

August 26, 2015

MEMORANDUM TO: Marissa G. Bailey, Director
Division of Fuel Cycle Safety, Safeguards,
and Environmental Review
Office of Nuclear Material Safety
and Safeguards

FROM: Margie Kotzalas, Chief **/RA/**
Programmatic Oversight
and Regional Support Branch
Division of Fuel Cycle Safety, Safeguards,
and Environmental Review
Office of Nuclear Material Safety
and Safeguards

SUBJECT: RESPONSE TO PUBLIC COMMENTS ON DRAFT NRC
DOCUMENT, "CORNERSTONE DEVELOPMENT"

A notice of opportunity for public comment on draft NRC document, "Cornerstone Development" was published in the *Federal Register* on June 11, 2015 (80 FR 33303). The staff solicited external stakeholder feedback on the development of the cornerstones for the Revised Fuel Cycle Oversight Program (RFCOP). The NRC received comments from Kevin Ramsey (Agencywide Document and Management System (ADAMS) Accession No. ML15181A410); Patricia Borchmann (ADAMS Accession No. ML15201A580); an anonymous submitter (ADAMS Accession No. ML15201A581), and the Nuclear Energy Institute (ADAMS Accession No. ML15195A422). Enclosed are the staff responses to these comments.

Enclosure:
Response to Public Comments
on Draft Cornerstone Development

CONTACT: April Smith, NMSS/FCSE
(301) 415-6547

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DATE	8/25/2015	8/26/2015	8/26/2015

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**RESPONSE TO PUBLIC COMMENTS ON
DRAFT NRC DOCUMENT, "CORNERSTONE DEVELOPMENT"**

Comments on the draft document, "Cornerstone Development" are available electronically at the U.S. Nuclear Regulatory Commission's (NRC's) electronic Reading Room at: <http://www.nrc.gov/reading-rm/adams.html>. From this page, the public can access Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The NRC received from the following individuals or groups:

Letter No.	ADAMS No.	Commenter Affiliation	Commenter Name	Abbreviation
1	ML15181A410	NRC	Kevin Ramsey	Ramsey
2	ML15201A580	No known affiliation	Patricia Borchmann	Borchmann
3	ML15201A581	No known affiliation	Anonymous	Anonymous
4	ML15195A422	Nuclear Energy Institute	Janet R. Schlueter	NEI

Below are the NRC's responses to the comments. For each comment, the NRC has either repeated the comment as written by the commenter or summarized the comment for conciseness and clarity. Each comment is referenced in the form, [XXX]-[YYY]-[ZZZ], where: [XXX] represents the "Abbreviation" from the above table, [YYY] represents the "Letter No." from the above table, and [ZZZ] represents the sequential comment number from that commenter.

Ramsey 1-1

Page 9 - The last paragraph states that a cornerstone on emergency preparedness is included to verify that emergency response actions are adequate. However, fuel facility regulations don't require a finding that response action actions are adequate. In fact, the published position of the Commission is that accidents at fuel facilities pose a very small risk to the public. Offsite radiation doses large enough to cause an acute fatality or even early injury are not considered plausible. In view of two factors - (1) realistically, exposures should generally be low compared to protective action guides, and (2) the fast moving nature of accidents of concern - formal evacuation planning is not considered necessary, appropriate, or feasible. Actions to move people out of areas of dense smoke/fumes or get them to seek shelter indoors are routine for fire and police personnel. Such actions would be expected whether response organizations had formal emergency plans or not.

The cost of emergency preparedness at fuel facilities cannot be justified in terms of protecting public health and safety. Rather, the NRC justifies it in terms of the intangible benefit of being able to reassure the public that, if an accident occurs, local authorities will be notified so they may take appropriate actions.

By failing to reference the published position of the Commission on emergency preparedness at fuel facilities, the cornerstone development document fails to acknowledge that our regulations in this area are not risk significant and there is no basis for a cornerstone on emergency preparedness. Since the basis for the regulations is the "intangible benefit of being able to reassure the public," I believe that emergency preparedness inspection findings should be a subset of the public safety cornerstone and the emergency preparedness cornerstone should be deleted.

Enclosure

Reference: NUREG-1140, A Regulatory Analysis on Emergency Preparedness for Fuel Cycle and Other Material Licensees, ADAMS No. ML062020791

Reference: Statements of Consideration for Final Rule, Emergency Preparedness for Fuel Cycle and Other Material Licensees, April 7, 1989, 54 FR 14051.

NRC Response

The staff modified the objective to more accurately reflect the agency's oversight activities in this cornerstone. The cornerstone will not be removed in further support of the Commission's recognition of the importance of emergency preparedness to the public. The full Commission quote from NUREG-1140 provides further context for maintaining the emergency preparedness cornerstone: "Rather we [the Commission] would justify it in terms of the intangible benefit of being able to reassure the public that if an accident happens local authorities will be notified so they make take appropriate actions. Although emergency preparedness for fuel cycle and other radioactive material licensees cannot be shown to be cost effective, the NRC feels that such preparedness represents a prudent step which should be taken in line with the NRC's philosophy of defense-in-depth, to minimize the adverse effects which could result from a severe accident at one of its facilities."

