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May 4, 2000

Mr. Theodore S. Sherr  
Chief, Regulatory and International Safeguards Branch  
U.S. Nuclear Regulatory Commission  
Two White Flint North 8A33  
Washington, D.C. 20555

**Reference: Comments on the March 2000 Draft Version of NUREG-1520  
'Standard Review Plan for the Review of a License Application  
for a Fuel Cycle Facility': Chapter 3 -- Integrated Safety  
Analysis**

Dear Mr. Sherr:

The Nuclear Energy Institute (NEI)<sup>1</sup> and its industry members have reviewed the March 2000 revisions of draft Standard Review Plan (SRP) Chapter 3 ('Integrated Safety Analysis'). We regret being unable to submit these comments prior to the April 18-19 NRC Public Meeting on the SRP, but we do hope they will be of assistance to the staff in revising this chapter of draft NUREG-1520. We have examined how the staff has addressed issues raised by NEI in its letter to you dated August 6, 1999 on the previous version of this chapter (May 1999). We have also taken into consideration discussions that took place at the February 9-10, 2000 NRC Public Meeting ('*Comment Resolution on Part 70 Standard Review Plan*').

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<sup>1</sup> NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

NEI appreciates the opportunity to have been able to review the March 2000 revisions to draft NUREG-1520 chapters. We are encouraged by the ongoing  
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resolution of industry concerns and with other improvements that have been made to this guidance document.

Please feel free to contact me should you have any questions concerning the proposed improvements in the attachment to this letter.

Sincerely,

Felix M. Killar, Jr.  
Director, Material Licensees and Nuclear Insurance

c. Mr. Marvin S. Fertel  
Dr. William F. Kane, Director NMSS

**REVIEW OF MARCH 2000 REVISION OF NUREG-1520**  
**CHAPTER 3: INTEGRATED SAFETY ANALYSIS**

**General Comments:**

Chapter 3 has been significantly improved through a restructuring into two sections: '*ISA Programmatic Commitments*' and '*ISA Results and ISA Summary*'. Several instances of unnecessary prescriptiveness remain and the continued focus on quantitative estimation of accident likelihood remains a significant concern. A majority of the following comments address editorial deficiencies that should be corrected to improve the clarity, flow and logic of the guidance.

**Outstanding Issues of Concern**

- *Clear Statement of Review Objective and Methods*: Chapter 3 is still lacking a clear and concise statement of what the reviewer is to examine. Although the required direction is provided piecemeal in several sections of Chapter 3, we strongly encourage the NRC to consolidate individual statements of guidance into a single section -- ideally the first paragraph of §3.3 ('Areas of Review'). By placing this clear statement of purpose at the beginning of the chapter, the reviewer will understand from the start what data sources are to be consulted and what ISA information is to be evaluated. (A proposed §3.3 introductory paragraph is presented below).
- *ISA Summary*: the chapter should be consistent in directing the reviewer to the ISA Summary to evaluate the adequacy and acceptability of the applicant's ISA. The statement in §3.1 (last sentence on the page) very clearly and correctly directs the reviewer to the ISA Summary, but elsewhere in the chapter the reviewer is variously directed to the ISA, supporting documentation, etc. This is both confusing and inappropriate.
- *Probabilistic Analyses*: industry does not support the implied requirement of this SRP chapter to perform quantitative frequency calculations for every accident event. The NRC's approach of setting quantitative values for likelihood based on the performance of industry as a whole is not justified. Quantitative likelihood values assumed by the NRC (for  $N_h$  and  $N_i$  in §3.4.3.2(7)) appear to be arbitrary and unsupported and their relation to the bounding accident analyses unclear. The SRP compounds its inappropriate treatment of likelihood by defining 'highly unlikely' in terms of the consequences, rather than the probability, of the event.
- *NMSS Goals and Prescriptiveness*: agency goals, rather than regulatory requirements, appear to be used to establish guidance in the SRP (e.g. no nuclear criticalities). If an agency goal is deemed to be of such importance or significance, it should first be incorporated into 10 CFR 70. Many instances remain where the SRP is inconsistent with the risk-informed nature of Part 70 (e.g. need for '*conservative*' rather than '*realistic*' or

'reasonable' estimates in §3.4.3.2(8) for estimates of source terms and process specific data; need for 'conservative' rather than 'realistic' or 'reasonable' estimates of an IROFS failure duration; IROFS 'failure' and violation of safety limits (Appendix A)).

- Acceptance Criteria and Areas of Review: There still remain disconnects between the 'acceptance criteria' and 'areas of review' (i.e. acceptance criteria provided for areas of review that are not specified, and vice versa). For example, acceptance criteria (items (3) & (7) in §3.4.3.1) have no corresponding 'area of review' in §3.3.1. Reconciliation is needed.
- Evaluation Findings: The Evaluation Findings section of Chapter 3 requires significant revision. As written, it does not accurately state what was reviewed in Chapter 3 and draws conclusions that are inappropriate to an assessment of the applicant's ISA Programmatic Commitments and ISA Summary.
- Appendix: NEI continues to recommend that Appendix A be deleted from NUREG-1520 and consolidated into NUREG-1513 ('*Integrated Safety Analysis Guidance Document*'). The appendix seems out of place in Chapter 3. NUREG-1513 and other ISA guidance documents, such as the ISA Summary document under preparation by industry, should be referenced to obtain examples of how to present ISA results.

