COMMENTS ON DRAFT NUREG-1520 SRP CHAPTER 3
(NRC March 30, 2001 Version)

A. ***Introduction***

Industry has reviewed the March 2001 revision of NUREG-1520 in light of the discussions held at the January 4, 2001 NRC Senior Management Meeting and the February 8, 2001 Public Meeting. Our comments also reflect the feedback from NRC staff on the adequacy of ISA Summaries that have already been submitted by Part 70 licensees.

While we commend the NRC for addressing certain concerns raised by industry with previous versions of Chapter 3, we still believe the proposed March 2001 revision (and especially Appendix A) to be seriously deficient. Industry is concerned that assessments and approvals of licensee submissions can not be conducted in an expeditious and consistent manner until the Chapter 3 guidance is finalized. This memorandum first addresses the five issues on which the NRC staff have substantially different viewpoints and the sources of such differing expectations (Section B). It then provides an overall assessment of the chapter (Section C) with detailed comments on three specific concerns (Section D). Finally, a red-lined version of Chapter 3 is appended on which industry's suggested improvements -- both substantive and editorial -- are noted (Section E).

B. ***Where do Industry and the Staff Disagree?***

1. Content of the ISA Summary

The NRC must assess the adequacy of an applicant's ISA. Although the rule provides for the preparation of an ISA Summary, industry and the staff have long agreed that the ISA and supporting documentation used to perform the ISA must also be consulted. The ISA Summary is not an "all-inclusive" document that can establish and defend the complete safety basis of a facility. Industry has always considered as reasonable and necessary the staff's need to go beyond the ISA Summary and to, for example, examine 'vertical slices' in the ISA to examine the underpinnings of calculations, conclusions and design of safety programs. This additional work should give the reviewers the necessary reasonable assurance that the processes and management programs are appropriate, in-place and capable of ensuring safe operation of the facility.

The substantive issue remains "how much information should be included in the ISA Summary?" Industry contends that the ISA Summary should be drafted as the title suggests and be a concise synopsis of issues, such as the method(s) used to conduct the ISA, the general types of high- and intermediate risk accident sequences, IROFS, etc. As both industry and the staff concur that the ISA and

supporting documentation will be consulted, the ISA Summary should not attempt to reproduce anywhere near all of the information contained in the ISA. The ISA Summary should, instead, provide a roadmap of the information maintained at the facility that can be checked by the staff reviewers. In the early stages of development of 10 CFR 70 Subpart H, Dr. Carl Paperiello sought to reduce the amount of licensee information that is routinely sent to NRC Headquarters and that is not needed for licensing actions. Part 70 was revised, therefore, to maintain the ISA and supporting documentation at the facility and to have the applicant only submit a summary of the ISA to Headquarters. This led to a revision in the wording used to outline the information to be submitted to Headquarters from, for example, '*all types of accident sequences*' to '*general types of accident sequences*'. Additionally, information on licensee commitments and descriptions of safety programs would be reviewed by the staff.

Industry's principal concern with Chapter 3 is the amount of information that is sought in the ISA Summary. The chapter's Acceptance Criteria make excessive use of the adjectives 'all' and 'each' when seeking information appropriate to the ISA Summary. Chapter 3 appears to contain Acceptance Criteria more appropriate to an ISA rather than an ISA Summary.

Industry recommends that the contents of the ISA Summary be limited to those topics in 10 CFR 70.65(b) and that the Acceptance Criteria in §3.4.3 be revised accordingly. Further text may be appropriate for the Purpose of Review (§3.1) to direct the staff to examine the ISA and supporting documentation to complete a review of the safety basis of the facility.

2. Regulatory Philosophy

The most effective approach to licensing is a critical evaluation of the licensee's approach (both commitments and program outlines) and assessment of its adequacy to fulfill the regulatory objectives. The effectiveness of implementation of commitments and safety programs should be monitored by performance inspections and corrective actions (where real deficiencies are identified). NRC Headquarters staff should address licensee commitments and safety program elements and conclude, that if they are carried out as stated in the license, there is a reasonable expectation that the facility will operate in a safe manner. NRC inspection staff should ensure that the safety program and commitments are being carried out.

Chapter 3 does not reflect the safety-focused and performance-based regulatory philosophy which now constitutes a Commission strategic goal. Considering the excessive amounts of information that the reviewer is directed to seek and review, the license applicant might be tempted to simply submit the entire ISA as an ISA

Summary. But this is not the intent of the revised regulations which, in accordance with the NRC's safety-focused, performance-based regulatory approach, are designed to focus the staff and licensee resources on truly safety-significant plant issues. This is the rationale for having the license applicant prepare a summary of the ISA -- the ISA Summary -- to enable the staff to review plant features and operations that could pose the greatest threat to public health and safety and the environment. Reviewers should not be burdened with excessive amounts of submitted information so as to maintain their focus on truly safety-significant issues. This was exactly the intention of Dr. Paperiello as noted earlier.

Industry is concerned with overlapping responsibilities between Headquarters and the Regions in licensing actions for fuel cycle facilities. Such redundancy is time-consuming, costly and impairs the licensing process efficiency. An anticipated benefit resulting from the transition to a safety-focused, performance-based regulatory approach was to be allocation of license and NRC resources on safety-significant issues. Industry has, however, detected a shift in the licensing staff's approach to broadening its reviews of applicant information and to reducing reliance on licensee commitments. Decreasing credit seems to be given to licensees for the lengthy track record of safe operation of their facilities. This shift from "trust all" to "verify all" should not be necessary -- at least for existing Part 70 licensees -- and may sorely tax NRC resources for other important licensing actions. Industry would encourage clearer delineation of responsibilities between Headquarters and Region licensing and inspection actions and more focused guidance on the responsibilities and scope of review of licensing actions by Headquarters staff.

3. Probabilistic Numerical Analysis

The NRC Commissioners have repeatedly assured Part 70 licensees that probabilistic, numerical analysis is not expected in their ISAs or ISA Summaries. The NRC staff, however, believes that consistent, objective and transparent reviews of ISA Summaries can only be assured if some type of numerical evaluation scheme is used. NRC management stated at the January and February 2001 meetings that, regardless of the method used by the applicant to assess accident sequences and to designate IROFS, staff would use generic failure (or reliability) data to confirm the adequacy of such IROFS (or systems of IROFS) to meet the performance requirements of 10 CFR 70.61. The staff has specifically asked that reliability data for IROFS proposed for the new MOX facility be provided even though the rule does not state a need for such information. The March 2001 draft revision of Chapter 3 neither discusses the new IROFS evaluation approach ('rosetta stone' or template) nor presents the generic failure data that will be used in license assessments.

Two Part 70 licensees embarked on the ISA process in the mid-1990s following inclusion in their license renewal of a commitment to perform an ISA. Such ISAs were designed and executed without the benefit of the NUREG-1520 guidance. Neither licensee used probabilistic numerical analysis in designating IROFS, but rather relied on sound engineering judgement, qualitative Process Hazards Analysis, deterministic principles, risk insights and maintenance program results. Industry is concerned with the staff's new fixation on quantitative numerical analysis and with the possibility that the completed ISA Summaries may no longer be judged acceptable. To re-do the ISAs using a quantitative approach at a cost of $5-10 million per facility will place a significant financial burden on the licensees and will unlikely lead to a better understanding of important safety aspects of plant operation.

Industry is concerned with the encroachment of 'PRA thinking' into the licensing process. The Commissioners' directives on this matter do not seem to be accurately reflected in the Chapter 3 guidance. Part 70 licensees have never established or maintained a database of reliability data on safety systems. The risks of failure of an IROFS in a fuel fabrication plant are comparatively low compared to failure in a nuclear reactor, where reliability information on safety system components is essential. While there is a certain attraction and simplicity to using generic failure data to determine whether the types and numbers of IROFS designated for an accident sequence are adequate, the mechanical process of simply selecting and tabulating failure data may inadvertently supplant reliance on a thorough understanding of the process under evaluation and on the reasoning that lay behind selection of the IROFS. Such (apparent) expediency should be avoided at all costs.

4. Lack of Guidance

Two Part 70 licensees essentially completed their ISAs and ISA Summaries without the benefit of NUREG-1520 guidance. As noted above, there is a serious concern that these licensees' ISA Summaries may not be accepted due to the absence of a quantitative numerical analysis of plant risks and designated IROFS. At the time such ISA Summaries were performed, the chosen deterministic methods were considered to be adequate. Similarly, the continuing lack of guidance may delay approval of the 'ISA Approach' documents that were submitted by existing licensees in April 2001.

Chapter 3 remains a 'moving target' whose guidance is evolving as both the NRC staff and the license applicants proceed with ISAs. While such evolution can be expected, finalization of the guidance must be a high priority so as to provide the stability and clarity (that is, the 'level playing ground') that all parties warrant to conduct ISAs and to present ISA Summaries by October 2004.

5. Appendix A

Appendix A was added to Chapter 3 to provide examples of how the ISA Summary information could be presented. Industry supported this initiative. Unfortunately, Appendix A has been so modified and permeated with quantitative numerical analysis that that it no longer provides the useful and much-needed guidance expected from an appendix. The appendix is unnecessarily repetitive of information contained in the text of Chapter 3 and it is very prescriptive when discussing in the manner in which data can be presented for review. To its credit, it does provide instructive information on several isolated topics, but it fails to link the steps of accident and IROFS analysis in a meaningful manner. There is, for example, no linkage of the risk index values for different types of IROFS to the analysis in the examples. Unfortunately, there is no example of how the staff will use the template of generic IROFS reliability data in performing adequacy analysis of IROFS. In several instances the guidance in Appendix A is inconsistent with provisions of the rule.

The emphasis on numerical analysis, the lack of linkage of topical matters and the failure to incorporate material contained in industry's guidance for the preparation of an ISA Summary to make the former more of a 'formal and content' guide for the ISA Summary, make Appendix A unworkable. Appendix A will more likely confuse, than enlighten, a reviewer. In its present form Appendix A should be entirely deleted from Chapter 3.

C. ***Overall Assessment***

The March 2001 revision of Chapter 3 incorporates several changes discussed at the February 8, 2001 public meeting. For example, the clarification in §3.3.2 that accident sequences with low safety significance can be omitted from the ISA Summary is helpful. Increased reliance on license commitments rather than on detailed descriptions of how a performance objective will be met is also commendable.

However, the current draft of Chapter 3 remains unnecessarily complex, repetitive and contradictory to rule provisions. The chapter confusingly includes acceptance criteria appropriate for an ISA, and erroneously applies these criteria to the ISA Summary. Thus, far more information is sought for the ISA Summary than is required by the regulations. The draft revision contains no reference to the template (or 'rosetta stone') method that NRC management stated at the January 4th and February 8th was key to ensuring objective, transparent and consistent reviews of ISA Summaries. In view of the stated importance of this review methodology, its absence from the SRP makes the March 2001 revision seriously

incomplete. Few of the agreed-upon changes to Appendix A have been made. The appendix is far too repetitive of information presented in Chapter 3 and the guidance often contradicts what has been presented in the chapter text. Industry understood that Appendix A was to be revised to become more of a '*format and content*' guide for the ISA Summary while illustrating useful approaches for presenting the information required in an ISA Summary. This revision has not been made. Appendix A fails to provide the clarifications that should be included in such supplemental information.

