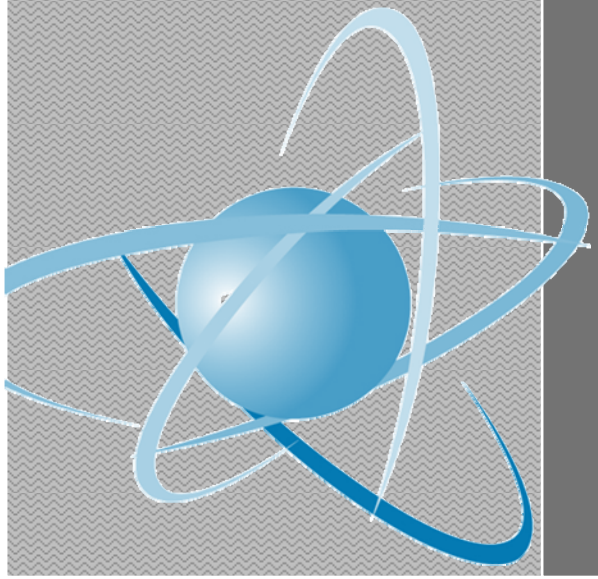
2009

Staff Response to Comments Received on Draft, NUREG-1520, Revision 1

U.S. Nuclear Regulatory Commission

NUREG-1520, "The Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility", has been updated to improve and enhance the guidance by providing increased clarity and definition in specific areas of the licensing program and adding additional guidance in areas where information was lacking or not suitably addressed. The first draft was published on August 05. 2009 (74FR39117) and the public had the opportunity to comment until October 24, 2009. This document summarizes the comments received by the public and the response from the staff to the comments received.



Contact: Cinthya I. Roman
Phone: 301-492-3224, Email: Cinthya.Roman@nrc.gov
2009

Table of Contents

Acronyms

ANS	American Nuclear Society
ANSI	American National Standards Institute
CAAS	criticality accident alarm system
CFR	*Code of Federal Regulations*
CM	configuration management
HFE	Human Factors Engineering
HSI	Human System Interface
IROFS	item(s) relied on for safety
ISA	integrated safety analysis
MOU	memorandum of understanding
NCS	nuclear criticality safety
NFPA	National Fire Protection Association
NMSS	Nuclear Material Safety and Safeguards, Office of (NRC)
NRC	U.S. Nuclear Regulatory Commission
OSHA	Occupational Safety and Health Administration
PHA	process hazard analysis
P&ID	piping and instrumentation diagram

QA	quality assurance
QC	quality control
RAI	request for additional information
SER	safety evaluation report
SNM	special nuclear material
SRP	standard review plan

Introduction

ID	Source	Comment/Question	Disposition
Int-1	NRC Staff	In the third full paragraph, in the sentence beginning "This is reflected in the above licensing requirements..." there is a non sequitur. The quotes given concerning "sufficient detail" are from 10 CFR 70.65, not 10 CFR 70.22, which is quoted above. 10 CFR 70.22 is taking about a general description of safety equipment, whereas 10 CFR 70.65 is talking about the contents of the ISA Summary.	Agree. The introduction was updated to correct this error.
Int-2	NRC Staff	It is not clear whether this section of the SRP is talking about the License Application (LA) review or the ISA Summary review. Then it switches back to talking about process system functions and IROFS. The discussion keeps switching back and forth between discussing the programmatic review and the technical review.	The introduction was revised to improve clarity and avoid confusion between LA and ISA Summary review.
Int-3	NRC Staff	The underlined text in following sentence is self contradictory: "The level of design required for a licensing decision, therefore, does not require a final facility design or an absolutely complete identification of all items relied on for safety and accident sequences, but instead sufficient information has to be provided to understand the process and functions of items relied on for safety and reasonable assurance that the integrated safety analysis summary is complete." A very important piece of the ISA Summary is the description of accident sequences and IROFS. 10 CFR 70.65 says it must contain these things. So how can the ISA Summary possibly be complete if the set of accident sequences and IROFS is not complete?	Agree in part. 10 CFR 70 does not require a final facility design. Every item relied on for safety used to reduce the likelihood of a high or intermediate consequences of a credible accident sequence needs to be identified in the ISA Summary. Every credible accident sequence that could exceed the performance requirements in 10 CFR 70.61 should be identified in the ISA Summary. Accident sequences that result in consequences below the performance requirements of 10 CFR 70.61 should be evaluated by the applicant; however, the applicant is not required to provide this information in the ISA Summary. The introduction was updated to clarify the information.

Int-4	NRC Staff	The statement that the ISA Summary does not have to include all accident sequences or IROFS (first underlined part in previous comment) is inconsistent with 10 CFR 70.61(e): "Each engineered or administrative control or control system necessary to comply with paragraphs (b), (c), or (d) of this section shall be designated as an item relied on for safety" as well as 10 CFR 70.65(b)(6), "A list briefly describing each item relied on for safety...".	See answer provided for comment Int-3.
Int-5	NRC Staff	If it were true that the ISA Summary does not have to be "absolutely complete", then there is no useful guidance provided on how complete is complete enough. The SRP uses the word "sufficient" without defining it, making the standard of level of completeness wholly subjective.	See answer provided for comment Int-3.
Int-6	NRC Staff	The discussion confuses two crucial but very different concepts. One is the concept of the level of detail with which accident sequences and IROFS must be applied. The other is the concept of completeness of the ISA. Obviously, one cannot describe anything in existence in absolute detail. There are certain things we need to know about a piece of equipment, and other things we do not need to know. This is the concept of defining something in sufficient detail. But this is different from the idea of completeness of the ISA. The ISA is complete it if includes all accident sequences that can credibly lead to a high or intermediate consequence event, and if it includes all the IROFS needed to reduce the risk of those sequences to an acceptable level. If this is not the right definition of completeness, then what is?	Agree. The introduction was revised to indicate that the ISA summary is complete if it includes all accident sequences that can credibly lead to a high or intermediate consequence event, and if it includes all the IROFS needed to reduce the risk of those sequences to an acceptable level.
Int-7	NRC Staff	The quotation from 10 CFR 40.41(g) is not relevant, since this is the SRP for Part 70. The quotation from 10 CFR 70.32(k) only applies to uranium enrichment facilities. However, the discussion that follows tries to generalize this to all fuel facilities, which do not have the same requirements.	Agree. 10 CFR Part 40 is for conversion facilities, and the SRP doesn't apply for those facilities, therefore the reference was deleted from the text.

Int-8	NRC Staff	To my knowledge, we do not routinely require licensees to provide "boundary definition packages." Is this going to be required in the future?	Regulations in 10 CFR 70 do not explicitly require the licensee to provide an "IROFS Boundary Package". However, the licensee's safety program must ensure that each IROFS will be available and reliable to perform its intended function when needed (10 CFR 70.61(e). Staff believes that in order to evaluate the availability and reliability of an IROFS in the license review, as well as to confirm these qualities through inspection, the support systems that are essential to the IROFS performing its safety function (i.e. within the boundary of the IROFS) need to be specified. Support systems that could prevent the IROFS from performing the intended function should be considered in the licensee's safety analysis and provided for Staff review. The boundary package concept used by some licensees is an acceptable means to provide the information needed to determine that the IROFS will be available and reliable to perform its safety function consistent with the assumptions made in the analyses. The introduction was revised. Note that NUREG-1520 is not a substitute for the NRC's regulations, and compliance with it is not required. This SRP does not preclude licensees or applicants from suggesting alternative approaches to those specified in the SRP to demonstrate compliance with applicable regulations.

Int-9	NEI	The term "IROFS boundary definition package" is a new term which is not defined in the regulations, and it has been included in this version of Draft NUREG-1520. At present, there is no regulatory basis for NRC requiring, through license condition as stated by staff during an October 8, 2009 public meeting, that licensees submit extensive information on IROFS and other structures, systems and components to facilitate the NRC's Operational Readiness Review (ORR). While it is acknowledged that NRC and licensees benefit from well-informed inspectors at the time of an ORR, industry suggests that NRC consider deleting this term and implied expectation in the absence of a regulatory basis. Instead, NRC inspectors should access the vast array of operations information available on site since the cost to industry of preparing such "packages" far outweighs the cost to NRC and industry for the associated inspection hours.	See answer provided for comment Int-8.

Chapter 1, Facility and Process Description

ID	Source	Comment/Question	Disposition
1-1	NEI	There are several references to facility /process descriptions being consistent with those in Chapter 8, Emergency Management. Several existing licensees simply refer to their emergency plan in Chapter 8, so this reference is not necessary.	Staff added those references to make sure facility/process description is consistent in both chapters of the license application. Therefore, the chapter was not modified.