### **Specific Concerns:**

(Note: In the following comments, suggested text for addition or inclusion is underlined.)

- §3.1 ('Purpose of Review'):
  - (i) Page 3.0-1, *ISA Programmatic Commitments* paragraph: 10 CFR 70.64 does not address ISA programmatic commitments. Part 70.64 requires a facility design commitment to incorporate certain baseline design criteria (BDC) into the facility, but provides no ISA requirements. The ISA will, of necessity, be conducted on the facility design incorporating these BDC. Recommend deletion of 10 CFR 70.64 from this sentence.
  - (ii) '...fulfill the ISA requirements...' may be a better expression than '...accomplish the ISA requirements...' in sentence 1
  - (iii) Page 3.0-1, *ISA Results and Summary* paragraph: The first sentence -- "...All the information items needed to perform...an ISA are referred to here as "ISA Results"" -- is incorrect. The output from the ISA process constitutes '*ISA Results*', but not the input data such as criticality safety analyses, dose calculations, P&I drawings, etc. For consistency with the foregoing *ISA Programmatic Commitments* paragraph, the first 2 sentences of

this section should be deleted and relocated to the proposed (new) first paragraph of §3.3.

- (iv) Page 3.0-2, *ISA Results and Summary* paragraph, item (2), 1<sup>st</sup> sentence: for clarity, state that the ISA does examine credible accident sequences: "...*Identified and evaluated in the ISA all credible accident sequences involving process deviations...*"
- (v) Page 3.0-2, *ISA Results and Summary* paragraph, item (2): the text in this item ("...*of the types specified in 10 CFR 70.61...*") is correct in stating that the ISA Summary addresses high- and intermediate-consequence events. NEI recommends that this statement be clarified as follows: "...*and credible external events whose consequences to the public, workers and the environment could exceed the performance requirements of 10 CFR 70.61. External events normally include...*"
- (vi) Page 3.0-2, *ISA Results and Summary* paragraph, item (2), sub-item (3):
  - (1) '*transportation accidents*' is not included in the Glossary definition of '*external events*'
  - (2) transportation accidents should only be of concern within the immediate proximity of the facility
  - (3) sub-item (3) could be read as follows: "*transportation accidents at nearby industrial facilities and accidents at nearby facilities*" i.e. it is just not transportation accidents, but rather transportation accidents at nearby industrial facilities which serve as the external event. The intended meaning should be clarified.
- (vii) Page 3.0-2, *ISA Results and Summary* paragraph, item (3): the first sentence could incorrectly be interpreted to expect the reviewer to examine each accident sequence in the ISA. As noted in item (2), the IROFS are only to be examined for those higher-risk accident sequences that could exceed the performance requirements of 10 CFR 70.61. Suggest clarifying this sentence to read: "...*Designed engineered and administrative items relied on for safety (IROFS) and correctly evaluated the set of IROFS addressing each accident sequence whose consequences could exceed the performance requirements of 10 CFR 70.61...*"
- §3.3 ('Areas of Review'):
  - (i) NEI recommends revision of the introductory paragraph of §3.3. to provide a clear and concise statement of what the reviewer is to review. The guidance in the existing §3.3 and from other sections of Chapter 3 (e.g. §3.1) should be consolidated into a revised §3.3:

"The staff should review the license applicant's ISA Programmatic Commitments and the results of the ISA. The ISA Programmatic Commitments are documented in the license application. The results of the ISA are presented in the ISA Summary which is submitted with the license application, but which does not constitute part of the license application.

The adequacy of the applicant's ISA will primarily be based on a review of the ISA Summary. The contents of the ISA Summary are specified in 10 CFR 70.65 and include, in addition to general facility information, descriptions of analyzed processes, methods used to perform the ISA, individuals performing the ISA and IROFS for accident sequences that could exceed the performance requirements of 70.61.

The ISA and supporting documentation used in its preparation (e.g. piping and instrumentation drawings, criticality safety analyses, dose calculations, process hazards analysis, process safety information, ISA worksheets) will be maintained at the facility site. The reviewer will likely 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 that low-risk accident sequences not reported in the ISA Summary were correctly identified and analyzed in the ISA.

Based upon a review of the license applicant's ISA Programmatic Commitments and the results of the ISA as presented in the ISA Summary, the reviewer should be able to establish reasonable assurance that the applicant's safety procedures and IROFS will comply with the regulations, especially the performance requirements of 10 CFR 70.61."

- (ii) 2<sup>nd</sup> paragraph, 2<sup>nd</sup> sentence, item (2): according to 10 CFR 70.62(a) process safety information is not part of the ISA program, but rather one of the three components of the facility safety program.
- §3.3.1 ('ISA Programmatic Commitments'):
  - (i) Item (5): to be consistent with the terminology in Part 70.62(c)(3)(iii), revise the last part of the 1<sup>st</sup> sentence to read: "...and the approach and schedule for *correcting any unacceptable performance deficiencies*..."

