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

## SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION FINDINGS ON SHAW AREVA MOX SERVICES QUESTION RELATED TO GOVERNING MOX PROJECT QUALITY ASSURANCE PLAN CRITERION FOR COMMERCIAL GRADE DEDICATION FOR THE MIXED OXIDE FUEL FABRICATION FACILITY

Dear Mr. Gwyn:

On March 29, 2012, Mr. Kelly Trice sent a letter requesting U.S. Nuclear Regulatory Commission (NRC) concurrence on MOX Services Position on the governing MOX Project Quality Assurance Plan (MPQAP) criterion for Commercial Grade Dedication (CGD). MOX Services position, as stated in the letter is: "Commercial grade dedication is implementing Criterion 7 of the MPQAP. MOX Services acknowledged that engineering involvement in the commercial grade dedication process is required." For clarity, we have broken your question into two parts. The following is a response to your question.

1a) Is the specification of critical characteristics of basic components and the development of criteria to be used for verification of these critical characteristics during the CGD process a: (1) design control process as implemented by Section 3, *Design Control*, of the MPQAP or (2) an acceptance and verification process as implemented by Section 7, *Control of Purchased Material, Equipment, and Services*, of the MPQAP?

In general, the specification of critical characteristics of basic components and the development of criteria to be used for verification of these critical characteristics during the CGD process is an acceptance and verification process as implemented by Section 7, *Control of Purchased Material, Equipment, and Services,* of the MPQAP. Furthermore, the activities of identifying critical characteristics for commercial-grade items and developing criteria to be used for verification of these critical characteristics are, in part, measures that should be established to assure that purchased material equipment and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents that satisfy Criterion VII. Also, these activities are required to ensure that the CGI will perform its intended safety function, resulting in an acceptable dedication of a CGI into a basic component.

MPQAP Section 7.2.8 (B), "Commercial Grade Items," requires that critical characteristics for CGIs be determined and approved by the manager responsible for the procurement based on the performance requirements for the item including the intended items relied on for safety (IROFS) safety function. Specific characteristics used for acceptance or dedication of the item are selected based on providing reasonable assurance that the item will meet their catalog or manufacturer specifications and perform the specified functions as intended.

The specification of critical characteristics basic components and the development of criteria to be used for verification of these critical characteristics during the CGD process is not a design control process, but the decision should be based on design output documents. Process controls must be established to ensure the item's safety design function is verified. The dedicating entity staff (e.g. procurement and design engineers) must ensure design configuration is maintained. Also, the answer might be heavily dependent on the extent of engineering involvement and specific activities required for the particular dedication being conducted by the dedicating entity.

As discussed in GL 89-02, "Actions to Improve the Detection of Counterfeit and Fraudently Marked Products," appropriate engineering involvement is warranted during the procurement and product acceptance processes, including testing, for products used in nuclear power plants. Involvement of a licensee's engineering staff in an effective procurement process would normally include (1) development of specifications to be used for the procurement of products to be used in the plant, (2) determination of the critical characteristics of the selected products that are to be verified during product acceptance, (3) determination of specific testing requirements applicable to the selected products, and (4) evaluation of test results. The extent of necessary engineering involvement is dependent on the complexity of the nature and use of the products involved.

Although your questions specifically applies to the MFFF, it is important to note that the specific regulatory basis for dedication is found in Regulatory Guide 1.33, Revision 2, "Quality Assurance Program Requirements (Operations)," which endorses American National Standards Institute N18.7/ANS3.2-1976, "Administrative Controls and Quality Assurance for the Operational Phase of Nuclear Power Plants," Section 5.2.13, which states: "...procedures shall be established and implemented to assure that purchased materials and components associated with safety-related structures or systems are purchased to specifications and codes equivalent to those specified for the original equipment, or those specified by a properly reviewed and approved revision. In those cases where the original item or part is found to be commercially 'off the shelf,' or without specifically identified quality assurance requirements, spare or replacement parts may be similarly procured but care shall be exercised to assure at least equivalent performance. In those cases where the quality assurance requirements of the original item cannot be determined, an engineering evaluation shall be conducted by qualified individuals to establish the requirements and controls. This evaluation shall assure that interface, interchangeability, safety, fit and function requirements are not adversely affected or contrary to applicable regulatory or code requirements. The results of these evaluations shall be documented."

