and administrative controls in accordance with proposed 10 CFR 70.62(d). If the applicant uses a system of graded management measures, the staff can determine the grade applied to each IROFS from information provided by the applicant. To show compliance with the performance requirements of proposed 10 CFR 70.61, the applicant's description of the IROFS and the

management measures applied to them must show how they meet all applicable provisions of the baseline design criteria (BDC) as described in Chapters 6.0 through 12.0 and Chapter 15.0, or a lesser set of measures if justified. If applicable, the applicant's primary justification for lesser management measures is lower risk significance.

The applicant's management measures include a description of the facility procedures for conducting and maintaining the ISA that includes: management policies; organizational responsibilities; administrative controls; and procedures governing the performance, review, and approval of the initial ISA and any revisions to the ISA. The applicant commits to evaluating the need for updating the ISA to reflect changes using a team with qualifications appropriate for the process in its changed configuration. In addition, the applicant commits to maintain the ISA under an adequate configuration management function. The applicant also identifies updates to the list describing the IROFS. The applicant describes facility procedures for reviewing process changes and new safety information to determine if prior NRC approval is required in accordance with proposed §70.72. Administrative controls ensure the independence of reviewing organizations and individual reviewers. The applicant establishes procedures to control records and supporting documentation concerning the ISA.

vii. Quantitative Standards for Chemical Consequences

The applicant's proposed quantitative standards to assess consequences from acute chemical exposure to licensed material or chemicals produced from licensed material includes:

a. Three unambiguous quantitative standards for each of the applicable hazardous chemicals on site corresponding to each of proposed: (1) §70.61(b)(4)(i), (2) §70.61(b)(4)(ii) and §70.61(c)(4)(i), and (3) §70.61(c)(4)(ii).

b. The quantitative standard for proposed §70.61(b)(4)(i) correctly categorizes as such, all exposures that could endanger the life of a worker. The applicant is appropriately conservative in applying the language "could endanger," which means death, although not the average result, could occur in a reasonable number of cases.

c. The quantitative standard for proposed §70.61(b)(4)(ii) and §70.61(c)(4)(i) correctly categorizes as such all exposures that could lead to irreversible or other serious, long-lasting health effects to individuals. Similar to Item b, the standard should have appropriate conservatism.

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

The staff finds the use of the Emergency Response Planning Guidelines (ERPG) and Accute Exposure Guideline Level (AEGL) series of standards to be acceptable sets that meet the performance criteria of proposed §70.61. When the applicant chooses to select ERPG or AEGL values, a reference to this fact is sufficient. However, if such standards are not available for all of the applicant's chemicals or if the applicant opts to select another standard, the ISA Summary lists the actual values the applicant selected for each chemical and provides information or a reference justifying that the selected standards meet Items a-c.

viii. Definitions of Likelihood

Proposed §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 taken together with the description in the ISA Summary of the applicant's method of assessing likelihoods, they provide reasonable assurance that the requirements of proposed §70.61 can be met. These likelihood, or frequency, definitions are needed because they are used in specifying the performance requirements of proposed §70.61 for each accident. Proposed §70.61 does not explicitly require the applicant to use quantitative definitions for these terms. However, in order to provide a basis for consistency, this section provides quantitative guidelines for the staff to interpret the applicant's definitions. An applicant may provided quantitative definitions, and these are acceptable if consistent with the quantitative guidelines in this section. If the applicant's definitions are qualitative, they are acceptable to the extent that they are (a) reasonably clear and objective and (b) reasonably consistent with the quantitative guidelines in this section.

Proposed §70.61 requires that accidents of a given level of consequences have a corresponding likelihood. Thus the meaning of the likelihood terms are on a "per accident" basis. To be acceptable, the applicant's definitions must be on a per accident basis.

The quantitative likelihoods are derived from Commission strategic safety performance goals. Hence, acceptable guidelines for quantitative frequencies for each level of likelihood depends on how many potential accidents there are in each of the two consequence categories. The number of accidents will not be known until ISA results are available for the industry. For this reason, the quantitative guidelines are expressed in terms of this, currently unknown, total number of accidents.

It should be noted that the quantitative likelihood definitions are maximum acceptable limits. That is, definitions based on lower limits are also acceptable.

