March 25, 2009

Mr. Dealis W. Gwyn, Licensing Manager
Shaw AREVA MOX Services
P.O. Box 7097
Aiken, SC 29804-7097

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION REGARDING THE INTEGRATED SAFETY ANALYSIS METHODOLOGY DESCRIBED IN THE LICENSE APPLICATION AND INTEGRATED SAFETY ANALYSIS SUMMARY FOR THE MIXED OXIDE FUEL FABRICATION FACILITY

Dear Mr. Gwyn:

We have reviewed the Integrated Safety Analysis (ISA) information in your license application submittal, dated November 17, 2006, and the ISA Summary, dated September 27, 2006, as revised on December 17, 2007. The submittal requests a license to possess and use special nuclear, source, and by-product material in the Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF). The MFFF, which is to be located on the U.S. Department of Energy's (DOE'S) Savannah River Site in Aiken, South Carolina, will process and fabricate MOX fuel for use in commercial nuclear power plants as part of the DOE's plutonium disposition program.

We have enclosed a list of additional information that is needed by the staff in order to complete the review of the ISA methodology for the MFFF. Please provide us with a summary document explaining how our questions were addressed and describing any other changes to licensing documents that were necessary. Your response should be provided within 90 days of the date of this letter.

In accordance to the Title 10 *Code of Federal Regulations* 2.390 of the U.S. Nuclear Regulatory Commission's (NRC's) "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html (the Public Electronic Reading Room).

Please contact me at (301) 492-3130 if you have any questions.

Sincerely,

/RA/

Kevin Morrissey, Project Manager
Mixed Oxide and Uranium
Deconversion Branch
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Docket: 70-3098

Enclosure: As stated

cc w/enclosure:

S. Glenn, NNSA/SRS
J. Olencz, DOE
S. Jenkins, SC Dept. of HEC
D. Curran, Esq., NWS
A.J. Eggenberger, DNFSB
L. Zeller, BREDL
G. Carroll, NWS
D. Silverman, Esq.

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Mixed Oxide Fuel Fabrication Facility
Request for Additional Information
Integrated Safety Analysis License Amendment and
Integrated Safety Analysis Summary Review

Questions based on the License Application (LA)

ISA-LA-1

The LA states in Section 5.1.2 that "Mixed Oxide (MOX) uses personnel with appropriate experience and expertise in engineering and process operations to perform the Integrated Safety Analysis (ISA). For revisions to the ISA, personnel having qualifications similar to those ISA team members performing the ISA are used, depending on the nature of the changes." How the terms "appropriate," "similar," and "nature" will be evaluated is not well defined. The requirements for qualification need to be referenced or included in the LA. The term "similar" needs to be more clearly described so that the experience and expertise requirements are understood. The nature of the changes needs to be expanded upon so that it is clear how and when this commitment will be implemented.

This information is needed to comply with § 70.22(a)(6). This regulation requires that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff to engage in the proposed activities in accordance with the regulations.

ISA-LA-2

In Section 5.1.3, a commitment is made to implement and maintain management measures. However, it is not clear how management measures will be applied (implemented) to specific items relied on for safety (IROFS) to assure their reliability and availability. It is also not clear how management measures will be maintained and what criteria will be used for maintaining them. Provide a discussion, or table, that shows how management measures will be applied to IROFS and will be maintained.

This information is needed to comply with § 70.62(d). This regulation requires that each applicant or licensee shall establish management measures to ensure compliance with the performance requirements of § 70.61.

ISA-LA-3

In Section 5.1.4, commitments are made regarding making changes to the ISA Summary and LA. Included in this section are statements about making changes to the LA that would not require the U.S. Nuclear Regulatory Commission (NRC) pre-approval of the changes. The commitment to make changes to the LA without NRC pre-approval should include: (1) the criteria for evaluating the need for pre-approval including the impact on safety and health, (2) requirements for documenting and maintaining the evaluation, and (3) a time frame when the changes not requiring NRC pre-approval will be provided to the NRC.

This information is needed to comply with § 70.9(a). This regulation requires that information provided to the Commission by an applicant for a license or by a licensee, or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee and be complete and accurate in all material respects.

ISA-LA-4

In Section 5.1.4, reference is made to member companies and affiliates for the purpose of evaluating new processes under § 70.72(c)(1)(ii). Provide clear definition for member companies and affiliates by providing a list of applicable member companies and affiliates or a discussion of the criteria used to determine the qualifying companies.

