

Response to Comments - Chapter 3 - Integrated Safety Analysis

Comment No.	Source	Comment	Disposition
3.1	NEI	“Exclusion of the results of the ISA from a facility’s licensing basis makes redundant to the license reviewer a majority of the content of the June, 1999 revision of draft SRP Chapter 3.”	Disagree. Even though it is not formally referenced in the license issued by NRC, the ISA summary is part of the licensing basis. According to the revised rule, it must “contain information that demonstrates the licensee’s compliance with the performance requirements of 70.61.” Staff notes that although the ISA Summary is not incorporated in the license by reference, it still contains binding commitments by the licensee.
3.2	NEI	“Rather than conduct a detailed review of the complete ISA, the license reviewer will now review the docketed ISA Summary.”	Agree in part. The license reviewer is not expected to review the complete ISA. However, the license reviewer will complement the review of the ISA summary with selective review of the ISA documentation at the site. See also disposition of comment 3.4 below.
3.3	NEI	“...the detailed guidance on establishing qualitative standards for the likelihood and consequence of an accident sequence, should be excluded. However, this guidance is valuable and should be considered for incorporation into NUREG-1513.”	Agree in part. The SRP should provide clear and unambiguous acceptance criteria including those that address the evaluation of the likelihood and consequence of an accident sequence. Staff acknowledges that part of the current discussion in the SRP is “tutorial” in nature; this discussion will be condensed to focus on establishing appropriate acceptance criteria. Regarding the placement of information in the SRP or other guidance documents, there is no difference, from a regulatory standpoint. Neither the SRP or other guidance documents contain <i>requirements</i> ; instead, they instruct the reviewer on how to recognize acceptable (But not unique) approaches for meeting requirements established in the rule.

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3.4.	NEI	"NEI recommends that Chapter 3 be restructured into two principal sections: ISA Commitments and ISA Summary."	Agree in part. Staff believes that a restructuring of the discussion into two parts, ISA Commitments and ISA Results, is warranted. The staff plans to review not only the ISA summary, but also selected portions of the ISA documentation (maintained at the site), as necessary, to reach informed and independent conclusions needed to have reasonable assurance that the licensee will establish and maintain a safety program that will satisfy the performance requirements of 10 CFR70.61. See also the disposition of comment 3.7.
3.5.	NEI	"NEI notes that Appendix A details an approach for quantitative risk evaluation of an ISA and NEI recommends that a second appendix, Appendix B, be developed that outlines a comparable <i>qualitative</i> approach for risk evaluation. NEI also recommends that the Appendices A and B be removed from the SRP and included instead in NUREG-1513.	Staff believes that Appendix A is characterized more accurately as a semi-quantitative risk evaluation. For example, it is significantly more qualitative than a Probabilistic risk assessment (PRA). It is difficult to envision a totally non-quantitative approach. Staff has been investigating the possibility, and welcomes suggestions from NEI, licensees, and other stakeholders. Staff is still considering the suggestion to move the Appendix/Appendices to the ISA guidance document.

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3.6.	NEI	"The SRP contains numerous errors in terminology"	Agree in part. Staff has reviewed the use of terminology and has attempted to correct deficiencies. In addition, the text will be subject to a thorough review by a technical editor.
3.7.	NEI	NEI recommends that Chapter 3 of the SRP be entitled "Integrated Safety Analysis (ISA) Commitments and ISA Summary."	<p>Disagree. Chapter 3 is appropriately titled. As NEI acknowledges in its submittal (Section 3.1, first paragraph):</p> <p style="padding-left: 40px;">"The purpose of this review is to establish reasonable assurance that the... licensee will establish and maintain a safety program that will satisfy the performance requirements of 10 CFR 70.61. A facility's safety program has three components: (i) maintenance of process safety information, (ii) performance and maintenance of an integrated safety analysis (ISA), and (iii) implementation of management measures....The review conducted in Chapter 3 will address the first two components of the facilities safety program (process safety information, ISA)."</p> <p>Clearly, it is the performance of the ISA, as part of the safety program, that provides assurance of adequate safety. The NRC reviews this ISA process by examining the results of the ISA which are summarized in the ISA summary. The NRC may also review additional documentation of the ISA kept at the facility.</p>