Chapter 3 is unacceptable in its current form. The 'Acceptance Criteria' section (§3.4) requires significant revision: to specifically address the information required by Part 70.65(b), to incorporate the generic template assessment methodology, to reduce its overall repetitiveness and prescriptiveness, to remove numerous qualitative and highly subjective criteria and to correct much imprecise language. Remnants from previous revisions of Chapter 3 must also be removed to improve the clarity and understanding of the guidance. Chapter 3 expects far too much information than §70.65(b) requires. We again wish to emphasize that there is a lot of information not contained in the ISA Summary, that can be used by the reviewer to judge the overall adequacy of a safety program and to establish the safety basis of the facility.

We suggest that all references to the 'ISA Approach' (§§3.1, 3.5.2.1) be deleted, for the requirement to submit this document has forever passed (as of 04/18/01).

Appendix A requires a complete re-write. Inconsistencies amongst the Appendix, Chapter 3 and the 10 CFR 70 persist. The appendix is not overly useful to a reviewer who was not engaged in its drafting.

D. ***Principal Concerns***

1. Chapter Purpose:

Issue: Chapter 3 confusingly presents review criteria for both the ISA and the ISA Summary. It should only provide guidance evaluating the acceptability of an ISA Summary. The SRP should only provide guidance in evaluating documents that, according to 10 CFR 70, require NRC approval. As the ISA Summary, but not the ISA, must receive agency approval, Chapter 3 should be far more succinctly defined. Based on a review of the ISA Summary, the staff will indirectly judge the adequacy of the applicant's underlying ISA. By mixing acceptance criteria for the ISA and the ISA Summary, Chapter 3 contains many serious errors that contradict provisions of 10 CFR 70. For example, Chapter 3 repeatedly directs the reviewer to examine aspects of "all accident sequences" when, in fact, the ISA Summary need

only contain information pertaining to high- and intermediate-consequence accident sequences.
Resolution: Chapter 3 should only address the review of the ISA Summary. Section 3.5.2.2 (correctly) states that the reviewer will visit the facility to consult the ISA, to assess the applicant's methods for identifying intermediate- and high-consequence accident sequences (and for eliminating other accident sequences of low safety significance from the ISA Summary). Separate 'Areas of Review' and 'Acceptance Criteria' for the ISA and ISA Summary are not required.

Revising the title of Chapter 3 to read "*Integrated Safety Analysis and ISA Summary*" may be appropriate to emphasize that the chapter primarily provides guidance on how to approve an ISA Summary. As noted earlier, approval of the ISA Summary will also reflect concurrence of the reviewer with the adequacy of the ISA as verified through consultation and examination of parts of the ISA and of the supporting ISA documentation maintained at the facility.

2. Information Expectations
Issue: Chapter 3 acceptance criteria generally go far beyond what is stated in the 'Purpose of Review'. Criteria appropriate for judging the completeness of an ISA are used in place of those appropriate for an ISA Summary. Thus, Chapter 3 erroneously requires the applicant to include in the ISA Summary information on *all* accident sequences, to determine compliance of *each* accident sequence with the performance requirements of Part 70, to identify the likelihood and consequences of *all* accidents identified in the ISA, to explain how *each* IROFS acts to prevent or mitigate an accident, etc. For example, §3.4.3.2 (3) requires information far beyond what is intended by the rule (arrangement drawings, process schematics, process operating limits and ranges, chemical flow sheets, geometry of fissile materials, etc.). This information is appropriate for inclusion in the ISA, but the rule does not expect its inclusion in the ISA Summary. Another example is in §3.4.3.2(5). The rule requires "*...a description of the...methods used to perform the ISA...*', but Chapter 3 directs the reviewer to perform a comprehensive analysis of the choice of ISA method(s). The comprehensive analysis can be performed in a review of the appropriate chapter of the ISA, but is not required by §70.65(b) in the ISA Summary.

The guidance in §3.4.3.2(10) ('*Types of Accident Sequences*') is particularly inconsistent with the requirements of §70.65(b). The guidance places untenable demands on the reviewer and seeks far more information than is required by the rule. The applicant is to provide information on the 'general types of accident sequences' and yet the guidance states that the information is acceptable if "*...it covers all types of accident sequences of initiating events and failures of IROFS...*"

and "*the ISA Summary must show what happened [to all accidents that can not exceed the performance requirements of §70.61]…*". Furthermore, the guidance proceeds erroneously to demand: "*…thus it [ISA Summary] must identify all accidents considered and identify accidents which, although possible, were not developed due to insufficient consequences…*". This statement is wrong and totally inconsistent with the rule §70.65(b)(3).

A final example of unwarranted information demands occurs in §3.4.3.2(11). The guidance seeks detailed information on safety margins, safety limits and 'margins to true failure' for IROFS. Such information may be appropriate for the ISA, but far to detailed to be included in a "*…list describing IROFS…to understand their functions…*" [§70.65(b)(6)]

Chapter 3 Acceptance Criteria should be revised to solicit information in the ISA Summary that is consistent with the requirements of 10 CFR 70.65(b).

3. Subjective Guidance

There are several instances where the reviewer is given very vague guidance with which to perform the review. For example, in §3.4.3.2(7) the guidance states: '*…The performance requirements of 10 CFR 70.61 are limits, not goals, thus staff should use these guidelines in that sense…*'. The meaning of this statement is unclear and we are unsure how the reviewer should meaningfully interpret it. Another example is in §3.4.3.2(8): '*…Section 70.61 effectively states that each credible accident sequence must have a likelihood corresponding to its consequences…*' This does not seem to be true as a high-consequence accident should not have a high likelihood of occurrence. In §3.4.3.1 the guidance states: '*…[the applicant] provides reasonable assurance that the elements, as described, would be effective in accomplishing the ISA function…*' What is the specific goal or benchmark against which the reviewer is to judge the ISA Summary? Finally, the concept of risk evaluation is introduced towards the end of the Acceptance Criteria [§3.5]: '*…the staff will evaluate the risk significance of accident sequences using information provided in the ISA Summary…'*. Nowhere in the guidance is any direction provided as to how the "risk" of an accident sequence is established, let alone how its comparative overall "risk significance" is evaluated. These terms are introduced in the last 2 pages of Chapter 3. If the reviewer is expected to address risk, then guidance must be provided as to how to do so.

Industry recommends that the guidance provide clear benchmarks against which the adequacy of the license application can be judged. The opportunities for subjective judgements should be constrained.

4. NUREG-1513
The continued references to NUREG-1513 could be confusing, especially in view of the discussions that took place at the February Public Meeting. Mr. Cox referred to NUREG-1513 as an introductory document that provides background information on the ISA process. "It is not a comprehensive guidance document either on how to do an ISA or an ISA Summary," he said. The recommendation was also made that the licensees stop looking at it, especially as it has not been updated since 1995 with the new rule changes. Industry believes the NRC should more clearly define the role NUREG-1513 is to play in the licensing process. Should it be updated from its 1995 issue date? What portions still serve a useful purpose?

D. ***Detailed Comments***

There are several general issues that should be addressed:

(1) Lack of Correspondence Between 'Areas of Review' and 'Acceptance Criteria'
There are several instances where the structure of the SRP could be improved due to the lack of correspondence of 'Areas of Review' of §3.3 with the 'Acceptance Criteria' of §3.4.3. For example, §3.4.3.1 lists four areas of review for the ISA Summary, but acceptance criteria are not given for one of the areas of review and acceptance criteria are given for two topics that are not in the areas of review. There should be a one-to-one correspondence between areas of review and acceptance criteria. Delete acceptance criteria for issues pertinent to the ISA but not to the ISA Summary. Maintain correspondence between the ISA Summary contents in 70.65 and the guidance for each in Chapter 3.

(2) Correspondence with Rule
The NRC may wish to have Chapter 3 follow the layout of 10 CFR 70.65(b) as closely as possible to facilitate consultation of the rule by the reviewer. For example, when the rule outlines nine topics to be addressed in the ISA Summary, we recommend that the Chapter 3 guidance address each of these nine topics specifically. Breaking down the nine topics into fourteen topics, as id done in the March draft of Chapter 3, simply adds confusion.

(3) Terminology (General Comments)
Many terms in Chapter 3 are used in a confusing or incorrect manner. Examples:
(i) '*ISA Results*': the statement in §3.1 that "*all the information items needed to perform, or that are produced from, an ISA are referred to here as "ISA Results"* is confusing. The inputs to the ISA can hardly be called 'results' in much the same way that the water, sand and cement that are mixed to form

concrete can not be called 'concrete'. Chapter 3 examines the ISA Summary and not directly the ISA Results.

(ii) '*Safety Program and ISA Commitments*': §70.62(a) defines the safety program to have three components, one of which is the ISA. As all ISA commitments are themselves 'Safety Program Commitments' and as Chapter 3 is to examine the ISA Summary rather than the ISA, we recommend this chapter sub-heading be revised to read '*Safety Program Commitments*'. To keep the existing words in Chapter 3, they should at least be revised to read "*Safety Program Including ISA Commitments*".

(iii) '*engineered IROFS boundary descriptions*': undefined term

(iv) '*...all applicable hazardous chemicals on site...*': this is incorrect and conflicts with §70.75(b)(7).

(v) '*...minimum consequences of 70.61...*": in several places the performance requirements of §70.61 are referred to as 'minimum requirements'. These requirements are neither 'minimum' nor 'maximum' requirements, but rather clearly stated performance objectives. By referring to them as 'minimum' the inference is that they will be tightened ('ratcheted') up over time.

(vi) '*...a list of all materials... or conditions that could result in hazardous situations...*' [§3.4.3.2(9)]. What is a 'hazardous situation'? This section should be rewritten to use language in the rule: '...that could <u>exceed the performance requirements of §70.61</u>...'

(vii) '*...risk significance...*' [§3.5]. At the end of Chapter 3 the reviewer is directed to evaluate the risk significance of accident sequences (presumably those reported in the ISA Summary). But no where else in the chapter is the concept of 'risk' specifically addressed or guidance provided to the reviewer on how to establish the comparative risks of accident sequences. While industry supports evaluation of the licensed facility's operation in terms of 'risk', to do so requires elaboration in Chapter 3 of how to establish the risk of an accident sequence and how to evaluate the comparative risk significance of such accidents. In the absence of such guidance, the reviewer may be confounded upon suddenly encountering at the end of Chapter 3 the following sentence, without any supporting guidance on how to perform the task: "*...the staff will evaluate the risk significance of accident sequences using information provided in the ISA Summary...*"

(viii) '*...IROFS & 70.61 criteria...*': the acronym for IROFS is defined on multiple occasions and 'accident sequences' are variously referred to as 'event sequences' or 'events'. The performance criteria of 70.61 are referenced in at least six different ways. These editorial inconsistencies have been flagged for correction in the red-lined version of Chapter 3.