Chapter 2, Organization and Administration

No comments

Chapter 3, Integrated Safety Analysis (ISA) & ISA Summary

ID	Source	Comment/Question	Disposition
3-1	NRC Staff	Page 3-3, last sentence: "…the reviewer could confirm that low-risk accident sequences that were not reported in the ISA Summary…". The only sequences that should not be reported in the ISA Summary are those that are not credible, not merely "low-risk."	Substituted less than intermediate consequence events or those which are not credible.
3-2	NRC Staff	Page 3-9, middle paragraph: "However, the applicant must describe the IROFS in enough detail to permit an understanding of the intended safety function." This is true, but it is not enough. The IROFS must also be described in sufficient detail to permit an assessment of its reliability.	Agree in part. An IROFS must be described in sufficient detail to permit assessment of its potential reliability. Ultimately, an IROFS can always be built or operated in an insufficiently reliable way to meet the performance requirements. But if the description of the IROFS and management measures is sufficient to provide reasonable assurance that the IROFS can and will be sufficiently reliable, then the application may be deemed acceptable.
3-3	NRC Staff	Page 3-22, paragraph (a): This states that all IROFS have to be identified, and is absolutely consistent with the rule. However, it contradicts the Introduction to the SRP, where is says that the list of IROFS and sequences does not have to be "absolutely complete." Either all IROFS have to be identified, or they don't. Which is it?	The list of IROFS is complete, when all IROFS used to reduce the likelihood of a high or intermediate consequences event are listed in the ISA Summary. This does not mean that each individual piece of hardware that is an IROFS or part of one need be listed.
3-4	NRC Staff	Page 3-25, underlined sentence: This sentence should cite something other than 70.61(d), because that regulation is only applicable to criticality. Did you mean 70.61(e)?	Change the reference at the end of the first paragraph of the section "Acceptance Criteria for the Def. of Credible" to just 70.61, no subsection reference.
3-5	NRC Staff	Page 3-29: In two places, you say that "highly unlikely" is now less than 10^{-4} per-event per-year. This occurs in the first paragraph on this page and in the table. Increasing the likelihood by an order of magnitude is a substantial increase in risk, and creates some logical difficulties:	The 10^{-4} was a typographical error and it was corrected.

3-6	NRC Staff	Page 3-32, middle: "If the ISA Summary includes sufficiently detailed information for a process, further examination of the onsite ISA documentation may not be required." I disagree with this sentence. Reviewers should *always* conduct an onsite review. Otherwise, how can we know that the process descriptions are accurate, that there are no safety hazards that have been ignored, etc? The rest of this paragraph goes on to state what should be done during such an onsite review, which seems to assume that one will be done.	This was clarified. What was intended is that there would be an on-site horizontal review element, but, if descriptions in the ISA summary are sufficiently detailed, one may not need to look at on-site descriptions to get more detail. The on-site review is for a reality check. Perhaps this section should elaborate on how to do a review for completeness by examining descriptions of the plant and safety controls from sources other than the ISA, such as configuration control documents and criticality and chemical safety evaluations. A diagram showing process locations in each building or a list of all plant processes should be cross-checked against the processes addressed in the ISA, and the list of IROFS.
3-7	NRC Staff	Page 3-33, top paragraph: Our experience shows that what is said here is absolutely correct, when it says: "If the ISA only declares as IROFS a set of controls that are minimally necessary to demonstrate compliance with 10 CFR 70.61 likelihood requirements, then such index scores would be misleading." It then goes on to talk about what else besides the ISA the reviewer has to consider to determine risk. This is an admission that the regulatory framework is inadequate. One key purpose of the revised Part 70 was to aid in making risk determinations, and to do that you have to make meaningful distinctions of risk. This is an admission that you can't do that, even if the licensee is in full compliance with the regulations. If the regulatory framework is inadequate, the regulations should be changed.	22 criticality events have occurred and 21 out of 22 were in solution systems. However, these all occurred in old weapons material processing plants of 1950's and 60 are vintage; where the process equipment was not safe by geometry. The response to the comment should be to revise the SRP language to provide guidance on two things: 1) How safe geometry systems fail – hence what to look for. 2) That the reviewer should look for unsafe geometry tanks, containers, sumps, etc. that could conceivably have SNM solutions placed in them or mis-routed to them. This could occur due to valve, vessel, or pipe leaks; by personnel errors in operating equipment or by process upsets

			such that the SNM content, pH, or presence of insoluble particles of process streams differs from normal.
3-8	NRC Staff	Also on page 3-33, it mentions two criteria for making risk distinctions when the ISA doesn't work: (1) based on experience (given different types and quantities of material), or (2) based on the robustness of IROFS. These two things are frequently at odds. For example, solution processes are where most criticalities have occurred, but typically rely on very robust geometry controls. Dry powder and pellet processes have seemingly lower inherent risk, but typically rely more on administrative mass, moderation, and spacing controls. So which is higher risk? The SRP doesn't say how to decide when these come into conflict, as they often do.	See answer to comment 3-7.
3-9	NRC Staff	In addition, reference to "index scores" should be deleted. Nothing requires use of an index method.	Agree partially. The text was clarified.
3-10	NRC Staff	In addition, in the fourth paragraph, it states that additional vertical slice reviews may be needed if the initial review identifies significant issues. Clearly if the initial vertical slice does not give us reasonable assurance of safety and compliance, we have to look deeper. But at some point we cannot just keep expanding the sample size. Would we have to look at all the sequences if we don't have confidence in the method? Or at some point would be conclude that the licensee has failed and the ISA Summary should be rejected? The chapter appears to suffer from the bias of assuming that the only successful result of the review is approval.	See answer to comment 3-6.
3-11	NRC Staff	Page 3-33 to 3-34: This discusses an "independent review" by the NRC staff, "if outstanding questions remain about compliance with the performance requirements…". Two comments: (1) too much emphasis is put on the performance requirements of 70.61. There are other parts of the regulation that presumably are important for licensees to comply with. (2) We should make it clear that the staff's independent review	The language regarding "independent" evaluation of PHA, consequences, or likelihoods by the staff was not intended to be a solution to a situation where the licensee's evaluation was incorrect; but rather one where, for some particular types

		cannot substitute for the licensee's performing a high-quality ISA. We run the risk of doing the licensees' work for them if we're not careful, which makes us primarily responsible for safety instead of the licensee?	of situations, the reviewer is unsure about either the adequacy of the methods used. In such cases the reviewer may regard some alternative method as providing greater assurance to himself about the effectiveness of the applicant's method. Here a positive result (applicant's method is acceptable) is expected. When a reviewer concludes that an applicant's method is inadequate, or is being improperly applied, we have a different problem, requiring a revision by the applicant.
3-12	NRC Staff	Page 3-34: "If the reviewer finds that the acceptance criteria are not met, the reviewer should recommend a license condition to rectify the deficiency." This again seems to be biased in favor of approval. To paraphrase this sentence: "*If the licensee has failed to adequately meet the regulatory requirements, the staff should find a way to justify approving it anyway.*" License conditions are an acceptable way to resolve issues in a licensing review, but are not always possible. They only work when the gap in regulatory compliance is relatively small. The SRP should say instead that there are three possible successful outcomes to a licensing review: (1) approval, (2) conditional approval (with license conditions), or (3) denial. We will work with licensees to strive towards approval—when feasible and consistent with the public interest.	Amend language to remove the implication that the reviewer should always fix things via license condition. Distinguish between process designs not being adequate to comply versus other deficiencies; such as ISA analysis being incorrect or required information not being documented.
3-13	NRC Staff	Page 3-6, middle of page: should state "The regulations in 10 CFR 70.65(b) list the types…"	Typographical errors were corrected.
3-14	NRC Staff	Page 3-9, middle of page: "While there may be an actual difference in level of detail that is known about processes and IROFS, as documented at the applicant's site, between existing and proposed new facilities." This is not a complete sentence/thought; there is no verb.	Typographical errors were corrected.

3-15	NRC Staff	Page 3-16, middle of page: "…the description of general types of accident sequences must be use systematic methods…". The word "be" does not belong here.	Typographical errors were corrected.
3-16	NRC Staff	Page 3-22, last sentence: The end of this sentence is missing. It does not continue on the next page.	Typographical errors were corrected.
3-17	NRC Staff	Page 3-25, last sentence: The end of this sentence is missing. It does not continue on the next page.	Typographical errors were corrected.
3-18	NRC Staff	Page 3-30, middle: should state "The reviewer examines the descriptions…"	Typographical errors were corrected.
3-19	NRC Staff	Page 3-30, last sentence: "…a visit to the facility to become familiar with the three-dimensional geometry of process equipment, to review components of the ISA, and to address any issues that arose during review of the ISA Summary." There's no verb in this sentence. Is the intent that such visits should be done? Must be done? May be done?	Typographical errors were corrected.
3-20	NRC Staff	Page 3-31, last sentence: should state "The following sections discuss each of the three facets of the onsite ISA review as discussed below."	Typographical errors were corrected.
3-21	NEI	Page 3-6, Section 3.4.1: This section implies that 10CFR70.72 (e) requires the ISA summary to be kept up-to-date on a change-by-change basis. The regulation actually states that "the affected facility documentation shall be updated promptly". However, the rule allows licensees who do not use the ISA summary on a day-to-day basis to update and submit	Agree. The section was updated to indicate that the ISA and other safety program documentation need to be updated promptly following to the facility change.