This information is needed to demonstrate compliance with § 70.72. This regulation allows the licensee to make changes to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel, without prior Commission approval, if the change does not use new processes, technologies, or control systems for which the licensee has no prior experience.

ISA-LA-5

The requirement in § 70.72(e) contains a timeliness component (promptly) that is not included in your commitment made in Section 5.1.4. The staff considers that the timeliness component is an integral part of the regulation and for consistency and clarity should be included in the LA.

This information is needed to demonstrate compliance with § 70.72(e). This regulation requires that if a change covered by § 70.72 is made, the affected on-site documentation must be updated promptly

ISA-LA-6

In Section 5.1.4, a commitment is made regarding changes that require NRC pre-approval. Reference to an undefined group is provided for submitting amendment requests to the NRC. It is not clear from this commitment the relationship between the responsible group and the responsibility to submit amendment requests. Modify or clarify the statement.

This information is needed to demonstrate compliance with § 70.72(d)(3). This regulation requires that for changes that require pre-approval under § 70.72, the licensee shall submit an amendment request to the NRC in accordance with § 70.34 and § 70.65 of this chapter, and for all changes that affect the ISA Summary, the licensee shall submit to the NRC annually, within 30 days after the end of the calendar year during which the changes occurred, revised ISA Summary pages.

ISA-LA-7

The requirement in § 70.62(a)(3) contains a timeliness component (promptly) regarding the updating of records with regard to failure of IROFS that is not included in your commitment made in Section 5.1.5. The staff considers that the timeliness component is an integral part of the regulation and for consistency and clarity should be included in the LA.

This information is needed to demonstrate compliance with § 70.72(e). This regulation requires

that if a change covered by § 70.72 is made, the affected on-site documentation must be updated promptly.

ISA-LA-8

In Section 5.2, in describing the ISA methods, is there a criterion for evaluating the consequences and likelihoods? If so, reference to the criteria should be included in the discussion of the methods used.

This information is needed to demonstrate compliance with § 70.62(a). This regulation requires that each licensee or applicant establish and maintain a safety program that demonstrates compliance with the performance requirements of § 70.61.

ISA-LA-9

In Section 5.2 and Table 5.1-2 reference is made to a "typical" risk matrix. It is not clear what typical means in these instances and whether other matrices exist or will be used. Clarify or modify the term to be consistent with implementation of the matrix.

This information is needed to demonstrate compliance with § 70.62(d). This regulation requires that each applicant or licensee establish management measures to ensure compliance with the performance requirements of § 70.61

ISA-LA-10

In Section 5.2.2, in describing subtasks of the safety evaluations, the identification and description of IROFS does not include how management measures are applied to IROFS. Is the application of management measures to IROFS considered part of the ISA method? If so, it should be included in the ISA methods discussion in the LA.

This information is needed to comply with § 70.62(d). This regulation requires that each applicant or licensee shall establish management measures to ensure compliance with the performance requirements of § 70.61.

ISA-LA-11

In Section 5.2.2, it is not clear what "design verification activities" refer to and the commitment that is being made regarding the design verification process. Provide a description of what these activities are and what activities are being committed to.

This information is needed to demonstrate compliance with § 70.62(a). This regulation requires that each licensee or applicant establish and maintain a safety program that demonstrates compliance with the performance requirements of § 70.61.

ISA-LA-12

In Section 5.2.2.1, it is not clear what constitutes the commitments for the methodology that will be performed versus what is a description of the methodology that was applied in the past. This is complicated by the use of both past and present tense verbs. Confirm what commitments relate to the methodology that will be used if a license is granted and what portions of the methodology represent either description only or historical documentation.

A review of the methodology description should be performed to sort out the historical, descriptive and commitment aspects of the ISA method that will apply to a possession and use license so that a clear understanding of the ISA method that is being committed to and that will be used in the future can be evaluated by the staff. This information is needed to demonstrate compliance with § 70.62(a). This regulation requires that each licensee or applicant establish and maintain a safety program that demonstrates compliance with the performance requirements of § 70.61.

ISA-LA-13

In Section 5.2.2.1, provide the basis for selecting the appropriate process hazards analysis (PrHA) method.

This information is needed to demonstrate compliance with § 70.62(a). This regulation requires that each licensee or applicant establish and maintain a safety program that demonstrates compliance with the performance requirements of § 70.61.