E. *Red-lined Version of Draft Chapter 3*

Eighty-six comments are noted in the following red-lined version of Chapter 3. Additionally, many other suggestions of lesser importance are included to improve the English expression and flow of the chapter.

No annotations have been made to Appendix A, as industry believes that this appendix should not remain part of Chapter 3.

3.0 INTEGRATED SAFETY ANALYSIS (ISA) AND ISA SUMMARY

[Comment #1: as this chapter is to provide guidance on approving the submitted ISA Summary, its title should be changed accordingly]

3.1 PURPOSE OF REVIEW3.1PURPOSE OF REVIEW

[Comment #2: we recommend that some additional language be added to this section to clarify how the ISA Summary review will be performed and how the reviewer will indirectly judge the adequacy of the applicant's ISA. Some of these ideas are presented elsewhere in Chapter 3, but clarification in this section to provide a broad overview of the review task may be helpful.]

An Integrated Safety Analysis (ISA) identifies potential accident sequences in the facility's operations, designates items relied on for safety (IROFS) to either prevent such accidents or mitigate their consequences to an acceptable level and describes management measures to provide reasonable assurance of the availability and reliability of IROFS. Applicants for new licenses and persons holding Part 70 licenses on September 18, 2000 must perform an ISA and submit a summary of it – referred to as an 'ISA Summary' – to the NRC for approval. The ISA Summary principally differs from the ISA by focusing on higher risk accident sequences whose consequences could exceed the performance criteria of 10 CFR 70.61.

The NRC neither receives nor approves the applicant's (or licensee's) ISA. The ISA and supporting documentation (such as piping and instrumentation diagrams, criticality safety analyses, dose calculations, process safety information and ISA worksheets) are, instead, maintained at facility. The NRC does, however, review and approve the applicant's ISA Summary which, although not part of the license application, is placed on the public docket. Neither the ISA nor ISA Summary is incorporated as part of the license.

Reviewers must confirm that an ISA Summary meets the regulatory requirements of 10 CFR 70.65 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 Summary are acceptable. An applicant may submit for NRC approval one ISA Summary for the entire facility or multiple ISA Summaries for individual processes (or groups of processes) in the facility as they are completed. Reviews of ISA Summaries will 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 review of two types of information submitted by licensees or applicants:

1) Commitments regarding the applicant's Safety Program ~~and~~ including the Integrated Safety Analysis (ISA) pursuant to the requirements of 70.62–[Comment #3: as the Safety Program includes the ISA, the referring language should be changed as noted -- see covering note.]

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

In the case of license applications (either initial or for renewal), both types of information would be submitted. In the case of a license amendment, either or both types of information may be submitted, as needed to address the areas amended.

[Comment #4: the following paragraph is not applicable after April 18,2001. It should no longer be included for clarity. -- see covering note.] ~~In the case of existing licensees, 10 CFR 70.62(c)(3)(i) requires a description of the ISA approach in a plan submitted by April 18, 2001. This SRP is not intended to explicitly address applicant submittal or NRC acceptance criteria for the 70.62(c)(3)(i) (ISA approach plan) requirement. That is because the rule requirement is of short duration (ending before publication of this SRP) and is applicable only to those entities licensed as of September 18, 2000. Separate guidance has been issued to affected licensees. However, a reasonable ISA approach plan will address many of the same descriptive elements regarding the ISA as would be described in a license application. Thus, an ISA approach plan meeting the acceptance criteria for the Safety Program and ISA commitments below would comply with section 70.62(c)(3)(i). The ISA Summary documenting completion of an ISA would be submitted later, in accordance with the approach and schedule in the plan.~~

Safety Program including ~~and~~ ISA Commitments

The purpose for the review of commitments relative to the Safety Program, including the ~~and~~ ISA, as presented in the license application, renewal, or amendment is to determine with reasonable assurance that the applicant will accomplish the requirements of Sec. 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 their ~~an~~ ISA. [Comment #5: by commitment, all changes to an existing facility must be examined using the licensee's ISA procedures. Some changes will not require changes to the ISA nor updates to the ISA Summary.]

ISA ~~Results and~~ Summary

~~All the information items needed to perform, or that are produced from, an ISA are referred to here as "ISA results."~~ [Comment #6: use of the term "ISA Results" for the input data to the ISA is confusing. The ISA results are used in preparing the ISA Summary, but they are not directly reviewed as part of the ISA Summary submission.] The ISA Summary summarizes the results of the facility ISA and ~~is the principal document summarizing these results that~~ [Comment #7: the ISA Summary is not just the 'principal document' that is submitted to the NRC; it is the only document submitted to the NRC pertaining to the ISA.] ~~-~~is submitted to the NRC. The purpose of the review of the ISA Summary is to establish reasonable assurance that the applicant has performed the following tasks.

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

2. Identified and evaluated in the ISA, all credible events (accident sequences) involving process deviations or other events internal to the plant (e.g., explosions, spills, and fires), and credible external events that could result in facility-induced consequences to the public, worker, or the environment, that could exceed the performance requirements of ~~of the types specified in~~ [Comment #8: for consistency and clarity, use the rule language.]10 CFR 70.61. External events normally include, as a minimum:
   1) natural phenomena events such as floods, high winds, tornadoes, and earthquakes;
   2) fires external to the facility;
   3) transportation accidents and accidents at nearby industrial facilities.

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

3.2 RESPONSIBILITY FOR REVIEW3.2RESPONSIBILITY FOR REVIEW

Primary:	Assigned staff licensing reviewer
Secondary:	Technical specialists in specific areas
Supporting:	Fuel Facility Inspection Staff

3.3 AREAS OF REVIEW

Two types of submittals are addressed by this chapter of the Standard Review Plan, (1) submittals containing descriptive commitments regarding the Safety Program, including ~~and~~ the ISA, and (2) ISA Summaries. The descriptive commitments regarding the Safety Program should be found in license applications, renewals, and amendments. ISA Summaries may be submitted for an entire existing facility, a new facility, a new process, or for altered processes requiring revision of the ISA.

The Safety Program, including the ~~and~~ ISA commitments and descriptions to be reviewed consist of: 1) process safety information (70.62(b)), 2) methods used to perform the ISA, 3) qualifications of the team performing the ISA (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 (70.62(d)). These commitments and descriptions, as appropriate, will 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 the rule are presented in an ISA Summary. This ISA 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.

[Comment #9: for clarity, the nine items that are to be included in the ISA Summary, in accordance with 10 CFR 70.65(b), should be listed here. Later in Chapter 3 the list expands to 14 requirements, which may result in confusion to the reviewer.] The ISA Summary will be used to determine the adequacy of the applicant's ISA. The contents of the ISA 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
(4) demonstration of compliance with §70.61 performance requirements
(5) description of the ISA Team and their qualifications
(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, highly unlikely

~~, in addition to general facility information, descriptions of analyzed processes, descriptions of methods used to perform the ISA, a description of the group of individuals performing the ISA, and descriptions of the IROFS that cause accident sequences to meet or exceed the performance requirements of 70.61.~~

The ISA and supporting documentation used in its preparation (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 may need to consult the ISA and 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 should confirm that low-risk accident sequences not reported in the ISA Summary were correctly identified and analyzed in the ISA.

3.3.1 Safety Program Including ~~and~~ ISA Commitments

The staff 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 phrases, "process node" or "process", are used to refer to a single reasonably compact piece of equipment or workstation where a single unit process or processing step is conducted. A typical fuel cycle facility is divided into several major process lines or areas, each consisting of many process nodes. The areas of review for ~~an~~ ISA commitments ~~program~~ are as follows:

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

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

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 methodology includes evaluating the applicant's methods in the following specific areas:

a. Hazard identification.

b. Process hazard analysis (accident identification).

c. Accident sequence construction and evaluation.

d. Consequence determination and comparability to 10 CFR 70.61.

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

4. The applicant's description of, and commitments to, management procedures for conducting and maintaining the ISA. Specific review areas include the applicant's procedures for:
   (1) performance of, and updates to, the ISA;
   (2) review responsibility;
   (3) ISA documentation;

(4) reporting of ISA Summary changes per 10 CFR 70.72(d)(1) and (3), and
(5) maintenance of ISA records per 70.62(a)(2).

3.3.2 ISA Summary ~~Results~~

[Comment #10: change section title to be consistent with that of §3.1. A minor point of clarity: the staff does not directly review the "ISA Results", but rather those results that are presented in the ISA Summary. The staff reviews ~~the ISA results (primarily~~ the ISA Summary~~, but may include other ISA documentation)~~ to find reasonable assurance that the applicant has performed a systematic evaluation of the hazards and credible accident sequences; and has identified IROFS and management measures that satisfy the performance requirements of 10 CFR 70.61. The review boundary includes those accidents that result in a release of radioactive material, a nuclear criticality event, or any other exposure to radiation resulting from use of licensed material. In addition, the staff reviews accidents involving hazardous chemicals produced from license materials. That is, chemicals that are licensed materials, or have licensed materials as precursor compounds, or substances that physically or chemically interact with licensed materials, and that are toxic, explosive, flammable, corrosive, or reactive to the extent that they endanger life or health. These include substances that are commingled with licensed material or are produced by a reaction with licensed material. If a chemical accident has the potential to cause, or reduce protection from, a radiation exposure accident, then it also must be addressed. On the other hand, [Comment #11: use consistent terminology -- "accident sequences" instead of "event sequences"] ~~event~~ accident sequences having unmitigated consequences [Comment #12: use consistent terminology -- "performance requirements of §70.61"] that will not exceed the performance requirements of ~~less than those identified in~~ 10 CFR 70.61(c), once identified as such, do not require reporting in the ISA Summary.

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

[Comment #13: to facilitate reference to the rule by the reviewer, we recommend that the nine issues to be addressed in the ISA Summary, as stated in §70.65(b), be addressed as nine issues within Chapter 3. Enlarging the list from nine to fourteen, and changing the order in which they are presented, is both confusing and unneeded.]

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

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

3. PROCESSES: The description in the ISA Summary of each process analyzed as part of the ISA. Specific areas reviewed include basic process function and theory, functions of major components and their operation, process design and equipment, and process operating ranges and limits. [Comment #14: include items (9) and (10) into this item (3) so as to be consistent with the rule tabulation.] Also to be provided is a list of the hazards (and interactions of hazards) for each process and the accident sequences that could result from such hazards and whose consequences could exceed the performance requirements of §70.61. [Comment #15: the idea in the following sentence is better presented above as it applies to the entire ISA Summary evaluation and not just to examination of the process

descriptions.].~~It is expected that, for certain processes, additional information or a visit to the facility will be necessary to permit staff to understand the process.~~

5~~4~~. TEAM QUALIFICATIONS AND ISA METHODS: The applicant's ISA Team qualifications and ISA methods as described in the ISA Summary.

