November 3, 2008

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 REVIEW OF THE RADIOLOGICAL PROTECTION SAFETY ASPECTS OF THE MIXED OXIDE FUEL FABRICATION FACILITY LICENSE APPLICATION REQUEST

Dear Mr. Gwyn:

We have reviewed the radiological protection information in your license application (LA) submittal, dated November 17, 2006, and the Integrated Safety Analysis (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 Fuel Fabrication Facility (MFFF). The MFFF, which is to be located on the Department of Energy's Savannah River Site in Aiken, South Carolina, will process and fabricate mixed oxide fuel for use in commercial nuclear power plants as part of the 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 radiological safety aspects of the MFFF. Please provide us with a response describing how our questions were addressed and any other changes to other licensing documents that may have been necessary to incorporate the responses (e.g., LA and ISA Summary change pages). The revisions should be provided within 60 days of the date of this letter.

A copy of this letter will be available electronically for public inspection in the U.S. Nuclear Regulatory Commission's (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).

If you have any questions, we would be happy to meet with you and other Shaw AREVA MOX Services staff on these issues. Please feel free to contact me at (301) 492-3229.

Sincerely,

/RA/

David Tiktinsky, Senior Project Manager
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Docket: 70-3098

Enclosure:
RAIs for Radiological Protection (Non-Sensitive)

cc:
G. Smith, NNSA
J. Olencz, DOE
S. Jenkins, SC Dept. of HEC
D. Curran, Esq., NWS
D. McIntyre, OPA
A.J. Eggenberger, DNFSB
L. Zeller, BREDL
G. Carroll, NWS
D. Silverman, Esq.
D. Gwyn, MOX Services

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MB r/f	W. Gloersen, RII	
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OFFICE	MB	MB	ECB	MB
NAME	DTiktinsky	CGibbs	MBartlett	MKotzalas
DATE	9/17 /08	9/18 /08	9/25 /08	10/ 3 /08

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Requests for Additional Information Regarding Radiological Protection Safety for the Mixed Oxide Fuel Fabrication Facility

Management:

HP-1. LA section 9.0 generally addresses the purpose of the Radiation Safety Program. Consistent with Regulatory Guide 8.8.C.1.a&b, specifically describe the MFFF management commitment to implement the Radiation Protection Program, stating management policy and identifying responsibilities of key personnel, such as the Plant Manager, Radiation Protection Manager, Health, Safety and Environment Director, Shift Supervisor and facility personnel.

HP-2. LA section 9.2.1.1, under Management Commitment, states the responsibility for complying with radiological safety requirements and the maintaining of exposures As Low as Reasonably Achievable (ALARA) starts with the individual worker. Consistent with Regulatory Guide 8.10.C.1, describe the significance of the role of management, in addition to the individual worker, to set standards and provide positive leadership to ensure a robust and successful ALARA program.

ALARA:

HP-3. The first sentence in LA section 9.2.1 states the licensee's purpose of the ALARA program is to maintain radiation exposures within regulatory limits. This purpose is not consistent with the definition of ALARA as stated in 10 CFR 20.1003 'ALARA.' In addition the second portion of the first sentence is circulatory since the word ALARA is used to define the ALARA program. Consistent with ALARA definition in 10 CFR 20.1003 and the requirements in 10 CFR 20.1101(b),

- Modify the purpose of the ALARA program to conform to the regulatory definition by ensuring doses will be maintained as far below regulatory limits as reasonable.
- Modify the second sentence in the first paragraph to indicate that management will ensure the work force is committed to this policy.
- Modify the first bullet of the description of the ALARA program to state that the ALARA principle will be incorporated, when appropriate, into plant procedures involving radioactive material, rather than a separate set of ALARA procedures.

HP-4. LA section 9.2.1.2 describes the roles of the ALARA Committee such as reviewing and conducting audits at least annually, but does not specify a time frame for how often the Committee meets. Consistent with 10.CFR 20 1101(c),

- Clarify how often the ALARA Committee will meet, and provide a minimum time between meetings.
- State whether the ALARA Committee is the "qualified organization" involved in the design reviews for modifications as described in the last paragraph of section 9.1.1.4 on page 9-3. If not, clarify who makes up the "qualified organization" mentioned in the same paragraph.
- The applicant states in section 9.1.1.1, design personnel are qualified in radiation protection design and ALARA concepts. Describe how design personnel achieve qualification and the expected level of experience in radiation protection, radiation shielding and general radiation safety.