- §3.4 ('ISA Results'):
  - (i) for consistency with the terminology in §3.1 and §3.4.3.2 (among others), the title of this section should read: "*ISA Results and ISA Summary*"
  - (ii) 1<sup>st</sup> sentence, 1<sup>st</sup> paragraph, page 3.0-4: correct to read: "...*The staff reviews the ISA Summary (and, if required, the ISA and supporting documentation) to find reasonable assurance...*"
  - (iii) 2<sup>nd</sup> sentence, 1<sup>st</sup> paragraph, page 3.0-4: the last clause in this sentence ("...or any other exposure to radiation resulting from the use of licensed material...") is inaccurate due to inclusion of the word "or" and should be deleted. There will be constant occupational exposures to radiation below the Part 20 limits and which do not result from an accident. Delete this clause.
  - (iv) Item (1), page 3.0-4: the site description in the ISA Summary differs from that presented in §1.3. The summary information in §1.3 need only be consistent with that presented in the ISA Summary. Delete the parenthetical.
  - (v) Item (3): 3<sup>rd</sup> and 4<sup>th</sup> sentences are not needed. §3.3 and §3.5 ('Review Procedures') already grant the reviewer the option to visit the facility; this need not be repeated here again. The last sentence is unnecessarily prescriptive. The applicant has the responsibility to decide what information should be included in the ISA Summary to enable the reviewer to make an assessment.
  - (vi) Item (4): delete the words "...and ISA methods..." as ISA methodology is discussed under Item (5). Item (4) should be limited to the ISA Team Qualifications.
  - (vii) Item (5): the second "sentence" is not a sentence (a verb is missing). It appears to be redundant and should be deleted.
  - (viii) Item (6): the gist of this requirement can be better expressed as the following: "...*CHEMICAL CONSEQUENCE STANDARDS: Quantitative chemical standards used by the applicant and reported in the ISA Summary to assess the consequences for acute chemical exposures to licensed material or hazardous chemicals produced from licensed material*"
  - (ix) Item (7): 10 CFR 70.65(b)(9) requires the definition of four terms (likely, unlikely, highly unlikely, credible). The term "unlikely" should be added to the list in item (7) for completeness.
  - (x) Item 8(a): this item could be construed to have the reviewer examine both the mitigated and unmitigated consequences for an accident sequence. There is no regulatory requirement to evaluate unmitigated consequences. The criteria here should be

to simply demonstrate that the process design meets the regulation. Revise (a) to read: "...The mitigated consequences evaluated for each postulated accident sequence that could exceed the performance requirements of 70.61". The second sentence is missing a verb. Revise to read: "...Information, such as inventory, release path factors, supporting the results of the consequence evaluation may be required..."

- (xi) Item 8(b): this sentence is poorly expressed. Revise to read: "...Information showing how each accident sequence has been assigned to a likelihood category and comparison to the 10 CFR 70.61 performance requirements..."
- (xii) Item (8c): delete the clause "...for each process..." as it is redundant. Clarify the last part of the sentence to read: "...by the IROFS listed in the ISA Summary so as to comply with 10 CFR 70.61 performance requirements..."
- (xiii) Suggest adding an additional item 8(d) that addresses management measures in a very cursory manner. Management measures are important to ensure compliance with the provisions of 70.61. Suggest adding the following text: "...d) identification and description of management measures that the applicant will use to provide reasonable assurance that the performance requirements of 10 CFR 70.61 will be met for each accident sequence presented in the ISA Summary..."
- (xiv) Item 10: for consistency with the rule language in 10 CFR 70.65(b)(3), revise to read: "...information provided in the ISA Summary that describes all types of accident sequences..."
- (xv) Item (11): in accordance with discussions at the February 2000 NRC Public Meeting, revise this item to read: "...The list, in the ISA Summary, describing the IROFS at the systems level for all accidents that could exceed the performance requirements of 10 CFR 70.61 in each process sufficiently to understand their safety function..."
- (xvi) Item (12): simplify this sentence to read: "...The list, in the ISA Summary, identifying those IROFS which are the sole item relied on to prevent or mitigate an accident sequence..."
- (xvii) Item (14): for consistency with the Rule language in 10 CFR 70.64(a), revise the middle of this sentence to read: "...facilities, or new processes at existing facilities that require a license amendment under 70.72, and required to be submitted..."
- (xviii) Final paragraph in section: delete this paragraph. The information -- advising the reviewer to visit the facility to consult the ISA documentation or to see a process -- is addressed in both §3.3 and §3.5. Redundant to state again.

