

MFFFNPEm Resource

From: Dotson, Wesley D. [WDDotson@moxproject.com]
Sent: Wednesday, December 19, 2007 7:03 AM
To: David Tiktinsky
Cc: 'Dealis W. Gwyn'
Subject: Part 21 Exemption Request
Attachments: Part 21 Exemption ReSubmittal Draft 19 Dec 2007.doc

Dave,

Dealis asked me to modify the MOX Services Part 21 Exemption Request Resubmittal to clarify that MOX Services assumes Part 21 responsibilities as the dedicating entity when MOX Services performs the commercial grade item procurement and dedication process. The paragraph discussing *Dedicating entity* on Page 4 of 5 has been revised.

If you have additional comments concerning the acceptability of this wording or the need additional clarifications, please contact me via email or phone at 803 819-2723. Our desire is to issue this transmittal on Thursday 20 Dec 2007.

Wesley Don Dotson
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Subject: Docket Number 070-03098
Shaw AREVA MOX Services, LLC
Mixed Oxide Fuel Fabrication Facility
Request for Exemption from Definition of Commercial Grade Item

Reference: W. L. Elliott (MOX Services) letter to Document Control Desk (NRC), Request for Exemption from Definition of Commercial Grade Item, DCS-NRC-000209, 03 October 2007

Shaw AREVA MOX Services, LLC (MOX Services) hereby resubmits our request for an exemption from 10 CFR 21.3 *commercial grade item*, as described in more detail in the attachment to this letter. The requested exemption will provide needed flexibility for procurement for construction of the Mixed Oxide Fuel Fabrication Facility (MFFF) at the Savannah River Site in a fiscally prudent and efficient manner.

The requested exemption is authorized by 10 CFR 21.7, "Exemptions," which provides for exemptions that are authorized by law, will not endanger life, property, or the common defense and security, and are otherwise in the public interest. The attachment to this letter demonstrates that the requested exemption meets each of these requirements. The attachment also identifies the specific requirements of the regulation for which an exemption is requested and provides the associated justification.

Approval of the exemption is requested by the end of January 2008 to allow procurement of long lead-time components to proceed consistent with the construction schedule for the MFFF.

If you have any questions, please feel free to contact me or Dealis Gwyn, Licensing and Regulatory Compliance Manager, at (803) 819-2780.

Sincerely,

Walter L. Elliott
Vice President, Engineering

WLE:DAY
Enclosure

Document Control Desk
U.S. Nuclear Regulatory Commission
DCS-NRC-000213
| ~~2017~~ December 2007
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cc:

Mostafa (Mosi) Dayani, NNSA/SRS
Carol R. Elliott, NNSA/SRS
David Stinson, MOX Services
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EDMS: Corresp\Outgoing\NRC\2007 NRC\DCS-NRC-000213

Exemption Request

Background

Shaw AREVA MOX Services, LLC (MOX Services) is preparing for procurement of long lead-time components for the Mixed Oxide Fuel Fabrication Facility (MFFF) at the Savannah River Site. In accordance with 10 CFR 21.31 Procurement Documents, each procurement document for a basic component must specify that the provisions of 10 CFR Part 21 apply. Each supplier of a basic component for the MFFF subject to 10 CFR Part 21, unless it is exempted, is required by 10 CFR 21.21(a) to adopt procedures to evaluate deviations and failures to comply and notify the Commission or the purchaser of any deviations and failures to comply that are associated with a substantial safety hazard. An exemption is provided by 10 CFR 21.7 for suppliers of commercial grade items.

Because of the high cost of maintaining and implementing an Appendix B quality assurance program coupled with a relatively small demand e.g., the MFFF is the only planned MOX facility in the United States, many of the manufacturers and suppliers of equipment necessary to construct the MFFF (many of which are foreign suppliers) neither presently implement or plan to implement quality assurance programs, nor the evaluation and notification procedures that satisfy the reporting requirements of Part 21.