HP-5. LA section 10.1 describes the ALARA goals to minimize release of radioactive material to the environment, but does not specify if the radiation function is responsible for the radiological environmental monitoring program. Consistent with 10 CFR 20.1101(d),

- In LA section 10.1, state which function is responsible for conducting the radiological environmental monitoring program.

HP-6. LA Section 9.1.1.1 describes the responsibilities for ALARA design, stating the design function is split between regulatory and engineering functions. The section also states the nuclear safety function provides design criteria associated with radiation protection. Clarify what the nuclear safety function is. Clarify if this function is overseen by the Radiation Protection Manager (RPM). If it is not, explain why the RPM is not included in ALARA design, consistent with Regulatory Guide 8.8.C.b.(3).

Experience:

HP-7. LA pages 9-18, 4th and 7th paragraphs describe the minimum experience and training requirements for the RPM. Consistent with 10 CFR 70.23(a)(2),

- In the 4th or 7th paragraph of section 9.2.2 establish a commitment for a portion of the management experience to have been received at a nuclear facility (power plant, navy, fuel fabrication, etc.) (see ANSI/ANS Standard 3.1, section 4.3.3).
- Page 9-18 section 9.2.2 7th paragraph in the last sentence states, "Management may waive specific qualifications for the RPM when education, experience, certifications, and overall qualification of the supporting staff meet the above requirements." State that instances where management waives specific qualification requirements for the RPM will be evaluated on a case-by-case basis, approved and documented (see ANSI/ANS Standard 3.1, section 4.1.1.1 and 4.1.2.1).

Procedures:

HP-8. LA section 15.5.4 page 15-13 states operating and maintenance procedures are reviewed every five years to verify their continued applicability and accuracy. There is no comparable commitment to conduct periodic reviews of radiation protection procedures. Consistent with 10 CFR 20.1101(c),

- State a periodic review of radiation protection procedures will be conducted in accordance with internal procedures.
- State that respiratory protection procedures will be revised as necessary, whenever changes are made to the facility, process, or equipment.

HP-9. LA section 9.2.3 page 9-19 second paragraph states RWPs are required for specific purposes only. The submittal does not provide any description of the criteria which determine when an RWP will be used. In addition, the last sentence of the last paragraph on page 9-19 indicates that RWPs are not required under certain unspecified conditions. Consistent with 10 CFR 70.22(a)8 and 70.23(a)4,

- Specify under what conditions an RWP will be required. State whether RWPs will be required for activities involving licensed materials not covered by operating procedures.

- Clarify the meaning of the first paragraph of section 9.2.3 regarding RWPs which states they are used to "control radiological work." The section seams to indicate an RWP must be used for every entry into the restricted area.
- State who may generate RWPs, and specify how long these documents are retained.
- LA section 9.2.3 page 9-19 last sentence of the last paragraph indicates that some organizational groups that use licensed materials are not required to use RWPs. Change the wording of the last paragraph on page 9-19 to clarify that RWPs are not required when established procedures exist.
- In LA section 9.2.3, the last paragraph on page 9-19 contains one sentence stating that "procedures that involve the use of licensed materials without an RWP require review and approval by the RPM." Expand upon this single sentence to describe the process for drafting, authorizing, and reviewing new or modified procedures, both RWP and non-RWP radiation procedures. State that major procedure modifications involving licensed material will be reviewed and approved by appropriate management, e.g. radiation protection manager.

Training:

HP-10. LA page 9-22 section 9.2.4 last 3 sentences indicate that the radiation safety training program will be updated as items are identified. Consistent with the requirements in 10 CFR 19.12 and Regulatory Guide 8.29 section C,

- State which function (HS&E Manager, RP, etc.) will be responsible for reviewing/auditing and updating the radiation safety training program.
- Specify that the radiation safety training program will be reviewed and updated on some periodic basis consistent with Regulatory Guide 8.29 section C (which states 3 years), to account for facility or process changes and ensure that the programs are current and adequate.
- Section 9.2.4 describes radiation safety training for general employees as well as visitors entering restricted areas. Consistent with 10 CFR 19.12, add a sentence committing to meet all the training requirements listed in 10 CFR19.12. Consult Regulatory Guides 8.10, 8.13 and 8.29 for additional information on training criteria acceptable to the NRC.