Ramsey 1-2

Page 10 - The document states that the objective of the emergency preparedness (EP) cornerstone is to verify that the licensee is capable of implementing adequate measures to protect public health and safety during an emergency. As noted above, this objective is beyond the scope of regulatory requirements for fuel facilities. There is no requirement in 10 CFR Parts 40 and 70 for NRC staff to find that adequate protective measures can and will be taken at a fuel facility (like the reactor requirement in 10 CFR 50.47(d)). The objective of the oversight should be to verify that a program is established and maintained in accordance with the emergency plan, if an emergency plan is required. This objective is consistent with the objective in Inspection Procedure 88050, Emergency Preparedness.

NRC Response

The staff modified the objective, as mentioned in the response to Ramsey 1-1, to more accurately reflect the agency's oversight activities in this cornerstone.

Ramsey 1-3

Page B-2 - Under Attribute 2(a), Human Performance, the scope states that inspectors focus on whether the licensee's ISA appropriately weighs the complexity of actions workers are required to perform. However, the basis doesn't refer to ISA regulatory requirements (such as 10 CFR 70.62(c)). The basis refers to requirements for brief descriptions in an emergency plan (which may not even be required). If the objective is to review how worker actions were scored in the ISA, then the basis should be the regulation governing the ISA.

NRC Response

The staff modified the document to correct the basis and reference Title 10 of the *Code of Federal Regulations* (10 CFR) 70.62 (c) and (d) for Attribute B.2(a).

Ramsey 1-4

Appendix E - The key elements listed for emergency preparedness don't make sense. They look a lot like the key elements of emergency preparedness from the Reactor Oversight Program, but Parts 40 and 70 don't impose the prescriptive requirements that are imposed on reactors in Part 50. If you want to define reasonable key elements for a fuel facility, you should look at the inspection procedures uses by fuel facility inspectors. Based on Inspection Procedures 88050 and 88051, I would suggest the following key attributes:

a. Program Implementation (with the following inspectable areas):

- i. Program Changes
- ii. Implementing Procedures
- iii. Training and Staffing
- iv. Equipment and Facilities
- v. Audits and Assessments

b. Tests, Drills, and Exercises (with the following inspectable areas):

- i. Planning
- ii. Execution
- iii. Critiques

c. Offsite Response Organizations (with the following inspectable areas):

- i. Coordination
- ii. Training Offers
- iii. Right-to-Know Act

NRC Response

The staff agrees to revise the elements of the emergency preparedness cornerstone to better align with the current inspection program. Specifically, the key attributes will be emergency preparedness program implementation and maintenance; human performance and training; offsite emergency preparedness support; and problem identification and resolution. Program implementation and maintenance will include program changes, implementing procedures, and equipment and facilities. Human performance and training will cover the administration of tests, drills, and exercises and the adequacy of training. Offsite emergency preparedness support will cover coordination, adequacy of training offers, and the Emergency Planning and Community Right-to-Know Act of 1986. Problem identification and resolution will include audits and assessments and emphasize the resolution of safety significant issues.

Ramsey 1-5

Page E-2 - The scope of Attribute 3 states that some activities are more risk significant than others. As noted above, the entire emergency plan rule has no risk significance for fuel facilities so there is no basis for stating that certain provisions within the rule are risk significant. I recognize that these provisions are considered risk significant for reactors, but that doesn't make them risk significant at a fuel facility.

NRC Response

Per NRC response to comment 1-4, the staff will revise the document to emphasize safety significance in reference to emergency preparedness. Furthermore, the staff will reference NUREG-1140 and highlight its role in the cornerstone. Specifically, the staff will cite the summary of the Commission's decision to develop the current emergency preparedness regulations, i.e. although the cost-benefit analysis did not meet the numerical criteria to justify the rule, the Commission recognized the intangible benefit of reassuring the public that licensees would take appropriate actions in the event of an emergency.

Ramsey 1-6

Page E-3 - Attribute 4(a) refers to a public warning system. There is no requirement in Parts 40 and 70 for a public warning system. Please delete the erroneous information.

NRC Response

Per NRC Response to comment 1-4, the staff revised the emergency preparedness cornerstone. The revised cornerstone no longer includes the public warning system as a specific inspectable area.

Ramsey 1-7

(Editorial) Page 10 - The description of the Public Radiation Safety Cornerstone states activities that could involve inadvertent exposure to the public include routine effluents, treatment and storage of contaminated materials and routine transportation. Public exposure from a routine activity isn't an inadvertent exposure. Routine activities are intentional and the exposures are legal if they stay within the public dose limits. NOTE: This error is repeated in the first paragraph of Appendix D also.

