3.0 INTEGRATED SAFETY ANALYSIS (ISA) AND ISA SUMMARY

3.1 PURPOSE OF REVIEW

An ~~I~~integrated ~~S~~safety ~~A~~analysis (ISA) identifies potential accident sequences in the facility's operations, designates items relied on for safety (IROFS) to either prevent such accidents or mitigate their consequences to an acceptable level, and describes management measures to provide reasonable assurance of the availability and reliability of IROFS. Applicants for new licenses and persons holding 10 CFR Part 70 licenses on September 18, 2000, must perform an ISA and submit a summary of it (referred to as an "ISA ~~S~~summary") to the NRC, for approval. The ISA ~~S~~summary principally differs from the ISA by focusing on higher risk accident sequences ~~whose~~of which the consequences could exceed the performance criteria of 10 CFR 70.61. The ISA summary is a synopsis of the results of the ISA and contains information specified in 10 CFR 70.65(b).

The ISA and supporting ISA documentation (such as piping and instrumentation diagrams, criticality safety analyses, dose calculations, process safety information, and ISA worksheets) are maintained at the facility. The NRC determines the acceptability of the applicant's ISA. ~~The NRC does this~~ by reviewing a portion of the ISA documentation and any supporting documentation maintained onsite and by reviewing and approving the applicant's ISA ~~S~~summary which, although not part of the license application, is placed on the public docket. Neither the ISA~~,~~ nor the ISA ~~S~~summary~~,~~ is incorporated as part of the license.

Reviewers must confirm that an ISA ~~S~~summary meets the regulatory requirements of 10 CFR 70.65 and, specifically, that suitable IROFS and management measures have been designated for higher-risk accident sequences and that programmatic commitments to maintain the ISA and ISA ~~S~~summary are acceptable. An applicant may submit, for NRC approval, one ISA ~~S~~summary for the entire facility, or multiple ISA ~~S~~summaries for individual processes (or groups of processes) in the facility as they are completed. Reviews of ISA ~~S~~summaries may necessitate examination of the ISA and its supporting documentation to confirm the underpinnings of calculations, conclusions, and components of safety programs.

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

(1) ~~C~~commitments regarding the applicant's ~~S~~safety ~~P~~program including the ISA, pursuant to the requirements of 10 CFR 70.62~~, and~~

(2) ISA ~~S~~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), applicants would submit both types of information ~~would be submitted~~. In the case of a license amendment, an applicant may submit either or both types of information ~~may be submitted~~, as needed, to address the areas amended.

3.1.1 Safety Program and ISA Commitments

The purpose ~~for~~of the review of commitments relati~~ve~~ed to the ~~S~~safety ~~P~~program, including the ISA, as presented in the license application, renewal, or amendment, is to determine with reasonable assurance that the applicant will accomplish the requirements of 10 CFR~~:~~ 70.61; 70.62(a)(1), (2)~~,~~ and (3); 70.62(c)(1)~~,~~ and (2); 70.62(d); 70.64 for new facilities; and 70.72 for changes requiring updates of the~~ir~~ ISA.

3.1.2 ISA Summary

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

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

(2~~.~~) Identifi~~ed~~y and evaluate~~d~~, in the ISA, all credible events (accident sequences) involving process deviations or other events internal to the ~~plant~~facility (e.g., explosions, spills, and fires); and credible external events that could result in facility-induced consequences to workers, the public, ~~worker,~~ or the environment, that could exceed the performance requirements of 10 CFR 70.61. As a minimum, ~~E~~external events normally include~~, as a minimum~~ the following:

~~(1)~~a. ~~N~~natural phenomena events such as floods, high winds, tornadoes, and earthquakes~~;~~
~~(2)~~b. ~~F~~fires external to the facility~~; and~~
~~(3)~~c. ~~T~~transportation accidents and accidents at nearby industrial facilities~~.~~

(3~~.~~) Designate~~d~~ engineered and administrative IROFS, and correctly evaluate~~d~~ the set of IROFS addressing each accident sequence, as providing reasonable assurance, through preventive or mitigative measures, and through application of supporting management measures (discussed in Chapter 11) that the 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
Supporting:	Fuel ~~F~~facility ~~I~~inspectors~~ion Staff~~

3.3 AREAS OF REVIEW

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

The ~~S~~safety ~~P~~program and ISA commitments and descriptions to be reviewed consist of~~:~~ (1) process safety information [10 CFR 70.62(b)]~~;~~, (2) methods used to perform the ISA ~~;~~, (3) qualifications of the team performing the ISA [10 CFR 70.62(c)(2)]~~;~~, (4) methods of documenting and implementing the results of the ISA ~~;~~, (5) procedures to maintain the ISA current when changes are made to the facility ~~;~~, and (6) management measures [10 CFR 70.62(d)]. These commitments and descriptions, as appropriate, will primarily be documented ~~primarily~~ within an ISA chapter, in the license application. However, commitments and descriptions regarding management measures will be in a separate chapter of an application, pursuant to Chapter 11 of this SRP.

The results of ISA analyses performed for compliance with Subpart H of 10 CFR Part 70 are presented in an ISA ~~S~~summary. This ISA ~~S~~summary may be submitted with an application for a new license, a license renewal, or a license amendment, but is not to be incorporated as part of the license.

The ISA ~~S~~summary submitted to the NRC, and portions of the ISA and ISA documentation ~~and any supporting documentation~~ maintained on~~-~~site, will be reviewed to determine the adequacy of the applicant's ISA. The contents of the ISA ~~S~~summary are specified in 10 CFR 70.65 and include the following nine topics:

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

The ISA (referred to here as the standalone document that presents the results of the ISA) ~~documentation~~ and supporting ISA documentation (e.g., piping and instrumentation drawings, engineered IROFS boundary descriptions, criticality safety analyses, dose calculations, process hazards analysis, process safety information, ISA worksheets, etc.) will be maintained at the facility site. The reviewer(s) may need to consult the ISA ~~documentation~~ and ~~its~~ supporting documentation at the facility site to establish the completeness and acceptability of the ISA~~,~~ or, in the case of an existing facility, to visit the site to fully understand a process operation. For example, the reviewer(s) should confirm that low-risk accident sequences that were not reported in the ISA ~~S~~summary were correctly identified and analyzed in the ISA.

3.3.1 Safety Program and ISA Commitments

The ~~staff~~NRC reviews the application to determine whether the applicant's commitments to establish a safety program and to perform and maintain an ISA are adequate. In the following, the phrase "process node" or "process" is 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 ISA commitments 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") for those individuals who will conduct and maintain the ISA and ISA Ssummary.

(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). The review of the ISA method(s) includes evaluating the applicant's methods in the following specific areas:

a. Hhazard identification;
b. Pprocess hazard analysis (accident identification);
c. Aaccident sequence construction and evaluation;
d. Cconsequence determination and comparability to 10 CFR 70.61; and
e. Llikelihood categorization for determination ofing 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 following applicant's procedures for:

(1)a. performance of, and updates to, the ISA;
(2)b. review responsibility;
(3)c. ISA documentation;
(4)d. reporting of ISA Ssummary changes per 10 CFR 70.72(d)(1) and (3); and
(5)e. maintenance of ISA records per 10 CFR 70.62(a)(2).

3.3.2 ISA Summary and ISA Documentation

The staffNRC reviews the ISA Ssummary and, if necessary, other the ISA documentation and any supporting ISA documentation to finddetermine whether there is 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 NRC confirms that 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 that exceeds the exposure limits stated in 10 CFR 70.61, are "highly unlikely" or "unlikely," as appropriate. In addition, the staffNRC reviews accidents involving hazardous chemicals produced from licensed 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, accident sequences having unmitigated consequences that will not exceed the performance requirements of 10 CFR 70.61(c), once identified as such, do not require reporting in the ISA ~~S~~summary.