		the ISA summary to NRC on an annual basis - see (d)(3). Clarification of what is actually required by the rule is needed so that licensees can implement a performance-based approach to demonstrating compliance with the rule.	
3-22	NEI	Page 3-14, Section 3.4.3.1 (2) d. This item states, "If a proposed change results in a new type of accident sequence (e.g., different initiating event…". The example implies that a new initiating event constitutes a new type of accident sequence. According to 10CFR70.72 (1)(i), if a facility modification results in a "new type of accident sequence" a license amendment is required. The implied threshold for what constitutes "a new type of accident sequence" is too low relative to requiring a license amendment. Therefore, industry recommends that the text be changed to "If a proposed change results in a revised accident sequence in the ISA summary or increases the consequences and/or likelihood of a previously analyzed accident sequence within the contest of 10 CFR 70.61, the applicant commits to promptly evaluating the adequacy of existing IROFS and associated management measures and making necessary changes if required".	Agree. The section was updated to reflect the recommendation from the industry.
3-23	NEI	Page 3-14, Section 3.4.3.2 (3) a. This section seems to confuse the ISA and the ISA Summary. Specifically, 10 CFR 70.65 (b) pertains to the ISA summary, not the ISA. The second sentence, "The description of the processes analyzed as part of the ISA…" should be changed to read "The description of the processes included in the ISA summary is considered adequate if it describes…". Also, the fourth sentence states "If the information is available elsewhere…and is adequate to support the ISA, reference…". "ISA" at this location should be "ISA Summary".	Agree. Text was corrected to clarify what information pertains to the ISA Summary (not the ISA). Sections I through III were not deleted however the following sentence was added: "The level of detail in process

		The last sentence in this section (newly added) and the following sections i, ii, and iii seem to describe a level of detail that will only be in the ISA and not the ISA Summary. During past NRC interactions with licensees, this type of material was reviewed on site and it was not expected to have this level of detail in the ISA summary. As such, these sections should be deleted.	safety documentation held at the site would normally be greater than the descriptions in the ISA Summary; and may include some or all of the information listed as items i through iv below as needed."
3-24	NEI	Page 3-15, Section b second paragraph: This paragraph states"Any locations where hazardous regulated material, including fissile material, could ever be located, even only by accident, should be considered". Licensees consider abnormal conditions / accidents that could put licensed materials where it is not expected under normal conditions. However, the phrase "could ever be located" is unclear, not bounded, and implies an event more remote than "highly unlikely". Industry suggests that this sentence be revised to read "Locations where hazardous regulated material, including fissile material, could accidentally be located should also be considered".	Agree. The sentence was revised based on NEI recommendation.
3-25	NEI	Page 3-15, Section iv: This section is not clear as to what information should be included in the ISA summary versus what information should be included in the safety documentation on site.	The text was updated for clarification.
3-26	NEI	Page 3-15, Section c. i.: This section states "The applicant has identified all accidents…". Industry suggests that this sentence be changed to read "The applicant has identified all types of accidents…". The book "Guidelines for Hazards Evaluation Procedures" second edition published by the center for chemical process safety on pg. 21 states "It is impossible for a hazard analyst to identify and assess the significance of all possible things that can go wrong—even for a very limited, well-defined set of circumstances". The guideline listed in the Draft NUREG-1520 sets an unreasonable and potential unachievable expectation and is not risk-informed and performance-based in its approach.	Agree. The text was modified based on NEI recommendation.
3-27	NEI	Page 3-16, Section C paragraph following ii and indented section iii See previous comment. The guideline listed here also sets an unreasonable expectation, in that, it is not possible to identify all	The text was modified to read: "…all types of accident sequences…" as suggested in comment 3-26.

		accident sequences.	
3-28	NEI	Page 3-16, Section C third paragraph third sentence This sentence states "Initiating events can be either a failure of an IROFS or an external event". This sentence is misleading because initiating events can also be process upsets, non-IROFS failures, events internal to the facility but external to a process system etc. The description of an initiating event here should be consistent with appendix C pg 3-C-2.	The section was updated to improve clarity. The quoted sentence in comment 3-28 was deleted and replaced with the following sentence: "Initiating events can be (1) an external event such as a hurricane or earthquake, (2) a facility event external to the process being analyzed (e.g., fires, explosions, failures of other equipment, flooding from facility water sources), (3) deviations from normal operations of the process (credible abnormal events), or (4) failures of an IROFS in the process."
3-29	NEI	Page 3-18, Section ii Consequence, bullet one: The only sections of 10CFR 70.61 that indicate a quantitative standard is required are sections b (4) (ii) and c (4) (ii) and these are only for an individual outside of the controlled area. Currently, there is disagreement between NRC and industry on this rule interpretation. As such, it is the topic of discussion at a public meeting scheduled for November 9, 2009 between NRC and stakeholders. We respectfully suggest that the guidance be modified to reflect NRC's final position on this matter or, if unavailable at the time of issuing this NUREG in final, the topic not be addressed at all in NUREG-1520.	Staff considers that Section ii should remain unchanged. This issue was also addressed in the letter from NRC to NEI, June 12, 2009 (ML090920296).
3-30	NEI	Page 3-19, Section b. Management Measures: This paragraph could lead a reviewer to assume the management measure discussion for IROFS is provided on an accident sequence-by-accident sequence basis. However, the rule only requires this description on an IROFS basis. Industry suggests revising this portion of the paragraph to "…the application must describe the management measures to be applied to the IROFS listed in the ISA summary as required to meet the requirements of 10CFR 70.61."	The section was updated based on NEI recommendation.
3-31	NEI	Page 3-22, Section (6) b.: This section leads a reviewer to expect that assumptions and conditions such as safety margins are included in the	Agree. The text was revised to avoid misinterpretations.

		ISA Summary. Typically this information is not in the ISA Summary but is available on site for review at any time.	
3-32	NEI	Page 3-22, Section (6) a. (not indented): This section states that for the list of IRFOS to be complete "…no items, aspect, feature, or property of a process that is needed to show compliance with the safety performance requirements of the regulation may be left of this list". This item has been a source of disagreement between industry and the NRC. This item needs to be clarified as it is not possible to perform a safety analysis when a design is not present first. It appears to industry that certain basic items must be present prior to doing the safety analysis and determining credible abnormal conditions to evaluate for potential high and intermediate consequences.	Disagree. 10 CFR 70.61 clearly states that each engineered or administrative control necessary to comply with the performance requirements shall be designated as an IROFS. Each means "every one", "all", "both". Therefore the section remains unchanged.
3-33	NEI	Page 30-24, Section (7) a. and b.: Industry has historically interpreted the rule as follows and has reflected this interpretation in its ISAs, the Summaries of which have been accepted by NRC. The only sections of 10CFR 70.61 that indicate a quantitative standard is required are sections b (4) (ii) and c (4) (ii) and these are only for an individual outside of the controlled area. Industry believes that the implication that 10CFR 70.61 (b) (4)(i) and 10CFR 70.61 (c) (4)(i) require quantitative standards is in error. As such, we look forward to discussions on this topic scheduled for November 9, 2009 which may impact this language. As such, the Draft NUREG-1520 should not address this matter until a final NRC position is articulated to stakeholders.	See response to comment 3-29.
3-34	NEI	Page 3-25, Definition of "Credible": This section states that " One cannot claim that a process does not need IROFS because it is "not credible" due to characteristics provided by some other controls or features of the plant that are not IROFS, such an evaluation would be inconsistent with 10 CFR 70.61 (d)." This item has been a source of disagreement between industry and the NRC. A meeting between industry and the NRC was held on October 8, 2009 to discuss this issue. The concerns that industry expressed at this meeting need to be resolved prior to issuing this NUREG. Also, this section makes a distinction between "not credible" and highly	Agree in part. The definition of "credible" is consistent with 10 CFR 70.61 requirements. Therefore, the definition of "credible" was not modified. However, another sentence was added to clarify that a highly unlikely or unlikely (credible event) due to an infrequent external initiating event, without the use of IROFS will satisfy the performance requirements in 70.61.

		unlikely. If an event is not credible, IROFS are not needed. If an event is credible they must be controlled (using IROFS) so that they are highly unlikely---the definitions of credible and highly unlikely do not make it clear how to handle an event (accident sequence) that is highly unlikely without IROFS but is still "credible". Perhaps these matters will be addressed further through additional dialogue with NRC or potential guidance alluded to by NRC staff during the October 8, 2009 public meeting on design features versus IROFS.	
3-35	NEI	Page 3-25, Definitions of "unlikely and highly unlikely": The frequency designations on these definitions need to be consistent. Highly unlikely was changed to 10-4 events per-year for any individual accident sequence. The frequency indicator for unlikely should likewise be reduced an order of magnitude for consistency.	See answer provided for comment 3-5.
3-36	NEI	Page 3-25, Section 3.5.2.3, last paragraph second sentence: Industry suggests that "…he or she has fully understands…" be revised to "…he or she has fully understood…".	Agree. The text was modified to incorporate NEI's recommendation.