NRC Response

Although an activity may be routine, its performance may present the opportunity for inadvertent exposure. Implementation of this cornerstone would verify adequate public health and safety in the event of an inadvertent exposure. For instance, the licensee may employ measures that limit inadvertent exposures to within legal limits.

The staff did not change the document as a result of this comment.

Borchmann 2-1

The submitter makes several assertions that the NRC bases its decisions on unverified and unanalyzed information from licensees before issuing its decisions.

NRC Response

On July 28, 2015, the staff forwarded these comments to its Office of the Inspector General (OIG) which investigates fraud, waste, and abuse. The staff did not make any changes to the document as a result of these comments.

Anonymous 3-1

The submitter strongly advises retention of the emergency preparedness cornerstone and provides reference to NUREG-1198, "Ruptured Mode A 48Y Cylinder at Sequoyah Fuel's Corporation Facility: Lessons-Learned Report" as the basis. The submitter also suggests termination of an NRC employee because of the employee's documented position to remove the EP cornerstone.

NRC Response

On July 28, 2015, the staff forwarded these comments to its OIG which investigates fraud, waste, and abuse. The staff did not make any changes to the document as a result of these comments.

Anonymous 3-2

You should delete your 21 uses of the word "credible". It is a loophole in your regulations as big as the universe.

NRC Response

The term "credible" is appropriate. Identifying credible accident scenarios allows licensees to optimally apply their resources to protect public health and safety. Licensees are required in 10 CFR 70.61 to define the term "credible." The staff reviews the definition, along with other factors, to determine whether approval of the licensee's definition is warranted. NUREG-1520 and NUREG-1718 provide the staff with guidance on the acceptance criteria for a licensee's definition.

The staff did not change the document as a result of this comment.

NEI 4-1

In the "Inspectable Areas" section each cornerstone, in the Basis, describes the review of a licensee in "identifying and correcting problems in accordance with the corrective actions program license condition". There are no regulatory requirements for CAP for fuel cycle facilities. Further detail and understanding of this is warranted. Maintaining more than one oversight process for fuel cycle facilities creates the potential for confusion and over burdensome

processes. Discussions during the June 11, 2015 public meeting seemed to indicate a CAP was a requirement for entry into the RFCOP.

NRC Response

Discussion of the Corrective Action Program (CAP) requirements for participation in the Revised Fuel Cycle Oversight Program (RFCOP) is beyond the scope of this document. However, the staff is willing to provide some historical context regarding an effective CAP. Via SRM to SECY-11-0140, the Commission approved Option 1. SECY-11-0140 specifically states that under Option 1, the staff would give credit to licensees with an effective CAP. Furthermore, the SRM to SECY-11-0140 directs the staff to develop and implement incentives for licensees to maintain effective CAPs. Therefore, the staff and the Commission recognized that some licensees will forego the benefits and choose not to have an effective CAP. Given these considerations, while engaging the fuel cycle industry and keeping it informed, the staff has taken several steps to familiarize fuel cycle licensees with the project plan for developing the RFCOP and assist them in developing effective CAPs.

- 1) The staff has and will continue to conduct public meetings and workshops with industry to discuss progress on the RFCOP project plan which is based on the SRM.
- 2) The staff provides guidance for applying for NRC approval of a licensee's corrective action program in Regulatory Guide 3.75, "Corrective Action Programs for Fuel Cycle Facilities" to which the Nuclear Energy Institute provided comments.
- 3) The staff developed Inspection Procedure (IP) 88161, "Corrective Action Program (CAP) Implementation at Fuel Cycle Facilities" which includes inspection objectives, requirements, and guidance on implementing an effective CAP. This document is publically available.

The staff did not change the document as a result of this comment.

NEI 4-2

The document identifies dozens of "Inspectable Areas" but gives no indication how these compare with the areas inspected under the existing inspection program. How would the scope of the inspection program change from the status quo if the RFCOP is implemented according to the Cornerstones document?

By identifying only Inspectable Areas, the document implies the RFCOP would be based entirely on inspection findings. How would performance indicators figure into the Cornerstones and their objectives?

NRC should show that the Inspectable Areas do not add to the scope of the existing FCF inspection program. Conversely, if the identified Inspectable Areas go beyond what is currently inspected, the NRC should demonstrate why this is essential to assure adequate protection of public health and safety.

NRC Response

Performance indicators and a comparison of the proposed inspectable areas with the current inspection program are beyond the scope of this document. However, the staff is willing to provide further discussion and a brief synopsis of upcoming activities related to this comment.

The staff states in Section 4.3 of the document, "The cornerstones define the baseline inspection program under the RFCOP." This statement clearly indicates that the cornerstones, and therefore, the inspectable areas with which they are associated, are part of the RFCOP, not its entirety. Per the RFCOP project plan, the staff will revise applicable inspection manual chapters and procedures to reflect the proposed key attributes and inspectable areas. After developing the remaining elements of the program, the staff will conduct a pilot program of the proposed RFCOP. The staff will analyze the results of the pilot and make improvements, as necessary, including the revision of inspection manual chapters and IPs.

