Public Comments Resolution of Technical Issues

	Commenter	Comment	Responses
1	NEI	Section B.1 of the draft ISG, second paragraph: First sentence has two separate issues, one dealing with the "significant consequences" and one dealing with the means of release of the chemical. Also as "significant consequences" is not defined it is recommended that a reference to intermediate or high consequences as defined by the ISA be used. Also the consequence statement focuses on toxicity which is just one aspect of the hazard that a chemical may possess, there could also be none toxic aspects that could lead to intermediate or high consequences.	Agree. A new first sentence was added referencing typical material properties that should be considered in reviewing chemical hazards. Additionally, the draft ISG's use of the undefined "significant consequences" term is replaced by references to intermediate and high consequence chemical exposure events as described in the 10 CFR 70.61(b)(4) and (c)(4) performance requirements.
2	NEI	Section B.1 of the draft ISG, second paragraph, the word "some": This is the critical part of the issue not only with this ISG but with the entire characterization of the rule as interpreted requiring quantitative standards. This table and the references within the ISG does not contain information on all the chemicals used (especially when taking into account the concentration, and mixtures, cocktails, of chemicals used in the Fuel Cycle industry). Also there are many other aspects of a dosing phenomenon that impact the consequence of an exposure area, duration, transport characteristics of the dermal area. There are also mitigative characteristics both naturally occurring as well as induced, first aid, sense and flee, etc.	Agree in part. In response to this comment, the rest of the subject paragraph is revised to clarify (1) that while ISG Table 1 identifies some chemicals commonly used at fuel cycle facilities, it is not an exhaustive list of such chemicals; (2) that for chemicals not listed in the Table, the staff reviewer may need to examine the information sources listed in Table 1 to find relevant information for any chemicals of concern identified by the applicant or licensee; and (3) that the information in Table 1 will likely change over time as new information and scientific data about the hazardous characteristics of chemicals becomes available. The comment's reference to chemical concentrations, cocktails and mixtures used in fuel cycle facilities pertain to the staff's evaluation of chemical hazards and accident sequences that are presented for review on a case specific basis. Unlike the chemicals listed in Table 1, chemical mixtures may include proprietary information and be facility-specific. This ISG is a general guidance document, and it accordingly does not contain the level of detail that would be necessary to provide guidance on facility-specific chemical mixtures.

			The meaning of the commenter's reference to "aspects of a dosing phenomenon," and the degree to which these aspects may "impact the consequences of an exposure area, duration, transport characteristics of the dermal area," is not clear. Staff interprets "aspects" as a reference to the many physical factors that may need to be considered by licensees or applicants when estimating the chemical exposures that may arise from postulated accident sequences. To the extent that this comment may be regarded as relating to the information needed to estimate chemical exposures, this issue is discussed below in the comment #6 response. The mitigation issues raised by this comment are addressed below in the response to comment 3.
3	NEI	Section B.2 of the draft ISG, first statement: This statement gives no potential credit for mitigation vs. prevention as allowed in the rule.	The staff agrees that mitigating the consequences of a chemical exposure is an acceptable way to meet the performance requirements, as reflected in the 10 CFR 70.61 and 70.62 provisions relating to controls designated as items relied on for safety (IROFS). However, as indicated in the ISG's Introduction, the ISG's focus is on the part of the staff's required chemical safety review that evaluates an applicant's or licensee's proposed quantitative standards submitted in accordance with 10 CFR 70.65(b)(7). While credit for mitigating the effects of a high or intermediate consequence event is allowed pursuant to the 10 CFR 70.61 and 70.62 IROFS provisions, mitigation of these effects is a topic outside the scope of this ISG.