Chapter 4, Radiation Protection

ID	Source	Comment/Question	Disposition
4-1	NEI	Page 4-5, Section 4.4.3 second bullet: Specifying how radiation protection procedures will be prepared, authorized approved and distributed is an overly prescriptive expectation for information in a license application or amendment and not consistent with the risk-informed, performance-based intent of the rule.	Agree. Staff revised the second bullet so that we're now looking for a commitment to a "process" for procedure generation or modification, authorization, distribution, and training such that changes in technology or practices are communicated effectively and in a timely manner. It shouldn't be considered necessary to provide details for the various steps of procedure generation through distribution.
4-2	NEI	Page 4-13, Section 4.4.7.3 first bullet Requiring licensees to maintain equipment and instruments in accordance with manufactures' recommendations gives recommendations the force of regulation which is not	Agree in part. NUREG-1520 is not a regulation and so is not a requirement unless it is directly quoting from regulation. Being consistent with the manufacturer's recommendations is one way of running an effective

		appropriate and without a regulatory basis.	calibration and maintenance program for instrumentation but there may be situations where the manufacturer recommends use of standards or settings that are not particularly relevant to how the instrument will be utilized or for the radiations being measured. This section was revised to be less prescriptive for manufacture's recommendations and allow licensee reliance on applicable ANSI standards which, typically, have general discussion of instrument calibration and maintenance and should allow the licensee to establish calibration procedures appropriate for how the instrument is being utilized. Due to the relatively large number of standards available for a large variety of instruments.
4-3	NEI	Page 4-13, Section 4.4.7.3 second bullet: This bullet refers to Appendix B of this Chapter however this appendix is not included in the document.	Typographical errors were corrected.
4-4	NEI	Page 4-13, Section 4.4.7.3 third bullet: If a licensee is not located in an Agreement State, these requirements fall under State Regulations. The guidance should make this clear to the reviewer and applicant.	Staff believes that this section should not be modified, and instead rely on reader's and reviewer's knowledge that certain materials (sources) are not licensed by the NRC and fall under other regulatory authority. It is suggested that licensees track their sealed sources in a database and, if needed, one of the fields in the database should be the regulatory agency with authority for the material. However since this is just a suggestion to the applicant and not a suggestion to perform a license review, staff believe that the text should remain unchanged.
4-5	NEI	Page 4-14, Section 4.4.8.3 second bullet: If a scenario is not an intermediate or high consequence event, there is no reason that accuracy of the dose is needed; rather, only	Staff acknowledges that a sequence may have an intermediate or high consequence that is not the result of potential radiation exposure associated with

		that the dose does not meet the criteria for intermediate or high consequences.	the sequence. In those sequences, it is acceptable to note that the potential exposure is less than the criteria for intermediate consequences. However, staff may ask for documentation and seek to verify that the calculations were performed appropriately and that the potential exposure truly does not exceed the intermediate criteria. If exposure estimates are performed, it would seem a relatively simple practice to include them in the sequence documentation. No changes to this bullet were made because noting that radiological consequences are less than the intermediate criteria is considered an adequate description of the exposure estimate.

Chapter 5, Criticality

ID	Source	Comment/Question	Disposition
5-1	NEI	Page 5-1, Section 5.1: A primary sanity check for this revision is that if a new reviewer were given this guidance to evaluate the Nuclear Criticality Safety program of an existing license, the reviewer should conclude that the licensee has an acceptable program. The second paragraph, third sentence, could lead a reviewer to expect that the items listed in this chapter are required to demonstrate compliance with the applicable regulatory requirements. It should be clearly stated here, as it is in other locations, that other approaches are acceptable to demonstrate compliance.	Agreed. The reference to the items in this chapter has been deleted.
5-2	NEI	Page 5-2, Section 5.3.1 last paragraph: The use of "credible abnormal	No change was made. The use of the

		conditions" here and in the regulation implies a higher degree of "unlikely" then is expected by the rule and guidance for other high consequence events, i.e., 10^{-6} or less for incredible vs. a 10^{-4} or less for highly unlikely. This likely occurred because the language of the rule came from ANSI/ANS 8.1 section 4.1.2. The context of "credible" in "credible abnormal conditions" as used in this standard is different than used in the rule and elsewhere in this regulatory guide. Section 3.4 on page 3-35 contains a note that explains that use of the word "unlikely", as it appears in 10CRF 70.61(c), does not have the same meaning as when that word is used in the definition of double contingency, which also has origins in ANSI/ANS 8.1. Industry believes it would be prudent to make a similar clarification here as high consequence events (accidental nuclear criticality is a high consequence event) only need to be controlled to highly unlikely. Industry has interpreted the rule to mean that credible abnormal conditions must be evaluated, however only those that are not at least highly unlikely need to be controlled by IROFS.	phrase "credible abnormal conditions" is taken directly from 70.61(d). The use of the phrase here is only to refer to the 70.61 (d) requirements. There is no intent to provide a new standard of acceptance. Industry interpretation that the rule means that credible abnormal conditions must be evaluated, and only those that are not at least highly unlikely need to be controlled by IROFS is consistent with the Staff position and the intent of the guidance.
5-3	NEI	Page 5-2, Section 5.3.2 first bullet: The term "parameters" as used in this context should either be clarified, footnoted or deleted to avoid confusion.	Agreed. The reference to the term "parameters" has been removed and replaced by practices.
5-4	NEI	Page 5-2, Section 5.3.2 second bullet: This item implies that licensees must list both safety limits and controls, and operating limits and controls, in the Nuclear Criticality Safety documentation. The rule only requires that systems be controlled to be Subcritical including an approved margin of sub-criticality. This item leads the reviewer to expect a double tier of limits and controls which goes beyond the requirements of the rule. This expectation is also repeated on pg 5-14 at the first indented hollow bullet.	Agreed. There is no specific requirement to commit to operating limits. The phrase "NCS operating limits for controls" has been removed and replaced by "and procedures for establishing operating limits.
5-5	NEI	Page 5-2, Section 5.3.2 seventh bullet: The word "an" should be changed to "any".	Agreed.
5-6	NEI	Page 5-3, Section 5.3.3 second bullet: The word "unmitigated" really doesn't add anything as accidental criticality is a high consequence event whether it is mitigated or not. Therefore, the word should be	Agreed. The word "unmitigated" has been removed.

		deleted.	
5-7	NEI	Page 5-4, Section 5.3.3 first bullet following Review Interface This bullet refers the reader to chapter 1 to ensure the process descriptions contained within are consistent with Chapter 5. The chemical safety chapter is chapter 6 not chapter 1.	The word chemical has been changed to criticality.
5-8	NEI	Page 5-5, Section 5.4.3.1 second bullet, first indentation: This statement is consistent with Regulatory Guide 3.7.1 and the common definition of handled, stored, or used. Recent NRC documentation has stated that the mere presence of special nuclear material in any quantity requires a Criticality Accident Alarm System if the licensee is licensed to posses greater than 700 grams U-235. NUREG-1520 should confirm that the Regulatory Guide 3.7.1 approach and common definition of "handled", "stores", or "used" is correct.	No change has been made. The language is consistent with the regulatory requirement.
5-9	NEI	Page 5-6, Section 5.4.3.1 bullets one and two: These bullets pertain to the Criticality Accident Alarm System (CAAS). These sections lead the reviewer to expect that the CAAS will be designed to withstand "credible" events, i.e., 10^{-6}. This design requirement for new CAASs is an excessive expectation and is not required by the rule. Licensees are required to protect against accidental nuclear criticality so that such an event is highly unlikely event, i.e., 10^{-4}. As such, this guidance should be performance-based and allow licensees flexibility on how it will protect against such criticality events.	No change has been made. The requirements for the CAAS are taken from the ANSI/ANS-8.3 standard and are meant to be one acceptable way to meet the guidance for the CAAS.
5-10	NEI	Page 5-8, Section 5.4.3.1: The first paragraph on this page again discusses "credible" in relationship to abnormal conditions. As in previous comments, the term as used here should probable be equated to "highly unlikely". This sentence is further complicated by the definition in chapter 3 for "not credible" which specifically states that process designs cannot be credited in defining conditions that are "not credible".	No change was made. The use of the phrase "credible abnormal conditions" is taken directly from 70.61(d). The use of the phrase here is only to refer to the 70.61 (d) requirements. There is no intent to provide a new standard of acceptance. Industry interpretation that the rule means that credible abnormal conditions must be evaluated, and only those that are not at least highly unlikely need to be controlled by IROFS is consistent with the Staff position and the intent of the guidance.
5-11	NEI	Page 5-15, second bullet: The term "augmented administrative control"	Agreed. The change has been made.

		should be revised to "enhanced administrative control" for consistency with other portions of the document.	
5-12	NEI	Page 5-16, first bullet under reflection: This paragraph is confusing as written. The second sentence should be clarified to read "The materials adjacent to the unit should be farther than 30 cm (12-inches) from the unit".	Agreed. The change has been made.
5-13	NEI	Page 5-16, Section of moderation controls: The language used in this section should be carefully reviewed so as not to confuse the important distinction between moderators (a material that can moderate neutrons) and moderation (the process of slowing down neutrons). For example, "the ingress of moderation is precluded…" should more correctly be stated as "the ingress of moderators is precluded…".	Agreed. The change has been made.
5-14	NEI	Page 5-16, Section on moderation controls: The sixth bullet calls for the restriction on using moderator material during firefighting. In many cases, this is an excessive restriction. Firefighting foam, although a moderator, is of a low enough density that in many cases it can be safely used and its use is frequently the best safety choice to minimize overall risk.	Agreed. The term restrict has been changed to evaluate.
5-15	NEI	Page 5-18, fifth bullet: This section relates to appendix A of 10 CFR 70. As appendix A of the rule is concerned with more than Nuclear Criticality Safety issues, compliance with Appendix A should be handled elsewhere and in a more universal manner. Discussing compliance with Appendix A in individual technical chapters may result in the NUREG being internally inconsistent, thus making it confusing for NRC staff and potentially difficult for licensees to implement. Additionally some of the sub-bullets redundantly require a licensee to commit to follow federal regulation. Such a statement is unnecessary since all licensees must follow federal regulations whether or not a specific license condition is imposed.	A change was made to reflect that the Appendix A program is based on all areas and that the guidance applies only to review of the criticality safety related areas.
5-16	NEI	Page 5-22, last paragraph: This section again discusses the likelihood of each credible high-consequence event needing to be highly unlikely after the implementation of IROFS. In many cases, credible events are already highly unlikely without the use of IROFS. This issue needs to be consistently addressed throughout the document.	Agreed. The text has been changed to remove the phrase "after the implementation of IROFS."