With respect to performance indicators (PIs), the staff has discussed the concept internally and with external stakeholders and determined that PIs will not be part of the RFCOP. Should this decision change, the staff will continue to engage industry on the mechanisms for including PIs in the RFCOP.

The staff did not change the document as a result of this comment.

NEI 4-3

Attributes are inconsistently identified as "Key Attributes" or simply "Attributes", inviting readers to infer that the key attributes are more important than others. If the proper term in the RFCOP framework is Key Attributes, then use this term consistently and always.

NRC Response

Every instance of the word "attribute" is appropriately implemented in the document. The staff did not change the document as a result of this comment.

NEI 4-4

The attribute descriptions, like the cornerstone objective statements, vary greatly in focus and detail. Some of the attribute statements present philosophy, scope and justification for the choice of attribute.

Reduce the text that follows the title of each attribute to a simple declarative sentence or two that clearly defines the scope of the attribute. Eliminate all other extraneous text or put the elaborative text into a new subsection or footnotes. The extraneous text will become confusing to future readers and will raise questions about the sufficiency and purpose of the Inspectable Areas as knowledge of the thinking behind the foundational documents fades.

NRC Response

For those objectives and key attributes where the staff could improve the clarity and quality of the document, the staff considered the level of detail. At this time, the staff believes the objectives and key attributes contain the appropriate level of detail.

The staff did not change this document as a result of this comment.

NEI 4-5

The Objective statements in Appendices A-D include supplemental information (e.g., definition of terms, scope statements, and how-to statements) that goes beyond a simple declaration of the purpose of the cornerstone. This could lead to confusion. The Objective statements in Appendices E-G exemplify the clear, concise statement of purpose we would expect to see in defining the objectives of all the cornerstones.

Revise Objective statements for the cornerstones presented in Appendices A-D as described in the comment. If it is necessary to specify "How To Meet This Objective", we suggest adding a section with exactly that heading in Appendices A-G.

NRC Response

Per NRC Response 4-4, at this time, the staff believes the objectives and key attributes contain the appropriate level of detail.

The staff did not change this document as a result of this comment.

NEI 4-6

The draft only references NUREG-1520. Should NUREG- 1718 (MOX) also be referenced in the appropriate chapters when discussing cornerstones (chapter references are different for NUREG-1520 and NUREG- 1718).

Reference NUREG-1718 where appropriate.

NRC Response

The staff revised the document to include references to NUREG-1718, where appropriate.

NEI 4-7

There appears to be overlap in attributes and inspectable areas. For example, configuration management of NCSEs could be under Criticality Analyses, Criticality Implementation, Criticality Operational Oversight, and Criticality Programmatic Oversight. Specifically, there appears to be overlap between Operational Safety, Occupational Radiation Safety, and Public Radiation Safety. The overlap is reinforced by the Appendices (e.g., operational safety verifies availability of IROFS...to protect worker and public; occupational safety scope includes IROFS in the ISA to prevent or mitigate radiological consequences; public radiation safety - licensees can maintain

public protection by meeting applicable regulatory limits). One could interpret Operational Safety to be protection against events (10CFR70.61) and occupational radiation safety and public radiation safety are associated with normal operation protection (e.g., 10CFR20, ALARA); however, it is not clear this is what is intended. The concern is that a single issue could be associated with multiple cornerstones leading to a single minor issue linked to multiple attributes in multiple cornerstones.

Combine cornerstones, where possible, to minimize overlap.

NRC Response

The key attributes, human performance and training and problem identification and resolution, are common among all cornerstones. As discussed in Section 5.0, it is likely these attributes will become cross-cutting areas. Degraded licensee performance in these areas could manifest in multiple cornerstones. Inspection findings, however, would be specific to the cornerstone and the applicable key attribute. For instance, in the example the commenter cited, the staff would determine the appropriate key attribute for a finding related to configuration management of nuclear criticality safety evaluations. Failure to specify a new control would affect the performance of criticality analyses, where failure to implement a new control in the appropriate procedures would affect the performance of criticality implementation. The staff will conduct a pilot program of the RFCOP. The staff will assess the results and identify improvements, including the identification and elimination of potential overlaps.

The staff did not make any changes to the document as a result of this comments.

NEI 4-8

Some of the attributes appear to be repeating the License Application and ISA reviews. The Cornerstone document attributes should clearly focus on operating facilities and not program and process commitments submitted in a license application.

NRC Response

As defined in the document, key attributes are those characteristics of licensee performance necessary to achieve the cornerstone objective. The staff derived these attributes from a combination of expert elicitation and review of the applicable regulations and guidance documents such as NUREG-1520. Therefore, the attributes are germane to all operating facilities.

The staff did not change the document as a result of this comment.

NEI 4-9

Clarify what is intended by "other safety controls" under Operational Safety ("verify availability and reliability of IROFS and other safety controls").