The areas of review for the ISA ~~S~~summary are as follows:

(1~~.~~) S~~ITE~~ite: The site description in the ISA ~~S~~summary (see Section 1.3, "Site Description") focus~~ing~~es on those factors that could affect safety, such as geography, meteorology (e.g., high winds and flood potential), seismology, demography, and nearby industrial facilities and transportation routes.

(2~~.~~) F~~ACILITY~~acility: The facility description in the ISA ~~S~~summary focus~~ing~~es on features that could affect potential accidents and their consequences. Examples of these features are facility location, facility design information, and the location and arrangement of buildings on the facility site.

(3~~.~~) P~~ROCESSES~~rocesses, Hazards and Accident Sequences: The process description in the ISA ~~S~~summary ~~of~~addresses each process that was analyzed as part of the ISA. Specific areas reviewed include basic process function and theory, functions of major components and their operation, process design and equipment, and process operating ranges and limits. ~~Also to be provided is~~This description must also include a list of the hazards (and interactions of hazards) for each process and the accident sequences that could result from such hazards and ~~whose~~for which unmitigated consequences could exceed the performance requirements of 10 CFR 70.61.

(4~~.~~) D~~EMONSTRATION~~emonstration ~~OF~~of C~~OMPLIANCE WITH~~ompliance with 10 CFR 70.61: For each applicable process, this section presents t~~T~~he following information developed in the ISA that demonstrates compliance with the performance criteria of 10 CFR 70.61~~. This information includes for each applicable process~~:

a~~)~~. ~~The~~ postulated consequences and comparison to the consequence levels identified in 10 CFR 70.61~~. I~~, as well as such information, such as inventory and release path factors~~,~~ supporting the results of the consequence evaluation ~~should be provided.~~

b~~)~~. ~~I~~information showing how the applicant established the likelihoods of accident sequences that could exceed the performance requirements of 10 CFR 70.61 ~~were established.~~

c~~)~~. ~~I~~information describing how designated IROFS protect against accident sequences that could exceed the performance requirements of 10 CFR 70.61~~.~~

d~~)~~. ~~I~~information on management measures applied to the IROFS (addressed in greater detail in Chapter 11)

e~~)~~. ~~I~~information on how the criticality monitoring requirements of 10 CFR 70.24 are met~~,~~ ~~and~~

f~~)~~. ~~I~~if applicable, how the baseline design criteria of 10 CFR 70.64 are addressed~~.~~

(5.) TEAMeam QUALIFICATIONS ANDualifications and ISA METHODSethods: TheThis section should discuss the applicant's ISA Tteam qualifications and ISA methods, as described in the ISA Ssummary. (If methods are adequately described in the license application, there will be no need to duplicate this information in the ISA Ssummary. Documentation of sSpecific examples of the application of ISA methods should be included in the ISA Ssummary will enhance the reviewer's understanding of specific methodsto enable the reviewer(s) to understand their selection and use.)

(6.) LIST OFist of IROFS: TheThis list, in the ISA Summary, describinges the IROFS for all intermediate- and high-consequence accidents in sufficient detail to understand their safety function(s).

(7.) CHEMICALhemical CONSEQUENCEonsequence STANDARDStandards: TheThis discussion identifies the applicant's quantitative standards for assessing the chemical consequence levels specified in 10 CFR 70.61, as described in the ISA Ssummary.

(8.) LIST OFist of SOLEole IROFS: TheThis list, in the ISA Ssummary, identifyingies those IROFS that are the sole item preventing or mitigating an accident whosefor which the consequences could exceed the performance requirements of 10 CFR 70.61.

(9.) DEFINITIONS OFefinitions of "UNLIKELYnlikely", "HIGHLYighly UNLIKELYnlikely" ANDand "CREDIBLEredible": The applicant's definitions ofmust define the terms "unlikely," "highly unlikely," and "credible," as used in the ISA Ssummary.

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

In some simple cases, the information normally contained in the ISA Ssummary process descriptions and list of IROFS might be sufficient to enable the reviewer(s) to understand how compliance is achieved when taken together with the description of ISA likelihood evaluation methods and criteria. However, in general, a description of how the licensee'sapplicant's ISA team evaluated credible accident likelihood to be "highly unlikely" or "unlikely" needs to be supplied.

The reviewer(s) should evaluate the efficacy of the licensee'sapplicant's ISA methods. To do this, in addition to reviewing the description of the ISA methods, the reviewer(s) will need to understand how these methods have been applied in practice to the wide diversity of process safety designs in the facility. Examples included in the ISA Ssummary of how the methods are applied to a representative sample of processes should allow the reviewer(s) to understand the applicant's ISA method(s). In addition, a thorough understanding of the applicant's ISA

method(s) will enable the reviewer(s) to better select other processes for which additional "vertical slice" reviews may need to be performed on-site. The method for selecting specific processes or accidents for additional on-site reviews is described in Section 3.5 of this chapter, "Review Procedures."

For an average-sized fuel fabrication facility, inclusion in the ISA Ssummary should include of a detailed demonstration of the application of the ISA methods to three or four nuclear criticality accident sequences, one fire accident sequence, and one environmental/radiological/chemical accident sequence, may be sufficient. The number and selection of example accident sequences for which a demonstration of the ISA method(s) should be included in the ISA Ssummary will depend on the (1) size and number of processes at the facility, (2) number of accident sequences for which the consequences could exceed the 10 CFR 70.61 performance requirements, and on the (3) diversity of process designs, and (4) types and numbers of designated IROFS.

The NRC review of the licensee'sapplicant's example accident sequence evaluations included in the ISA Ssummary is not a substitute for the "vertical slice" and "horizontal" reviews based on fully that should be performed using detailed information at the site. This on-site evaluation of ISA documentation and processes must be NRC-selected in order to be a confirmation of the fact that the ISA was actually implemented performed as described in the ISA Ssummary.

3.4 ACCEPTANCE CRITERIA

3.4.1 Regulatory Requirements

10 CFR 70.62 specifies tThe requirement to establish and maintain a safety program, including performance of an ISA, is specified in 10 CFR 70.62. 10 CFR 70.62(c) specifies requirements for conducting an ISA including a demonstration that credible high-consequence and intermediate-consequence events meet the safety performance requirements of 10 CFR 70.61. The requirement to prepare and submit an ISA Ssummary for NRC approval is stated in 10 CFR 70.65(b). 10 CFR 70.65(b) also describes the contents of an ISA Ssummary. 10 CFR 70.72 sets forth requirements for keeping the ISA, ISA documentation and the ISA Ssummary current when changes are made to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel.

The information to be included in the ISA Ssummary can be divided into four categories: including (i1) site and facility characteristics;, (ii2) ISA method(s);, (iii3) hazards and accident analysis; and (iv4) IROFS. The following table summarizes the information requirements of each category, the corresponding regulatory citation, and the section of NUREG-1520, Chapter 3, in which the expectations for such information are described, are presented below.