5-17	NEI	Page 5-24, Section 5.5.3: This section states that the results of the ISA are the basis for the criticality safety evaluation. This is not correct. Generally, the Criticality Safety Evaluation, k_{eff} sensitivity studies, feed into the evaluation of accident conditions so that the ISA team understands the impact of process deviations etc. This sentence should be changed to read "The results of the ISA and the results of the criticality safety evaluation are closely connected".	Agreed. The text has been changed to reflect that the ISA results are part of the overall safety basis and not the basis itself.
5-18	NRC Staff	A considerable amount of material concerning ISA has been added to Sections 5.1, 5.3.1, and 5.3.3. This material duplicates information found in Chapter 3, which is where it more appropriately belongs. Including this material here blurs the distinction between the technical ISA review and the programmatic NCS review. The purpose of Chapter 3 is to provide general guidance for review of the ISA and ISA Summary. This includes both the overall ISA methodology review, by the ISA reviewer, and the horizontal and vertical slice reviews, by the individual technical reviewers (including the criticality safety reviewer). The purpose of Chapter 5 is to provide guidance for the review of programmatic NCS commitments in the license application (LA). It is also guidance for review of the technical aspects of license renewals and amendments (criticality safety evaluations, calculations, validation documents, etc.) These items are part of the ISA, but go beyond what is included in the ISA Summary. The suggestion is to clearly specify what guidance applies to what kind of review. One way to do this is segregate all the ISA-related guidance in Chapter 3, as was done in the previous version of NUREG-1520	Generally agree. Some ISA review guidance is included in Chapter 5 for the purpose of convenience to the reviewer. It is not the intent to blur the distinction between the programmatic NCS review and the safety program review. The chapter was reformatted to create a clearer distinction between the review of the LA commitments, the NCS program and the safety program review. In Areas of Review there are: 5.3.1. License Application 5.3.2 Criticality Safety Program 5.3.3 Safety Program In acceptance criteria there are: 5.4.3.1 License Application 5.4.3.2 NCS Program 5.4.3.3 Safety Program (corrected) In safety review there are: 5.5.2.1 License Application 5.5.2.2 NCS Program 5.5.2.3 Safety Program
5-19	NRC Staff	Each paragraph or bullet should be labeled (e.g., (a), (b), (c), or (1), (2), (3)…). There should also be more subheadings. Section 5.4 comprises most of the chapter and has a lot of different topics strung together without any apparent organizing structure. Doing this will make it easier to locate guidance on specific topics, and also make it	Agree. Some of the headings on this chapter were modified and the document will be technically edited to make sure the paragraphs are correctly labeled.

		easier to make reference to the SRP in RAIs, SERs, and so forth.	
5-20	NRC Staff	For several years, it has been the practice in FCSS to include regulatory citations along with requests for additional information (RAIs). The idea was that this would cut down on unnecessary questions, but, since experienced reviewers do not ask unnecessary questions, the only effect has been to add unnecessary burden to the staff. To alleviate this wasteful and inefficient practice, the SRP should include regulatory citations along with its acceptance criteria whenever possible. (An example of where this was done is on page 5-10, with regard to 70.62.) That way, the regulatory citation would be established for all time, rather than having to reinvent the wheel for every RAI.	Agreed. This comment will be considered for future revisions as a means ease reviewer burden.
5-21	NRC Staff	Referring to the numerous specific comments, which include typographical mistakes and inconsistencies in the text, it is apparent that the development of this revision of the SRP was a rush job. The quality of the draft is very good, given the very limited time allowed, but NRC management should consider taking the time needed to polish the product rather than meet some arbitrary, self-imposed deadline for rushing the SRP out onto the street.	Typographical errors were corrected.
5-22	NRC Staff	In many cases, it is unclear who the guidance document is talking to—is the intent to be primarily guidance to the applicant, or to the reviewer? Since it is called a "Standard Review Plan," I am assuming the main intent is to provide guidance to a reviewer on how to do a technical review. If that assumption is correct, then everywhere it says that "the applicant should" do something, it sounds like guidance to the applicant rather than the staff. Suggestion is to replace this language with something like "the application should state…" rather than telling the applicant what to do.	Guidance is for the reviewer. The chapter was revised for consistency.
5-23	NRC Staff	Page 5-1, 2nd paragraph: Rewrite as follows: …nuclear criticality safety (NCS) program as described in the license application ~~and integrated safety analysis (ISA) summary~~…The review should examine the parts of the license application ~~and ISA summary~~ that describe the NCS program. The NCS program is not typically described in the ISA Summary, but	Agreed. Change made to text.

		rather in the LA. Also, remove superfluous references in this chapter to 10 CFR 70.61. Calling 70.61 out specifically tends to diminish other parts of the rule that are just as important for safety.	
5-24	NRC Staff	Page 5-1, last paragraph: Remove "ISA Summary, if applicable". This section is entitled "License Application," to which review of the ISA Summary is not relevant. Even if the ISA Summary were to contain a description of the NCS program, the LA must contain all the enforceable commitments.	Agreed. Change made to text.
5-25	NRC Staff	Page 5-2, 1st paragraph: Remove the last sentence. It is not the function of the NCS review to verify compliance with 10 CFR 70.61; that is the purpose of the ISA review. As stated above, this puts too much emphasis on 70.61, which tends to downplay other equally important parts of the regulations.	Agreed. Change made to text.
5-26	NRC Staff	Page 5-3, Section 5.3.3: Remove the introductory paragraph and first five bullets, up to the discussion of configuration management. Including this material here confuses things, because there's another section labeled "Nuclear Criticality Safety Program" and then this section labeled "Safety Program." That implies that the NCS Program and Safety Program are two separate things. They are not. The NCS Program is the safety program for NCS. The guidance contained herein is just simply a summarized version of what is in Chapter 3. Including it here is confusing, and, as it contains nothing new, it adds no value.	Disagree. This section relates to review of the safety program from an NCS perspective. The bullets describe the basic areas that need to be reviewed. A change to the text was added to clarify that this part of the review is for the NCS-related review of the safety program.
5-27	NRC Staff	Page 5-4, third bullet: Note that not all licensees have commitments to a corrective action program, as is assumed here. Unless we require that all licensees have such a corrective action program, this should be removed.	The text was changed to refer to the corrective action program if applicable.
5-28	NRC Staff	Page 5-4, paragraph under "Review Interfaces": This should not refer to "Chapter 5 of the license application." There is no requirement to follow the format of the SRP. Rather, this should simply say "the NCS section of the license application."	Agreed. The text has been changed to refer to the criticality safety chapter without a numerical designation.
5-29	NRC Staff	This idea that the criticality reviewer should look at other portions of the license application is admirable, but unrealistic. The aggressive	Disagree. The reviewer should look at other portions of the LA if time permits to

		schedules that have recently been established for licensing reviews generally preclude this possibility.	get a better understanding of the facility.
5-30	NRC Staff	Page 5-4, 1st bullet: inappropriately refers to "chemical safety" instead of "NCS"	Agreed. Change made to the text.
5-31	NRC Staff	Pages 5-4, Technical Practices are omitted from Section 5.3 on "Areas for Review." They are discussed in the section on "Acceptance Criteria". This is a significant omission.	This section was removed based on the initial comments of the criticality reviewers to remove all the bullets associated with Technical Practices in this section. However, staff will evaluate if this information should be incorporated in future revisions to the SRP.
5-32	NRC Staff	Page 5-4, Section 5.4: The sentence "Commitments and descriptions are expected when the acceptance criteria are relevant to the possession and use of nuclear materials and the materials to be licensed" should be removed. It doesn't say anything, and is also redundant (i.e., "materials to be licensed" are "nuclear materials.").	Agreed. Sentence has been removed.
5-33	NRC Staff	Page 5-4, Section 5.4.1: Since this is a chapter about NCS, regulatory requirements listed should be those specific to NCS (mainly 70.24, 70.61(d), and 70.64(a)(9)). Those listed here are generic regulatory requirements that apply across the board, and there is no value to repeating them here.	Disagree. The requirements are provided to give the reviewer a complete scope of the requirements.
5-34	NRC Staff	Page 5-5, Section 5.4.2: Remove reference to NUREG-1513. This is not relevant to doing the NCS review, and is not even a very good reference for doing the ISA review. There are many other references that would be more relevant, if we need to include something, such as NUREG/CR-6361, NUREG/CR-6698, etc.	Agreed. The reference is not applicable to review of the NCS program and has been removed.