NRC Response

The staff explains the term "other safety controls" in Section 3.1 and the objective statement for the cornerstone. Specifically, "other safety controls" are those the licensee identified as available to prevent or mitigate the consequence of an accident but not identified as IROFS.

The staff did not change the document as a result of this comment.

NEI 4-10

The stated objective for the Emergency Preparedness cornerstone to verify adequate measures to protect public health and safety" is beyond the scope of the regulatory requirements for fuel facilities.

Modify the objectives to be consistent with the stated objectives for the Emergency Preparedness Inspection Procedure 88050 "provide assurance that the emergency preparedness program is being properly maintained and implemented in accordance with requirements and commitments in the license or certificate."

NRC Response

As noted in the NRC response to comments 1-1 and 1-2, the staff modified the objective to more accurately reflect the agency's oversight activities in this cornerstone.

NEI 4-11

With reference to Fig. 4, a simple dotted line with the words "cross-cutting areas" oversimplifies the content (e.g. examples such as CAP, Human performance, etc.) that will go into the RFCOP.

Have additional narrative as to how the Cross-Cutting areas will be used in the Oversight Process or provide some pointers to the SDP, or Performance Assessment Process as indicated in the Figure 1 of the Conceptual Diagram of Option 1 of the SECY.

NRC Response

The staff modified Section 5.0 of the document to provide further context of cross-cutting areas, describing their role in the RFCOP as inputs to the performance assessment process.

NEI 4-12

Are the proposed cross-cutting areas limited to "human performance, problem identification and resolution (PI&R), and safety conscious work environment" as noted in this paragraph? A more thorough explanation of the Cross-Cutting areas would be beneficial.

NRC Response

As mentioned in the NRC response to Comment 4-11, the staff modified Section 5.0 of the document to provide further context of cross-cutting areas, describing their role in the RFCOP as inputs to the performance assessment process. As stated in Section 5.0 of the document, the staff will re-evaluate cross-cutting areas after the pilot program and during the development of the performance assessment process. As further stated in Section 5.0, the staff anticipates the RFCOP cross-cutting areas will be similar to those of the Reactor Oversight Process (ROP), e.g., human performance, problem identification and resolution, and safety conscious work environment. However, after re-evaluation, the staff may include areas of licensee performance in several activities related to change management.

NEI 4-13

The treatment of Cross-Cutting Areas is an important attribute of the overall RFCOP, yet it is limited to replicating the ROP without consideration towards the Fuel Cycle industry. This treatment is inadequate and deserves further dialogue. The deferral of this important aspect to reconsideration after the pilot is inappropriate.

The staff goes on in the third paragraph and suggests potential inclusion of management of facility changes; design of structures, systems, and components (SSCs); selection of human actions appropriate to maintain safety; procurement and testing of components that are appropriate to meet design function, and feedback from monitoring and PI&R processes into design, procurement, and maintenance processes". This list of significant aspects needs careful consideration and is representative of processes and management measures that in some cases are inappropriate as Cross-Cutting areas.

The staff should consider further expansion of this important aspect within the draft and consider a workshop with stakeholders on this topic. Have additional narrative as to how the Cross-Cutting areas will be used in the Oversight Process or pointers to the SDP or Performance Assessment Process as indicated in the Figure 1 of the Conceptual Diagram of Option 1 of the SECY.

NRC Response

As mentioned in the NRC responses to comments 4-11 and 4-12, the staff modified Section 5.0 of the document to provide further context of cross-cutting areas, describing their role in the RFCOP as inputs to the performance assessment process. As stated in Section 5.0 of the document, the staff will re-evaluate cross-cutting areas after the pilot program and during the development of the performance assessment process. Lessons-learned from the pilot program will appropriately inform the decision making process in determining the final cross-cutting areas relevant to the fuel cycle industry and the mechanism for incorporating them into the performance assessment process.

The staff has engaged external stakeholders on the topic of cross-cutting areas during public meetings held on February 25, March 5, and June 11, 2015. However, as the staff continues its progress on the RFCOP project plan, it will continue to engage external stakeholders.

NEI 4-14

The meaning and use of Cross-Cutting Areas is unclear. In the ROP, CCAs are relevant to the ROP feature now known as Cross-Cutting Issues. It remains unclear how the staff would use CCAs in the RFCOP.

Staff should specify the intended use of CCAs, in addition to defining them as called for by other comments.

NRC Response

As mentioned in the NRC responses to comments 4-11, 4-12 and 4-13, the staff modified Section 5.0 of the document to provide further context of cross-cutting areas, describing their role in the RFCOP as inputs to the performance assessment process. As stated in Section 5.0, the staff will re-evaluate cross-cutting areas after the pilot program and during the development of the performance assessment process to determine the cross-cutting areas and the appropriate mechanism for incorporating them in the performance assessment process.

NEI 4-15

RE: "The objective of this cornerstone is to protect against the consequences of a nuclear criticality accident, preferably by prevention of the accident." The attributes appear to address prevention and learning, but consequences.