Ventilation:

HP-11. On LA page 9-5 section 9.1.2.2 the last sentence of the first paragraph states, "Airborne contamination and pressure are monitored to detect changes in containment barriers." Consistent with 10 CFR Part 20.1501 and 20.1701, state that differential pressure across HEPA filters will be checked on a periodic bases consistent with the manufacturer's specification or the filters will be connected to automatic monitoring or alarms.

Respiratory Protection:

HP-12. LA page 9-28 section 9.2.10 describes the licensees Respiratory Protection Program. Consistent with 10 CFR 20.1703(c)4,

- State that written procedures will be used for the selection, fitting, issuance, maintenance, testing, training of personnel, monitoring, and record-keeping for individual respiratory protection equipment.
- Consistent with 20.1703(c)f(viii), provide a commitment to maintain records of the respiratory protection program, including training for respirator use and maintenance.

Surveys:

HP-13. LA section 9.2.6 contains a general description of the licensee's survey program but does not provide an explicit commitment to conduct the surveys according to planned and approved written procedures, nor does the section describe what function is responsible for conducting the survey program. Consistent with 10 CFR 20.1501(a),

- State that written procedures specific to the type of contamination will be followed for the survey program.
- Specify that the procedures will include such items as an outline of the program objectives; sampling procedures; data analysis methods; types of equipment and instrumentation to be used; frequency of measurements; record-keeping and reporting requirements.
- State that the Radiation Protection function is responsible for conducting the survey program.
- The third paragraph on page 9-24 in section 9.2.6 states that surfaces will be surveyed for contamination which exceeds limits in Table 9.2-1. Yet, there are no commitments to conduct a cleanup within a specified time frame. Specify the corrective actions for contaminated surfaces and that removable contamination will be cleaned up in accordance with internal written procedures.
- Section 9.2.6 page 9-24 paragraph 3, last sentence states, "After historical data have been collected, the frequencies of surveys are adjusted to optimize resources." This "optimization of resources" is not well defined. Provide a commitment to conduct surveys on a frequency in accordance with RG-8.24 section 2 or specify a minimum frequency which demonstrates an equivalent program. Or, describe the program to collect historical data with sufficient detail to demonstrate the survey program will be representative. Include the type of data collected, the length of time the data will be collected, how often the historical data is reviewed to ensure it remains representative, etc.
- Consistent with 10 CFR 20.2103, add a statement to the second paragraph on page 9-24 to document surveys and corrective actions and to maintain records on these items.

Dosimetry:

HP-14. LA section 9.2.7 page 9-25 to 9-26 last partial sentence, states, "Personal dosimeters are analyzed at a frequency described in approved procedures." Consistent with 10 CFR 20.1502, identify a maximum time frame for processing TLDs, such as at least quarterly.

HP-15. In the middle of the first paragraph of LA section 9.2.12 page 9-32 states, "In that case, significant exposure dosimetry…." This reference to "significant exposure dosimetry" is unclear since it does not apply to the TLD or the electronic pocket dosimeter listed in the previous sentence. Consistent with 10 CFR 70.9,

- Define the term "significant exposure dosimetry," and clarify whether this refers to a pocket ionization chamber, personal dosimetry, portable survey equipment, CAMs, etc.
- Consistent with 10 CFR 20.1501(a), clarify which individuals will be required to carry this type of "significant exposure dosimetry." If a dose exceeds the electronic pocket

dosimeter, state that internal procedures will define what actions will be taken. Provide a summary of these actions in the RAI response.

HP-16. The last sentence in LA section 9.2.7 page 9-26 states, “Radiation protection program policies and approved procedures establish action levels for personal dosimetry analyses results.” Although administrative control levels are listed in Table 9.1-2, the dosimetry section does not reference these action levels. Consistent with 10 CFR 20.1101 and 20.1201,

- Incorporate into section 9.2.7 a statement that the administrative limits in Table 9.1-2 apply to direct exposure control.
- Describe the corresponding follow up actions that will be required if direct reading dosimetry indicates the administrative limit has been exceeded.
- Identify any quarterly administrative limits and specify the associated action levels.