Information Requirements for the ISA Summary and

Information Category and Requirement	10 CFR Part 70 Regulatory Citation	NUREG-1520, Chapter 3 Section Reference
Site and Facility Characteristics:		
•Site description	70.65(b)(1)	3.4.3.2(1)
•Facility description	70.65(b)(2)	3.4.3.2(2)
•Criticality monitoring and alarms	70.65(b)(4)	3.4.3.2(34C)

•Compliance with baseline design criteria	70.64 (if applicable)	3.4.3.2(~~3~~4D)
***ISA Method(s)*:**		
•ISA method(s) description	70.65(b)(5)	3.4.3.2(5)
•ISA team description	70.65(b)(5)	3.4.3.2(5)
•Quantitative standards for acute chemical exposures	70.65(b)(7)	3.4.3.2(7)
•Definition of "unlikely," "highly unlikely," and ~~in~~"credible"	70.65(b)(9)	3.4.3.2(9)
***Hazards and Accident Analysis*:**		
•Description of processes analyzed	70.65(b)(3)	3.4.3.2(3)
•Identification of hazards	70.65(b)(3)	3.4.3.2(3)
•Description of accident sequences	70.65(b)(3)	3.4.3.2(3)
•Characterization of high- and intermediate-consequence accident sequences	70.65(b)(3)	3.4.3.2(3)
***Items Relied on For Safety*:**		
•List and description of items relied on for safety (IROFS)	70.65(b)(6)	3.4.3.2(6)
•Description of IROFS' link to accident sequences to show 10 CFR 70.61 compliance	70.65(b)(6)	3.4.3.2(4) and (6)
•IROFS management measures	70.65(b)(4)	3.4.3.2(4B) and (6)
•List of sole IROFS	70.65(b)(8)	3.4.3.2(8)

3.4.2 Regulatory Guidance

Guidance applicable to performing an ISA and documenting the results is contained in NUREG-1513, "Integrated Safety Analysis Guidance Document," May 2001." 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~~contingent on meeting the relevant requirements of 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 the performance requirements of 10 CFR 70.61. Some of the acceptance criteria address the programmatic commitments made by the ~~licensee~~applicant to perform and maintain an ISA. The remainder of the criteria address the ISA results, as documented in the ISA ~~S~~summary, and whether those documented results demonstrate that the applicant's IROFS and management measures can reasonably be expected to ~~as~~ensure that the relevant accident sequences will meet the performance requirements of 10 CFR 70.61.

3.4.3.1 Safety Program and ISA Commitments

This section discusses the a~~A~~cceptance criteria for license commitments pertaining to the facility's ~~S~~safety ~~P~~program, including the performance of an ISA~~, are presented in this Section 3.4.3.1~~. 10 CFR Part 70 contains a number of specific safety program requirements related to the ISA. Acceptance criteria for ~~those requirements addressed by~~ the contents~~s~~ of the ISA

~~S~~summary appear in 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. For each component of the ~~S~~safety ~~P~~program, there may be several necessary elements, including~~, for example,~~ organization, assignment of responsibilities, management policies, required activities, written procedures for activities, use of industry consensus standards, and technical safety practices, among others.

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

~~A.~~(1) Process Safety Information

~~1~~a. The applicant commits to compile and maintain an up-to-date database of process-safety information. Written process-safety information will be used in updating the ISA and in identifying and understanding the hazards associated with the processes. The compilation of written process-safety information shall include information pertaining to:

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

ii. 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, and concentration)~~;~~, and evaluation of the health and safety consequences of process deviations.

iii. Equipment used in the process~~. I~~ should include general 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~~;~~, IROFS (e.g., interlocks, detection, or suppression systems)~~;~~, electrical classification~~;~~, and relief system design and design basis~~ should be provided~~.

~~2~~b. The applicant includes procedures and criteria for changing the ISA, along with ~~it's~~a commitment to design and implement a facility change mechanism that meets the requirements of 10 CFR 70.72. The applicant should discuss the evaluation of the change within the ISA framework, ~~and~~as well as procedures and responsibilities for updating the facility's ISA.

~~3~~c. The applicant commits to engage personnel with appropriate experience and expertise in engineering and process operations to maintain the ISA. The ISA team for a process shall consist of individuals who are knowledgeable in the facility's ISA method(s) and ~~in~~ the operation, hazards, and safety design criteria of the particular process.

~~B.~~(2) ISA

a. The applicant commits to conduct an ISA of appropriate complexity for each process,

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

b. The applicant commits to maintain the ISA and ~~ISA~~ supporting documentation so that it is accurate and up-to-date by means of a suitable configuration management system and to submit changes ~~in~~to the ISA ~~S~~summary, to the NRC, in accordance with 10 CFR 70.72(d)(1) and (3). The ISA must account for any changes made to the facility or its processes (e.g., changes to the site, operating procedures, or control systems). Management policies, organizational responsibilities, revision time frame, and procedures to perform and approve revisions to the ISA should be outlined succinctly. The applicant commits to evaluat~~ing~~e 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 method(s). For any revisions to the ISA, the applicant commits to use ~~using an ISA Team with member~~ personnel having qualifications similar to those ~~used in conducting~~of ISA team members who conducted the original ISA.

c. The applicant commits to train personnel in the facility's ISA method(s) and/or to use suitably qualified personnel ~~for updating and maintaining~~to update and maintain the ISA and ISA ~~S~~summary.

d. The applicant commits to evaluate proposed changes to the facility or its operations by means of the ISA method(s) and to designate new or additional IROFS and appropriate management measures as required. The ~~licensee~~applicant also agrees to promptly evaluate the adequacy of existing IROFS and associated management measures and to mak~~ing~~e any required changes that may be impacted by changes to the facility and/or its processes. 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 consequences and/or likelihood of a previously analyzed accident sequence within the context of 10 CFR 70.61, the applicant commits to promptly evaluate the adequacy of existing IROFS and associated management measures and to mak~~ing~~e necessary changes, if required.

~~5.~~e. The applicant commits to address any unacceptable performance deficiencies that are identified through updates ~~of~~to the ISA.

~~6.~~f. The applicant commits to maintain written procedures on site ~~for carrying out that function, if necessary~~.

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

In citing industry consensus standards, the applicant should delineate specific commitments in the standards ~~which~~that will be adopted. The applicant should provide justifications if a

standard is not adopted in its entirety.

~~C.~~(3) Management Measures

~~1~~a. The applicant commits to establish management measures (which are evaluated using SRP Chapter 11) ~~which~~that comprise the principal mechanism by which the reliability and availability of each IROFS is ~~as~~ensured.

3.4.3.2 ISA Summary and ISA Documentation

Information in the ISA ~~S~~summary should provide the basis for the reviewer(s)~~'~~ to conclude that there is reasonable assurance that the identified IROFS will satisfy the performance requirements of 10 CFR 70.61. To do this, the reviewer must conclude that the applicant's ISA program has the capability to identify appropriate IROFS, and that IROFS identified in the ISA ~~S~~summary are adequate to control the potential accidents of concern at the facility. The accidents of concern are those ~~whose~~for which the 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 so that the performance requirements of 10 CFR 70.61 can be met. To support such a review, sufficient information about an accident sequence and the proposed IROFS must be included in the ISA ~~S~~summary to allow the reviewer(s) to assess their contributions to prevention or mitigation. The ISA ~~S~~summary must contain enough information concerning the ISA ~~procedures,~~ methods~~,~~ and the qualifications of the ISA team who performed the ISA and any other~~human~~ resources employed to ~~have~~give the reviewer(s) confidence that the potential accidents identified are reasonably complete.

In addition, the reviewer(s) need to determine that appropriate management measures will be in place to ensure the availability and reliability of the identified IROFS, when needed. Review of designated management measures is addressed in ~~SRP~~ Chapter 11 of this SRP.