4	NEI	Section B.2 of the draft ISG, first statement, “chemical exposure”: Chemical exposures within the jurisdiction of the NRC ISA.	Agree. In response to this comment, the revised introductory text in Section B.2 references hazardous chemicals “that are within the NRC’s jurisdiction.”
5	NEI	Section B.2 of the draft ISG, second paragraph, third sentence: The basis of this aspect of the evaluation is not clear. The difference between exposures of the worker vs. the public is clear but the relevance of this statement is not clear nor what it might mean during the NRC review process.	Agree. In response to this comment, the revised second paragraph of Section B.2 includes a statement that the high-consequence and intermediate-consequence events described in the 10 CFR 70.61 performance requirements are different, and that this difference depends on whether the receptor is a worker or an individual outside the controlled area.
6	NEI	Section B.2 of the draft ISG, third paragraph: It is unclear whether NRC considered the exposure area and concentration of the chemical, absorption, buffering mechanisms of the transport phenomena of the chemical through the dermal or other tissue layers. Also mitigation mechanisms such as sense and flee including but not limited to showering, buffering agents, first aid and or medical treatment etc. should be considered.	Agree. In response to this comment, the fourth paragraph of Section B.2 was revised as specified below. Staff recognizes there can be many physical factors for licensees to consider when estimating chemical exposures and their consequences. Such factors include exposure area, duration, and the chemical’s concentration. The specific physical factors will vary for different accident sequences and different chemicals. The ISG is a general guidance document, and it accordingly does not contain the level of detail that would be necessary to cover all the various physical factors that may be relevant when a licensee or applicant analyzes a given accident sequence. Regarding the staff’s review of chemical accident consequences, the second paragraph of Section B.2 now ends with the following general guidance: “The reviewer should determine if the methods for estimating release rate and release conditions are reasonable (i.e., the results are not clearly biased in a way that underestimates consequences) for the physical properties of the material being released.” Regarding the staff’s review of chemical accident consequences, section B.2 of the draft ISG described a

			multistep process for estimating and classifying chemical exposure consequences. The draft ISG stated in relevant part (section B.2, second paragraph) that estimating and classifying chemical exposure consequences involves "an assessment of multiple parameters such as vessel size and pressure, hole size, building ventilation characteristics, building dimensions, and local meteorology." The final ISG retains this statement, and the staff is accordingly prepared to consider these and other parameters in its review of any chemical accident analyses provided by an applicant or licensee. To further clarify the ISG in response to this comment, the third paragraph of Section B.2 includes a statement that the staff reviewer should determine if the methods the licensee or applicant uses for estimating exposure are reasonable, given factors such as the layout of the plant and the qualifications and training of workers. The mitigation issues raised by this comment are addressed above in the response to comment 3.
7	NEI	Section B.4 of the draft ISG, top paragraph, second sentence: Only with regard to the "likeliness" of the event. The matrix requires the consequence for those events for likely. Not sure this is a completely accurate characterization of the matrix referenced.	Agree. In response to this comment, the draft ISG paragraph referencing the NUREG-1520 risk matrix has been deleted and replaced. In considering the comment, the staff determined that the risk matrix discussion did not properly focus on the staff's review of proposed quantitative standards. The replacement text in Section B.4 corrects this problem.
8	NEI	Section B.4.1 of the draft ISG, first line: Meaning of the word "reliable". Not sure of the expectation or meaning of "reliable" in practical terms. Clarification would help.	Agree. In response to this comment, "reliable" was deleted, and the sentence was otherwise revised to clarify the types of information that staff would find acceptable when evaluating the supporting documentation of any proposed standard.
9	NEI	Section B.4.1 of the draft ISG, third sentence: For many chemicals, especially when taking concentration and "mixes" of chemicals into	Disagree. No changes were made to the draft ISG in response to this comment. The ISG identifies sources of