~~5.~~ [Comment #16: consistent with the rule -- and as correctly stated in item (5) -- this topic is merged into item (5) above.~~ISA METHODS: The description of ISA methods in the ISA Summary. If methods are adequately described in the license application, there will be no need to duplicate this information in the ISA Summary. Documentation of specific examples of the application of methods may be requested or reviewed on site to confirm understanding of specific methods.~~

7~~6~~. CHEMICAL CONSEQUENCE STANDARDS: The applicant's quantitative standards for assessing the chemical consequence levels specified in 10 CFR 70.61, as described in the ISA Summary.

9~~7~~. ~~LIKELIHOOD~~ DEFINITIONS OF TERMS: [Comment #17: as a definition of a non-likelihood term is required, we recommend that this heading be changed as noted.] The applicant's definitions of unlikely, highly unlikely, and credible used in §~~70.61 as described in~~ the ISA Summary.

4~~8~~. COMPLIANCE WITH 10 CFR 70.61: The information developed in ~~resulting from~~ the ISA that demonstrates compliance with the performance criteria of 10 CFR 70.61. [Comment #18: (i) the following clause is not needed and is not consistent with the rule,(ii) the rule also requirements mention of management measures, (iii) criticality monitoring and baseline design criteria are incorporated into this topic for the ISA Summary.] ~~In addition to the information specifically required as noted in items 9 through 11 below,~~ T~~t~~his information includes for each applicable process:

a) The postulated consequences [Comment #19: use of the term "each" in the following deleted clause is inconsistent with the rule and section 3.3.2 -- which state that only information for intermediate- and high-consequence accident sequences need be included in the ISA Summary.] ~~evaluated for each postulated accident sequence;~~ and comparison to the consequence levels identified in 10 CFR Part 70.61. Information, such as inventory, release path factors, supporting the results of the consequence evaluation.

b) Information showing how [Comment #20: use of the term "each" in the following deleted clause is inconsistent with the rule and section 3.3.2 -- which state that only information for intermediate- and high-consequence accident sequences need be included in the ISA Summary.] the likelihood of accidents that could exceed the performance requirements of §70.61 was established. ~~each accident sequence has been assessed to have the likelihood required by 10 CFR 70.61.~~

b0 c) Information describing how [Comment #21: use of the term "each" in the following deleted clause is inconsistent with the rule and section 3.3.2 -- which state that only information for intermediate- and high-consequence accident sequences need be included in the ISA Summary.] ~~each~~ designated IROFS protect against accident sequences that could exceed the performance requirements of §70.61 ~~, for each process, is protected sufficiently by the IROFS listed in the ISA Summary to comply with 10 CFR 70.61.~~

d0 Information on management measures applied to the IROFS (addressed in greater detail in Chapter 11)

e0 Information on how the criticality monitoring requirements of §70.24 are met [Comment #21: The applicant may want to refer the reviewer to Chapter 5 for a detailed discussion of how this license requirement is met.], and

f0 If applicable, how the baseline design criteria of §70.64 are addressed.

~~9.~~ [Comment #22: for consistency with §70.65(b), this topic has been incorporated into item (3) above.] ~~PROCESS HAZARDS: Information in the ISA Summary listing hazards and interactions for each process.~~

~~10.~~ [Comment #23: for consistency with §70.65(b), this topic has been incorporated into item (3) above. Note also that use of the term "all" is inconsistent with the rule and section 3.3.2]~~ACCIDENT SEQUENCES: Information provided in the ISA Summary that describes all accident sequences.~~

6~~11~~. LIST OF IROFS: The list, in the ISA Summary, describing the IROFS for all intermediate- and high-consequence accidents ~~in each process~~ in sufficient~~ly~~ detail to understand their safety function ~~in meeting the appropriate consequence and likelihood requirements of 10 CFR 70.61.~~

8~~12~~. LIST OF SOLE IROFS: The list, in the ISA Summary, identifying those IROFS which are the sole item preventing or mitigating an accident whose consequences could exceed the performance requirements of ~~relied on in an accident sequence to assure compliance with~~ 10 CFR 70.61. [Comment #24: use exact rule language for consistency]

~~13.~~ [Comment #25: for consistency with §70.65(b), this topic has been incorporated into item (4) above. The applicant may want to refer the reviewer to Chapter 5 for a detailed discussion of how this license requirement is met.]~~CRITICALITY MONITORING: The information in the ISA Summary demonstrating compliance with the criticality monitoring requirements of 10 CFR 70.24.~~

~~14.~~ [Comment #26: for consistency with §70.65(b), this topic has been incorporated into item (4) above. Note that this is really a design philosophy and it should be better described as a license commitment rather than after the ISA and ISA Summary have been completed.] ~~NEW FACILITIES AND PROCESSES: The information in the ISA Summary demonstrating compliance with baseline design criteria required by 70.64(a)(1) through (5) and (7) through (10) for new facilities, or new processes at existing facilities, and required to be submitted in accordance with 10 CFR 70.65(b)(4). Since these elements all bear on the adequacy of IROFS, it is efficient to include their review in the ISA Summary review.~~

[Comment #27: poor English style: "*...it is expected that...*"]: ~~It is expected that, in~~ In addition to reviewing the application and ISA Summary, the NRC staff will select subsets of certain areas for which additional information will be reviewed, in some cases at the site. The method for selecting specific processes or accidents for additional review is described in Section 3.5 of this chapter, Review Procedures.

3.4 ACCEPTANCE CRITERIA3.4ACCEPTANCE CRITERIA

3.4.1 Regulatory Requirements3.4.1Regulatory Requirements

[Comment #28: as the Chapter 3 guidance addresses review of the ISA Summary (and not the ISA), recast this introductory paragraph to focus on regulations pertaining to the ISA Summary.] The requirement to establish and maintain a safety program, including performance of an ~~Integrated Safety Analysis (~~ISA~~)~~ is specified in 10 CFR 70.62. 10 CFR 70.62(c) specifies requirements for the tasks comprising the ISA and the evaluation that credible high-consequence and intermediate-consequence events meet the safety performance requirements of 70.61. The requirement to prepare and submit for NRC approval an ISA Summary is stated in 10 CFR 70.65(b). 10 CFR 70.72 sets forth requirements for keeping the ISA, the ISA ~~and its~~ documentation and the ISA Summary current when changes are made to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel. ~~10 CFR 70.65(b) describes the contents of an ISA Summary.~~

The information to be included in the ISA Summary can be divided into four categories: (i) site and facility characteristics, (ii) ISA methodology, (iii) hazards and accident analysis, and (iv) IROFS ~~items relied on for safety~~ [Comment #29: 'the acronym for IROFS has previously been defined in §3.1. No need to repeat]. The information requirements of each category, the corresponding regulatory citation and the section of NUREG-1520 Chapter 3 in which expectation for such information are presented below.

Information Requirements for the ISA Summary and Corresponding Part 70 and NUREG-1520 Citations

Information Category and Requirement	10 CFR 70 Regulatory Citation	NUREG-1520 Chapter 3 Reference
Site and Facility Characteristics:		
te description	70.65(b)(1)	§3.4.3.2(2)(ii)
acility description	70.65(b)(2)	§3.4.3.2(2)(I)
ompliance with baseline design criteria and riticality monitoring and alarms	70.64 (if applicable) & 70.65(b)(4)	§3.4.3.2(2)(viii) if applicable & §3.4.3.2(2)(ix)
ISA Methodology:		
SA methodology description	70.65(b)(5)	§3.4.3.2(2)(iii)
SA team description	70.65(b)(5)	§3.4.3.2(2)(iv)
uantitative standards for acute chemical posures	70.65(b)(7)	§3.4.3.2(2)(v)
efinition of unlikely, highly unlikely, and redible	70.65(b)(9)	§3.4.3.2(2)(vi)
***Hazards and Accident Analysis*:**		
escription of processes analyzed	70.65(b)(3)	§3.4.3.2(3)(i)
entification of hazards	70.65(b)(3)	§3.4.3.2(2)(vii)
escription of accident sequences	70.65(b)(3)	§3.4.3.2(3)(ii)

haracterization of high and intermediate- k accident sequences	70.65(b)(3)	§3.4.3.2(3)(iii)
***Items Relied on For Safety*:**		
st and description of items relied on for fety (IROFS)	§70.65(b)(6)	§3.4.3.2(4)(I)
• description of IROFS relation in analyzed accident sequences for assuring performance requirements	§70.65(b)(6)	§3.4.3.2(4)(I)
ROFS management measures	§70.65(b)(4)	§3.4.3.2(4)(iii)
st of sole IROFS	§70.65(b)(8)	§3.4.3.2(4)(ii)

3.4.2 Regulatory Guidance3.4.2Regulatory Guidance

[Comment #30: see note regarding the use of NUREG-1513. Regulatory guidance should focus on the ISA Summary, as this is the document being reviewed and approved.] Guidance applicable to performing an ISA and documenting the results is contained in NUREG-1513, "Integrated Safety Analysis Guidance Document." NUREG/CR-6410, “Nuclear Fuel Cycle Accident Analysis Handbook”, March 1998, provides guidance on acceptable methods for evaluating the chemical and radiological consequences of potential accidents.

3.4.3 Regulatory Acceptance Criteria

The acceptance criteria for an ISA Summary are based on the requirements of 10 CFR 70.65(b).~~meeting the relevant requirements in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."~~ The ISA will form the basis for the safety program by identifying potential accidents, designating IROFS and management measures, and evaluating the likelihood and consequences of each accident sequence for compliance with the performance requirements of 10 CFR 70.61. Some of the acceptance criteria address the programmatic commitments made by the licensee to perform and maintain an ISA. The remainder of the criteria address the ISA results, as documented in the ISA Summary, and whether those documented results demonstrate that the applicant’s IROFS and management measures can reasonably be expected to assure that the relevant accident sequences will meet the performance requirements of 10 CFR 70.61.

3.4.3.1 Safety Program Including ~~and~~ ISA Commitments

[Comment #31: the first 2 sentences are not relevant to the issue at hand -- review and assessment of the ISA Summary. Replace as suggested. As the ISA will have already been completed before the license application is submitted, there is no commitment included '*to perform an ISA*']. License commitments pertaining to the facility's Safety 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 contents of the ISA Summary appear in SRP section 3.4.3.2. These include the primary requirements that an ISA be conducted, and that it evaluate and show that the applicant's facility complies with the performance requirements of 10 CFR 70.61. Acceptance criteria for the other ISA requirements are provided in this section (3.4.3.1) of the SRP.~~ For each component of the Safety Program ~~required function~~ there may be several necessary elements, including, for example,~~. These elements may include~~: organization, assignment of responsibilities, management policies, required activities, written procedures for activities, use of industry consensus standards, and technical safety practices.