If the objective is actually prevention of criticality accidents, then say it plainly rather than with the equivocal "preferably by prevention". If the objective is to address consequences, then provide attributes that address consequences.

NRC Response

The objective of the criticality safety cornerstone is consistent with 10 CFR 70.61(d) which states, "Preventive controls and measures must be the primary means of protection against nuclear criticality accidents." Criticality alarms and emergency preparedness are the primary elements relied upon to mitigate criticality events. The staff addresses criticality alarms in Attribute 5, "Criticality Problem Identification and Resolution" and emergency preparedness in the emergency preparedness cornerstone.

The staff did not change the document as a result of this comment.

NEI 4-16

The statement "The criticality controls relied on to maintain subcriticality under normal and credible abnormal conditions must be designated as IROFS consistent with 10 CFR70.61(e)." is accurate. The critical wording "consistent with 10 CFR70.61(e)" can be the important qualifier depending on one's interpretation: That is not all barriers included in the Nuclear Criticality Analysis on which the ISA summary is based are declared IROFS and don't need to be, the licensee has the duty to specify which barriers are chosen to be IROFS and treated as such.

Rewording would provide further clarification.

NRC Response

The staff agrees that the statement is accurate. Section 3.1 explains the interpretation that the commenter describes. Specifically, "Typically, licensees designate only a subset of the safety controls identified in the PHAs [process hazards analysis] as IROFS in order to comply with the performance requirements of 10 CFR 70.61. The licensees document the IROFS in the ISA Summary. The remaining safety controls are not included in the ISA Summary..."

The staff did not change the document as a result of this comment.

NEI 4-17

Pg. A-4, a, Basis (This issue is not unique to this Cornerstone.) "This area is inspected for licensee compliance with 10 CFR 70.62 (d). Once management measures have been established, it is necessary to verify whether the licensee properly performs them." How will management measures be treated within the RFCOP and in the Cornerstones?

Provide information on how management measures will be consistently treated in all Cornerstones or a separate means, i.e., Cross-Cutting Area treatment, should be considered.

NRC Response

The framework for the oversight of management measures within the RFCOP is beyond the scope of this document. However, the staff recognizes that management measures play a significant role in licensee programs to provide adequate assurance that IROFS and other safety controls are reliable and available, when needed. To that end, the document provides the context under which the staff will consider management measures in the cornerstones. Specifically, Table 1, "Relationship between Cornerstones of Safety and NUREG-1520 Chapters," emphasizes where the staff considered management measures with the cornerstones, specifically within the cornerstones of criticality safety, operational safety, and public and occupational safety. The staff further include management measures within the appropriate key attributes and inspectable areas, supported via applicable regulation, e.g. 10 CFR 70.4, 70.62 (d), 70.64.

With respect to management measures as a potential cross-cutting area, the staff recognizes that further consideration of cross-cutting areas may be warranted. Specifically, within the document, the staff states, "After the RFCOP pilot program and during development of the performance assessment process, the staff will reevaluate the cornerstones, their key attributes and inspectable areas to identify improvements, and determine the cross-cutting areas, and the appropriate mechanism for incorporating them in the performance assessment process. This assessment may necessitate the revision of the cornerstones, including the re-categorization of some key attributes and inspectable areas as cross-cutting."

The staff did not change the document as a result of this comment.

NEI 4-18

Pg. A-7, b, Basis. While industry does not argue with the statement "Prompt and effective restoration of the baseline safety basis is crucial for compliance with the performance requirements and maintenance of the double contingency principle". This area is also inspected to verify the licensee is identifying and correcting problems in accordance with the corrective action program license condition." The interpretation of these concepts into the practical Inspection Manual treatment must be developed. Revise Inspection Manual Chapters to accurately capture this interpretation.

NRC Response

The staff has already issued IP 88161, "Corrective Action Program (CAP) Implementation at Fuel Cycle Facilities." Per the RFCOP project plan, after Commission approval of the cornerstones, the staff will revise the applicable inspection manuals and procedures to reflect the cornerstones and their key attributes.

The staff did not change the document as a result of this comment.

NEI 4-19

Pg. A-7. RE: "As no single occurrence must lead to an accident, such occurrences afford valuable opportunities to eliminate possible precursors before they can lead to an accident." It is impossible to eliminate all precursors, due to random variations in human and system performance.

Modify to read: "As no single occurrence must lead to an accident, such occurrences afford valuable opportunities to learn from such potential precursors before they can lead to an accident."

NRC Response

The statement, as written, does not imply that it is possible to eliminate all possible precursors. The statement emphasizes that the opportunity exists to eliminate possible precursors.

The staff did not change the document as a result of this comment.

NEI 4-20

Figure A-1 identifies Attribute 5 as "Criticality Problem Identification and Resolution", as if criticality safety has unique PI&R features. Other cornerstones include a simpler, generic PI&R attribute that is identical from cornerstone to cornerstone. Why can't Criticality use the same generic PI&R attribute description?