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3.8.	NEI	NEI recommends that Chapter 3 be significantly condensed through removal of a majority of the detailed guidance on conducting an ISA.	Agree in part. As noted in response to comment 3.3 above, staff acknowledges that part of the current discussion in the SRP is “tutorial” in nature; this discussion will be condensed to focus on establishing appropriate acceptance criteria.
3.9	NEI	NEI recommends that Chapter 3 should be structured to allow license applicants to commit to performance indicators rather than to specific detailed procedures explaining how a performance goal will be achieved.	At the September 14 public meeting, in response to NRC staff request for clarification of the meaning of “performance indicators”, NEI suggested that this term be considered as meaning “performance requirement.” With this substitution, the NEI suggestion is basically to rely on general commitments to satisfy the performance requirements. As noted in comments 3.4 and 3.7 above, staff needs to reach informed and independent conclusions of the adequacy of the licensee program.
3.10.	NEI	Proposes a rewrite of Chapter 3 with suggested text at various paragraphs.	Agree in part. Staff has reviewed the suggested word changes and will adopt them where appropriate.

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3.11	DOE	<p>The thrust of the comments is that the approach developed in SRP is deficient in a number of respects (specifics follow); DOE appears to be recommending a probabilistic safety analysis using failure rate data that is developed with a high degree of accuracy.</p>	<p>Agree in part. NRC staff concurs with the comments that a fully detailed, systematic, probabilistic safety analysis (PSA) is an acceptable and desirable type of analysis that meets the proposed regulation. Such quantitative methods can be more objective. This is stated in the SRP. However, the establishment of objective or endorsed failure rates is an area that needs development. Generic component failure rate data, while available, will need to be adjusted based on an applicant's operating conditions and applied management measures to assure availability and reliability. For this reason it was judged to be inefficient to devote resources to development of guidance on quantitative data for specific components applicable to fuel cycle facility processes.</p>

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3.12	DOE	<p>The likelihood index, which is a summation of preventive and mitigation control failure rates, does not consider the interdependency of these controls, nor does it reflect actual performance of these controls under the expected operating conditions.</p>	<p>Agree in part. As noted in response to comment 3.11, a quantitative PSA that takes into account the interdependency of controls is an acceptable and desirable approach. However, the semi-quantitative approach developed in the SRP is an improvement over decisions based solely on “expert judgement” that does not employ any measurement indices. Further, the SRP approach does account for the effect on risk of the conditioned failure of one control of a two control system. While not as sophisticated as a full PSA, the approach does force a logical breakdown of the accident sequence and justification for the conclusion that the implemented controls provide adequate protection. Regarding the “performance of ...controls under the expected operating conditions,” staff’s view is that the failure rates used in the analysis should reflect such conditions. However, in the absence of historical operating data, reasonable estimates must be made.</p>

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3.13	DOE	The criteria [used to perform the ISA] are subjective and open to arbitrary interpretation by a reviewer.	Agree in part. While the criteria may be somewhat subjective, they are less so than a single overall judgement that an accident sequence is "highly unlikely." The indexing method of a semi-quantitative ISA has, in fact, been applied in one fuel cycle facility to a wide variety of processes. The assignment of failure rates is achieved by expert judgement of the analysts, based in part on actual experience with the equipment analyzed in the specific environment of that plant. The indexing methods are viewed as one acceptable method of complying with the requirements of 70.61.
3.14	DOE	Without comprehensive and valid equipment failure data, the performance-based, risk-informed approach cannot be implemented in a meaningful fashion.	Disagree. While data specific to a particular plant environment are not generally available, a considerable amount of generic data exists for components that can be adjusted to specific applications. The semi-quantitative approach described in the SRP calls for estimating failure rates where such data are not available. Given that the compilation of "comprehensive and valid equipment failure data" is primarily a plant-specific activity to be undertaken by an applicant, staff does not see an alternative that is more "meaningful" than the one proposed in the SRP.