The applicant's commitments for ~~to~~ each of the three elements of the Safety Program defined in 10 CFR 70.6l(a) should be acceptable if: ~~ISA requirement of the rule is acceptable if it:~~

(1) ISA

~~a) describes each necessary ISA element sufficiently for the reviewer to understand how well it supports the safety program function;~~ [Comment #32: far too vague to be useful. There is no benchmark provided against which the reviewer can judge the applicant's compliance with this statement. Delete.]

a0 commits to maintain the ISA and ISA supporting documentation accurate and up-to-date by means of a suitable configuration management system and to submit changes in the ISA Summary to the NRC in accordance with 10 CFR 70.72(d)(1) and (3)

b0 commits to train personnel in the facility's ISA methodology(ies) and/or to use suitably qualified personnel for updating and maintaining the ISA and ISA Summary

c0 commits to evaluate proposed changes to the facility or its operations by means of the ISA methodology(ies) and to designate new or additional IROFS and appropriate management measures as required. The licensee also agrees to promptly evaluate the adequacy of existing IROFS and associated management measures and to making any required changes that may be impacted by changes to the facility and/or its processes.

d0 commits to address any unacceptable performance deficiencies that are identified through updates of the ISA.

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

~~c) provides reasonable assurance that the elements, as described, would be effective in accomplishing the ISA function.~~ [Comment #33: far too vague to be useful. Delete.]

In citing industry consensus standards, the applicant should delineate specific commitments in the standards which will be adopted. The applicant should provide justifications if a standard is not adopted in its entirety.

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

(2) Process Safety Information

~~3~~. The applicant commits to compiling and maintaining an up-to-date database of process-safety information. Written process-safety information will be used in updating the ISA and in identifying and understanding the hazards associated with the processes. The compilation of written process-safety information shall include information pertaining to:

a. The hazards of all materials used or produced in the process. Information on chemical and physical properties such as toxicity, acute exposure limits, reactivity, and chemical and thermal stability such as are included on Material S~~s~~afety Data Sheets [meeting the requirements of 29 CFR 1910.1200(g)] should be provided.

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

c. Equipment used in the process. Information of a general nature on topics such as the materials of construction; piping and instrumentation (PI&Ds); ventilation; design codes and standards employed; material and energy balances; IROFS ~~safety systems~~ (e.g. interlocks, detection or suppression systems); electrical classification; and relief system design and design basis should be provided.

[Comment #34: the contents of this paragraph relate to the ISA. They have been relocated to the "(1) ISA" heading section.]~~4. The applicant commits to keeping the ISA and ISA Summary accurate and up-to-date by means of a suitable configuration management system. The ISA must account for any changes made to the facility or its processes (e.g. changes to the site, operating procedures, control systems). Management policies, organizational responsibilities, revision time frame and procedures to perform and approve revisions to the ISA should be outlined succinctly. The applicant commits to evaluating any facility changes or changes in the process safety information that may alter the parameters of an accident sequence by means of the facility's ISA methodology. The applicant commits to using an ISA Team for any revisions to the ISA with member qualifications similar to those used in conducting the original ISA. The applicant commits to review of any facility changes that may increase the level of risk and, if dictated by revision of the ISA, to select and implement new or additional IROFS and appropriate management measures. The applicant commits to submitting to the NRC revisions of the ISA Summary within the time frame specified in 10 CFR 70.72(d)(3).~~

[Comment #35: there is no 'Area of Review' corresponding to this 'Acceptance Criterion'. It has been consolidated into the "(1) ISA" section. "Safety significant vulnerability" is an undefined term -- replace by "unacceptable performance deficiency"] ~~3. The applicant commits to promptly address any safety-significant vulnerabilities or unacceptable performance deficiencies identified in the ISA. The applicant commits to taking prompt and appropriate actions to address any vulnerabilities that are identified in an update of the ISA. If a proposed change results in a new type of accident sequence (e.g. different initiating event, significant changes in the~~

~~consequences) or increases the risk of a previously analyzed accident sequence within the context of 10 CFR 70.61, the applicant commits to promptly evaluating the adequacy of existing IROFS and associated management measures and to making necessary changes, if required.~~

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

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

[Comment #36: as the ISA will have already been completed by the lime the license application is filed, there is no need for this item (6). Delete.] ~~6. 10 CFR 70.62(c) requires that an ISA of appropriate complexity be conducted for each process; and that it accomplish six (i-vi) results. The application is acceptable if it describes sufficiently specific methods and criteria that would be effective in accomplishing each of these tasks. Such effective methods and criteria are described in NUREG-1513, NUREG-6410, item 5 of SRP section 3.4.3.2, and Appendix A of this chapter. Sufficient features, criteria, equations, and data must be provided so that the staff can evaluate how the Integrated Safety Analyses of particular processes show that the performance requirements of 10 CFR 70.61 can be met.~~

~~7.~~ [Comment #37: there is no 'Area of Review' corresponding to this 'Acceptance Criterion' The thrust of this item has been included in "(1) ISA". ~~The applicant commits to implement all IROFS (if not already implemented) and to maintain them so that they are available and reliable when needed.~~

(3) Management Measures

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

3.4.3.2 ~~ISA Results including~~ ISA Summary

[General Section Comment #38: this section solicits very detailed and voluminous information that is appropriate for inclusion in the ISA and its supporting documentation, but which far exceeds what is called for in the §3.1 '*Purpose of Review*'. Far too liberal use of the terms "all" and "each" is made (e.g. in seeking information on all accident sequences) and the guidance does not recognize that the ISA Summary is only to address accident sequences whose consequences could exceed the performance requirements of 10 CFR 70.61 -- that is, high- and intermediate-consequence sequences.]

[Comment #39: there is no need for the first sentence as part of the ISA Summary guidance. Delete.] ~~The preceding section addressed commitments to ISA requirements of the safety program. This section addresses whether the results of carrying out that program, i.e., the ISA methods and results, demonstrate compliance with the performance criteria of 10 CFR 70.61.~~ Information in the ISA Summary should provide the basis for the staff's conclusion~~s~~ that there is reasonable assurance that the identified IROFS will satisfy the performance requirements of the rule. ~~-~~[Comment #40: condense the following sentence as suggested. Recall, we are addressing the ISA Summary and not the ISA.] ~~However, the basis for the staff conclusion would not be limited to a determination that the applicant's ISA program has the capability only to identify the appropriate IROFS. Rather, the focus of the staff review would be on the sufficiency of the IROFS identified in the ISA Summary. This requires a determination of whether the identified IROFS are adequate to control the potential accidents of concern at the facility. The accidents of concern are those whose consequences would be at the high and intermediate consequence levels absent any preventive or mitigative controls. In this context, adequacy means the capability of the IROFS to prevent the related accidents with sufficient reliability, or to sufficiently mitigate their consequences. This, in turn, requires staff to make a determination concerning the completeness of the accident sequences identified in the ISA Summary. To support such a review, the information in the ISA Summary needs to provide enough information concerning the accidents to which the IROFS relate to be able to assess their contributions to prevention or mitigation.~~ To do so, sufficiently detailed information for each high- and intermediate-consequence accident sequence must be supplied to enable the staff reviewer to understand the preventive or mitigative function of each IROFS. The ISA Summary must contain enough information concerning the ISA procedures, methods, and human resources employed to have confidence that the potential accidents identified are reasonably complete.

~~The completeness and adequacy of the IROFS is not the only consideration for satisfying the performance requirements of 70.61.~~ In addition, staff needs to determine that appropriate management measures will be in place that will ensure the availability and reliability of the identified IROFS. Review of designated management measures is addressed in SRP Chapter 11. ~~, to the degree needed to satisfy the likelihood element of the performance requirement.~~

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

[Comment #41: as noted in Comment #9, the nine principal components of an ISA Summary, as defined in 10 CFR 70.65(b) should also be tabulated here. Changing the number of components from 9 to 14 simply adds unnecessary confusion.]

10 general description of the site
20 general description of the facility
30 description of facility processes
40 demonstration of compliance with §70.61 performance requirements
50 description of the ISA Team and their qualifications
60 descriptive list of IROFS
70 description of acute chemical exposure standards used
80 descriptive list of sole IROFS
90 definition of the terms: credible, unlikely, highly unlikely

~~1) The site,~~

~~2) The facility,~~
~~3) The processes,~~
~~4) Team qualifications,~~
~~5) ISA methods,~~
~~6) Quantitative standards for chemical consequences,~~
~~7) Definitions of likelihood terms,~~
~~8) Information demonstrating compliance with the performance requirements,~~
~~9) Process hazards,~~
~~10) Description of accident sequences,~~
~~11) Descriptive list of all IROFS,~~
~~12) List of sole IROFS,13) Information demonstrating compliance with the requirements for criticality monitoring,~~
~~14) Information demonstrating compliance with the requirements for new facilities.~~

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

1. SITE

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

a. A description of the site geography, including its location relative to ~~from~~ prominent natural and man-made features such as mountains, rivers, airports, population centers, possibly hazardous commercial and manufacturing facilities, transportation routes, etc., adequate to permit evaluation of: i) the likelihoods of accidents caused by external factors; and ii) the consequences of potential accidents.

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

c. Characterization of natural phenomena (e.g., tornadoes, hurricanes, floods, and earthquakes) and other external events sufficient to assess their impact on plant safety and to assess their likelihood of occurrence. At least the 100 year flood should be postulated, consistent with U.S. Army corps of Engineers flood plain maps. Also, an earthquake acceleration on the site associated with an earthquake of 10^{-3}/yr likelihood on the nearest capable fault should be evaluated for new facilities and processes, to determine its resulting consequences on the structural integrity of the facility. [Comment #42: the following sentence is not clear. Wouldn't the shorter the remaining life of the facility result in a lower the likelihood of a natural event occurring. For example, if the 100-year storm occurred last year and there is one more year remaining in the plant's life, would not the likelihood of another 100-year storm be somewhat diminished?] A higher likelihood may be justified on the basis of relatively low hazards and/or short remaining facility or process lifetime. 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. FACILITY

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

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

b. locations of the controlled area boundaries

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

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

3. PROCESSES

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

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

b. Major components-their function and operation. This information includes the general arrangement, function, and operation of major components in the process. [Comment #43: the information in the next sentence is not required by the rule. It is available in the ISA for consultation by the reviewer.]~~It includes arrangement drawings and process schematics showing the major components and instrumentation and, if appropriate, chemical flow sheets showing compositions of the various process streams.~~

c. Process design and equipment. This information includes a discussion of process design, equipment, and instrumentation that is sufficiently detailed to permit an adequate

understanding of the results of the ISA. [Comment #44: the level of detail in the requested information is excessive and is not called for in the rule. The reviewer can consult the ISA. Criticality analyses will be presented in Chapter 5 of the license application and need not be repeated here. Consult the ISA for additional back-up information.]~~It includes schematics indicating safety interrelationships of parts of the process. In particular, it is usually necessary for criticality safety to diagram the location and geometry of the fissile and other materials in the process, for both normal and bounding abnormal conditions. This can be done using either schematic drawings or textual descriptions indicating the location and geometry of fissile materials, moderators, etc. sufficient to permit an understanding of how the IROFS limit the mass, geometry, moderation, reflection, etc.~~.