In other words, dedication shall be conducted in accordance with the requirements contained in Appendix B to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50 and shall have engineering involvement and controls as necessary, to assure the component will perform its safety function.

## 1b) Is the process of identifying and modifying specified critical characteristics for basic components and the criteria for verifying the critical characteristics subject to the requirements of MPQAP Section 3, Design Control or subject to the requirements of Section 7, Control of Purchased Material, Equipment, and Services?

The answer is dependent on the extent to which engineering involvement was required to identify the critical characteristics. For instance, in a like-for-like dedication scenario, there may be little engineering involvement other than to verify that the item is indeed identical.

MPQAP Section 7.2.8, "Commercial Grade Items," requires that critical characteristics for CGIs be determined and approved by the manager responsible for the procurement based on the performance requirements for the item including the intended IROFS safety function. Specific characteristics used for acceptance or dedication of the item are selected based on providing reasonable assurance that the item will meet their catalog or manufacturer specifications and perform the specified functions as intended.

The process of identifying critical characteristics for CGIs and the criteria for verifying the critical characteristics should be subject to the requirements of MPQAP Section 7, "Control of Purchased Material, Equipment, and Services," and Criterion VII of Appendix B to 10 CFR Part 50.

Provided that the change to critical characteristics is not representative of a change to the form, fit, or function of the item, the process of modifying specified critical characteristics for CGIs, should be subject to the requirements of MPQAP Section 7, "Control of Purchased Material, Equipment, and Services." In the case that the CGI has been dedicated to a basic component, any modification the form, fit, or function of the item must be subject to the requirements of MPQAP Section 3, "Design Control" (Section 3.2.5, Design Change Control). In addition, in the case of modifying specified critical characteristics, the expectation would be that engineering was heavily involved to ensure design configuration is maintained. Modification of critical characteristics that are necessary for adequate commercial-grade dedication would not be acceptable.

The criteria for verifying the critical characteristics should be subject to the requirements of MPQAP Section 7, "Control of Purchased Material, Equipment, and Services."

In accordance with 10 CFR 2.390, of the 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).

If you have any questions, please contact me at 301-492-3229, or via e-mail to <u>David.Tiktinsky@nrc.gov</u>.

Sincerely,

/**RA**/

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

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## D. Gwyn

MPQAP Section 7.2.8, "Commercial Grade Items," requires that critical characteristics for CGIs be determined and approved by the manager responsible for the procurement based on the performance requirements for the item including the intended IROFS safety function. Specific characteristics used for acceptance or dedication of the item are selected based on providing reasonable assurance that the item will meet their catalog or manufacturer specifications and perform the specified functions as intended.

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The criteria for verifying the critical characteristics should be subject to the requirements of MPQAP Section 7, "Control of Purchased Material, Equipment, and Services."

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If you have any questions, please contact me at 301-492-3229, or via e-mail to David.Tiktinsky@nrc.gov.

Sincerely, /RA/ David Tiktinsky, Senior Project Manager Conversion, Deconversion and MOX Branch Division of Fuel Cycle Safety and Safeguards Office of Nuclear Material Safety and Safeguards

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Mr. Sam Glenn, Deputy Federal Project Director NA-262.1 P.O. Box A Aiken, SC 29802

Dr. Peter Winokur, Chairman Defense Nuclear Facilities Safety Board 625 Indiana Ave., NW, Suite 700 Washington, DC 20004

Mr. Kelley Cummins, NNSA/HQ 1000 Independence Ave., SW Washington, DC 20585

Ms. Susan Jenkins Division of Radioactive Waste Management Bureau of Health and Environmental Control 2600 Bull St. Columbia, SC 29201

D. Silverman Morgan, Lewis, & Bockius 1111 Penn. Ave., NW Washington, DC 20004

G. Carroll Nuclear Watch South P.O. Box 8574 Atlanta, GA 30306

Diane Curran Harmon, Curran, Spielburg & Eisenberg, LLP 1726 M St., NW, Suite 600 Washington, DC 20036 L. Zeller Blue Ridge Environmental Defense League P.O. Box 88 Glendale Springs, NC 28629