		account, the referenced standards possess a limited amount of information on which to base a quantitative standard. Even a qualitative evaluation involves a number of assumptions used in the judgment of the ISA team when determining the likelihood and severity of consequence for prevention or mitigative purposes.	information on which proposed quantitative standards may be based. As stated in Section B.4.1, the staff does not expect that applicants or licensees will need to conduct any testing to generate data supporting their proposed standards.
10	NEI	Section B.4.1 of the draft ISG, second paragraph, last sentence: This represents the same judgment and assessment of the assumptions that inevitably the ISA team must make.	Disagree. While the staff recognizes that judgment may be required by the licensee's ISA team to estimate the health effect consequences of a chemical exposure event, the ISG text at issue pertains to the staff's review of proposed quantitative standards pursuant to 10 CFR 70.65(b)(7). Unrelated to this comment, the sentence was clarified to state that the staff reviewer should ensure that the proposed standard is consistent with available toxicological information and provides a reasonable estimate of event severity.
11	NEI	Page 7, Emergency Response section: Language in paragraphs 2 and 3 (and NUREG-1520, Chapter 3, Appendix D) could lead NRC reviewers to expect this information to be contained in the ISA Summary and/or license amendment instead of in the Emergency Plan. Proposed resolution: NRC should add a statement that this information is expected to be contained only in the Facility Emergency Plan as discussed in NUREG-1520 Chapter 8.	NEI withdrew this comment. No response is necessary.
12	NEI	Section B.4.2 of the draft ISG, first sentence after the URL's: This statement implies a hierarchy of standards in the eyes of the NRC. Is this NRC's intent? If so, what is this hierarchy based on?	It was not the staff's intent to imply a hierarchy of standards or a hierarchy of information sources. To focus on the staff's review of proposed standards, the sentence was deleted and replaced with the following statement: "The staff may also use the information available in the GHS database when evaluating a proposed standard." The staff notes that the ISG is not intended to impose any limitation on licensees or applicants in their choice of information sources on which to base a proposed standard. The staff will review each proposed

			quantitative standard on its merits, regardless of what information source the standard is based on.
13	NEI	Section B.4.2 of the draft ISG, middle of first full paragraph, sentence beginning with "Acceptable quantitative standards…": The characterization of a hazard tag to be equated to a quantitative standard is of concern. These tags provide a characterization of the chemical provided by the manufacturer typically for a given concentration (not necessarily that used in the process). So it may provide some general characterization of the hazard but without typically body surface area, exposure time and obviously the concentrations or other chemical dynamic effects worse or better when mixed with other chemicals.	Disagree. No changes were made to the draft ISG in response to this comment. While it is not clear what is meant by the comment that the "characterization of a hazard tag to be equated to a quantitative standard is of concern," the staff has determined that acceptable standards can be proposed based on available information. To the extent that this comment may be read as raising chemical mixture issues, such issues are addressed in the comment 2 response above. To the extent that this comment may be raising a concern with the staff's use of hazard statements in the GHS database when evaluating a proposed quantitative standard, the GHS does provide useful information about the hazardous characteristics of a chemical. But factors such as body surface area and exposure time go beyond the level of detail discussed in the ISG. While these factors may need to be considered by an applicant or licensee in conducting an ISA, they are not part of the staff's review of a proposed quantitative standard. Text in Section B.4.2, 5th paragraph, first sentence, has been clarified to state that the GHS database is an acceptable data source that staff may use in the staff's evaluation of proposed standards.
14	NEI	Section B.4.3 of the draft ISG, second sentence: Indicates these are the only "standards" determined acceptable to the NRC staff.	Agree. In response to this comment, the sentence was clarified by adding the following underlined text to state: "The reviewer needs to verify that an applicant's proposed dermal standards are consistent with available and technically sound information or well-established data sources."