- §3.4.1 ('Regulatory Requirements'):
  - (i) 3<sup>rd</sup> sentence: not strictly correct as written. Provisions of 10 CFR 70.72 also apply to changes made to IROFS (and associated management measures). Suggest revising this sentence to read: "*...10 CFR 70.72 states requirements for keeping the ISA and its documentation current when facility changes are made...*"
- §3.4.3 ('Regulatory Acceptance Criteria'):
  - (i) 3<sup>rd</sup> and 4<sup>th</sup> sentences: modify these sentences to specifically refer to the sections of Chapter 3 that present the acceptance criteria for the ISA Programmatic Commitments and the ISA Results and ISA Summary: "*..The acceptance criteria in §3.4.3.1 address the programmatic commitments made by the licensee to perform and maintain an ISA. The acceptance criteria in §3.4.3.2 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 meet the performance requirements of 10 CFR 70.61...*"
- §3.4.3.1 ('ISA Programmatic Commitments'):
  - (i) the first four sentences of §3.4.3.1 should be deleted. They bear no relation to ISA Programmatic Commitments. These sentences appear to be holdovers from an earlier version of Chapter 3 and are more suited for inclusion in §3,4,3 than §3.4.3.1. Delete all.
  - (ii) Last paragraph on page 3.0-7: based on discussions held at the April 18-19 Public Meeting, further clarification of the use of industry standards by a license applicant is required. This paragraph should be revised to read:
 

*"In citing industry standards, the applicant should clearly identify which specific provisions of the standard are being endorsed as a commitment. The applicant must also state whether there is a commitment to follow any recommendations of a standard ('should statements')."*
  - (iii) 2<sup>nd</sup> paragraph, page 3.0-8: clarify the language to be consistent with that used earlier in the chapter: "*...The staff will find the ISA Programmatic Commitments in the application to be acceptable if the following criteria are met...*"
  - (iv) §3.4.3.1, item (3), pages 3.0-8 & 3.0-9: the first 2 sentences should be combined, otherwise several changes should be made to the 2<sup>nd</sup> sentence to make it consistent with the 1<sup>st</sup>. Recommend combining the 2 sentences to read: "*...The applicant commits to promptly address any safety-significant vulnerabilities or unacceptable performance deficiencies identified in the ISA or in updates of the ISA...*"

- (v) §3.4.3.1, item (8), page 3.0-9: simplify the final words of this sentence to read: "...and completing any needed modifications within the specified timeframes..."
- §3.4.3.2 ('ISA Results including ISA Summary'):
  - (i) [editorial comment]: for consistency, the title of this section should be the same as those for §§3.1 and 3.3.2: '*ISA Results and ISA Summary*'
  - (ii) Paragraph 1, 1<sup>st</sup>-5<sup>th</sup> sentences: the introduction to the acceptance criteria for this second topic (ISA Results and ISA Summary) is not well expressed, especially in light of the clear statements offered in §§3.1 and 3.3.2. Recommend revising the first five sentences to read: "...*The staff should review the ISA Summary to verify that the results of the ISA, and specifically the process designs, IROFS and specific management measures applied to IROFS, are sufficient to provide reasonable assurance to the staff that the performance requirements of 10 CFR 70.61 will be met. Review of the ISA Summary requires a determination of whether...*"
  - (iii) Paragraph 2: a sentence should be added to indicate that detailed review of management measures is deferred to SRP Chapter 11. Revise this paragraph to read: "...*The staff needs to determine that appropriate management measures will be applied to IROFS to provide reasonable assurance of their availability and reliability when needed. Detailed evaluation of management measures is undertaken in SRP Chapter 11..*"
  - (iv) List on page 3.0-10: [editorial comment]. For consistency with the text used in 10 CFR 70.65, we suggest re-naming five of the individual topics for review as follows:
    - (1) Site description
    - (2) Facility description
    - (8) Information demonstrating compliance with the performance requirements of 10 CFR 70.61
    - (13) Information demonstrating compliance with the requirements for criticality monitoring of 10 CFR 70.24
    - (14) Information demonstrating compliance with the baseline design criteria requirements of 10 CFR 70.64 for new facilities
  - (v) Item (1): [editorial comments]: section title should be 'SITE DESCRIPTION', capitalization of "Corps" in 1<sup>st</sup> sentence of section (c), and correct verb ending in last sentence: '*indicates*'
  - (vi) Item (2) [editorial comment]: section title should be 'FACILITY DESCRIPTION'
  - (vii) Item (3), 1<sup>st</sup> paragraph, 4<sup>th</sup> sentence: the requirement in this sentence to explain how management measures will ensure the

reliability of an IROFS is too prescriptive. The commitments in Chapter 11 ('*Management Measures*') to implement management measures for maintenance should suffice. Delete this sentence.

- (viii) Item (4), paragraph (a), 2<sup>nd</sup> sentence: replace '*should*' by '*need*' in the last part of this sentence. There should be no prohibition on the ISA team leader from being a cognizant engineer in a process being evaluated: "...*the team leader should have an adequate understanding of all process operations and hazards under evaluation, but need not be the cognizant engineer or expert for that process...*"
- (ix) Item (5a): 1<sup>st</sup> three sentences of this item should be modified to direct the reviewer to examine the applicant's basis for selecting a particular ISA Method for a process. The wording of the first sentence ("...*the reviewer [must] determine what the methods and criteria used in the ISA...*") suggests a sleuthing exercise; it is the responsibility of the applicant to lay out clearly what methods, criteria and assumptions were used. Revise these sentences to read: "...*The reviewer should examine what method(s) and criteria were used to perform the ISA for each process and the applicant's basis for selecting each method, so that the adequacy of the method is clear and appropriate according to the criteria described in this SRP and NUREG-1513. If the applicant selects an alternate method, acceptable justification should be provided. Specific acceptance criteria for methods...*"
- (x) Item (5b), paragraph (ii), second sentence: [editorial comment]: this sentence could be reworded to read more clearly: "...*The methodology justifies any hazards eliminated from further consideration...*"
- (xi) Item (5b), paragraph (vii): delete reference to human-systems interface to be consistent with prior revisions of this SRP. Revise this sentence in part: "...*It adequately considers initiation of, or contribution to, accident sequences by human error through appropriate methods...*" [note corrected placement of comma].
- (xii) Item (5b), paragraph (ix) [editorial comment]: place parentheses around the roman numerals: "...*effectively accomplish (ii) through (viii) above...*"
- (xiii) Item (5c), paragraph (ii): the text does not unambiguously convey the correct meaning which should be: "...*They provide a scientifically correct and a reasonable estimate; and...*"
- (xiv) Item (5d), 1<sup>st</sup> sentence: clarify the meaning to be: "...*The method for evaluation of the likelihood of accident sequences, as described in the ISA Summary, is considered acceptable if it provides*"