The quantitative consequence categories defined in proposed §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 proposed

§70.61. In deriving the quantitative likelihood guidelines below, the typical high consequence accident is assumed to be equivalent to a nuclear criticality, in which a few workers would receive doses exceeding 100 rem, some of them possibly fatal. Thus for accidents producing “high consequences” similar to a typical criticality, the quantitative guideline for “highly unlikely” given below is appropriate. But, if an accident would produce much larger consequences, the quantitative definition of “highly unlikely” must be appropriately lower to be acceptable.

The term “credible” is used in proposed 10 CFR 70.61 in the following context: “The risk of each credible high consequence event shall be limited ... through the application of ...controls ...”. Thus credible is a criterion for exemption from use of controls; controls mean IROFS. This implies that the reason that an event would not be credible must not depend on IROFS, but on external or natural phenomena or some feature of the facility that can be relied on without being in the facility change control system. In general, events which are not credible are either physically impossible, require very low likelihood external initiators, involve a long series of very unlikely events, or involve an extremely improbable series of human actions for which no motivation exists. Actions deliberately intended to cause accidents are also ignored; however, actions such as nuclear sabotage should be considered separately as part of the evaluation for physical protection (see Section 13.1).

The term credible is used in the rule in a way that implies that events that are not credible can be ignored. The guideline given is that a credible accident is one with a frequency greater than 10^{-6} per year. The rationale behind use of the term credible in the rule is that there may be events that have about the same maximal consequences as the typical high consequence event, but are of much lower likelihood. Such events can be ignored if their cumulative risk is negligible compared to the risk from the more typical events assessed. However, there is a potential for misinterpretation by the applicant. Such events must be incredible for reasons that are extremely unlikely to be changed. An accident cannot be incredible because of a feature of the plant that might be changed, because the feature could be changed so that the event is no longer unlikely. Thus any plant feature that makes events “incredible," or is otherwise needed to meet proposed §70.61, is an IROFS, and must be declared as such.

Subject to this guidance, the applicant’s definitions of the terms likely, unlikely, highly unlikely, and credible as applied to each accident sequence in the ISA show compliance with proposed 10 CFR 70.61 if they are reasonably consistent with the following quantitative guidelines on a per accident basis:

(1) Unlikely: Less than 0.04/Ni per year;
(2) Highly unlikely: Less than 10^{-2}/Nh per year; and
(3) Credible: Greater than 10^{-6} per year.

where:

Ni = the total number of potential intermediate consequence accidents in regulated facilities. Staff currently expects that Ni will be less than 100.

Nh = the total number of potential high consequence accidents in regulated facilities. Staff currently expects that Nh will be on the order of 1000.

If the applicant provides qualitative definitions of the terms in Items (1)-(3), the definitions are acceptable if: (a) they are used within a consistent, systematic, and reasonably objective method for evaluating each accident sequence and (b) they are reasonably consistent with the above quantitative values.

5.5 REVIEW PROCEDURES

5.5.1 Acceptance Review

The primary reviewer should perform an acceptance review to determine if the application for construction approval or the license application adequately addresses the items in Section 5.1.3, "Areas of Review."

Guidance specific to the application for construction approval and the license application is provided below.

A. Application for Construction Approval

Specifically, the application for construction approval should addresses the items in Section 5.3.1.

B. License Application

Specifically, the license application should address Section 5.3.2.

If the primary reviewer verifies that the subject area material is adequately addressed in the application for construction approval or the license application, the primary reviewer should accept the application for the safety evaluation in Section 5.5.2. If the primary reviewer identifies significant deficiencies in the material provided, the primary reviewer should request that the applicant submit additional information prior to the start of the safety evaluation.

5.5.2 Safety Evaluation

After determining that the application is acceptable for review in accordance with either Section 5.5.1(A) (application for construction approval) or Section 5.5.1(B) (license application), the primary reviewer should perform a safety evaluation against the acceptance criteria described

in Section 5.4. On the basis of its review, the staff may request that the applicant provide additional information or modify the application to meet the acceptance criteria in SRP Section 5.4.

Guidance specific to the application for construction approval and the license application is provided below.