ISA-LA-14

In Section 5.2.2.5, the criteria for “not credible” for natural phenomena and external man-made events is satisfied because of an extremely low initiating event frequency. Quantify what corresponds to extremely low for these particular events. Also provide the acceptance criteria for other events that are based on frequency of occurrence of an initiating event.

This information is needed to demonstrate compliance with § 70.62(a). This regulation requires that each licensee or applicant establish and maintain a safety program that demonstrates compliance with the performance requirements of § 70.61. This information is also needed to demonstrate compliance with § 70.64(a)(2). This regulation requires that the design must provide for adequate protection against natural phenomena with consideration of the most severe documented historical events for the site.

ISA-LA-15

In Section 5.2.2.7, what are the criteria for determining which of the PrHA methods is used to demonstrate the likelihood of an event?

This information is needed to demonstrate compliance with § 70.62(a). This regulation requires that each licensee or applicant establish and maintain a safety program that demonstrates compliance with the performance requirements of § 70.61.

ISA-LA-16

In Section 5.2.2.7, a statement is made that implementation of management measures cannot be performed because the procedures are not available. Commit to implement management measures when procedures are available or justify why implementation is not necessary.

This information is needed to demonstrate compliance with § 70.62(a). This regulation requires that each licensee or applicant establish and maintain a safety program that demonstrates compliance with the performance requirements of § 70.61. This information is also needed to comply with § 70.62(d). This regulation requires that each applicant or licensee shall establish management measures to ensure compliance with the performance requirements of § 70.61.

ISA-LA-17

In Section 5.2.2.7.1, the statement is made that a summary is provided in the Nuclear Safety Evaluations (NSEs) that includes how the performance requirements are met with the application of the identified IROFS. Provide this information in the ISA summary.

This information is needed to demonstrate compliance with § 70.62(a). This regulation requires that each licensee or applicant establish and maintain a safety program that demonstrates compliance with the performance requirements of § 70.61.

ISA-LA-18

In Section 5.2.2.7.1, the statement is made that the demonstration that the single failure criterion is applied to each IROFS is in the NSEs. How does this apply to sole IROFS?

This information is needed to demonstrate compliance with § 70.62(a). This regulation requires that each licensee or applicant establish and maintain a safety program that demonstrates compliance with the performance requirements of § 70.61.

ISA-LA-19

In Section 5.5, what specific criteria apply to ISA Team qualification in terms of knowledge, experience, MOX-specific experience and education? What are the training or re-training requirements associated with ISA Team qualifications?

This information is needed to comply with § 70.22(a)(6). This regulation requires that each application for a license shall contain the technical qualifications, including training and experience of the applicant and members of his staff to engage in the proposed activities in accordance with the regulations.

ISA-LA-20

In Figure 5.2-2, the method shows a step that the frequency of the event crediting the IROFS will be determined. Define the term “frequency.” Explain whether this step is part of the ISA methodology described in that section.

This information is needed to demonstrate compliance with § 70.62(a). This regulation requires that each licensee or applicant establish and maintain a safety program that demonstrates compliance with the performance requirements of § 70.61.

<u>Additional questions from radiological review that pertain to Chapter 5 of the LA</u>

ISA-LA-RAD-1

Section 5.3.1.2, top of page 5.3.1-3, indicates the ISA evaluates credible events for four separate areas which are facility worker, site worker, individual outside the Mixed Oxide Fuel Fabrication controlled area (IOC), and the environment. However, Section 5.3.2, second full paragraph on page 5.3.2-1, only lists three of these four. In the following paragraph, all four areas are again listed. Consistent with 10 CFR 70.62(c), confirm that the evaluation described

in the second full paragraph of Section 5.3.2 was conducted on all the groups of concern.

Also, in Section 5.3.2 third paragraph, second sentence states, "the unmitigated event consequences have been determined to be low to the site worker, facility worker, the IOC, and the environment." As currently written, this sentence states that all unmitigated event consequences have been determined to be low. The intent of this paragraph is to indicate that some of the unmitigated event consequences were determined to be low and thus no IROFS were assigned. However, the current text is unclear, since 5.3.3 through 5.3.11 contains unmitigated events which have high and intermediate consequences. Consistent with 10 CFR 70.62(c), add additional information to the third paragraph of Section 5.3.2 to clarify which unmitigated event consequences are being referenced. In addition the third sentence in paragraph three begins with, "these events…." Clarify to which events the sentence refers.