*reasonable assurance of compliance with the graded performance criteria of 10 CFR 70.61; and the method...*"

- (xv) Item (5d), paragraph (i): this first point is not clearly related to the issue of likelihood determination. Clarify?
- (xvi) Item (5d), paragraph (v), 6<sup>th</sup> sentence: correct the reference to ISA Summary: "...commitments, but the ISA methods and ISA Summary must consider..."
- (xvii) Item (6a): [editorial comment]: there is some superfluous text here -- perhaps from a previous editing? Correct to read, in part: "...hazardous chemicals on site corresponding to, and consistent with each of the following sections of 10 CFR: 70.61(b)(4)(i)..."
- (xviii) Item (6), last paragraph: for the first occurrence of an acronym, the complete definition should be used: "...staff finds the use of the Emergency Response Planning Guidelines (ERPG) and Acute Exposure Guidance Level (AEGl) series of standards..."
- (xix) Item (7), 1<sup>st</sup> sentence: 10 CFR 70.65(9) also requires definition of the term '*likely*'. The first sentence is, therefore, incomplete and should be corrected.
- (xx) Item (7), paragraph 2, page 3.0-17: 10 CFR 70.65(9) also requires definition of the term '*likely*'. The first sentence is, therefore, incomplete and should be corrected.
- (xxi) Item (7), paragraph 2, last sentence, page 3.0-17: this sentence is redundant and should be deleted. In the prior 2 sentences the same idea has been expressed (i.e. consistency amongst reviewers).
- (xxii) Item (7), paragraph 3, last sentence: in the 5<sup>th</sup> sentence of this paragraph, the terms '*accident sequences with high consequences*' and '*high consequence event*' are defined. But in the last sentence, neither term is used. '*Potential high consequence accidents*' should be replaced by '*high consequence events*'. Similarly, there is no term '*low consequence accidents*' used in 10 CFR 70.61 and this term should not be used. Potential accidents that are neither high- nor intermediate-consequence are not referenced in the Rule.
- (xxiii) Item (7), last paragraph, page 3.0-17: consistent with the corrected text in the preceding paragraph, revise the term to read "...*high consequence events...*". We have some general concern with the thrust of this paragraph that seems to try to incorporate an NMSS goal (i.e. no high consequence events) into a regulatory requirement. If this goal is of critical importance, it should be stated in the Rule.
- (xxiv) Item (7), 1<sup>st</sup> paragraph under '*Credible*', page 3.0-16:

- (1) first sentence is redundant. Delete. Revise 2<sup>nd</sup> sentence to begin: "...'Credible' is used in 10 CFR 70.61 in the following..."
- (2) this paragraph states that an accident can not be considered to be incredible based upon the protection afforded by a design feature that is not classified as an IROFS, because such a feature might be changed and result in a credible accident. This provision should be deleted for the following reasons: (i) as provided in 10 CFR 70.72 a licensee is required to evaluate design changes for impact on the ISA. This provision ensures that a licensee will not make a design change that transforms an incredible accident into a credible accident without first establishing appropriate IROFS, and (ii) some design features may provide a measure of protection (or may limit the consequences of accident), even assuming they fail. It would be unreasonable to classify such features as IROFS. Delete this provision that states that an accident cannot be considered to be incredible based upon the protection afforded by a design feature that is not classified as an IROFS.
- (3) 5<sup>th</sup> sentence should, therefore, be modified to read:
 

*"...the fact that an event is not credible must not depend on an IROFS, but on external or natural phenomena or some feature of the facility that can be relied on without being in the facility change control system. In general, events that are not credible are physically impossible, require very low likelihood external initiators, involve a long series of very unlikely events or involve an extremely improbable series of human actions for which no motivation exists..."*

(xxv) Item (7), 1<sup>st</sup> paragraph under '*Quantitative Guidelines for Use with Acceptance Criteria*', page 3.0-19: several comments:

- (1) as industry has stated before, we do not see any reason to do a quantitative frequency calculation for all events
- (2) definition of  $N_i$  (number of potential intermediate consequence events) is inconsistent with that stated on page 3.0-17
- (3) definition of  $N_h$  (number of potential high consequence events). On page 3.0-17 the reviewer was told to assign a value of 1,000 to  $N_h$ , and yet on page 3.0-19, the reviewer is directed to assume that  $N_h$  has a value of at least 1,000. Which is correct?