15	NEI	Section B.4.3 of the draft ISG, third paragraph, the word ‘derived”: The use of this word indicates an "interpretive" step in taking the information in the GHS database and using judgment when comparing that chemical exposure in the accident scenario by the ISG team. This is Quantitative?	Agree in part. The sentence containing “derived” was unclear and has been deleted. But the comment’s reference to the staff’s use of “judgment,” and questioning whether this is “quantitative” warrants a response. ISG Section B.4.3 concerns the staff’s review of proposed quantitative standards developed by an applicant or licensee and submitted to the staff pursuant to 10 CFR 70.65(b)(7), which requires that the ISA summary contain a description of such standards. The staff uses its best engineering judgment in reviewing <u>any</u> licensee or applicant submittal. The fact that the staff performs such reviews does not call into question, as the comment might imply, the validity of requiring the development of quantitative standards.
16	NEI	Section B.4.3 of the draft ISG, fourth paragraph, first sentence: With no assessment of concentration, quantity, body surface area, etc.	No changes were made to the draft ISG in response to this comment. The point of the comment is not clear. The purpose of the discussion is to provide guidance to the NRC staff by identifying information the staff should consider when reviewing proposed standards. The general criteria for accepting proposed standards are stated in Section B.4.1. As indicated by the discussion within the proposed rule’s preamble of what became 10 CFR 70.61(b)(4) (64 FR 41342-43, July 30, 1999), the rule’s qualitative language provides the applicant or licensee with flexibility to propose or adopt an appropriate standard for its specific operation. This flexibility allows applicants or licensees to utilize the most current toxicological information for the chemical hazard being analyzed.
17	NEI	Section B.4.3 of the draft ISG, fourth paragraph, last sentence: To worker, public or both?	Agree. In response to this comment, the text was clarified to reference worker exposure events.
18	NEI	Section B.4.3 of the draft ISG, last paragraph, first sentence: At some facilities, only two of the near two dozen chemicals used at the site are addressed within this table.	The staff has no basis to agree or disagree with this vague comment. The ISG text references an OSHA table that lists chemicals noted for skin adsorption. As stated in the ISG text, if a chemical is not listed in either the OSHA table or in the other referenced information sources, the

			staff would generally expect the dermal exposure effects to be minimal.
19	NEI	Section B.4.3 of the draft ISG, last sentence: While industry agrees, this is the first time we have seen it stated. Further clarification and acceptance of this mechanism should be included.	Agree. The last sentence was modified to clarify that for individuals outside the controlled area, chemical exposures via the dermal pathway are "generally expected to be" highly unlikely or not credible. Additionally, the following statement addressing all exposure pathways was added to Section B.2, 3rd paragraph: "In general, for chemical exposures via the inhalation pathway, it is reasonable to expect that both workers and individuals outside the controlled area may be subject to such exposures. For chemical exposures via the dermal and ocular pathways, it is reasonable to expect that only workers would be subject to such exposures."
20	NEI	Section B.4.4 of the draft ISG, first sentence: Is GHS the only source for ocular quantitative standards?	The GHS data base is the only source of information the staff has identified regarding the review of proposed quantitative standards for ocular exposures. The GHS data base covers a broad range of chemicals on which to base a proposed standard for the ocular exposure pathway. Unrelated to this comment, the staff has supplemented the Section B.4.4 introductory text as follows: "The staff reviewer needs to verify that an applicant or licensee's proposed ocular standards are consistent with available and technically sound information or well-established data sources. If the applicant or licensee proposes other sources of information as the basis for a proposed ocular standard, the reviewer should evaluate the adequacy of the information the applicant is referencing."