Bioassay:

HP-17. LA section 9.2.8 page 9-26 states that routine bioassay monitoring will be conducted for personnel likely to receive intakes resulting in a CEDE greater than 100 mrem. However, the last sentence in the preceding paragraph states that “the 100 mrem action level is difficult to achieve.” These two statements taken together imply most staff at the MFFF are not required to undergo routine bioassay monitoring. Consistent with 10 CFR 20.1502(b),

- In LA section 9.2.5, modify your commitment to conduct bioassay to a percentage of the ALI (e.g. 2%), rather than 100 mRem.
- Clarify what members of the MFFF staff will be required to undergo routine bioassay monitoring. Replace the term “personnel likely to receive intakes” with a more concrete criteria such as individuals handling radioactive material, individuals working in controlled areas, etc.
- State that the bioassay program will be conducted consistent with ANSI.HPSN 13.22 (1995) or provide sufficient description to demonstrate equivalence. Consistent with this standard, provide a maximum interval for conducting a routine bioassay, e.g. quarterly. Provide an overview of the types of bioassay measurements to be conducted, and provide sufficient description to demonstrate equipment and instrumentation have sufficient sensitivity for the type or types of radiation being measured.
- Describe the type of bioassay measurements, e.g. urinalysis, whole body scan, lung scan, etc.

Dose Limits:

HP-18. LA section 9.2.9 page 9-27 lists the types of doses that will be tracked. The section states the exposure limits listed in 10 CFR 20, but does not provide a commitment to sum internal and external doses. Consistent with 20.1202(a), state that external and internal dose will be summed when applicable. Commit to meeting the Regulatory Guides 8.7 (NRC, 1992a) and 8.34 (NRC, 1992c). Or provide a commitment to maintain procedures in agreement with these Regulatory Guides.

Air Samples:

HP-19. The first five paragraphs of LA section 9.2.5 page 9-22 to 9-23 indicate air samples will be used if individuals are likely to receive 2% of the ALI. This section also refers to air sampling equipment and air monitoring equipment. In addition LA section 9.2.11.1.1 indicates airborne contamination surveys will be processed. Based on these sections, the licensee appears to be using CAMs to identify releases above a certain action level and air samples to monitor internal radiation levels. The submittal provides a thorough description of when CAMs will be used but insufficient information on air sampling. Consistent with 10 CFR 20.1204(a),

- Modify the third paragraph on LA page 9-23 to provide an overview of how CAMs and air samples will be used to calculate daily internal doses.
- State the frequency of air sample measurements; provide a description of the recordkeeping of air samples; and list the minimum detection levels.
- State that administrative limits are established for air contaminations at which actions are taken to investigate and correct the levels.
- Consider committing to conduct air sampling in accordance with industry standards such as Regulatory Guide 8.25 (NRC, 1992b); NUREG-1400 (NRC, 1991); and ANSI/Health Physics Society (HPS) Standard 13.1
- Specify how air samplers will be positioned so that sampled air is representative of inhaled air.
- LA section 9.2.8 describes how the licensee will monitor internal exposure. The section focuses on bioassay measurements, and does not include doses based on air sampling. Yet, the second paragraph indicates that bioassays will not be conducted unless “workplace monitoring” (undefined) identifies a potential intake. Modify the second paragraph of LA section 9.2.8 to clarify how the air sampling program is used in conjunction with the bioassay program to determine the internal dose. Clarify that air sampling will be used to track daily internal doses and bioassay will be used to verify these measurements on a periodic basis or in rare high exposure instances.

Controlled Areas:

HP-20. Section 9.2.6 page 9-24 second full paragraph states, “Initially, contamination surveys (i.e., instrument, swipe and large-area wipes) are conducted in the Radiological Control Area established for the control of contamination, and other areas with the potential for becoming contaminated.” In addition the second bulleted item on page 9-24 refers to “contamination, high contamination, and airborne radioactivity areas.” The application makes multiple references to contamination and radiological areas which are not well defined in the application. Consistent with 10 CFR 70.9(a) and 10 CFR 20.1501(a),

- Add a paragraph to section 9.2.6 which defines a “controlled area,” “Radiological Control Area,” “contamination area,” “high contamination area,” and “radioactivity areas” with sufficient description to differentiate between each area.
- Section 9.2.6 discusses radiological control areas, restricted areas, contamination areas, high contamination areas and airborne radioactivity areas. There is no indication of how these areas will be posted. Consistent with 10 CFR 20.1902, add a description of each type of area listed in section 9.2.6 with sufficient detail to determine which areas correspond to radiation areas (RA), high radiation areas (HRA) and radioactive material storage areas. State how each area is posted.