If NRC insists on treating as an attribute of each cornerstone, instead of as a cross-cutting aspect, the PI&R attribute should be identical across all cornerstones (which further begs the question - why list it as an attribute of each cornerstone?).

NRC Response

The areas of criticality and operational safety have specific requirements for problem identification and resolution, as outlined in 10 CFR 70.62; therefore, the staff acknowledges this specificity and references those key aspects in the PI&R discussions for those cornerstones. The regulation specific to PI&R for the remaining cornerstones is primarily 10 CFR 70.4, i.e., management measures which includes the basic elements of a corrective action program.

The staff did not change the document as a result of this comment.

NEI 4-21

Operational Safety Cornerstone (general). This Cornerstone has the most significant changes from the March version provide to industry. It also brings to bear the overall treatment concerns regarding the means of including Management Measures now a separate Attribute, Cross Cutting areas, and P&IR. The Attribute 4 now entitled Performance of Management Measures while including some of the Management Measures as defined in 10 CFR 70.4 also introduces the areas of NPH, such as Fire, Flood, Cold or Hot Weather as well as additional second order challenges such as Offsite and Onsite power reliability and "other natural phenomena ..." Yet the Management Measure of Configuration Control gets listed as its own Attribute. Cross Cutting Areas of Human Performance and Training are now considered Attributes. Additionally "Human Performance" gets double billing under Attribute 2 & 3 leading to inconsistent treatment and confusion. Also the concept of "Procedure Quality" is important yet this Attribute/Inspectable Area is clearly subjective and difficult to measure.

This Cornerstone appears to cover the scope of the ISA treatment of SSC's yet needs noteworthy revision to add clarity and careful treatment of topics so as to not have redundancy or inconsistent treatment with other Cornerstones.

NRC Response

In the operational safety cornerstone, the staff describes key attributes 2 and 3 and the specific role human performance plays in each. As written, there would be no overlap in the inspection activities associated with these attributes.

With respect to attributes 4 and 5, the staff developed key attributes for some management measures because there are specific regulations and requirements applicable to those management measures. The staff modified the document to specify the regulations or requirements related to the management measures in key attributes 4 and 5. Specifically, the staff emphasizes that attribute 4 refers to the management measures in 10 CFR 70.62(d) and 70.64, while attribute 5 refers to the management measures in 10 CFR 70.72.

As stated in other NRC responses, the staff will continue to engage external stakeholders as it progresses through the RFCOP project plan.

NEI 4-22

The use of the term "Operational" in the titles of "Design Development" & "Implementation" denotes a specific scope or perspective that is hard to define and perhaps too restrictive. The focus should be on the control of the design and its implementation function to be on the safety attributes not necessarily on its operational or some may say its process attributes.

Consider reverting to characterization used in the version discussed during the March 2015 public meeting.

NRC Response

The staff modified the document to clarify the context of this attribute with respect to the design of structures, systems, and components.

NEI 4-23

Pg. B-3, Attribute 3. The use of the specific characteristics in the examples "elevated hydrogen fluoride concentrations in air, uranium hexafluoride (UF₆) in air, or the weight of a UF₆ cylinder" seem out of place. This level of detail is not necessary. Response to alarms, procedure use and adherence, IROFS knowledge, etc. would be more appropriate. Suggest deleting this level of detail.

NRC Response

The staff removed the example.

NEI 4-24

Pg. B-3, Attribute 3. RE: "Human performance during initial training and re-qualification provide an indication of expected staff performance." What value does this statement add? The meaning of the word "expected" is unclear here (e.g., does it mean "minimum acceptable standard of performance" or "predicted"?).

Delete or clarify this sentence.

NRC Response

The staff removed the sentence. The concept from that sentence is already expressed in the first sentence describing the attribute.

NEI 4-25

Pg. D-4, a, Scope. The statement "Inspection activities verify the licensee appropriately corrects identified radiation worker performance events, prevents their reoccurrence, and performs trending to identify underlying performance issues. Of special concern are maintenance activities when contract staff, having varying levels of experience, performs radiologically significant work." appears out of place in this cornerstone. The focus on 'worker

performance' and 'contract' staff may be appropriate if in another Cornerstones under HP. Also the phrase "performs radiologically significant work" can infer performance that my attribute to worker or contractor dose vs. public dose which should be treated under the Occupational Dose Cornerstone.

Reconsider these treatments within this Cornerstone, move to Occupational doses Cornerstone.

NRC Response

These statements are still relevant within the public radiation safety cornerstone because radiation worker events and the performance of radiologically significant work can potentially affect public health and safety.

The staff did not change the document as a result of this comment.

NEI 4-26

Pg. D-4, b, Basis. The reference to "subsection II of Appendix G to 10 CFR Part 20" appears out of place as this reference applies to a waste generator "certification" of a waste transports manifest contents".