A. Application for Construction Approval

The primary reviewer should review the design basis and the safety assessment of the design basis. The primary reviewer should coordinate with the secondary reviewers to ensure consistency between the review conducted under this chapter and reviews of the design basis and safety assessment of the design basis conducted for other subject areas, e.g., Chapters 6.0-15.0.

B. License Application

i. The primary reviewer should review the ISA programmatic commitments, as described in the license application, and the ISA results, as described in the ISA Summary. The primary reviewer should coordinate with the secondary reviewers to ensure consistency between the review conducted under this chapter and the review conducted under other chapters. For example, the primary reviewer of the ISA Summary should coordinate with the primary reviewer of nuclear criticality safety to ensure that NCS is consistent throughout the license application.

ii. The primary reviewer should evaluate the risk significance of the accident sequences using the risk indices from in Appendix A, which provides an example for evaluating risk significance. For accident sequences categorized as lower risk significance, the primary reviewer selects a representative sample of sequences for specific evaluation, while the remainder receive a less detailed review.

iii. The primary reviewer should coordinate with the secondary reviewer that is reviewing Chapter 15.0, “Management Measures,” to ensure that the management practices proposed by the applicant are consistent with the material submitted in support of Chapter 15.0.

When the safety evaluation is complete, the primary reviewer, with assistance from the other reviewers, should prepare the input for the Safety Evaluation Report (SER), as described in Section 5.6 using the acceptance criteria from Section 5.4. The secondary reviewers should coordinate the input with the balance of the reviews and the SER.

5.6 EVALUATION FINDINGS

The primary reviewer should document the safety evaluation by preparing material suitable for inclusion in the SER. The primary reviewer should describe the review, explain the basis for the findings, and state the conclusions.

The staff could document the safety evaluation for the application for construction approval as follows:

> *The staff reviewed the application for construction approval for [insert facility name] to possess and use SNM according to Chapter 5.0 of NUREG-1718. The staff evaluated [insert a summary statement of what was evaluated] and found [insert a summary statement of the findings]. The staff found that the applicant's safety assessment of the design basis demonstrates that the applicant's principle structures, systems, and components will provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents. The staff concluded that the applicant's safety assessment of the design basis show that it meets the requirements for issuing a construction approval in accordance with 10 CFR Part 70.*

The staff could document the safety evaluation for the license application as follows:

> *The staff reviewed the ISA programmatic commitments in the license application and ISA Summary for [insert facility name] to possess and use SNM according to Section 5.0 of NUREG-1718. The staff evaluated [insert a summary statement of what was evaluated] and found [insert a summary statement of the findings]. The staff verified that the applicant performed an Integrated Safety Analysis (ISA) to identify and evaluate the hazards and potential accidents associated with the facility, and to establish engineered and administrative controls to ensure facility operation will be within the bounds of the ISA.*
>
> *The staff confirmed that the applicant's license applications contains appropriate commitments, including commitments to: (1) compile and maintain process safety information; (2) engage personnel with appropriate training to conduct the ISA; (3)use appropriate methods to conduct the ISA; and (4) implement appropriate measures and procedures to ensure that the ISA stays accurate and up-to-date.*
>
> *The staff confirmed that the applicant's ISA Summary (1) identified all hazards at the facility; (2) analyzed for accident sequences through the use of process hazards analysis; (3) evaluated and assigned consequences to the accident sequences; and (4) evaluated the likelihood of each accident consistent with the guidance in NUREG-1718. Moreover, the applicant identified all items relied on for safety, including administrative and engineered controls. As a result, the NRC staff concluded that the applicant's postulated accidents resulting from the facility hazards that may be anticipated to occur (or are considered unlikely or highly unlikely) should be in compliance with the performance requirements of 10 CFR Part 70.*

The staff concludes that (1) the identification and evaluation of the hazards and accidents as part of the ISA and (2) the establishment of controls to maintain safe facility operation from their consequences meet the requirements for a license to possess and use SNM under 10 CFR Part 70, and provide reasonable assurance that the health and safety of the public, the workers, and the environment will be adequately protected.

5.7 REFERENCES

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

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

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

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

E. NUREG-1513, *Integrated Safety Analysis Guidance Document*, 1995.

F. U.S. Dept. of Commerce, Bureau of the Census, Statistical Abstract of the United States 1995, Table No. 688.