The following acceptance criteria address each of the content elements of the ISA ~~S~~summary required by 10 CFR 70.65(b). For new facilities, the reviewer(s) should also evaluate those aspects of the design that address baseline design criteria of 10 CFR 70.64 applicable to individual processes. Thus, the following content elements ~~for which there are~~have defined acceptance criteria ~~include~~:

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

Detailed acceptance criteria for each element of the ISA ~~S~~summary follow:

(1~~.~~) S~~ITE~~ite

The description in the ISA ~~S~~ssummary of the site for processing nuclear material is considered acceptable if the applicant includes, or references, the following safety-related information, with emphasis on those factors that could affect safety:

a. A description of the site geography, including its location, taking into account prominent natural and 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~~facility safety and to assess their likelihood of occurrence. At least the 100-year flood should be postulated, consistent with U.S. Army eCorps of Engineers flood plain maps. ~~The applicant also describes the maximum earthquake magnitude, peak ground acceleration, and return period expected at the site, for existing facilities.~~ The applicant also provides earthquake accelerations on the site associated with a 250-year and 500-year earthquake~~ on the nearest capable fault for new facilities and processes, to determine its resulting consequences for the structural integrity of the facility~~. The discussion identifies all design basis natural events for the facility, indicates which events are considered incredible, and describes the basis for that determination. The assessment also indicates which events could occur without adversely impacting safety.

(2~~.~~) F~~ACILITY~~acility

The description of the facility is considered acceptable if the applicant identifies and describes the general features that affect the reliability or availability of IROFS. If such information is available elsewhere in the application, reference to the appropriate sections is considered acceptable. The information provided should adequately support an overall understanding of the facility structure and its general arrangement. As a minimum, the applicant 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. Restricted area and controlled area boundaries.

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

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

(3~~.~~) P~~ROCESSES~~rocesses, H~~AZARDS~~azards, ~~AND~~and A~~CCIDENT~~ccident S~~EQUENCES~~equences

Processes

The description of the processes analyzed as part of the ISA [10 CFR 70.62(c)(1) (i-vi)] is considered acceptable if it describes the following features in sufficient detail to permit an understanding of the theory of operation, and to ~~determine~~assess compliance with the performance requirements of 10 CFR 70.61. A description at a systems level is acceptable, provided that it permits the ~~staff~~NRC reviewer to ~~conduct~~ adequately evaluate~~:~~ (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 high and intermediate consequence accident sequence.

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,~~ ~~i~~If appropriate, it also includes arrangement drawings and process schematics showing the major components and instrumentation, and~~,~~ chemical flow sheets showing compositions of the various process streams.

c. Process design and equipment~~. This information~~ include~~s~~ 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, a~~As appropriate, it includes schematics indicating safety interrelationships of parts of the process. In particular, it is usually necessary for criticality safety to diagram the location and geometry of the fissile and other materials in the process, for both normal and bounding abnormal conditions. This can be done using either schematic drawings or textual descriptions indicating the location and geometry of fissile materials, moderators, etc., sufficient to permit an understanding of how the IROFS limit the mass, geometry, moderation, reflection, etc. If such details are not included in the ISA ~~S~~summary, ~~then~~ the information may be verified as part of an on~~-~~site ISA review.

d. Process operating ranges and limits~~. This information~~ include~~s~~ the operating ranges and limits for measured process variables (e.g.,temperatures, pressures, flows, and compositions) that are controlled by IROFS to ~~as~~ensure safe operations of the process. If such details are not included in the ISA ~~S~~summary, ~~then~~ the information may be verified as part of an on~~-~~site ISA review.

Hazards

The description of process hazards provided in the ISA ~~S~~summary is acceptable if it identifies, for each process, all types of hazards that are relevant to determin~~ing~~e compliance with the performance criteria of 10 CFR 70.61. That is, the acceptance criterion is completeness. All hazards that could result in an accident sequence ~~whose~~in which the consequences could exceed the performance requirements of 10 CFR 70.61 should be listed, even if later analysis of a particular hazard shows that resulting accident sequences do not exceed these ~~minima~~limits. Otherwise the reviewer(s) cannot determine completeness. General exclusion from consideration of certain hazards for an entire facility can be justified by bounding case analyses showing that, for the conditions or credible

inventories on site, the performance requirements of 10 CFR 70.61 cannot be exceeded. In this case, the bounding inventories or conditions, if under the control of the applicant, become IROFS. The list of process hazards is acceptable if the ISA ~~S~~summary provides the following information:

a. ~~A~~a list of materials (radioactive, fissile, flammable, and toxic) or conditions that could result in hazardous situations (e.g., loss of containment of licensed nuclear material)~~.~~ ~~The list~~, includes~~ing the~~ maximum intended inventory amounts and ~~the~~ location(s) of the hazardous materials at the facility~~.~~

b. ~~P~~potential interactions ~~between or~~ among materials or conditions that could result in hazardous situations~~.~~

Accident Sequences

The general description of types of accident sequences in the ISA ~~S~~summary is acceptable if the reviewer can determine the following considerations:

a. ~~That~~The applicant has identified all accidents ~~whose~~for which the consequences could exceed the performance requirements of 10 CFR 70.61 ~~have been identified; and~~.

b. The applicant has identified h~~H~~ow the IROFS listed in the ISA ~~S~~summary protect against each such type of accident.

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

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

One acceptable way to do this is to show a fault tree on which the basic events are IROFS failures ~~of IROFS~~. Another acceptable way is to provide a table on which each row displays the events in an accident sequence, such as in Appendix A, Table A-~~6~~7, where, in general, each event is a failure of an IROFS. Another acceptable way is to provide a narrative summary for each process describing the sequence of events in each type of accident.

To demonstrate completeness, the description of general types of accident sequences must be identified ~~by~~ using systematic methods and consistent references. Therefore, each description of a general type of accident sequence is acceptable if it meets the following criteria:

a. An acceptable method of hazard identification and process hazard analysis was used in accordance with the criteria of NUREG-1513~~;~~.

b. The selected method was correctly applied~~;~~.

c. ~~No~~The applicant did not overlook any accident sequence ~~whose~~for which the consequences could exceed the performance requirements of 10 CFR 70.61 ~~was overlooked; and~~.

d. ~~A~~The applicant used a method of identifying ~~plant~~facility processes ~~was used~~ that ensured identification of all processes.

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

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

a. The initiating events have the same effect on the system~~;~~.

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

(4) I~~NFORMATION~~nformation D~~EMONSTRATING~~emonstrating C~~OMPLIANCE WITH THE~~ompliance with the P~~ERFORMANCE~~erformance R~~EQUIREMENTS OF~~equirements of 10 CFR 70.61, I~~NCLUDING:~~ ncluding ~~(A)~~a. M~~ANAGEMENT~~anagement M~~EASURES;~~easures ~~(B)~~b. R~~EQUIREMENTS OF~~equirements of C~~RITICALITY~~riticality M~~ONITORING; AND (C)~~onitoring, and c. R~~EQUIREMENTS FOR~~equirements for N~~EW~~ew F~~ACILITIES OR~~acilities or N~~EW~~ew P~~ROCESSES AT~~rocesses at E~~XISTING~~xisting F~~ACILITIES~~acilities

~~A~~a. Accident Sequence Evaluation and IROFS Designation

10 CFR 70.65(b)(4) requires that the ISA ~~S~~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 ISA ~~S~~summary should provide sufficient information to demonstrate ~~that~~the following considerations:

~~a~~(i) Credible high-consequence events are highly unlikely~~; and~~.

~~b~~(ii) Credible intermediate-consequence events are unlikely.

The performance requirements of 10 CFR 70.61 have three elements~~:~~, including (a~~1~~) completeness~~;~~, (b~~2~~) consequences~~;~~, and (c~~3~~) likelihood.