- (4) The SRP implies that a licensee must determine values for  $N_h$  and  $N_i$ . Such a requirement is unduly burdensome and unnecessary, especially since a licensee is not required to perform a probabilistic risk assessment. Furthermore, the values assumed by the NRC appear to be arbitrary and unsupported and their relation to the bounding accident analyses is not clear. The licensee should be able to estimate likelihood as permitted by 10 CFR 70
- (5) The PRA definition of '*unlikely*' in this section differs from that state in Appendix A, §A3. ( $4 \times 10^{-3}$  versus  $10^{-2}$ . Which is correct? We note that an event with a likelihood below  $10^{-2}$ /year is not expected to occur during the lifetime of the facility (~ 25-40 years) which corresponds to the definition of the word '*unlikely*'.
- (xxvi) Item (7), last paragraph, 2<sup>nd</sup> sentence, page 3.0-19: this sentence states that the term 'highly unlikely' should be graded in inverse proportion to the magnitude of consequences when the consequences are significantly greater than the lower limits. This sentence should be deleted for the following reasons: (i) it is inconsistent with the definition provided in the table on page 3.0-19, (ii) the provision is vague and highly subjective, and (iii) the provision is inconsistent with 10 CFR 70.61 which does not require the determination of 'highly unlikely' events to be contingent upon the consequences of the accident in question (i.e. the definition of highly unlikely should be based upon the probability of the event, not the consequences of the event).
- (xxvii) Item (8) [editorial comment]: for consistency with the terms used in 10 CFR 70.65, the title of this item should be revised to read: '*INFORMATION DEMONSTRATING COMPLIANCE WITH THE PERFORMANCE REQUIREMENTS OF 10 CFR 70.61*' (see comment (iv) above)
- (xxviii) Item (8), 1<sup>st</sup> sentence, 1<sup>st</sup> paragraph, page 3.0-20: this sentence is redundant and provides no guidance to the reviewer. Delete.
- (xxix) Item (8), 4<sup>th</sup> sentence, 1<sup>st</sup> paragraph, page 3.0-20: the last few words of this sentence should be re-written in terms of risk: "*...each credible accident sequence must have a likelihood commensurate with risk level...*"
- (xxx) Item (8), 3<sup>rd</sup> sentence, 1<sup>st</sup> paragraph, page 3.0-20: the last few words of this sentence could be better expressed as follows: "*...Since the requirements of 10 CFR 70.61 are expressed in terms of consequences and likelihoods of events, the information needed*

*is that which shows that the consequences and likelihood of potential accident sequences have been appropriately established...*"

- (xxxix) Item (8), 3<sup>rd</sup> sentence, 2<sup>nd</sup> full paragraph, page 3.0-20: [editorial comment] better expression: "...radiological doses specified in 10 CFR 70.61..."
- (xxxii) Item (8), 2<sup>nd</sup> sentence, 3<sup>rd</sup> paragraph, page 3.0-20: for clarification, add the words "...discussed in the ISA Summary..." to the end of this sentence to remind the ISA Summary reviewer that not all accident sequences will be reviewed -- but only those intermediate- and high consequence events presented in this document. "...The information must show the basis and the results of applying these measures to each process discussed in the ISA Summary..."
- (xxxiii) Item (8), item (iii) under 'Consequences', page 3.0-21: this paragraph states that the applicant should use 'reasonably conservative' estimates. This demand is inconsistent with the risk-informed nature of 10 CFR 70.61 and should be modified to refer to 'reasonable' or 'realistic' estimates that account for uncertainties.
- (xxxiv) Item (8), item (iv) under 'Consequences', page 3.0-21: there are only 2 'consequence categories' specified in 10 CFR 70.61. Correct the reference to 'low consequence category'.
- (xxxv) Item (8), 2<sup>nd</sup> paragraph under 'Consequences', page 3.0-21: based on a risk-informed approach, a shielded criticality need not be highly unlikely as allowed by this paragraph. The comparable discussion in Chapter 5 (nuclear criticality safety) §5.4.3.4.6(3) should be made consistent with this possibility. Some short clarification to the 1<sup>st</sup> sentence of this paragraph should be given to explain why an unshielded nuclear criticality accident will be a high-consequence event: "Unshielded nuclear criticality accidents are considered to be high consequence events, because there is a substantial likelihood that the radiation dose received by a worker would exceed the 10 CFR 70.61(b) limit of 100 rem TEDE..."
- (xxxvi) Item (8), 1<sup>st</sup> item under 'Likelihood', page 3.0-21: insertion of 'ISA Summary' into this provision is in the wrong place, as it would imply evaluation of the likelihood of accident sequences that are not reported in the ISA Summary. This sentence must be re-written as: "...the applicant provides an evaluation of the likelihood of each type of accident sequence in the ISA Summary..."