21	NEI	Section B.4.4 of the draft ISG, second paragraph, last sentence: Industry takes exception of the characterization in table 4 that there is a high consequence event based on the GHS tag H310 “Fatal in contact with the skin”	Agree. The hazard statement was deleted from ISG table 4.
22	NEI	Section B.4.4 of the draft ISG, third paragraph, second sentence: Industry takes exception of the characterization in table 4 that there is a high consequence event based on the GHS tag H310 "Fatal in contact with the skin".	Agree. The hazard statement was deleted from ISG table 4.
23	NEI	Section B.4.4 of the draft ISG, last paragraph: It is unclear whether this paragraph is a general summary pertaining to the entire ISG or specific to the ocular exposure pathway discussed in that section. If a summary pertaining to the entire ISG, a section heading of "Summary" may be appropriate.	Agree. In response to this comment, the paragraph was deleted and replaced by a brief summary statement referring to the Section B.4 discussion as determining “the potential need to consider a broad range of information sources when reviewing licensee or applicant-proposed quantitative standards.”
24	NEI	Section C: While the statements are accurate with regard to the worker, it is not clear why references to 70.61(b)(4)(ii) and 70.61(b)(c)(ii) are not included for the public in this discussion.	Agree. In response to this comment, references to “any individual outside the controlled area” were added to reflect these regulatory provisions.
25	NEI	Section D, fourth sentence: This statement acknowledges that this process is an ISA team judgment method taking many characteristics and aspects into account, actually with many more than "release location, worker location position and initial actions” (whatever they are).	No changes were made to the draft ISG in response to this comment. The sentence in question states: “The staff reviewer should further recognize the uncertainty in estimating the consequences of acute chemical exposures, which are functions of release location and rate, as well as worker location, position, and initial actions.” The staff finds that this guidance is clear and does not need to be revised.
26	NEI	Section C, second sentence, item 3: “Irreversible or other serious, long-lasting health effects” is undefined and leads to unnecessary confusion and disagreement between experts on its meaning.	Disagree. No changes were made to the draft ISG in response to this comment. The comment does not appear to recognize that the ISG wording is from 10 CFR 70.61(c)(4) The staff is not aware of any confusion or disagreement between experts caused by the subject wording in the regulation. The petition for rulemaking

			process provides a mechanism to address concerns with the meaning of rule language.
27	NEI	Table 1, fifth column, last row: "yes" for uranyl nitrate: Basis? Do we have one?	A protective action criteria (a TEEL) is presented on the Emergency Management Issues Special Interest Group website. See http://orise.orau.gov/emi/scapa/chem-pacs-teels/aegls-erpgs-teels.htm. No change was made in response to this comment.
28	NEI	Table 1 Note: Critically important note to the interpretation and use of this table. This perhaps deserves a more thorough treatment in narrative for use of the table to qualify its use.	Disagree. No changes were made to the draft ISG in response to this comment. In the staff's view, the meaning of the Note in question is clear, and should provide adequate guidance to the staff reviewers using ISG table 1.
29	NEI	Table 3 footnote: The footnote on Table 3 is applicable to Table 4 as well. Repeat the Table 3 footnote on Table 4.	Agree. In response to this comment, a footnote was added to Table 4. The draft footnote 3 wording was clarified and a reference to "the details of the accident sequence" was added. Tables 3 and 4 contain the same footnote.
30	NEI	Table 4 High consequence designation: Industry takes exception to use of the "high consequence" designator for ocular exposures. There are no known chemical exposures to the eye that result in death and the basis for equating the eye to a skin surface is unfounded. Industry is also not aware of any scientific evidence (e.g., GHS or NIOSH standards) to suggest that a "skin" exposure to the eye surface must also be evaluated for a possible fatality. Thus, the intermediate consequence line item is accurate and appropriate but the high consequence table entry is not and should be deleted in its entirety.	Agree. In response to this comment, the reference to "H310 Fatal in contact with skin" was deleted from ISG table 4.
31	NEI	General comment: fix the interpretation or the rule to allow for a qualitative approach.	Disagree. Any request to fix this rule "to allow for a qualitative approach" needs to be submitted in a petition for rulemaking, rather than challenging the ISG on this point.
32	Anonymous	I believe this guidance will ensure that NRC regulated companies are conducting the proper analysis and identification of hazards.	While the NRC staff agrees with the general nature of this comment, it notes that this ISG will provide guidance for NRC staff review of an applicant or licensee's evaluation

			of chemical safety hazards. Thus, while the staff expects that the ISG may provide insight to applicants and licensees analyzing chemical exposure issues, this guidance will not necessarily "ensure that NRC regulated companies are conducting the proper analysis and identification of hazards."