d. [Comment #45: the information solicited by this section (d) is inappropriate for inclusion in the ISA Summary. See, for example, what information is provided in the Appendix A examples of processes.]~~Process operating ranges and limits. This information includes the operating ranges and limits for measured process variables (e.g., temperatures, pressures, flows, and compositions) that are controlled by IROFS to ensure safe operation of the process. The process operating limits and ranges are considered acceptable if they are consistent with those evaluated as adequate for safety in the ISA. One acceptable way of presenting this information is as a tabular summary of all IROFS grouped according to hazard type (i.e. nuclear criticality, radiological hazards, chemical hazards, etc.) as shown in Appendix A, Table A-12.~~

5~~4~~. TEAM QUALIFICATIONS AND ISA METHODS

The ISA teams [70.62(c)(2)] and their qualifications as stated in the ISA Summary are acceptable if the following criteria are met:

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

~~5. ISA METHODS~~

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

~~It is important that the reviewer determine the methods and criteria used in the ISA , and whether they are adequate in principle, before evaluating results for individual processes. The summary of ISA methods is considered acceptable if it describes the methods used for each ISA task. In accordance with NUREG-1513, it is expected that different specific analytical~~

techniques will be used in different processes depending on their nature and complexity. Specific acceptance criteria for methods used in each ISA task are as follows:

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

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

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

b. Process Hazard Analysis Method. The method for performing process hazard analysis is acceptable if it consists of selecting one of the individual methods described in [Comment #46: is continued reference to NUREG-1513 appropriate? See earlier discussion.]NUREG-1513 in accordance with the selection criteria of that document. Individual methods not described in NUREG-1513 may be acceptable provided that:

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

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

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

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

iv. It takes into account the interactions of identified hazards and proposed IROFS, including system interactions, to ensure that the [Comment #47: Poor choice of words here. This is the first time in the chapter that "risk" is discussed. Without any discussion as to how the absolute and comparative risks of accidents are established, this choice of terminology should be avoided. Revise to read: "*...that could result in an accident sequence whose consequences could exceed the performance* ~~overall level of risk at the facility is consistent with the~~ requirements of 10 CFR 70.61.

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

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

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

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

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

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

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

ii. [Comment #48: What does the following criterion mean? How can the reviewer use it? Delete.]~~They are scientifically correct as a reasonable estimate; and~~

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

---

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

d. Likelihood Evaluation Method. The method for evaluation of the likelihood of accident sequences, as described in the ISA Summary, is considered acceptable if it meets the criteria described below [Comment #49: the balance of this sentence is repetitive and not helpful. How can the reviewer assure 100% that the performance criteria will always be met. This is impossible. Delete.]~~such that, given the IROFS and management measures described by the applicant, the staff analyst can find reasonable assurance that the performance criteria of 70.61 are met. Specific criteria are:~~

i. The method ~~-~~clearly shows [Comment #50: use of the word "each" contradicts the rule. Revise as noted] how each designated IROFS ~~involved~~ acts to prevent, or mitigate the consequences to an acceptable level, of the accident sequence being evaluated.

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

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

iv. Finally, the method evaluates each accident sequence as unlikely, highly unlikely, or neither, as defined by the applicant in accordance with subsection 3.4.3.2, Item 7 of this chapter.

v. For nuclear criticality accident sequences, the method evaluates compliance with 70.61(d). [Comment #51: Accident sequences that could result in an inadvertent nuclear criticality must be demonstrated to be *highly* unlikely. Application of double contingency by and large means that the accident will be "highly unlikely".]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 assure 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 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 ~~and Summary~~ must consider and the ISA 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.

7~~6~~. QUANTITATIVE STANDARDS FOR CHEMICAL CONSEQUENCES.

[Comment #52: the language in the first paragraph is incomplete. Refer to §6.3 of Chapter 6 where the attention to hazardous materials as described as follows: "*…to licensed material, hazardous chemicals produced from licensed material and chemical risks produced from plant conditions that affect the safety of radioactive materials…*" Use of the phrase"…incident to the processing of licensed material…" addresses raw chemical stocks as well as recycled hazardous chemicals. We recommend that the language of Chapter 3 be consistent with language used in other chapters of the SRP]The applicant's description in the ISA Summary of proposed quantitative chemical exposure standards used to assess consequences from acute chemical exposure to licensed material or chemicals incident to the processing of ~~produced from~~ licensed material is acceptable if:

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

b. The quantitative standard of §70.61(b)(4)(i) addresses ~~proposed for chemical consequences correctly categorizes as such, all~~ exposures that could endanger the life of a worker. The applicant is appropriately conservative in applying the language "could endanger" so as to include exposures that would result in death, consistent with the methods used for EPA Acute Exposure Guidelines.

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

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

[Comment #53: the language in this section should be consistent with that in SRP Chapter 6. This chapter also finds acceptable OSHA and ISO standards as well as ERPG and AECL. For ease of use, we recommend that the terms ERPG and AECL be defined here. References should not be made to the Appendix, as the Appendix is just an example and does not establish precedents or acceptable approaches.] ~~As indicated in the Consequence Severity Category Table of Appendix A (Table A-1), t~~The staff finds the use of the Emergency Response Planning Guidelines (ERPG) established by the American Industrial Hygiene Association, ~~and~~ 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) ~~series of s~~tandards to be acceptable. ~~sets, each meeting the performance criteria of 10 CFR 70.61.~~ If the applicant does not use a published exposure standard, or if a chemical has an unknown exposure standard, the ISA Summary must describe how an alternate exposure standard was established for use in the ISA. The ISA Summary ~~However, since such standards may not cover all the appropriate chemicals, the ISA Summary to be acceptable~~ must list the actual exposure values ~~selected~~ for each chemical, the source of the data (e.g. ERPG, AECL, ISO, etc.) and provide information or a reference justifying that they meet the acceptance criteria stated above. ~~When the chemical is covered by ERPG or AEGL values, a reference to this fact is sufficient.~~

97. DEFINITIONS OF ~~LIKELIHOOD~~ TERMS

10 CFR 70.65 requires that the applicant's ISA Summary provide definitions of the terms unlikely, highly unlikely, and credible. The applicant's definitions of these terms 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. [Comment #54: improve the English structure in the following sentence.] ~~In fact, it is recommended that, in any case, t~~The reviewer should focus on objective qualities and information provided concerning accident likelihoods.

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

ACCEPTANCE CRITERIA FOR THE DEFINITION OF "CREDIBLE"

10 CFR 70.65 requires that the applicant define the term "credible". [Comment #55: the following sentence is wrong. The rule does not state that all credible events must have their likelihood controlled. Rather, only those accident sequences having high- and intermediate-consequences. Correct.] .This term "credible" is used in 10 CFR 70.61 to state the performance requirement~~s~~ that all credible accident sequences whose consequences could exceed the performance requirements of 10 CFR 70.761 must be ~~events be~~ controlled to be unlikely or highly unlikely, as appropriate. If an event is not credible, then IROFS ~~controls~~ 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 ~~controls~~. There is a danger of circular reasoning here. In the safety program embodied in the rule, the fact that an event is 'not credible' must not depend on any plant feature that could credibly fail to function, or be rendered ineffective as a result of a change to the system. Each plant feature that is needed to assure that accident events are sufficiently unlikely is an ~~"item relied on for safety" (~~IROFS~~)~~. There must be high assurance, provided by management measures, that such features are not removed or rendered ineffective during system changes. One cannot claim that a process does not need IROFS because it is 'not credible' due to characteristics provided by IROFS.

Three independent acceptable sets of qualities, any one of which could define an event as not credible, are:

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

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

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

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

ACCEPTANCE CRITERIA FOR QUALITATIVE DEFINITIONS OF LIKELIHOOD

If the applicant's definitions are qualitative, they are acceptable if ~~that~~ they are:

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

Reliability and Availability Qualities

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

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

5) failure modes
6) demand rate
7) failure rate

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

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

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

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

Acceptance Criteria for Likelihood Indexing Methods

One acceptable type of definition for the likelihood terms "unlikely" and "highly unlikely" could be based on a risk indexing method. Such a method is described in the example in Appendix A. The example described in Appendix A is intended to rely primarily on a qualitative evaluation of reliability / availability factors. In such methods, qualitative characteristics of the system of IROFS, such as those listed above, are used to 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: The quality of a process design that incorporates sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.

Double contingency addresses explicitly several reliability / availability qualities; namely:

factors of safety:	safety margins
at least two:	redundancy
unlikely:	low failure rate, low down time 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 in order 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

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: 1) they can be used as acceptance criteria for quantitative definitions, if provided; and 2) they provide guidance to the reviewer when objective quantitative reliability / availability information exists.

The 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, ~~it is only appropriate to use~~ this guideline should be used for accidents whose consequences are similar to a nuclear criticality accident, that is, one where a few fatal or near fatal worker doses may occur. For substantially more severe high consequence accidents, more stringent likelihood criteria would be acceptable. For less severe high consequence accidents, less stringent criteria may be applied. ~~It should also be noted that the q~~Quantitative guidelines are derived from goals, not limits, and have been judged to be the highest values consistent with those goals.

QUANTITATIVE GUIDELINES

Quantitative definitions of likelihood are ~~guidelines have been developed because the staff will need to correlate applicant's definitions of "highly unlikely", "unlikely", and "credible" with quantitative guidelines developed and used by the staff to assess compliance with 70.61. Limiting likelihood values directed by 70.61 have been quantitatively defined~~ based on NRC strategic risk performance goals. Quantitative likelihood values ~~Staff has verified that the derived values~~ are an appropriate fraction of the risks of other industrial accident risks in the U.S., and ~~they also~~ conform to comparable quantitative values already used in other countries for regulation of nuclear materials facilities. The development of quantitative guidelines here does not imply that quantitative demonstration of compliance with 10 CFR 70.61 is required.

Likelihood definitions are stated ~~The phrase "highly unlikely" applies~~ on a "per event ~~accident~~" basis [Comment #56: for consistency throughout this chapter, use "per event basis".] See earlier usage.] Hence, quantitative frequency guidelines for the likelihood definitions depend on how many potential accidents there are in each of the two categories.

At the time of submittal of the first ISA Summaries, the number of potential accidents in the industry will not yet be known. For review of early ISA Summaries the staff will use values of Nh and Ni[3] that are estimated to be sufficiently high to allow for the contribution not just of the one application being reviewed, but of the entire group of potential applicants. Since there are hundreds of processes in the industry, and, on the average, several accidents per process, Nh and Ni each could be on the order of 1000. If the total number of accidents identified in all the industry ISAs differs significantly from these initial assumptions, adjustments may be needed.

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. As t~~T~~he goal is to have no such accidents, ~~thus it is reasonable to reduce~~ accident frequencies should be reduced substantially below these guidelines when feasible.