ISA-LA-RAD-2

Section 5.1.2.3.5, the first sentence of the second full paragraph states, "to perform the mitigated consequence analysis, the unmitigated consequence analysis methodology was used with the following modification: applicable bounding leak path factors (LPFs) were used for the IROFS providing mitigation." The section goes on to provide a single example of an LPF being modified due to a ventilation IROFS. As stated in Section 5.1.2.3.5, the IROFS effectiveness to mitigate high and intermediate consequence events is directly related to the accuracy of the assigned LPF. Yet, the LPF value for each IROFS has not been provided, nor the method used to ensure accuracy of the chosen value. Consistent with 10 CFR 70.61(e) and 70.62(c)vi, list the IROFS which have mitigative effects in whole or part due to reduced LPF values. List the LPF value for these IROFS and provide a basis for the accuracy of the assigned value.

<u>Questions based on the ISA Summary</u>

ISA-ISAS-1

How will the IROFS boundaries be defined, controlled and maintained for determinations of IROFS failures, ability of the IROFS to perform their safety functions, and for assigning and determining the effectiveness of management measures?

This information is needed to comply with § 70.65(b)(4). This regulation requires that the ISA summary must contain information that demonstrates compliance with the performance requirements of § 70.61, including a description of the management measures.

ISA-ISAS-2

How are IROFS failures, or operability, defined? Define a time period for evaluation of whether an IROFS is no longer capable of performing its safety function. Describe the process for implementing compensatory measures for failed IROFS.

This information is needed to comply with § 70.62(a)(3). This regulation requires that each licensee or applicant shall maintain records of failures readily retrievable and available for NRC inspection, documenting each discovery that an IROFS or management measure has failed to perform its function upon demand or has degraded such that the performance requirements of § 70.61 are not satisfied. These records must identify the IROFS or management measure that failed and the safety function affected, the date of discovery, date (or estimated date) of the failure, duration (or estimated duration) of the time that the item was unable to perform its

function, any other affected IROFS or management measures and their safety function, affected processes, cause of the failure, whether the failure was in the context of the performance requirements or upon demand or both, and any corrective or compensatory action that was taken. A failure must be recorded at the time of discovery and the record of that failure updated promptly upon the conclusion of each failure investigation of an IROFS or management measure.

ISA-ISAS-3

Given that your methodology considers the entire set of IROFS when determining compliance with the 70.61 performance requirements, what is the process for determining whether replacement of an IROFS is equivalent?

This information is needed to demonstrate compliance with § 70.72(c)(2). This regulation requires that the licensee does not remove, without at least an equivalent replacement of the safety function, an IROFS that is listed in the ISA Summary and is necessary for compliance with the performance requirements of § 70.61.

ISA-ISAS-4

Are the criteria for meeting highly unlikely defined by your methodology the same for sole IROFS as they are for other IROFS?

This information is needed to comply with § 70.65(b)(4). This regulation requires that the ISA summary contain information that demonstrates compliance with the performance requirements of § 70.61.

ISA-ISAS-5

What is the relationship between performance of the supplemental likelihood assessments and demonstration of performance requirements? Are these assessments expected to be part of the methodology for evaluating future changes?

This information is needed to comply with § 70.65(b)(4). This regulation requires that the ISA summary contain information that demonstrates compliance with the performance requirements of § 70.61.

ISA-ISAS-6

A large number of the accident sequences in the ISA summary have conclusions that events are highly unlikely because of a partial set of the four elements used in your methodology for meeting the criteria of highly unlikely. It is not clear if only the elements provided in the conclusion are met or whether all four of the criteria required by your methodology have been met. Examples of this can be found on pages 5.3.3-8, 5.3.3-9b, 5.3.3-11 and 5.3.3-13. In cases where the full complement of elements defined for acceptability are not met, justification for making an exception to the methodology is required or revision to the ISA Summary is needed for consistency with the results of the ISA.

This information is needed to comply with § 70.65(b)(4). This regulation requires that the integrated safety analysis summary must contain information that demonstrates the licensee's

compliance with the performance requirements of § 70.61.

ISA-ISAS-7

Provide a discussion on how common mode failure is evaluated in the ISA methodology. Also provide a description of how independence is evaluated in the methodology when determining that the single failure criteria are acceptable for meeting the performance requirements.

This information is needed to comply with § 70.65(b)(4). This regulation requires that the ISA summary must contain information that demonstrates the licensee's compliance with the performance requirements of § 70.61.