5-35	NRC Staff	Page 5-5, Section 5.4.3: Remove the following: "The applicant may elect to incorporate some or all of the requested criticality safety information in the facility and process description (SRP Section 1.1) or in the ISA summary, rather than in this section. Either approach is acceptable, as long as the information is adequately cross-referenced." The SRP is not a standard format and content guide, and as such it is not intended to be guidance to the licensee. Its primary use is as guidance to the NRC staff. So it should not be speaking directly to licensees or offering advice on what it should put where. The part about "or in the ISA summary" is particularly problematic, because the ISAS is not part of the license. So any commitments they address there will not be legally binding and may be changed without prior approval. This statement is not regulatory correct or consistent with our past practices (as when we have required licensees to move their ISA methodology commitments from the ISAS to the LA).	Partially agree. The text has been changed to allow including some descriptive data in the ISA Summary by reference at the discretion of the reviewer, but not commitments.
		Page 5-6, last paragraph: Remove the following: "Using the reasonable assurance of safety standard as described in the introduction to this SRP, the reviewer should determine whether the applicant has met the requirements of 10 CFR 70.61. The introduction, as well as Section 3.1 of the SRP describing the review of the ISA and ISA Summary, includes guidance on the level of detail needed to achieve this standard." The reasons this should be removed are: (1) that the purpose of the NCS review is not, primarily, to ensure compliance with 70.61, (2) that this offers no useful guidance on what constitutes a "reasonable assurance of safety," and thus is highly subjective, and (3) that Section 3.1 of the SRP does not contain any actual guidance on the level of detail necessary to achieve this standard, either generally or for NCS. This merely has some generic verbiage to the effect that the level of detail may vary, but does not give the reviewer any actual concrete guidance.	Disagree. What guidance that does exist is in the referenced sections. Although the guidance may be general it does provide a useful function.

5-36	NRC Staff	Page 5-7, first bullet: The ANSI standards are not regulatory requirements, and should not be referred to as such.	Disagree. The text now states that "As one approach to meeting the requirements," and does not equate the standards to a requirement but a means to meet the requirements.
5-37	NRC Staff	Page 5-7, last bullet: "The applicant meets the acceptance criteria in SRP Chapter 3 as they relate to subcriticality of operations and margin of subcriticality for safety." This information is much more applicable to the NCS review than to the ISA review (even though the regulatory citation is 70.61(d)). All the guidance related to subcriticality should be placed in Chapter 5.	Disagree. The statement refers to meeting the performance requirements that are described in Chapter 3.
5-38	NRC Staff	Page 5-8, last bullet: This refers to the 1983 version of ANSI/ANS-8.1. This has been reaffirmed and later superceded, and the most recent version of the standard should be used in the guidance. All standards references should be double-checked for currency.	Agreed. A change was made to the text to update the reference.
5-39	NRC Staff	Pages 5-8 to 5-9: The section beginning with the discussion of baseline design criteria and ending just before Section 5.4.3.2, "NCS Program," does not belong here. This is generic ISA guidance and more appropriately belongs in Chapter 3, or else should be placed in its own section dealing strictly with the ISA review. Putting it here just blurs the distinction between the programmatic and technical reviews.	Agreed. The text was moved to the safety program section.
5-40	NRC Staff	Page 5-10, 2nd bullet: Rewrite as follows: "The applicant meets ~~the intent of~~ ANSI/ANS-8.1-1998 and ANSI/ANS-8.19-1996 (see Regulatory Guide 3.71), or proposes an equivalent alternative, as they relate to organization and administration." Guidance should not refer to the "intent" of a standard, as the intent can be difficult to ascertain. Also, this would make the NRC beholden to any re-interpretation of the standard that the standards body (ANSI) wishes to make in the future, which would make a government agency subservient to a non-governmental body. What is meant is that the licensee must commit to something that performs the same safety function if it does not wish to commit to the standard. Also, the SRP should be consistent in referring to specific versions of the standards	Agreed. The change to the text has been made.

		(i.e., the SRP should include dates). Examples of how this is handled inconsistently occur at the bottom of the page. In one place, it says "The applicant meets the intent of ANSI/ANS-8.19 and ANSI/ANS-8.20 as they relate to training," and in another place says "The applicant commits to ANSI/ANS-8.19-1996 is it relates to procedures." In one place, it includes the date, and in another place, it does not. In one place, it ask the licensee to meet "the intent" of a standard, and in another place, it asks the licensee to meet the standard. The latter approach, including the date and meeting the standard, are preferred.	
5-41	NRC Staff	Page 5-11, second bullet: Remove the sentence "A graded approach may be used to justify an alternate NCS walkthrough schedule." This sentence is no longer needed. It was put in place because the previous version had specific time frames listed, so this was needed to allow flexibility. However, the time frames have been removed, so this no longer refers back to anything.	Agreed. The text has been removed.
5-42	NRC Staff	Page 5-15, third bullet: The intent with regard to reflection control needs to be clarified. Specifically, the sentence "The adjacent materials should be farther than 30 centimeters (12 inches) from the unit" is unclear. For what purpose should the adjacent materials be one foot from the unit? I think that the intent of this paragraph is as follows: If there are materials that could potentially reflect neutrons closer than 12 inches, they should be explicitly included in the model. If they are further from 12 inches away, edge-to-edge, they do not need to be explicitly evaluated and are assumed bounded by a 1-inch nominal water reflector.	Agreed. This changed was proposed in another public comment was made to the text.
5-43	NRC Staff	Page 5-17, last bullet: This sentence was cut off, and does not continue on the next page.	Agreed. This has been corrected.
5-44	NRC Staff	Page 5-18, first paragraph: This refers to the August 1998 version of Reg Guide 3.71. This has since been updated, and the most recent version should be cited.	Agreed. The text has been changed to be consistent with other references in the text to the guide.
5-45	NRC Staff	Page 5-18, second paragraph: This also refers to meeting "the intent" of the standards. This phrase is vague and should be removed. The	Agreed. The text has been changed to remove "the intent."

		wording in the second bullet is better ("contains other commitments that are equivalent"). Even better would be to say that the licensee or applicant may meet the standard, or make other commitments that provide an equivalent level of safety.	
5-46	NRC Staff	Page 5-18, list of standards: The list is good and reasonably complete. It is necessary that Reg Guide 3.71 be updated soon so it will be consistent with the list in the SRP.	Agreed.
5-47	NRC Staff	Page 5-19, bottom of page: I disagree with the following statement: "The applicant may elect to incorporate some or all of the requested process information in the facility and process description (SRP Section 1.1) or the ISA Summary, rather than in this section." Note that per 10 CFR 70.65(b)(3) requires that the process information must be included in the ISAS. Also, reference to "this section" is unclear. This section of what? Is this talking about the license application or the SRP? The SRP is not a standard format and content guide (as commented above) and should not get into what information gets put in what section. There is no requirement to follow any specified format; that would cut against the idea of performance-based regulation.	Agreed. The text was redundant and has been removed.
5-48	NRC Staff	Page 5-19, last paragraph: Reference to "chemical processes" appears to be a typographical error, as this is not relevant.	Agreed. The reference was deleted.
5-49	NRC Staff	Page 5-19, last bullet: The bullet "Process descriptions are sufficiently detailed to allow an understanding of the criticality to allow development of potential accident sequences" is unclear. What does "an understanding of the criticality" mean? I think this is trying to say that you need an understanding of the controls and conditions relied on for NCS to do the ISA. That would be a true statement.	Agreed. The text has been changed to correct the language.
5-50	NRC Staff	Pages 5-20 to 5-21: Remove all the material on page 5-20 and the first half of 5-21. This information appears to have been cut-and-pasted from the ISA Chapter. Not only is it redundant to Chapter 3, it is also incorrect since general ISA requirements are not directly translatable into NCS. Adapting for NCS is not simply a matter of appending the phrase "for criticality hazards." For example, it talks about mitigating the consequences of an accident, which is a concept that is not applicable to NCS. It also contains a lot of bland and very generic	Partially agree. The text has been corrected to accurately refer to criticality related aspects of the safety program review. The text has been left in as a reference to the requirements of 70.65(b)(6) which are reviewed as part of the criticality safety review.

		motherhood and apple pie statements, such as: "The hazard evaluation should use appropriate accepted methods." (Of course) The sentence "Each accident sequence identified by the applicant in the ISA should include a criticality hazard evaluation of potential interactions and key assumptions, vessels, process equipment, and facility personnel" is not clear. I don't know what a "criticality hazard evaluation" is, or what "potential interactions and key assumptions, etc." are. In general, licensees and applicants perform a criticality safety analysis that demonstrates double contingency and subcriticality under normal and credible abnormal conditions, which is then used as input to the ISA. Suggestion is to simply refer the reviewer to the appropriate section of Chapter 3.	
5-51	NRC Staff	Page 5-21, Section 5.5.1, "Acceptance Review": This contains the sentence: "The reviewer should use the regulatory guidance of this chapter; references in this chapter; and the applicant's reports to the NRC (e.g., NRC Bulletin 91-01, 10 CFR 70.50, and 70.74)." Use them for what?	Agreed. The purpose has been added to the text.
5-52	NRC Staff	Page 5-21, last paragraph: Remove the phrase "requirements for approval specified in Section 5.4." The acceptance criteria in the SRP are not requirements.	Agreed. The text has been changed to remove the reference to 5.4.
5-53	NRC Staff	Page 5-22, last paragraph: I strongly disagree with the statement: "The results of the ISA are the basis for the criticality safety evaluation." This is not true. The results of the criticality safety evaluation are part of the basis for the ISA—NCS evaluations are almost always done first, and adequate double contingency controls established, and then they are used as input (along with fire hazard analyses, process hazards analyses, etc.) to the ISA, with certain NCS controls being flowed down as IROFS. The fact that criticality controls comprise a larger set than the set of IROFS is proof that the NCS analysis takes precedence over the ISA. The ISA then is the basis upon which the ISAS is built.	Agreed. The text has been changed to reflect that the ISA review supports the overall the safety basis of the facility.