Unlikely

Intermediate consequence events include significant radiation exposures of workers, those exceeding 0.25 Sieverts (25 rem). The NRC's goal is for ~~It is taken as a goal that~~ there to be no increase in the rate of such significant exposures, which~~. This rate is~~ currently average about one exposure per 2.5 years. Since the uranium fuel cycle industry has not contributed to such exposures, an allocation of one tenth of this value, or 0.04 per year has been used as appropriate for this industry. Once adjusted to a per accident basis, this value of 0.04 per year for the industry becomes 0.04/Ni, and can then be used as an appropriate guideline limiting all types of accidents with intermediate consequences. [Comment #57: the following sentence says nothing and is confusing to the reviewer. If the number of accidents increases beyond 1,000 to the 10,000 discussed at the February public meeting, the SRP guidance will simply be changed. This is not a matter that the reviewer must be concerned with.] ~~This is appropriate because the defining criteria for intermediate consequence accidents in 10 CFR 70.61 were selected so that~~

[3] Nh is the total number of potential high-consequence accidents for the industry; and Ni is the number of intermediate-consequence accidents, as identified in the ISA's.

~~events in this category are comparable. The definition and use of the term "unlikely" submitted in the ISA Summary, to be acceptable, should be consistent with this frequency guideline.~~

Quantitative Guidelines for use with Acceptance Criteria

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

Likelihood term of 70.61	Guideline	Guideline ~~Valuie~~Value
Unlikely	less than 0.04/Ni per year	4 x 10-5
highly unlikely	less than 0.01/Nh per year	10-5

In setting values for ~~of these quantities,~~ Ni and Nh, the staff should allow some added margin to account for extra accidents that may be added in the future by new facilities or processes.

~~It should be noted that t~~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. [Comment #58: What is the staff to do with the following sentence? It is so vague and subjective that it is more confusing than helpful. Delete.] ~~The performance requirements of 10 CFR 70.61 are limits, not goals, thus staff should use these guidelines in that sense.~~

[Comment #59: Disagree. The consequence categories are very clearly described. The following guidance is unnecessarily vague and should be re-written to assist the reviewer with clear guidance.]The quantitative consequence categories defined in 10 CFR 70.61 are broad, especially the "high-consequence" category, which is open ended. For this reason, the meaning of "highly unlikely" for an individual accident should be graded in inverse proportion to the magnitude of consequences when these consequences are significantly greater than the lower limits defining high consequences in 10 CFR 70.61.

4~~8~~. INFORMATION DEMONSTRATING COMPLIANCE WITH THE PERFORMANCE REQUIREMENTS

[Comment #60: delete redundant sentences. Ideas already expressed in Areas of Review for this topic. Note the incorrect use of terms "all" and "each" in reference to the ISA Summary.] ~~10 CFR 70.65(b) items 3,4,6, and 8 require certain information resulting from the ISA's performed on individual processes to be described in the ISA Summary.~~ Section 70.65(b)(4) requires that the ISA Summary contain: "information that demonstrates compliance with the performance criteria of 10 CFR 70.61." Since the requirements of 10 CFR 70.61 are expressed in terms of consequences and likelihoods of events, the ISA Summary should provide sufficient information

to demonstrate ~~the information needed is that which shows that all events are of appropriate consequences and likelihood. Section 70.61 effectively states that each credible accident sequence must have a likelihood corresponding to its consequences. Thus the information submitted is acceptable if it provides consequence and likelihood information for each accident showing~~ that:

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

b) credible intermediate-consequence events are unlikely.

The performance requirements of 10 CFR 70.61 have three elements: 1) completeness; 2) consequences; and 3) likelihood. Completeness refers to the fact that each credible event must be addressed in the ISA. Consequences refers 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 ~~used by 10 CFR 70.61 in categorizing accidents as being of~~ high or intermediate consequence~~s~~ 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 show the basis and the results of applying these methods to each process. In addition, the information must show that the methods have been properly applied in each case.

The information showing completeness, consequences, and likelihood for accident sequences can be presented in various formats, including logic diagrams, fault trees or tabular summaries. [Comment #61: the following sentence is prescriptive in that is directs use of tables to portray the data..] Appendix A ~~of this chapter~~ provides one example of how this information could be presented in an application. ~~includes a set of tables which include the information the staff will look for in assessing the completeness, adequacy, and quality of an applicant's submittals.~~

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

Specific acceptance criteria for consequence and likelihood information follow.

Consequences

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

i. the information in the ISA Summary [Comment #62: incorrect. Only consequences need be presented for accidents whose consequences could exceed the performance requirements of 70.61.]for each accident whose 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 summary that applies to or bounds that accident; and

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

iii. 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

iv. [Comment #63: this is incorrect. The rule only assigns 2 consequences classes. Accidents that do not meet either category are not addressed in the ISA Summary.]The ISA Summary correctly assigns each type of accident to one of the consequence categories of 10 CFR 70.61; namely, high, or intermediate, ~~or low (less than intermediate).~~

[Comment #64: the logic in the following sentence makes no sense. Revise to read:]
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 of 10 CFR 70.61(b)(1).~~there is a substantial likelihood that they would be.~~ For processes with effective engineered shielding, criticalities may actually produce doses below the intermediate consequences of 10 CFR 70.61. As stated in the regulation, primary reliance must be on prevention of 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 magnitudes of criticality events that can be applied for workers or members of the public at varying distances from the event.

[Comment #65: the following notes on 'likelihood' appear unnecessary in the outline of the ISA Summary. Why are they needed? Much of the material is better suited for SRP Chapter 5. Delete?]

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

i. The ISA Summary contains a specification of the likelihood of each type of accident sequence that could exceed the performance requirements of 10 CFR 70.61; and

ii. The likelihoods are derived from an acceptable method described in the ISA Summary's methods section; ~~and~~

iii. 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 of the requirement, which is not the intent; and

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

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

3. PROCESS HAZARDS [Comment #66: this section should be incorporated into Topic (3).]

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

[Comment #67: the language in the following 2 paragraphs should be exactly the same as in Topic (5) for internal consistency.]

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

2) [Comment #68: demanding a table is unnecessarily prescriptive. Other methods of data presentation should be acceptable.] A hazards interaction table showing Ppotential interactions among either between materials or between materials or and conditions that could possibly result in hazardous situations.

3~~10~~. TYPES OF ACCIDENT SEQUENCES [Comment #69: this section should be incorporated into Topic (3). There is an unacceptably large and frequent use of the terms "all" and "each" in this section which ignores the purpose of the ISA Summary.]

The general description of types of accident sequences in the ISA Summary is acceptable if ~~it is adequate to permit~~ the staff can ~~to~~ determine:

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

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

For this reason, it is not, in general, acceptable to merely list the type of hazard, or just the controlled parameters, without reference to the items relied on to control that parameter or hazard. The general description of accident sequences is acceptable if it covers all types of sequences of initiating events and failures of IROFS ~~(IROFS)~~. Initiating events may be either failure of an IROFS or an external event. Human errors can be initiating events or failures of IROFS. The accident description is acceptable if it permits the staff to determine how each accident sequence whose consequences could exceed the performance requirements of ~~that could exceed the minimum consequence levels in~~ 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 ~~where~~ the basic events are failures of the IROFS. Another acceptable way is to provide a table on which ~~where~~ each row displays the events in an accident sequence, such as in Appendix A Table A-6, where, in general, each event is failure of an IROFS. Another acceptable way is a narrative summary for each process describing the sequence of events in each type of accident.

To demonstrate completeness ~~T~~the general description of types of accident sequences~~, to show completeness,~~ must use systematic methods and consistent references. Therefore, each description of a general type of accident sequence is acceptable if:

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 ~~selected~~ was correctly applied;

c) no ~~hazard or~~ accident sequence whose consequences could exceed the performance requirements of ~~that could cause a failure to meet~~ section 70.61 was overlooked [Comment #70: How can the reviewer possibly determine this accurately?]; and

d) a method of identifying plant processes was used that ensured identification of ~~, so that the completeness of the analysis in covering~~ all processes ~~can be evaluated.~~

During the early phases of an ISA, accidents will be identified whose consequences may initially be unknown. These accidents will later be analyzed and may be shown to have consequences less than the levels identified in 10 CFR 70.61. [Comment #71: No. Only those accident sequences with consequences exceeding the 70.61 performance requirements are in the ISA Summary.] ~~which invoke requirements. The ISA Summary must show what happened to these accidents. Thus it must identify all accidents considered, and identify accidents which, although possible, were not developed due to insufficient consequences.~~

It is not necessary to list as a separate type of accident sequence every conceivable permutation of an ~~the~~ accident~~s~~. Accidents having characteristics that all fall in the same categories can be grouped as a single type of accident in the [Comment #72: 'table' is unnecessarily prescriptive. Change.] ISA Summary ~~table~~, if:

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.

6~~11~~. DESCRIPTIVE LIST OF ALL IROFS

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

1) It includes all IROFS in the identified high- and intermediate-consequence accident sequences.

2) The description of the IROFS, ~~the identification of the grade of~~ management measures applied to them (including and safety grading), [Comment #73: safety limits and safety margins are not required in the ISA Summary. Delete.]~~and the associated safety limits and margins is adequate to permit a determination of compliance with 10 CFR 70.61, that is, it~~ includes the characteristics of its preventive, mitigative, or other safety function, and the assumptions and conditions under which the item is relied upon to support compliance with the performance requirements of Sec. 70.61.

[Comment #74: defer the detailed discussion of management measures to Chapter 11. This paragraph is not needed. Delete.] ~~Although the regulations do not explicitly list the content and grading of management measures as a separate element of an ISA Summary, such information is required to "demonstrate compliance with the performance requirements" by the IROFS. Normally this information would be available in the current license application. If sufficiently detailed information is not provided in the current application, submittal of additional information may be required.~~

The above acceptance criteria are explained in greater detail below.

1) ALL ITEMS: The primary function of the "list describing each ~~all~~ IROFS ~~items relied on for safety"~~ is to document the safety basis of all processes in the facility. This list

assists in assuring that the items are not degraded without a justifying safety review. Thus the key feature of this list is that all IROFS are included. To be acceptable, no item, aspect, feature, or property of the processes that is needed to show compliance with the safety performance requirements of the regulation may be left off this list. IROFS may be hardware with a dedicated safety function or hardware with a property that is relied on for safety. Thus IROFS may be the dimension, shape, capacity, or composition of hardware. In some processes, the frequency of demands made on IROFS must be controlled or limited to comply with 10 CFR 70.61. In such processes, whatever features are needed to limit the frequency of demands are themselves IROFS.

2) THE DESCRIPTIONS OF ITEMS: The essential features of each ~~item relied on for safety (~~IROFS~~)~~ ~~that are required to achieve adequate reliability~~ should be described. Sufficient information should be provided about engineered hardware controls to permit an evaluation that, in principle, controls of this type will have adequate reliability. Because the likelihood of failure of items often depends on safety margins, the safety parameter controlled by the item, the safety limit on the parameter, and the margin to true failure should, in general, be described. For IROFS that are administrative controls, the nature of the action or prohibition involved must be described sufficiently to permit an understanding that, in principle, adherence to it should be reliable. Features of the IROFS that affect its independence from other IROFS, such as reliance on the same power supplies, should be indicated.