- Provide an objective criteria for identifying "… areas with the potential for becoming contaminated."
- Once these various areas are defined, describe how they will be identified and demarcated.

HP-21. The last paragraph in LA section 9.2.6 describes Radiological Control Zones (RCZ). The location of the RCZ is stated to be at the work site rather than at the entrance/exit to the controlled area. Also, the current wording states individuals must change in the RCZ before entering the RCZ. Consistent with 10 CFR 20.1101(a),

- Eliminate the contradictory language concerning RCZs.
- State that change areas will be set up at the entrance/exit to radiation controlled areas.
- State that procedures are established to require staff to don appropriate personal protective equipment (PPE), conduct personal surveys, decontaminate, and contact HP staff for assistance if contamination warrants.
- LA section 9.2.6 page 9-23 first paragraph states, "The use of personnel monitoring equipment is required when personnel leave a known contamination area." The term "known contamination area" is not well defined or differentiated from other areas listed in LA section 9.2.6. State that RCZs are located between clean areas and potentially contaminated areas, and personnel and equipment will be properly surveyed and decontaminated when leaving these areas.
- State that procedures are established to handle the disposition of PPE and other contaminated items and provide a brief overview.
- Describe the dedicated facilities for managing contaminated personnel or used anti-contamination clothing. Provide a general description and state how effluent from decontamination would be managed.

Corrective Action Program:

HP-22. Corrective actions are mentioned in sections 9.2.6 page 9-24 – first full paragraph, LA section 9.2.11 page 9-29 – second full paragraph, and in LA section 9.2.14 on page 9-33. Yet, there is not explicit commitment to require corrective actions if administrative limits are exceeded. Consistent with 10 CFR 20.1502 and RG 8.24,

- In LA section 9.2.7, "Direct Exposure Control" and 9.2.8, "Internal Exposure Control," state that internal procedures will define implementation of the facility's corrective action program when the results of personnel monitoring or contamination surveys exceed the applicant's administrative personnel contamination levels.
- LA section 9.2.6 third to the last paragraph on page 9-24 contains a commitment to decontaminate skin prior to exiting a controlled area. In LA section 9.2.6 third to last paragraph state that internal procedures will define RP approved contamination action levels for individuals exiting a controlled area. State that personnel will be aware of these action levels through postings or training.

HP-23. The emphasis of the corrective action program as described in LA section 15.7.1 is, "identifying, investigating, reporting, tracking, correcting, and preventing recurrence of conditions adverse to quality." Consistent with 10 CFR 20.1101(a), in you RAI response, clarify the meaning of this sentence since it seams to emphasize quality over safety. The corrective actions program for occupational exposures should be implemented to protect personnel safety, which may not have a direct impact on product quality.

Sealed Sources:

HP-24. Consistent with 10 CFR Subpart F, “Surveys and Monitoring,” demonstrate that sealed sources will be leak-tested on a periodic schedule. Refer to NRC Branch Technical Positions: (1) "License Condition for Leak-Testing Sealed Byproduct Material Sources," April 1993, (2) "License Condition for Leak-Testing Sealed Plutonium Sources," April 1993, (3) "License Condition for Plutonium Alpha Sources," April 1993, (4) "License Condition for Leak-Testing Sealed Source Which Contains Alpha and/or Beta-Gamma Emitters," April 1993, and (5) "License Condition for Leak-Testing Sealed Uranium Sources," April 1993

Reports:

HP-25. The application contains limited language on the reporting of occupational exposures to the NRC such as section 9.2.13 and 10.1.1. Consistent with 10 CFR 20.2202, 20.2206(b), and 10 CFR 70.74,

- Modify the language in the second paragraph of section 10.1.1 on page 10-1 to make the commitment apply to normal and off-normal operations. The current language only applies to off-normal operations.
- In LA section 9.2.13, since the last sentence in the first paragraph of LA section 9.2.13 only commits to reporting overexposures, modify the section to also require an annual report of all the results of individual monitoring carried out by the licensee, as required by 10 CFR 20.2206(b).