Completeness refers to the fact that the ISA must address *each* credible event ~~must be addressed in the ISA~~. Consequences refer~~s~~ to the magnitude of the chemical and radiological doses of the accident and is the basis upon which an accident in classified in 10 CFR 70.61 to be a high or intermediate consequence event. 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 also show the basis for 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, fault trees, or tabular summaries. Appendix A provides one example of how this information could be presented in an application.

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

Completeness

~~Completeness~~ is demonstrated by correctly applying an appropriate ~~method of~~ accident identification method, as described in NUREG-1513, "~~ISA~~Integrated Safety Analysis Guidance Document." Completeness can be effectively displayed by using an appropriate diagram or description of the identified accidents ~~identified~~. Specific acceptance criteria for completeness are covered in item 3 above.

Consequences~~s~~

~~The~~ information in the ISA ~~S~~summary ~~on consequences~~ is acceptable for showing compliance with 10 CFR 70.61 ~~if:~~, provided that the following conditions are met.

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

- 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 ~~S~~summary~~;~~.

- All consequences that could result from the accident sequence have been evaluated. That is, if an accident can result in a range of consequences, ~~then~~ all possibilities must be considered, including the maximum source term and most adverse weather that could occur. However, if such conditions are *unlikely* to occur, credit can be taken for this in the evaluation of likelihood~~; and~~.

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

Unshielded nuclear criticality accidents are considered to be high- consequence events, because the radiation exposure that an individual could receive exceeds the acute 1 Sv (100 rem) dose ofestablished by 10 CFR 70.61(b)(1). For processes with effective engineered shielding, criticalities may actually produce doses below the intermediate consequences of 10 CFR 70.61. As stated in the regulation, primary reliance must be on preventiion ofng inadvertent nuclear criticalities. This applies, notwithstanding shielding or other mitigative features. Therefore, regardless of the actual consequences, shielded criticalities must meet the likelihood criteria 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 the magnitudes of criticality events that can be applied for workers or members of the public at varying distances from the event.

Likelihood

The information addressing likelihood in the ISA Ssummary is acceptable forto showing compliance with 10 CFR 70.61 if, provided the following conditions are met:

- The ISA Ssummary contains a specification ofies the likelihood of each general type of accident sequence that could exceed the performance requirements of 10 CFR 70.61;.
- The likelihoods are derived fromusing an acceptable method described in the ISA Ssummary's methods section; and.
- The likelihoods comply with acceptable definitions of the terms "unlikely" and "highly unlikely," as described 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 ofe the requirement, which is not the intent.

Bb. Management Measures

10 CFR 70.65(b)(4) requires a description of the management measures to be applied to IROFS for each accident sequence whosefor which the consequences could exceed the performance requirements of 10 CFR 70.61. Chapter 11 of this SRP provides detailed criteria against which the adequacy of such management measures can be evaluated.

Cc. Criticality Monitoring

10 CFR 70.24 hasdefines specific sensitivity requirements for criticality monitors. To demonstrate compliance, the application should describe the method for evaluating an acceptable response of at least two detectors to a nuclear criticality at any location where Special Nuclear Material (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. The application should also provide iInformation 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. In addition, the application should provide iInformation 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. Specifically, the application should provide iInformation ~~should be provided~~to demonstrating that the applicant's equipment and procedures ~~of the applicant~~ are adequate to ~~as~~ensure that these requirements are met.

~~D~~d. New Facilities or New Processes at Existing 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 processes, ~~then~~ the ISA ~~S~~summary should explain how each baseline design criterion was addressed in the design of the facility. For deterministic design criteria such as double-contingency, the process-specific information may be provided, along with the other process information in the ISA ~~S~~summary. Design basis events and safety parameter limits should also be given. In addition, the application should provide m~~M~~ethods, data, and results of analysis showing compliance with these design bases ~~should be given~~ for individual processes and facilities.

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

(~~5.~~) ISA T~~EAM QUALIFICATIONS AND ISA METHODS~~eam Qualifications and ISA Methods

The ISA teams [10 CFR 70.62(c)(2)] and their qualifications as stated in the ISA ~~S~~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 method~~ology~~(s) chosen for the hazard and accident evaluations. In addition, the team leader should have an adequate understanding of all process operations and hazards under evaluation, but should not be the responsible, cognizant engineer or expert for that process.

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

The description of the ISA method(s) is acceptable if the following criteria are met:

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

(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 should 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 method is acceptable if it consists ofinvolves selecting one of the individual methods described in NUREG-1513 in accordance with the selection criteria ofestablished in that document. Individual mMethods not described in NUREG-1513 may be acceptable provided that they fulfil the following conditions:

(i) Criteria are provided for their use for an individual process, and thatare 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) ItThe method provides reasonable assurance that the applicant can identify all significant accident sequences (including the IROFS used to prevent or mitigate the accidents) that could exceed the performance requirements of 10 CFR 70.61. [2]

(iv) ItThe method takes into account the interactions of identified hazards and proposed IROFS, including system interactions that could result in an accident sequence whosefor which the consequences could exceed the performance requirements of 10 CFR 70.61.

(v) ItThe method addresses all modes of operation, including startup, normal operation, shutdown, and maintenance.

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

(vii) 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.

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

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

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

(ix) The ISA ~~S~~summary provides justification that the individual method would effectively accomplish conditions ii through viii, above.

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

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

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

d. Likelihood Evaluation Method. The method for evaluati~~on of~~ng the likelihood of accident sequences, as described in the ISA ~~S~~summary, is considered acceptable ~~if~~, provided the following conditions are met:

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

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

(iii) The method has objective criteria for evaluating, at least qualitatively, the likelihood of failure of individual IROFS. When applicable, s~~S~~uch 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 safety grading (if any) of the management measures applied to the IROFS.

(iv) Finally, the method evaluates the likelihood of each accident sequence as unlikely, highly unlikely, or neither, as defined by the applicant, in accordance with ~~subs~~Section 3.4.3.2, Item ~~7~~9, of this chapter.

(v) For nuclear criticality accident sequences, the method evaluates compliance with 10 CFR 70.61(d). That is, even in a facility with engineered features to limit the consequences of nuclear criticalities, *preventive* control(s) must be in place that are sufficient to ~~as~~ensure that the likelihood of criticality is controlled to be "highly unlikely." 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 the failure of any single IROFS ~~failure~~. In addition, potential criticality accidents must meet an approved margin of subcriticality for safety. Acceptance criteria for such margins are reviewed as programmatic commitments, but the ISA methods must consider and the ISA ~~S~~summary must document, the

actual magnitude of those margins when they are part of the reason why the postulated accident sequence resulting in criticality is highly unlikely.

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

(6) D~~ESCRIPTIVE LIST OF ALL~~escriptive List of all IROFS

The "list describing items relied on for safety" required by 10 CFR 70.62(c)(vi) is acceptable ~~if~~, provided the following conditions are met:

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

b. The *description* of the IROFS includes management measures applied to ~~it~~the IROFS (including the safety grading), characteristics of its preventive, mitigative, or other safety function, and assumptions and conditions under which the item is relied on to support compliance with the performance requirements of 10 CFR 70.61. If information on any safety limits and safety margins associated with an IROFS is not provided in the ISA ~~S~~summary, ~~then~~ it must be available for review in ISA documentation on~~-~~site.