Chapter 6, Chemical Safety

ID	Source	Comment/Question	Disposition
6-1	NEI	The 70.4 definition of "hazardous chemicals…" should be referenced in this chapter. The current text is a little misleading in how it refers to chemicals in that it could mean "all" chemical and not limited as defined below. "Hazardous chemicals produced from licensed materials means substances having licensed material as precursor compound(s) or substances that physically or chemically interact with licensed materials; and that are toxic, explosive, flammable, corrosive, or reactive to the extent that they can endanger life or health if not adequately controlled. These include substances commingled with licensed material, and include substances such as hydrogen fluoride that is produced by the reaction of uranium hexafluoride and water, but do not include substances prior to process addition to licensed material or after process separation from licensed material."	Chapter 6 was revised to include the definition of "hazardous chemicals" as defined in 10 CFR 70.4.
6-2	NEI	Page 6-1, Section 6.1, Section 6.3 pg 6-2, Section 6.4.3.3 bullet five pg. 6-5, Section 6.5.3 pg 6-9 first paragraph: These sections discuss quantitative standards for chemical exposures. However, none of these sections clearly articulate the need for quantitative standards for individuals outside of the controlled area versus qualitative consequence standards for the worker. See also comment on (pg 3-18) section ii, Consequences. This is an area where industry does not agree with NRC's interpretation of the rule and, as such, industry appreciates the opportunity to discuss this topic at the NRC public meeting scheduled for November 12, 2009.	After reviewing those sections, we have determined that they should remain unchanged. This issue was also addressed in the letter from NRC to NEI, June 12, 2009 (ML090920296).

Chapter 7, Fire Safety

ID	Source	Comment/Question	Disposition
7-1	NEI	Page 7-5, Section 7.4.3.2 Deviations from NFPA Codes and Standards: This section states that when a license meets the intent of the NFPA code that the commitment is the same as committing to the code. These two commitments are significantly different. Licensees who currently have commitments to meeting the intent of the code chose that wording specifically because they did not meet every aspect of the code. Meeting every aspect of a particular code does not reflect the performance-based intent of the rule.	Agree in part. Section 7.4.3.2 was updated to reflect the authority granted to local and state officials in regard to design for fire safety and code compliance for fuel cycle facilities. The revision establishes NRC is the authority having jurisdiction (AHJ) for IROFS relative to their effect on nuclear safety and designates the Director of the Office of Nuclear Material Safety and Safeguards as the AHJ on such issues.
7-2	NEI	Page 7-4, Section 7.4.3.2: The last sentence needs to be removed. The current language does not reflect past accepted practices and conflicts with some authority granted to local and State authorities regarding fire protection. Deviations from National Fire Protection Association codes and standards do not require NRC approval today and should not in the future. This approach invokes a requirement for NRC pre-approval which is not currently required by 10 CFR 70.21, 70.23, 70.32, or 70.72.	See answer to comment 7-2.

Chapter 8, Emergency Management

ID	Source	Comment/Question	Disposition
8-1	NEI	Page 8-4, Section 8.4.3.1 and 8.4.3.2: Industry recommends that these sections contain a note or parenthetical statement that this type of information is allowed to be included by reference. Licensees include similar information pertaining to the site in the ISA summaries. Therefore, referencing them should be recognized as an acceptable method of providing information, especially since they are updated annually which keeps the information current and available for NRC review.	Agree in part. Chapter 8 doesn't have any restriction about how is the data presented in the emergency plan. The applicant might want to reference the license application (e.g. facility description) or the ISA Summary (e.g. types of accidents), but the applicant needs to keep in mind that all the information required in 70.22(3)(i) needs to be added or referenced in the emergency plan. Since there is no restriction on how the data is incorporated on this chapter, the staff considered that no change is necessary.

Chapter 9, Environmental Protection

No comments

Chapter 10, Decommissioning

No comments

Chapter 11, Management Measures

ID	Source	Comment/Question	Disposition
11-1	NEI	Page 11-9, To expect a description of individual surveillances and associated frequencies for each IROFS in the application or ISA summary is an excessive expectation and not performance-based. This level of detail is available at the Licensee's facility and can be reviewed when needed. The SRP should not set the expectation that this information be included in the application or the ISA summary.	Agree. However, it is not the intent of this section to require the review of the description of individual surveillances and associated frequencies for each IROFS. The expectations are to review the surveillance function of the maintenance program and that the surveillances are conducted at a specified frequency.
11-2	NEI	Page 11-9, To expect a description of compensatory measures for individual surveillance or preventative maintenance activities in the application or ISA summary for each IROFS that needs to be taken off line to test is an excessive expectation. This level of detail is available at the Licensee's facility and can be reviewed when needed. The SRP should not set the expectation that this information be included in the application or the ISA summary.	Agree. However, it is not the intent of this section to require a review of the description of compensatory measures for individual surveillance or preventive maintenance activities. The expectation is to review that compensatory measures are in place for the continued normal operation.
11-3	NEI	Page 11-15, This section leads a reviewer to expect a specific commitment to report to the NRC as required by 10CFR 70.50 and 10CFR 70.74. As stated previously, it is redundant and unnecessary to have a license commitment to follow a federal regulation. The regulation must be followed regardless of a license commitment or condition.	Agree in part. Agree that is redundant and unnecessary to have a license commitment to follow a federal regulation. It is not the intent of this section to require review of specific reporting commitments. This section asks the reviewer to review that there is a formal procedure to investigate abnormal events that may occur during the operation of the facility.
11-4	NEI	Page 11-17, Many of these elements are covered in the other management measures sections. For example, configuration management includes: "design control, instructions, procedures and drawing control, and document control." Listing these items under a separate heading leads a reviewer to expect additional measures associated with these topics when in reality the management measures already discussed cover these areas. At a minimum, the	Agree in part. However, the acceptance criteria differ. Where appropriate, the SRP will guide the QA reviewer to refer to the appropriate SRP chapter/section that also addresses the management measure being reviewed.

		NUREG should acknowledge the overlap and specifically expect repeating information in the "other QA elements" section of an application. It would be preferable to simply remove these redundant elements.	
11-5	NEI	Page 11-9, To expect a description of individual surveillances and associated frequencies for each IROFS in the application or ISA summary is an excessive expectation and not performance-based. This level of detail is available at the Licensee's facility and can be reviewed when needed. The SRP should not set the expectation that this information be included in the application or the ISA summary.	Agree. However, it is not the intent of this section to require the review of the description of individual surveillances and associated frequencies for each IROFS. The expectations are to review the surveillance function of the maintenance program and that the surveillances are conduct at a specified frequency.
11-6	NEI	Page 11-9, To expect a description of compensatory measures for individual surveillance or preventative maintenance activities in the application or ISA summary for each IROFS that needs to be taken off line to test is an excessive expectation. This level of detail is available at the Licensee's facility and can be reviewed when needed. The SRP should not set the expectation that this information be included in the application or the ISA summary.	Agree. However, it is not the intent of this section to require a review of the description of compensatory measures for individual surveillance or preventive maintenance activities. The expectation is to review that compensatory measures are in place for the continued normal operation.
11-7	NEI	Page 11-15, This section leads a reviewer to expect a specific commitment to report to the NRC as required by 10CFR 70.50 and 10CFR 70.74. As stated previously, it is redundant and unnecessary to have a license commitment to follow a federal regulation. The regulation must be followed regardless of a license commitment or condition.	Agree in part. Agree that is redundant and unnecessary to have a license commitment to follow a federal regulation. It is not the intent of this section to require review of specific reporting commitments. This section asks the reviewer to review that there is a formal procedure to investigate abnormal events that may occur during the operation of the facility.
11-8	NEI	Page 11-17, Many of these elements are covered in the other management measures sections. For example, configuration management includes: "design control, instructions, procedures and drawing control, and document control." Listing these items under a separate heading leads a reviewer to expect additional measures	Agree in part. However, the acceptance criteria differ. Where appropriate, the SRP will guide the QA reviewer to refer to the appropriate SRP chapter/section that also addresses the management measure