- (xxxvii) Item (9), 1<sup>st</sup> paragraph, page 3.0-22: for consistency with the rule, terminology from 10 CFR 70.61 should be used in this section: 3<sup>rd</sup> sentence: "...*all hazards that were identified that could credibly exceed the performance requirements of section 70.61 should be listed...*" 5<sup>th</sup> sentence: "...*credible inventories on site, the performance requirement levels of section 70.61...*"
- (xxxviii) Item (10), 2<sup>nd</sup> sentence, 3<sup>rd</sup> paragraph, page 3.0-23: [editorial comment]: delete the parenthesis ("...*(IROFS)*...")
- (xxxix) Item (10), last sentence on page 3.0-23: consistency with Rule language. Revise to read: "...*no hazard or accident sequence that could cause a failure to meet the performance requirements of section 70.61 was overlooked; and...*"
- (xl) Item (10), 2<sup>nd</sup> sentence, 1<sup>st</sup> full paragraph on page 3.0-24: consistency with Rule language. Revise to read: "...*These accidents will later be analyzed and may be shown incapable of exceeding the performance requirements of section 70.61...*"
- (xli) Item (10), 4<sup>th</sup> sentence, 1<sup>st</sup> full paragraph on page 3.0-24: this statement is incorrect. The ISA Summary will not identify "...*all accidents considered...*", but rather only those analyzed to have the potential of exceeding the performance requirements of 10 CFR 70.61(b) and (c).
- (xlii) Item (11): acceptance criterion (1): consistent with discussions with the NRC, the IROFS should be described at the systems, rather than component, level. Revise to read: "...*It includes all IROFS at the systems level in the identified accident sequences...*"
- (xliii) Item (11), point (2), page 3.0-25: [editorial comment]: delete the words '*items relied on for safety*' in front of the IROFS acronym. IROFS has already been defined.
- (xliv) Item (13) [editorial comment]: for consistency with the terms used in 10 CFR 70.65, the title of this item should be revised to read: '*INFORMATION DEMONSTRATING COMPLIANCE WITH THE REQUIREMENTS FOR CRITICALITY MONITORING OF 10 CFR 70.24*' (see comment (iv) above)
- (xlv) Item (14) [editorial comment]: for consistency with the terms used in 10 CFR 70.65, the title of this item should be revised to read: '*INFORMATION DEMONSTRATING COMPLIANCE WITH THE BASELINE DESIGN CRITERIA REQUIREMENTS OF 10 CFR 70.64*' (see comment (iv) above)
- (xlvi) Item (14), 1<sup>st</sup> paragraph, 1<sup>st</sup> sentence, page 3.0-26: to the end of this sentence should be added the following words to be consistent with the language in 10 CFR 70.64(a): "...*for new facilities and new processes at existing facilities that require a license amendment under 10 CFR 70.72...*"

- §3.5.1 ('Acceptance Review'):
  - (i) 1<sup>st</sup> paragraph, 1<sup>st</sup> sentence: for consistency with the terminology used earlier in Chapter 3, this sentence should be revised to read: "...For the review of ISA programmatic commitments contained in a new license application, license amendment or in an ISA Plan, the primary ISA reviewer..."
  - (ii) 2<sup>nd</sup> paragraph, 1<sup>st</sup> sentence [editorial comment]: for consistency and balance with the 1<sup>st</sup> paragraph, revise the beginning of this sentence to read: "...For the review of an ISA Summary, the primary..."
- §3.5.2 ('Safety Evaluation'):
  - (i) NEI suggests addition of an introductory sentence in §3.5.2 to advise the reviewer that the safety evaluation is a two-part exercise: "...After determining that the application is acceptable for review in accordance with Section 3.5.1, the primary reviewer should perform a safety evaluation against the acceptance criteria described in Section 3.4.3. The safety evaluation includes assessment of the acceptability of the applicant's ISA Programmatic Commitments and the ISA results as presented in the ISA Summary. On the basis of its review, the staff may request the applicant to provide additional information or modify the application to meet the acceptance criteria in Section 3.4.3..."
- §3.5.2.1 ('Evaluation of ISA Programmatic Commitments'):
  - (i) 1<sup>st</sup> three sentences: the language in these sentences is very confusing, correct terminology is not used and the reviewer's task is not clearly stated. Revise these sentences to read: "...The staff performs a safety evaluation of the ISA Programmatic Commitments against the acceptance criteria presented in §3.4.3.1. ISA Programmatic Commitments may be contained in the ISA Chapter of a license application, renewal or amendment or in the ISA Plan submitted in accordance with 70.62(c)(3)(i). Additional programmatic commitments may also be found in chapters of the license application other than the ISA Chapter as the ISA is highly interrelated with all aspects of a safety program..."
- §3.5.2.1 ('Evaluation of ISA Summary and Results'):
  - (i) [editorial comment]: for consistency throughout Chapter 3, the section titles of §§3.3.2, 3.4.3.2 and 3.5.2.2. should all be the same. Recommend changing the title of this section to read: "...Evaluation of ISA Results and ISA Summary..."
  - (ii) For consistency with §3.5.2.1, NEI recommends that the first sentence of this section be revised to read: "...The staff performs a Safety Evaluation of the ISA Summary against the acceptance"

criteria presented in §3.4.3.2, This review would normally be performed..."