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3.15	DOE	Systems interactions and support system failures are not considered in the proposed indexing method of Appendix A.	In the methods outlined in the SRP, support system failures should be considered as another event(s) in an individual accident sequence. Generally, fuel cycle process safety systems lack the interactions that are found in highly integrated complex devices such as reactors. When interaction of safety controls is an issue, the independence of controls can be evaluated by a specific common cause analysis. The need for such common cause analysis will be emphasized in a revision to SRP Chapter 3.
3.16	DOE	DOE objects to the allocation of the safety performance goals, in particular their equal allocation. DOE states that a MOX facility could be allocated a much greater share of 10^{-2} per year frequency of high consequence accidents.	The regulation does not require quantification of accident frequencies. The regulation requires that high consequence accidents be “highly unlikely”. This is understood by the staff to mean that the requirement is implicitly a limit on the frequency of each accident. The SRP recognizes that this frequency limit should be made consistent with the Commission safety goals. To do so the SRP indicates that individual accident frequencies will be allocated equally among accidents identified. A discussion will be added pointing out that DOE or other applicants may specify their own quantitative acceptance criterion. The staff will evaluate any such criterion for consistency with the Commission safety performance goals.

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3.17	DOE	“The data used to set the safety performance goal numbers are insufficient and statistically insignificant.”	Disagree. The goal accident frequency for high consequence events is not based on data. It is the value consistent with the Commission goal of no criticality accidents. The goal frequency for intermediate consequence events is likewise chosen to be consistent with the Commission goal of no increase in reportable abnormal occurrences. Although there are few such abnormal occurrences on which to base the frequency, statistical significance is not relevant. The Commission’s goal is relative to the actual number, no matter how few.
3.18	DOE	“The bases for duration index numbers appears to be selected arbitrarily... The data and the methodology for assigning of index numbers also should be provided.”	Disagree. By comparison to many of the other indexed quantities, duration indices have an objective basis. The basis is the observed duration of failures of items relied on for safety. Such items should have surveillance intervals that establish the duration of failures. The discussion of duration index numbers in Appendix A will be clarified.

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3.19	DOE	“The ISA process includes the use of several tables to assess the risk from potential accidents... The process steps are...very hard to follow... A logic diagram or procedure should be included...”	Agree in part. For accident sequences involving multiple failures the indexing method described in Appendix A requires careful reading of the instructions in the Appendix. For such complex situations, a better method is to use fully quantitative methods with formal reliability equations. The sequences are best displayed with fault trees or similar logic diagrams. A recommendation to use such techniques will be included in the SRP.
3.20	DOE	“The minimal set of assurance measures for items relied on for safety appears to be selected arbitrarily, and there is no logic or basis to support it. The rule calls for the assurance measures to be selected based on the importance of the item to safety.”	Disagree. There is a logical basis for the minimal assurance measures. The primary minimum measure is change control, also called configuration management. The reason this should always be provided for IROFS is that there is a universal failure mode for IROFS; namely, that any item can be removed or rendered ineffective by human action. Thus it is always necessary to exercise change control over IROFS. The exact nature of procedures used for change control may be graded according to the importance of the item to safety, and to the risk that might be altered.

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3.21	DOE	<p>“The discussion appearing in this section [Appendix A] contains virtually no firm guidance as to how to quantitatively justify category assignments. It does, however, contain logical flaws and must be rewritten.”</p>	<p>Agree in part. The particular example method given in Appendix A is not fully quantitative or formal and depends on the judgement and plant failure data that has not been formally collected and analyzed. Formal PSA is an acceptable alternative. If PSA is used, justification of data used must be provided by the applicant. See previous response to comment 3.12 concerning Probabilistic Safety Analysis. Any method of reliability analysis is vulnerable to being applied illogically, particularly less formal methods like that of Appendix A. This is why the staff reviews such analysis.</p>
3.22	DOE	<p>Risk management cannot be the acceptance of a likelihood, but of a consequence. If a consequence is too large to be accepted, then the design must reduce its likelihood such that its occurrence can be viewed as <i>virtually impossible</i>.</p>	<p>Disagree. Risk (defined as consequence x likelihood) management is the acceptability of neither consequence or likelihood alone. It is the acceptability of the product of consequence x likelihood. The last sentence of the comment is illogical. “If a consequence is too large to be accepted,” then any design, no matter how effective in reducing the likelihood, could not make it acceptable. The NRC definition of “high consequence” and its limit of likelihood to “highly unlikely” does not require that the accident consequence be rendered incredible, a likelihood that is less than “highly unlikely.”</p>