The above acceptance criteria are explained in greater detail below.

a. A~~LL ITEMS~~ll Items: The primary function of the list describing each IROFS is to document the safety basis of all processes in the facility. This list assists in ~~as~~ensuring 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~~a process~~es~~ 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. The ISA ~~S~~summary need not provide a breakdown of hardware IROFS by component or identify all support systems. However, the ISA documentation maintained on~~-~~site, such as system schematics and/or descriptive lists, should contain sufficient detail about items within a hardware IROFS, such that it is clear to the reviewer(s) and the applicant, what structure, system, equipment, or component is included within the hardware IROFS' boundary and would, therefore, be subject to management measures specified by the applicant. Some examples of items within a hardware IROFS are detectors, sensors, electronics, cables, valves, piping, tanks, dykes, etc. In addition, ISA documentation should also identify essential utilities and support systems on which the IROFS depends to perform its intended function. Some examples of these are backup batteries, air supply, steam supply, etc. 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.

b. ~~THE DESCRIPTIONS OF ITEMS~~Description of Items: The essential features of each IROFS should be described. Sufficient information should be provided about engineered hardware controls to permit an evaluation that, in principle, controls of this type will have adequate reliability. Because the likelihood of failure of items often depends on safety margins, 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 IROFS within ISA documentation should identify its expected function, conditions needed for the IROFS to reliably perform its function, and the effects of its failure. The description of each IROFS within an ISA ~~S~~summary should identify what 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 in the ISA ~~S~~summary. 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 required reliability ~~required~~. The management measures shall ~~as~~ensure that IROFS are designed, implemented, and maintained, as necessary, to be available and reliable to perform their function when needed. The degree of reliability and availability of IROFS ~~as~~ensure d 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~~facility. In particular, the time interval between surveillance observations or tests of the item should be stated, since restoration of a safe state cannot occur until the failure is discovered.

One example of a tabular description of IROFS meeting these criteria is Table A-~~12~~13~~,~~ in Appendix A to this chapter.

(7) ~~QUANTITATIVE STANDARDS FOR CHEMICAL CONSEQUENCES~~uantitative Standards for Chemical Consequences

The applicant's description in the ISA ~~S~~summary of proposed quantitative standards used to assess consequences from acute chemical exposure to licensed material or chemicals incident to the processing licensed material is acceptable ~~if~~, provided the following criteria are met:

a. There are unambiguous quantitative standards~~,~~ for each of the applicable hazardous chemicals that meet~~ing~~ the criteria of 10 CFR 70.65(b)(7) on site, corresponding to, and consistent with, the quantitative standards in ~~each of the following~~ 10 CFR ~~sections:~~ 70.61(b)(4)(i), 70.61(b)(4)(ii), 70.61(c)(4)(i), and 70.61(c)(4)(ii).

b. The quantitative standard of 10 CFR 70.61(b)(4)(i) addresses exposures that could endanger the life of a worker. The applicant is appropriately conservative in applying the language "could endanger," so as to include exposures that would result in death, consistent with the methods used for the U.S. Environmental Protection Agency's-- "Acute Exposure Guidelines--40 CFR Part 68."

c. The quantitative standards for 10 CFR 70.61(b)(4)(ii) and 10 CFR 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 criterion (b), above, the

standard selected should have appropriate conservatism.

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

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

(8) L~~IST OF SOLE~~ list of Sole IROFS

The descriptive list in the ISA ~~S~~summary 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 IROFS~~;~~

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

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

(9) D~~EFINITIONS OF~~efinitions of "U~~NLIKELY~~nlikely", "H~~IGHLY~~ighly U~~NLIKELY~~nlikely" ~~AND~~and "C~~REDIBLE~~redible"

10 CFR 70.65 requires that the applicant's ISA ~~S~~summary ~~provide~~must defini~~tions of~~e the terms "unlikely," "highly unlikely," and "credible." The applicant's definitions of these terms are acceptable if, when used with the applicant's method of assessing likelihoods, they provide reasonable assurance that the performance requirements of 10 CFR 70.61 can be met. The applicant's *method* of likelihood evaluation and the *definitions* of the likelihood terms are closely related. Qualitative methods require qualitative definitions. Such a qualitative definition would identify the qualities of IROFS, controlling an accident sequence, that would qualify that sequence as "unlikely" or "highly unlikely."

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

10 CFR 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 are 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~~ cceptance Criteria for the Definition of "C~~REDIBLE~~redible"

10 CFR 70.65 requires that the applicant define the term "credible." This term ~~"credible"~~ is used in 10 CFR 70.61, which requires that all credible accident sequences ~~whose~~for which the consequences could exceed the performance requirements of 10 CFR 70.61 must be controlled to be unlikely or highly unlikely, as appropriate. If an event is not credible, ~~then~~ IROFS are not required to prevent or mitigate the event. Thus, to be "not credible" could be used as a criterion for exemption from use of IROFS. There is a danger of circular reasoning here. In the safety program embodied in Subpart H ~~of~~to 10 CFR Part 70, the fact that an event is not "credible" must not depend on any ~~plant~~facility feature that could credibly fail to function, or be rendered ineffective as a result of a change to the system. Each ~~plant~~facility feature that is needed to ~~as~~ensure that accident events are sufficiently unlikely is an 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" because of characteristics provided by IROFS.

Any one of the following t~~T~~hree independent acceptable sets of qualities~~, any one of which~~ could define an event as not credible~~, are~~:

a. ~~A~~an external event ~~whose~~for which the frequency of occurrence can conservatively be estimated as less than once in a million years~~.~~

b. ~~A~~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, must be considered. Necessarily, no such sequence of events can ever have actually happened in any fuel cycle facility.)

c. ~~P~~process deviations for which there is a convincing argument, ~~based on~~given physical laws, that they are not possible, or are unquestionably extremely unlikely~~.~~ (The validity of the argument must not ~~be~~ depend~~ent~~ on any feature of the design or materials controlled by the ~~plant~~facility's system of IROFS or management measures.)

The implication of ~~the use of~~ "credible" in 10 CFR 70.61 is that events that 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. 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~~cceptance

Criteria for Qualitative Definitions of Likelihood

If the applicant's definitions are qualitative, ~~then~~ they are acceptable if they meet the following criteria:

a. are reasonably clear and based on objective criteria~~; and~~

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

~~By t~~The phrase "objective criteria" ~~is~~ meant~~s~~ the extent to which the method relies on specific identifiable characteristics of a process design, rather than subjective judgments of adequacy. Objective criteria are needed to achieve consistency. ~~By c~~Consistency ~~is~~ meant~~s~~ the degree to which the same results are obtained when the method is applied by different analysts. This is important~~,~~ to maintain an adequate standard of safety, because ISAs of future ~~plant~~facility modifications may be performed by individuals not involved in conducting 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 are not necessarily complete, but contain many of the factors that are most commonly encountered. Some of these qualities relate to the characteristics of individual IROFS, such as the following examples:

a. safety margin in the controlled parameter, compared with process variation and uncertainty~~;~~
b. whether the IROFS is an active engineered control, a passive engineered control, an administrative control, or an enhanced administrative control~~;~~
c. the type and safety grading, if any, of management measures applied to the control~~;~~
d. fail-safe, self-announcing, or surveillance measures to limit down time~~;~~
e. failure modes~~;~~
f. demand rate~~; and~~
g. failure rate~~.~~

Other reliability qualities relate characteristics of the IROFS or system of IROFS, protecting against the following accident sequences as a whole~~, such as~~among others:

h. defense-in-depth~~;~~
i. degree of redundancy~~;~~
j. degree of independence~~;~~
k. diversity~~; and~~
l. vulnerability to common-cause failure~~.~~

Methods of likelihood evaluation~~,~~ and ~~the~~ definitions of the likelihood terms "unlikely" and "highly unlikely" may mix qualitative and quantitative information. Certain types of objective quantitative information may be available concerning specific processes in a ~~plant~~facility. Some examples of such objective quantitative information ~~are~~include the following:

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

Such items of quantitative information should be considered in evaluating the likelihood of accident sequences, even in purely qualitative evaluations. For example, knowing the value to which 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~~IROFS.