The description of each IROFS ~~item~~ must ~~contain any information needed to~~ identify what ~~how the~~ management measures, such as maintenance, training, configuration management, etc. are applied to it. If a system of graded management measures is used, the grade applied to each control should be determinable from information provided. [Comment #75: the following sentence does not pertain to the ISA Summary and should be deleted.] ~~Section 70.62(d) requires that applicants "...establish management measures to provide continuing assurance of compliance with the performance requirements of Sec. 70.61".~~ The reliability required for an IROFS is proportionate to the amount of risk reduction relied on. Thus the quality of the management measures applied to an IROFS may be graded commensurate with the reliability required. The management measures shall assure that IROFS are designed, implemented, and maintained, as necessary, to be available and reliable to perform their function when needed. The degree of reliability and availability of IROFS assured by these measures should be consistent with the evaluations of accident likelihoods. In particular, for redundant IROFS, all information necessary to establish the average vulnerable outage time is required in order to maintain acceptable availability. Otherwise failures must be assumed to persist for the life of the plant. In particular, the time interval between surveillance observations or tests of the item should be stated, since restoration of a safe state can not occur until the failure is discovered.

One example of a tabular description of IROFS meeting these criteria is Table A-12 in Appendix A.

8~~12~~. LIST OF SOLE ITEMS RELIED ON FOR SAFETY (IROFS)

The descriptive list in the ISA 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 ~~item~~;

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

c) ~~Provides~~ a clear and traceable reference to the description of the item as it appears in the full list of all IROFS ~~items~~.

~~13.~~ [Comment #76: this material is incorporated as part of Topic (3), and is even better discussed in terms of licensee commitments in Chapter 5.]INFORMATION DEMONSTRATING COMPLIANCE WITH THE REQUIREMENTS OF 10 CFR 70.24 FOR CRITICALITY MONITORING

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

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

3~~14~~. [Comment #77: this information is better considered as a licensee commitment at the time of facility design and preparation of the ISA. It is referenced in Topic (3)[INFORMATION DEMONSTRATING COMPLIANCE WITH REQUIREMENTS OF 10 CFR 70.64 FOR 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 Summary should explain how each baseline design criterion was addressed in the design of the facility.~~an acceptable set of information would address each baseline design criterion listed in 10 CFR 70.64, and would show how the criterion is met~~. For deterministic design criteria such as double contingency [Comment #78: there is no requirement that every process be designed consistent with the double contingency principle -- e.g. those not handling licensed material]~~to which each individual process must comply~~, the process-specific information may be provided along with the other process information in the ISA Summary. Design basis events and safety parameter limits should be given. Methods, data, and results of analysis showing compliance with these design bases should be given for individual processes and facilities ~~structures~~.

10 CFR 70.64 states that the design process must be based on defense-in-depth principles, and must incorporate, to the extent practicable, preference for engineered controls over administrative controls and reduction of challenges to IROFS. Because of this regulation, new facilities with system safety designs lacking defense-in-depth, ~~or~~ consisting of purely

administrative controls, or relying on IROFS that are frequently or continuously challenged are not acceptable unless justification is provided showing that alternatives achieving the design criteria are not feasible.

3.5 REVIEW PROCEDURES3.5REVIEW PROCEDURES

[Comment #79: this section should be expanded to include guidance on, for example, (i) handling partial submissions of ISA Summaries,(ii) selection of a set of ISA Summary processes and accident sequences for examination and examination of some sections of the ISA and supporting ISA documentation, (iii) and use of the rosetta stone template of generic IROFS failure data.] 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 Safety Program including ~~and~~ ISA commitments there may only be a primary ISA reviewer. However, for an initial ISA Summary submittal, this primary ISA reviewer will be assisted by specialists in the various safety disciplines and management measures. An ISA Summary update submitted as part of an amendment for a process that has hazards in multiple disciplines would also require a team approach. In general, there will be a primary ISA reviewer who evaluates generic methods, 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 Safety Program commitments, including commitments pertaining to the ISA and ISA Summary, (~~an ISA programmatic~~ application, amendment), ~~or ISA Plan,~~ the primary ISA reviewer will conduct a review to determine if the submittal contains appropriate information addressing each of the areas of review identified in Section 3.3.1 of this chapter. If the application does not contain sufficient information addressing the areas of review to permit a safety evaluation, then the application will not be accepted for review.

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

3.5.2 Safety Evaluation

3.5.2.1 Evaluation of Safety Program Including ~~and~~ ISA Commitments

The staff reviews the descriptions and commitments to program elements in the application or other documents for ~~in~~ the Areas of Review ~~subject areas~~ described in Section 3.3.1 to ascertain whether the program elements are sufficient to meet the acceptance criteria of section 3.4.3.1. The required information ~~addressing the subject areas listed in 3.3.1~~ or ~~may be contained in the ISA Chapter of a license application, renewal or amendment; or in the ISA approach described in an ISA Plan submitted in accordance with 70.62(c)(3)(i). Part of the information required to evaluate these areas may also be found~~ in other chapters of a license application. ~~other than the ISA chapter. ISA is highly interrelated with all other aspects of a safety program. Hence~~ The ISA reviewer must co-ordinate with reviews being conducted under

other chapters of this SRP. ~~Specific review steps correspond closely to the areas of review in section 3.3.1~~ [obviously]~~.~~

3.5.2.2 Evaluation of ISA Summary ~~and Results~~

Evaluation of the ISA Summary to determine if the acceptance criteria of section 3.4 have been met would normally be performed by a team consisting of a primary ~~ISA~~ reviewer together with specialists in each category of accidents. These categories of accidents depend on the facility, but, in general, are: nuclear criticalit~~ies~~y, fires, chemical accidents, and radiological accidents. If external event analysis is complex, specialists may be employed to review these separately as well. The primary ISA reviewer would normally evaluate the acceptability of the generic elements of the ISA Summary, such as site and facility descriptions, ISA methods, criteria, and consequence and likelihood definitions. However, each specialist should also review these elements to obtain information in support of their own evaluations.

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

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

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

[Comment #80: the next two paragraphs focus on "risk significance" of accident sequences. And yet nowhere in Chapter 3 is this determination ever made (i.e. how is the "risk" of an accident sequence established and how its overall and comparative "risk significance" is evaluated. If the staff wishes to use comparative "risk significance" to review the ISA Summary, then guidance is needed somewhere in Chapter 3 to explain this concept. What these 2 paragraphs are trying to provide is guidance to the reviewer on how to select a sub-set of the accident sequences reported in the ISA Summary for more detailed review. This selection can be done by simply looking at the applicant's tabulation of high- and intermediate-risk 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 may warrant a lesser degree of scrutiny. Perhaps some very broad guidance should be included as to what percentage of the high- and intermediate-consequence accident sequences should be examined in detail and how the reviewer should look at other accident sequences in the ISA that are not reported in the ISA Summary -- 25-50% of the former and 1-5% of the latter?] Selection of specific accident sequences and IROFS for more detailed evaluation should then be made using the following approach. The staff will evaluate the risk significance of accident sequences using information supplied in the ISA Summary [Comment #81: but how will this evaluation be performed? No guidance is offered to the reviewer -- other than reference to an

example in the appendix..] The applicant's own method for evaluating significance may provide information sufficient for this purpose. [Comment #82: the applicant is not required by the rule -- or by any section of Chapter 3 -- to lay out a method for evaluating risk significance.] If not, the NRC staff may make an evaluation of risk significance using risk indexing, or similar qualitative screening criteria, analogous to Table A-6 in Appendix A. One such procedure for evaluating risk significance is described in the last section of Appendix A. [Comment #83: in the following sentence typical "other analyses" should be identified to assist the reviewer.] Other, more rigorous reliability or consequence analyses may be performed as judged necessary. Based on this risk screening, accident sequences will be placed in risk categories. Engineered and administrative controls appearing in those sequences in the category of highest risk significance may be selected for review in greater detail. Independent evaluation of these sequences, or site visits, will be performed, if warranted. [Comment #84: based on the content of an ISA Summary, accident sequences of "lower risk significance" are, presumably "intermediate-consequence events". They can not be accident sequences whose consequences could exceed the performance requirements of 70.61. Recommend revising this sentence to give clearer guidance to the reviewer.] From intermediate-consequence accident sequences ~~categorized as of lower risk significance~~, staff will select a small sample of representative sequences for specific evaluation.

For the list of ~~describing~~ the IROFS, the reviewer should categorize IROFS so that items of a similar nature, and similar [Comment #85: How is the "risk significance" established?. See comments above.] risk significance, are grouped together. The reviewer should then assure that he has a full understanding of one or more prototype IROFS selected from each category. For these selected prototypes, the reviewer may, if necessary, request additional information to reach such a full understanding of particular IROFS. For complex processes, it may be necessary to visit the plant to reach an adequate understanding of how the IROFS work for the process.

3.6 EVALUATION FINDINGS3.6EVALUATION 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 the information submitted in that area supports the related regulatory requirement. Specifically, the staff findings in the SER should state conclusions of the following types:

General conclusion resulting from staff evaluation of safety program commitments:

> The staff concludes that the applicant's ~~s~~Safety ~~p~~Program, if established and maintained pursuant to Sec. 70.62 is adequate to provide reasonable assurance that IROFS ~~ensure that each item relied on for safety~~ will be available and reliable to perform their ~~its~~ intended function when needed and in the context of the performance requirements of 10 CFR 70.61. [Comment #86: keep in mind that the applicant's overall "safety program" is defined by the other SRP chapters (e.g. fire, chemical, radiation, etc.). For clarity and to ensure that we are talking about the Safety Program defined in §70.62(a), recommend using capital letters on this term.]

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

General conclusions resulting from staff evaluation of an ISA Summary:

> Many hazards and potential accidents can result in unintended exposure of persons to radiation, radioactive materials, or toxic chemicals incident to the processing of ~~associated with~~ licensed materials. The staff finds that the applicant has performed an Integrated Safety Analysis (ISA) to identify and evaluate those hazards and potential accidents as required by the regulations. The staff has reviewed the ISA Summary and other information, and finds that it provides reasonable assurance that the applicant has identified IROFS ~~items relied on for safety~~ and established engineered and administrative controls to ensure compliance with the performance requirements of 10 CFR 70.61. Specifically, the staff finds that the ISA results, as documented in the ISA Summary, provide~~s~~ reasonable assurance that the IROFS, the management measures, and the licensee'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 9 ~~14~~ elements in the ISA Summary. In particular, these findings should include statements concerning compliance with the requirements of 10 CFR 70.64 (regarding new facilities and new processes at existing facilities) for those processes to which they are applicable.

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

3.7 REFERENCES3.7REFERENCES

American Institute of Chemical Engineers (AIChE), “Guidelines for Hazard Evaluation Procedures, Second Edition with Worked Examples,” New York, September 1992.

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

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

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

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

ADAMS Accession Number: ML011270388