		associated with these topics when in reality the management measures already discussed cover these areas. At a minimum, the NUREG should acknowledge the overlap and specifically expect repeating information in the "other QA elements" section of an application. It would be preferable to simply remove these redundant elements.	being reviewed.
11-9	NEI	Page 11-9, To expect a description of individual surveillances and associated frequencies for each IROFS in the application or ISA summary is an excessive expectation and not performance-based. This level of detail is available at the Licensee's facility and can be reviewed when needed. The SRP should not set the expectation that this information be included in the application or the ISA summary.	Agree. However, it is not the intent of this section to require the review of the description of individual surveillances and associated frequencies for each IROFS. The expectations are to review the surveillance function of the maintenance program and that the surveillances are conduct at a specified frequency.
11-10	NEI	Page 11-9, To expect a description of compensatory measures for individual surveillance or preventative maintenance activities in the application or ISA summary for each IROFS that needs to be taken off line to test is an excessive expectation. This level of detail is available at the Licensee's facility and can be reviewed when needed. The SRP should not set the expectation that this information be included in the application or the ISA summary.	Agree. However, it is not the intent of this section to require a review of the description of compensatory measures for individual surveillance or preventive maintenance activities. The expectation is to review that compensatory measures are in place for the continued normal operation.
11-11	NEI	Page 11-15, This section leads a reviewer to expect a specific commitment to report to the NRC as required by 10CFR 70.50 and 10CFR 70.74. As stated previously, it is redundant and unnecessary to have a license commitment to follow a federal regulation. The regulation must be followed regardless of a license commitment or condition.	Agree in part. Agree that is redundant and unnecessary to have a license commitment to follow a federal regulation. It is not the intent of this section to require review of specific reporting commitments. This section asks the reviewer to review that there is a formal procedure to investigate abnormal events that may occur during the operation of the facility.
11-12	NEI	Page 11-17, Many of these elements are covered in the other management measures sections. For example, configuration management includes: "design control, instructions, procedures and	Agree in part. However, the acceptance criteria differ. Where appropriate, the SRP will guide the QA reviewer to refer to the

		drawing control, and document control." Listing these items under a separate heading leads a reviewer to expect additional measures associated with these topics when in reality the management measures already discussed cover these areas. At a minimum, the NUREG should acknowledge the overlap and specifically expect repeating information in the "other QA elements" section of an application. It would be preferable to simply remove these redundant elements.	appropriate SRP chapter/section that also addresses the management measure being reviewed.
11-13	NRC Staff	It does not appear that this proposed revision to NUREG-1520 has incorporated applicable aspects of FCSS ISG-04. To a certain extent, in the original draft of NUREG-1520, and in the current draft, some guidance has been provided regarding the evaluation of management measures that ensure that IROFS are <u>maintained</u> as necessary to ensure their availability and reliability when needed. However, no guidance is provided for reviewers who need to evaluate whether there is reasonable assurance that the applicant's proposed management measures will ensure that engineered or administrative controls designated as IROFS are <u>designed and implemented</u> to ensure they are available and reliable to perform their function when needed.	Several sections of ISG-04 were incorporated to the SRP. However, ISG-04 was not directly incorporated to Chapter 11. It was divided among the applicable technical chapters. The section specific to I&C in ISG-04 weren't added since currently we don't have a chapter to address plant systems or I&C.
11-14	NRC Staff	In Section 11.3, the Management Measures section of NUREG-1520 should acknowledge the need for reviewers to perform evaluations of the applicant's proposed management measures that will be applied to the design and implementation of IROFS, not solely the quality practices specifically listed as being "included" in the definition, among which is "maintenance." Section 10 CFR 70.62(d) is clear in its requirement that management measures shall ensure that engineered and administrative controls and control systems identified as IROFS are *designed, implemented, and maintained*, as necessary, to ensure that they are available and reliable to perform their function when needed,	Chapter 11 of the SRP describes programmatic aspects for a Management Measures program. However, the chapters where management measures will be applied to the design and implementation of IROFS regarding those chapters include a management measures section within the chapter.

		to comply with the facility performance requirements	
11-15	NRC-Staff	The introductory sentence mis-quotes the requirement in Section 70.62(d). The correct paraphrase of the requirement should include the phrase: "…provide reasonable assurance that they will be designed, implemented, and maintained, to ensure that they are available and reliable to perform their intended functions when needed."	Agree. This has been done
11-16	NRC Staff	In Section 11.3, an area of review that is not listed in this section but is needed to support an evaluation of the design and implementation aspects of management measures could include the "Incorporation of Reliability Design Criteria", which could include the sub-topics of: a) provisions for reliable utility supplies; b) the use of redundant, independent, and/or diverse controls; c) features ensuring that IROFS are protected from faults occurring in adjacent or associated non-IROFS equipment; and potentially other key design criteria that are used to ensure the reliability and availability of IROFS.	Agree in part. Provisions for reliable utility supplies are discussed in sub-sections such as Procurement Document Control and Control of Purchased items in Other QA elements section. The use of redundant, independent, and/or diverse controls is discussed in Chapter 3, ISA Summary. Features ensuring that IROFS are protected from faults occurring in adjacent or associated non-IROFS equipment are discussed in the introduction as part of the IROFS boundary packages discussion.
11-17	NRC Staff	In Section 11.3, "Diagnostic Capabilities," and "Design Provisions to Support Periodic Maintenance and Functional Testing" could be included as areas of review. The paragraph on "Maintenance" briefly describes the staff's evaluation of how the site organization implements preventative and corrective maintenance; surveillance and monitoring; and functional testing. However none of these activities would be possible to perform if the provisions for performing them had not been incorporated during the design and implementation stages. Review guidance should be provided to ensure the quality and	The staff does not consider additional areas of review necessary in this chapter. The maintenance section includes a review of periodic maintenance and functional testing areas. Diagnostics capabilities are reviewed under corrective maintenance. Chapter 11 of the SRP describes programmatic aspects for a Management Measures program. Any required design

		uniformity of staff reviews of the management measures proposed for ensuring that IROFS are designed and implemented to ensure their availability and reliability in accordance with the requirements of 10 CFR 70.62(d).	provisions for periodic maintenance and functional testing of specific IROFS will need to be review by the appropriate technical reviewer under that section.
11-18	NRC Staff	On page 11-6 the requirement from 10 CFR 70.62(d) of the code is again mis-quoted. The correct paraphrase of the requirement should include the phrase: "…provide reasonable assurance that they will be designed, implemented, and maintained, to ensure that they are available and reliable to perform their intended functions when needed."	Agree. This has been done.
11-19	NRC Staff	In Section 11.4.3.2, review acceptance criteria could be added for the design of IROFS to include design provisions supporting the performance of periodic maintenance, functional testing, and the capability for diagnostics.	Chapter 11 of the SRP describes programmatic aspects for a Management Measures program. Acceptance criteria related to programmatic maintenance functions are already discussed.
11-20	NRC Staff	In Section 11.5.1.2 heading should probably be changed to "Design Control Requirements." Also, note that the paragraph numbering does not include (2).	Agree. This has been done.
11-21	NRC Staff	In Section 11.5.2, for a new facility or a new process at an existing facility, the reviewer should also evaluate the applicant's management measures that provide for the design and implementation of the IROFS testability, and maintainability features.	Chapter 11 of the SRP describes programmatic aspects for a Management Measures program. The review evaluates programmatic testability and maintainability topics as discussed in Other QA elements, when applicable.

11-22	NRC Staff	In Section 11.6.1, the second item should probably be re-named as Design Control Requirements.	Agree. This has been done.

Additional Comments

ID	Source	Comment/Question	Disposition
A-1	NRC Staff	Since the Request was submitted, RES has provided assistance for two licensing projects (i.e., LES and USEC) that were performed using the existing guidance in NUREG-1520. The current version of NUREG-1520 and the proposed draft (Revision 1) do not contain guidance for performing a human factors engineering licensing review of fuel cycle facilities. The omission of regulatory criteria for conducting a human factors engineering assessment creates a significant problem for both the staff and the license applicant; the staff's reviews are less likely to be performed in a standardized manner and the applicant is not provided with a clear understanding of what constitutes a satisfactory human factors engineering program. It is with this experience, and concern, that the Human Factors and Reliability Branch (HFRB) of RES proposes Revision 1 to NUREG-1520 incorporate sufficient guidance for conducting a human factors engineering review of a fuel cycle facility's licensee application before being issued. As a possible approach, criteria contained in NUREG-1718 (SRP for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility) might be considered. RES/HFRB would be pleased to discuss this recommendation further with NMSS at their convenience.	Agree. Additional guidance for human factors has been provided in Chapter 3 (a new appendix was added). .
A-2	ACRS	Staff should address the interface between safety and security in the SRP or in any other document.	Agree. Security reviews are conducted by NSIR. There some guidance available to conduct of the security review (e.g. NUREG-1322, NUREG/CR 6667, etc.).

			However, there is no guidance available to address this issue for Part 70 licensees. NRR developed a Reg. Guide (RG 5.74) to address this issue for nuclear power plant. However, for nuclear power plant, addressing this issue is a requirement under Part 73. For fuel cycle facilities this is not required. Staff considers that this issue should be carefully evaluated and staff will consider this issue during future revisions of the SRP.
A-3	ACRS	The current and the proposed revised guidance doesn't address the how to consider/treat the issue of hot shorts in conducting our reviews.	Staff will evaluate fuel cycle events related to hot shorts if staff determines that it is a common event or has significant risk for fuel cycle facilities then staff will issue guidance.
A-4	ACRS	Operations and Maintenance should be considered as part of the licensing review. People with operations and maintenance experience are valuable when conducting licensing review and will identify issues that others won't.	Agree. The staff uses all the available information provided by the licensee when performing their review. Also, staff is encouraged to use lessons learned, operating experience and any other applicable information. Although this is implied in the current SRP. In addition, part of the oversight process includes interviewing licensee personnel as part of the inspection program.