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~~ which primarily relies ~~primarily~~ on a qualitative evaluation of reliability~~/~~and availability factors. In such methods, qualitative characteristics of the system of IROFS, such as those listed above, are used to estimate a quantitative likelihood index for each accident sequence. 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: T~~, 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 addresses several reliability ~~/~~and availability qualities~~, namely~~:

Factors of safety:	Safety margins
At least two:	Redundancy
Unlikely:	Low failure rate, low down time of one of two controls
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, where each of the applicable qualities is present to an appropriate degree. For example, as implied by the modifier~~,~~ "at least," sometimes more than just two-fold redundancy may be appropriate.

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

~~ACCEPTANCE CRITERIA FOR QUANTITATIVE DEFINITIONS OF LIKELIHOOD~~Acceptance Criteria for Quantitative Definitions of Likelihood

An applicant may choose to provide quantitative definitions of the terms "unlikely" and "highly unlikely." Quantitative guidelines are developed below. These guidelines serve two purposes~~:~~. Specifically, (1) they can be used as acceptance criteria for quantitative definitions, if provided~~;~~, and (2) they provide guidance to the reviewer(s) when objective quantitative reliability ~~/~~and availability information exists.

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 nuclear criticalities. Thus, this guideline should be used for accidents ~~whose~~that have consequences ~~are~~ similar to a nuclear criticality accident (i.e., 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. Quantitative guidelines are derived from goals, not limits, and have been judged to be the highest values consistent with those goals.

~~QUANTITATIVE~~uantitative G~~UIDELINES~~uidelines

Quantitative definitions of likelihood are based on the NRC's strategic risk performance goals. Quantitative likelihood values are an appropriate fraction of the risks of other industrial accident risks in the United States, and conform to comparable quantitative values that are already used in other countries for regulation of nuclear materials facilities. A discussion of quantitative guidelines here does not imply that quantitative demonstration of compliance with 10 CFR 70.61 is required.

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 inadvertent nuclear 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 to 10^{-5} per-event per-year. As the goal is to have no such accidents, accident frequencies should be reduced substantially below this guideline when feasible.

Unlikely

Intermediate- consequence events include significant radiation exposures to workers; (those exceeding 0.25 Sieverts (or 25 rem). The NRC's goal is for there to be no increase in the rate of such significant exposures. This has been translated below into a guideline of 4 X 10^{-5} per-event per-year. This guideline may be more generally considered as a range between 10^{-4} and 10^{-5} per-event per-year, since exact frequencies at such levels cannot accurately be determined.

Quantitative Guidelines for use with Acceptance Criteria

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

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

The stated quantitative guidelines are used to define the *largest* likelihood values that would be acceptable limits. Definitions based on lower limits are also acceptable.

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 the applicant's Ssafety Pprogram and ISA commitments, there may only be a primary ISA reviewer. However, for an initial ISA Ssummary submittal, this the primary ISA reviewer will be assisted by specialists in the various safety disciplines and management measures. An ISA Ssummary 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, risk, and reliability criteria used in the ISA, and generic information about individual processes. This primary reviewer will be assisted by secondary reviewers who evaluate selected individual accidents, and advise on the completeness of the accident list for specific safety disciplines.

3.5.1 Acceptance Review

For review of Ssafety Pprogram commitments, including commitments pertaining to the ISA and ISA Ssummary; (a renewal or amendment application), 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 review.

For an ISA Ssummary, 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 sSection 3.3.2, including specifically each of the elements required

by 10 CFR 70.65(b), to permit an evaluation of safety for compliance with the regulations. If sufficient information is not present, the ISA ~~S~~summary will not be accepted for review.

3.5.2 Safety Evaluation

3.5.2.1 Evaluation of Safety Program and ISA Commitments

The ~~staff reviews~~reviewer(s) examine the descriptions and commitments to program elements in the application or other documents for the "Areas of Review" described in ~~s~~Section 3.3.1~~,~~ to ascertain whether the program elements are sufficient to meet the acceptance criteria of ~~s~~Section 3.4.3.1. The ISA reviewer must coordinate his or her review, with reviews being conducted under other chapters of this SRP.

3.5.2.2 Evaluation of ISA Summary

Evaluation of the ISA ~~S~~summary to determine if the acceptance criteria of ~~s~~Section 3.4.3.2 have been met would normally be performed by a team consisting of a primary reviewer together with specialists in each category of accidents. These categories of accidents depend on the facility~~,~~ but, in general, are~~:~~ nuclear criticality, fires, chemical accidents, and radiological accidents. If external~~-~~ event analysis is complex, specialists may be employed to review these separately, as well. The primary ISA reviewer would normally evaluate the acceptability of the generic elements of the ISA ~~S~~summary, such as site and facility descriptions, ISA methods, criteria, and consequence and likelihood definitions. However, each specialist should also review these elements to obtain information in support of his ~~/~~or her own evaluations.

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

Reviews of accident sequence descriptions and the likelihood and consequence information showing compliance with 10 CFR 70.61 should be undertaken by separate specialists for each category of accidents~~. These accident categories are:~~ (i.e.nuclear criticalities, fires, radiological releases, and chemical accidents). As indicated in Appendix A, one acceptable format for the ISA ~~S~~summary is to separately tabulate or give logic diagrams for accident sequences in each accident category.

After a preliminary team review of the ISA ~~S~~summary, a visit to the facility would normally be made for familiarization with the 3-D geometry of process equipment, to review components of the ISA, and to address any issues that arose during review of the ISA ~~S~~summary.

To select a sub~~-~~set of the accident sequences reported in the ISA ~~S~~summary for more detailed review, the reviewer(s) should look at the applicant's tabulation of high and intermediate consequence accident sequences and the types of IROFS designated for each. High~~-~~consequence accident sequences protected by administrative controls should be examined very carefully, whereas intermediate~~-~~ consequence accident sequences protected by redundant passive engineered controls ~~should~~ warrant a lesser degree of scrutiny. Selection of specific accident sequences and IROFS for more detailed evaluation should then be made using the following approach.

The ~~staff~~reviewer(s) should evaluate potential accidents using information supplied in the ISA ~~S~~summary. The applicant's method for identifying and establishing the consequences and likelihood of an accident sequence may provide information sufficient for this purpose. The NRC ~~staff~~reviewer(s) may ~~make an~~ evaluat~~ion of~~e the accidents using qualitative screening criteria analogous to Table A-6 in Appendix A. Other more rigorous reliability or consequence analyses may be performed as ~~judged~~deemed necessary. ~~Based o~~On the basis of this analysis, accidents will be categorized. Engineered and administrative controls for accidents appearing in the highest category may be selected for review in greater detail. While on~~-~~site, ~~staff~~the reviewer(s) should also select for specific evaluation a small sample of accident sequences determined by the applicant to either result in less than intermediate consequences or to be not credible.