- (iii) 4<sup>th</sup> complete paragraph, page 3.0-28: suggest adding text to the end of this sentence to convey the other purposes for which a site visit may be warranted: "...3-D geometry of process equipment and to consult the ISA and supporting ISA documentation used to prepare the ISA..."
- (iv) 2<sup>nd</sup> paragraph, page 3.0-29 [editorial comment]: first word of sentence should probably be 'from' instead of 'for'
- §3.6 ('Evaluation Findings'):
  - (i) General Comment: the introductory paragraph of §3.6 is unnecessarily vague and provides little guidance to a reviewer. It should state that the Primary Reviewer will prepare an SER that incorporates the results of the two safety evaluations made in §3.5. Verifying that "...the information submitted by the applicant is sufficiently complete so that compliance with the regulations can be evaluated..." is a task that was previously in §3.5 and need not be repeated in §3.6. The suggested text for evaluation of the ISA Programmatic Commitments is inappropriate and relates more to an evaluation of management measures than programmatic commitments. The Chapter 3 review does not constitute a complete review of the facility safety program (cf. 10 CFR 70.62(a)(1)). The proposed text does not accurately reflect what was reviewed. Both the introductory text and suggested SER text should be changed as follows:

"...The primary reviewer should document the safety evaluations of the applicant's ISA Programmatic Commitments and ISA results as presented in the ISA Summary by preparing information suitable for inclusion in the Safety Evaluation Report (SER). The primary reviewer should describe these reviews, explain the basis for the findings and state the conclusions.

The staff could document the safety evaluation of the applicant's ISA Programmatic Commitments as follows:

"The staff reviewed the ISA Programmatic Commitments in the license application for [name of facility] and confirms that they include appropriate commitments to: (1) compile and maintain process safety information, (2) engage personnel with appropriate training to conduct the ISA, (3) use appropriate methods to conduct the ISA, and (4)

implement appropriate measures and procedures to ensure that the ISA stays accurate and up-to-date."

- (ii) Bottom paragraph on page 3.0-29 (suggested SER text): again, the suggested language is very imprecise. For example, the first sentence ("...Many hazards and potential accidents can result in unintended exposure of persons to radiation, radioactive materials, or toxic chemicals associated with licensed materials...") is a 'motherhood-apple pie' type of statement that may be appropriate for the introduction to the SRP, but not in the SER. It says nothing about the review of the ISA Summary and should, therefore, be deleted. This paragraph of suggested SER text could be improved as follows:

*The staff could document the safety evaluation of the applicant's ISA Summary as follows:*

"The staff has reviewed the ISA Summary for [insert name of facility] and verifies that the applicant has performed an Integrated Safety Analysis (ISA) to identify and evaluate the hazards and potential accident sequences associated with the facility and has selected and implemented appropriate engineered and administrative controls to ensure facility operation will be within the bounds of the ISA. The staff confirms that the applicant's ISA Summary has: (1) identified risk-significant hazards at the facility, (2) analyzed for accident sequences through the use of process hazards analysis (or equivalent methodologies), (3) evaluated and assigned consequences to the accident sequences, and (4) evaluated the likelihood of each accident sequence that could exceed the performance requirements of 10 CFR 70.61. The applicant has identified items relied on for safety (IROFS) and systems of IROFS which, when supported by management measures, provide reasonable assurance that postulated accidents resulting from the facility hazards that may be anticipated to occur (or are considered unlikely or highly unlikely) should be in compliance with the performance requirements of 10 CFR 70.61. The staff concludes that the health and safety of the public, the workers and the environment will be adequately protected ."

- (iii) 3<sup>rd</sup> paragraph, 2<sup>nd</sup> sentence, page 3.0-30: for consistency with the 10 CFR 70.64(a) language, the last half of this sentence should be revised to read: "...*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 that require a license amendment under §70.72) for those processes to which they are applicable...*"
- Appendix A ('Example Procedure for Risk Evaluation'):
  - (i) General Comments:
    - (1) as NEI previously recommended, we believe that Appendix A should be incorporated into NUREG-1513 as a guidance document. NEI recommends that Appendix A be removed from NUREG-1520 and the ISA guidance documents be referenced to obtain examples of how to present ISA results
    - (2) terminology should be made consistent with 10 CFR 70. For example: use '*IROFS*' instead of '*controls*' (in most circumstances) and '*performance requirements*' instead of '*levels*' or '*thresholds*' when referring to 70.61.
  - (ii) Section A.1, paragraph 2, 4<sup>th</sup> and 6<sup>th</sup> sentences, page 3.0-33: insert '*acute*' before '*chemical exposure*' or '*exposure levels*'.
  - (iii) Section A4, paragraph 2, page 3.0-39: this section states that the failure duration for an unmonitored process should be '*conservatively*' estimated. To reflect the risk-informed nature of Part 70, this provision should be revised to state that the duration should be '*reasonably estimated*', accounting for uncertainties.
  - (iv) '*Determination of Failure Frequency Index Numbers Table A-3*' discussion, 2<sup>nd</sup> sentence, page 3.0-39: this sentence states that the term 'failure' includes violation of a safety limit. Given the design margins for IROFS, not all violations of a safety limit will result from the failure of a safety function. Therefore, in accordance with the risk-informed nature of 10 CFR 70, this statement should be qualified to state that 'failure' should include a violation of a safety limit, if there is not a high probability that the IROFS in question can still perform its safety function.