Delete or correct reference.

NRC Response

The reference is correct. Properly trained and qualified licensee or contractor personnel must perform the certification of radioactive waste.

NEI 4-27

Appendix E. 10CFR70 includes criteria for determining if an emergency plan is required. Provide clarification in the cornerstone that some attributes may not be applicable to certain licensees.

NRC Response

As stated in the NRC response to Comment 1-1, the staff modified the objective to more accurately reflect the agency's oversight activities in this cornerstone. This modification also takes into consideration whether the emergency plan is required.

NEI 4-28

Appendix E and Figure E-1. Treatment of P&IR as noted above. Also the use of the acronym CAP is not needed on the figure after the March version.

See above suggestions regarding P&IR. Delete note on CAP from figure

NRC Response

As stated in the NRC response to Comment 4-20, problem identification and resolution for criticality and operational safety is specifically outlined in 10 CFR 70.62; therefore, the particulars with respect to the rule are covered in the PI&R discussions for those cornerstones. The regulation specific to PI&R for the remaining cornerstones is primarily 10 CFR 70.4, i.e., management measures to include the elements of a corrective action program. Therefore, the treatment of PI&R in Appendix E is appropriate. With respect to the use of the acronym, "CAP," the staff removed the reference from Figure E-1.

NEI 4-29

Pg. E-2. Why is Procedure Quality called out as a separate Inspectable Area in this cornerstone but not all? Why is the scope of this Inspectable Area defined so differently here compared to the definition in the Operational Safety Cornerstone?

Provide clarification

NRC Response

Per NRC response to comment 1-4, the staff will revise the key attributes and inspectable areas for the emergency preparedness cornerstone. With that revision, "Procedure Quality" will no longer be an inspectable area.

NEI 4-30

Pg. F-1, Objective. Numbering/format problem - "3&4"vs, 1&2. Correct numbering

NRC Response

The staff corrected the typographical error.

NEI 4-31

Appendix F, Figure F-1. Why is the structure of the Inspectable Areas here so different than the structure presented in other cornerstones? For example, five of six security attributes show Security Plans and Procedures as an inspectable area of each. In other cornerstones, Procedure Quality is called out as its own inspectable area. Similarly, training is identified as an inspectable area of two attributes in Security, but addressed as part of a Human Performance attribute in other cornerstones.

Provide clarification

NRC Response

Similar to the NRC response for Comments 4-20 and 4-28, the applicable regulations to the Security cornerstone include specific performance requirements. In recognition the regulatory

framework already in place, the staff structured the key attributes and inspectable areas to reflect those specific requirements.

NEI 4-32

For security and MC&A, link objectives to regulatory requirements that are consistent with 10CFR 73, 10CFR 74 and 10CFR 95).

Provide clear linkage between regulations and the objectives.

NRC Response

The objectives for the security and material control and accounting cornerstones, as stated, are consistent with 10 CFR Parts 73, 74, and 95. The bases sections for each cornerstone further cite the applicable regulations.

The staff did not change the document as a result of this comment.

NEI 4-33

Pg. G-4, c, Scope. Remove "the clarity of" and "to determine if it results from inadequate, deficient, or unclear procedures" from this section. While industry agrees that procedures should be clear, clarity is a matter of opinion which if inspected will result in more disagreements between licensees and NRC inspectors simply because of differences in opinions that I have no regulatory basis. Procedure clarity is not regulated and therefore should not be inspected.

Modify to read: Inspection activities in this area focus on plant procedures with regard to MC&A-related activities. Inspection activities include observation of plant staff performance during MC&A-related activities and walkthroughs. Inspectors evaluate any deficient performance. Inspection activities also include an evaluation of whether the procedure and activities observed result in compliance with regulations and license requirements. Additional inspection activities include review of selected changes to procedures to determine whether the procedures provide adequate guidance to plant staff to meet NRC requirements.

NRC Response

The staff modified the wording in this section to focus on evaluating the adequacy of the procedures.

NEI 4-34

Pg. G-5, c, Basis. Remove "clear and" and "Unclear procedures could result in errors that lead to the failure to control and account for material." While industry agrees that procedures should be clear, clarity is a matter of opinion which if inspected will result in more disagreements between licensees and NRC inspectors simply because of differences in opinions that have no regulatory basis. Procedure clarity is not regulated and therefore should not be inspected.

Modify to read: MC&A procedures are required by 10 CFR 74.31(c)(1), 74.33(c)(1), 74.43(b)(3), and 74.59(b)(2). Appropriate licensee procedures entail coverage of all MC&A functions in a technically correct manner. Measurement system procedures influence the capability of adequately assigning appropriate quantities of SNM to processing units and items. Inventory and item control procedures are essential to preventing the indicator response procedures are important to adequately assess the indicators, determine if a loss actually occurred, and recover from said loss.

NRC Response

As stated in the NRC response to comment 4-33, the staff modified the wording in this section to focus on evaluating the adequacy of the procedures.