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

3.5.2.3 On~~-~~site ISA Review

The reviewer(s)~~, or team of reviewers~~, should plan on visiting the applicant's facility at least once as part of the application review process. Th~~ese~~is visit~~s~~ should be scheduled after the applicant's ISA ~~S~~summary has received a preliminary review. The visits will enable the reviewer(s) to confirm through detailed examination of the ISA and ISA documentation that the ISA method(s) were selected and applied in a reasonable and thorough manner to all facility processes, that all credible high~~-~~ and intermediate~~-~~ consequence accident sequences were correctly identified, that accident sequence consequences and likelihoods were reasonably determined, and that appropriate IROFS and supporting management measures have been proposed. By means of a "horizontal" review and several "vertical" slice reviews (defined below) of processes selected by the reviewer(s), the completeness and adequacy of the applicant's ISA method(s) can be established. The reviewer(s) may use the ISA documentation to perform independent evaluations of process hazards and accident sequences using methods selected from NUREG-1513, Appendix A to this SRP chapter, or other NRC guidance.

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

Each of the three facets of the on~~-~~site ISA ~~R~~review are discussed below.

ISA M~~ETHODS REVIEW~~ethods Review

The purpose of the ISA method(s) review is two-fold: (1) to ensure that the applicant selected

appropriate ISA method(s) for each facility process ~~were selected by the applicant~~, and (2) to ensure that they were correctly applied in conducting the ISA. Descriptions of the ISA method(s) and a few example applications of the ISA method(s) should be provided in the ISA ~~S~~summary. The ISA method(s) review should answer any questions that the reviewer(s) may have concerning ISA methods and procedures after completing a preliminary review of the ISA ~~S~~summary. In reviewing process-specific information in the ISA ~~S~~summary and ISA documentation maintained on~~-~~site, a few processes and accident sequences should be selected to review the adequacy of the selected ISA method(s) and its/their application. The reviewer(s) should examine any procedures, checklists, or guidance documents that the applicant may have on~~-~~site as guidance to ISA ~~T~~team members to ~~as~~ensure a complete understanding of the applicant's ISA methods. The reviewer(s) should then examine the ISA documentation, including the selected processes and accident sequences, showing how the ISA methods were applied as part of the horizontal and vertical slice reviews discussed below.

~~HORIZONTAL REVIEW~~orizontal Review

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

Reviewer(s) should consult the ISA and ISA documentation ~~and any supporting documentation~~ to answer questions or to resolve outstanding issues resulting from the preliminary review of the ISA ~~S~~summary. If the ISA ~~S~~summary includes sufficiently detailed information for a process, ~~then~~ further examination of the on~~-~~site ISA documentation may not be required. In particular, the reviewer(s) should examine safety information that is not ~~identified~~included in the ISA ~~S~~summary. For example, ISA documentation related to hardware IROFS, such as system schematics and/or descriptive lists, should contain sufficient detail about hardware IROFS, such that it is clear to the reviewer(s) what components (such as cables, detectors, alarms, valves, piping, etc.) are included within the boundary of the hardware IROFS system ~~boundary~~ and would therefore be subject to management measures specified by the applicant. In addition, such documentation should also identify support systems (such as backup batteries, air supply, steam supply, etc.) on which the IROFS depends to perform its intended function. ~~In addition,~~ ~~t~~The reviewer(s) should also examine a few processes to confirm that ~~the necessary~~ all accident sequences were considered and that those having potential consequences exceeding the performance requirements of 10 CFR 70.61 are included in the ISA ~~S~~summary.

V~~ERTICAL SLICE REVIEW~~ertical Slice Review

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

The ISA ~~S~~summary review will have categorized accidents according to their consequences, likelihoods, and IROFS. The subset of processes for vertical slice review should be selected from these categories. The subset should include accident sequences of relatively high levels of consequence and likelihood~~,~~ and~~/or~~ accident sequences to which IROFS of different types and relatively low robustness are designated. Vertical slice reviews should be performed on processes for which less robust IROFS are designated (e.g., greater reliance on administrative rather than engineered controls). While on~~-~~site, the reviewer(s) may confirm the adequacy of ~~any examples~~sample accident analyses that the applicant included ~~by the applicant~~ in the ISA ~~S~~summary. However, the reviewer(s) should focus on processes and/or accident sequences that were not included as ~~examples~~sample accident analyses in the ISA ~~S~~summary to ensure the completeness of the ISA.

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

The total number of vertical slice reviews ~~needed would~~to be conducted will depend on the facility's total number of accident sequences ~~whose~~for which the consequences could exceed the performance requirements of 10 CFR 70.61, the diversity of the types of processes at the facility, and the results of initial ~~results~~reviews of the ISA ~~S~~summary and the horizontal and vertical slice reviews. For most fuel fabrication facilities, the reviewer(s) should plan on conducting vertical slice reviews for 5~~-~~ to 10 NCS-significant processes, 1~~-~~ to 3 fire-significant processes, and 1~~-~~ to 3 chemical/radiological/environmental-significant processes. But if the initial reviews of the ISA ~~S~~summary and the horizontal and vertical slice reviews identify significant issues then additional vertical slice reviews may be warranted.

Another criterion for selecting the process subset is prior accident and precursor experience showing vulnerability to design weakness. For example, 21 of 22 process criticality accidents have occurred in solution systems. Exothermic chemical reaction processes have frequently resulted in accidents. Thus, ~~an effort would be made to~~the reviewer(s) should include these types of processes and accident sequences in the subset for detailed review. Another criterion for selection is safety designs where high reliability is inherently difficult to achieve. Examples are (1) designs with high dependence on correct operator action and (2) complex active engineered control systems.

Each vertical slice review should include (1) familiarization of the reviewer(s) with the safety design of the selected process and (2) examination of all on~~-~~site documentation related to the ISA of that process. If the content of the documentation leaves certain issues unclear, interviews with facility personnel may be necessary. The review should focus on the information on~~-~~site that is not provided in the ISA ~~S~~summary, but is key to understanding compliance with 10 CFR 70.61 requirements. Following the horizontal and vertical slice reviews, if outstanding questions remain about compliance with the performance requirements of 10 CFR 70.61, the reviewer(s) may conduct an independent evaluation using appropriate methods selected from NUREG-1513, ~~the~~ Appendix A to this chapter, or other agency

guidance. The purpose of such an independent review is to identify strengths and weaknesses of the applicant's ISA methods or implementation practices, not simply to check compliance in this one case per se.

The reviewer(s) should take care to document findings and evaluations made during this 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 the ISA Summary, 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 and why the information submitted in that area ~~supports~~ complies with the related regulatory requirement. Specifically, the ~~staff~~reviewer's(s') findings in the ~~Safety Evaluation Report (~~SER~~)~~ should state conclusions of the ~~following~~ types described in the following paragraphs:

General conclusion resulting from ~~staff~~the reviewer's(s') evaluation of ~~s~~Safety ~~p~~Program commitments:

> The NRC staff concludes that the applicant's ~~S~~safety ~~P~~program, if established and maintained pursuant to 10 CFR 70.62, is adequate to provide reasonable assurance that IROFS will be available and reliable to perform their intended safety function(s) 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~~ that state how the applicant's information demonstrates compliance with the acceptance criteria of ~~s~~Section 3.4.3.1. If ~~staff~~ the reviewer(s) find(s) 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~~ NRC's SER should contain a finding that the alternative is acceptable ~~for~~to meet~~ing~~ the basic regulatory requirement addressed.

General conclusions resulting from the staff's evaluation of an ISA ~~S~~summary:

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

Findings should be made~~,~~ concerning any specific requirements statements in 10 CFR 70 that address the nine elements in the ISA ~~S~~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 10 CFR 70.61 or other parts of the regulation, for those processes that receive specific detailed review. However, such findings should be limited to a finding~~,~~ of reasonable assurance~~,~~ that a process having the IROFS, as described in the ISA ~~S~~summary, is capable of meeting the requirements~~,~~ if properly implemented, operated, and maintained.

3.7 REFERENCES

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