Based on the current Part 21.3 (2) definition for Part 70 facilities, *commercial grade item* means an item that is:

- (i) Not subject to design or specification requirements that are unique to those facilities or activities;*
- (ii) Used in applications other than those facilities or activities; and*
- (iii) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).*

Parts (i) and (iii) are unnecessarily restrictive for defining commercial grade items. This definition of commercial grade item for Part 70 facilities greatly complicates and in some cases prohibits necessary procurement of certain components to support the design, construction and safe operation of the MFFF. Some MFFF components will be subject to unique design or specification requirements, based upon their critical safety functions for their intended application in the MFFF system. For example, MOX Services will need to procure pellet grinders and pellet presses. While other fuel fabrication facilities could possibly procure these items commercial grade, MOX Services requires that these items have certain unique characteristics. The pellet grinders and pellet presses for the MFFF will provide part of the glovebox confinement boundary and therefore must also be designed to satisfy our seismic requirements. As such, these components may not be ordered from the manufacturer/supplier on the basis of specifications set forth in the

manufacturer's published product description. The manufacturer/supplier can provide the component in full compliance with the MFFF specifications but only consider offering the item as a commercially available item not subject to 10 CFR 50, Appendix B Quality Assurance Criteria and Part 21. When applying the requested Specific Exemption Request discussed below MOX Services proposes to procure these items as a commercial grade item and would assume full responsibility as the *Dedicating entity* for compliance with the evaluation and reporting requirements of Part 21. As the *Dedicating entity*, MOX Services would evaluate identified potential defects or failures to comply for creation of a substantial safety hazard. For MOX Services, a substantial safety hazard is a deviation that affects the ability of an IROFS to meet the applicable performance criteria of 10 CFR 70.61.

In 1995, in response to a petition filed on behalf of operators of nuclear power plants, the Commission determined that the definition of commercial grade item was unnecessarily restrictive, and resulted in very limited use of the commercial grade item designation. To provide added flexibility in using commercial grade items for safety-related service, the Commission adopted a new definition of commercial grade item for nuclear power plants. The amended definition added flexibility only for nuclear power plants, and did not change the requirements applicable to other facilities and activities. In response to a comment from the public that the new definition should also apply to such other facilities and activities, the Commission stated that proposed changes for nonreactor licensees are currently being considered. 60 Fed. Reg. 48,370 -371 (Sept. 19, 1995). No such changes have been adopted. MOX Services has identified the urgent need for, and is requesting, an exemption from paragraph (2) of 10 CFR 21.3 "Commercial grade item" that is consistent with the added flexibility given to Nuclear Power Plants. This exemption request will support procurement of long lead-time components for the MFFF in a fiscally prudent manner and not adversely impact the MFFF construction schedule.

Specific Exemption Request

In accordance with 10 CFR 21.7, "Exemptions," MOX Services requests NRC approval of an exemption from the requirements of 10 CFR 21.3, "Definitions," *Commercial grade item*, paragraph (2). In lieu of the definition of commercial grade item for facilities and activities licensed under Part 70, MOX Services will, upon exemption approval, revise the MOX Project Quality Assurance Plan (MPQAP) to specify a different definition of commercial grade item along with associated definition clarifications, based on the definition applicable to nuclear power plants in 10 CFR 21.3, "Definitions," *Commercial grade item*, paragraph (1). The revised MPQAP would provide the same added flexibility in procuring commercial grade items for safety related (or IROFS) service as the Commission provided for nuclear power plant licensees when it amended the definition of commercial grade item in September 1995. MOX Services would use the following definition of commercial grade item:

A commercial grade item means a structure, system, or component, or part thereof that affects its Items Relied on for Safety (IROFS) function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

Other terms in Part 21 also need clarification to provide consistency with the above definition of commercial grade item. These terms (basic component, critical characteristics, dedicating entity and dedication) are defined below consistent with their applicability to the MFFF.

Basic component. (2) When applied to MOX Services MFFF licensed under 10 CFR 70, basic component means a structure, system, or component, or part thereof that affects their IROFS function, that is directly procured by the licensee or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission would create a substantial safety hazard (i.e., exceed performance requirements of 10 CFR 70.61).

(3) In all cases, basic components includes IROFS related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware whether these services are performed by the component supplier or others.

Critical characteristics. When applied to MOX Services MFFF licensed pursuant to 10 CFR 70, critical characteristics are those important design, material, and performance

characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended IROFS function.

Dedicating entity. When applied to MOX Services MFFF licensed pursuant to 10 CFR 70, dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to Section 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process. In cases where MOX Services utilizes the commercial grade item procurement and performs the dedication process, MOX Services would assume full responsibility as the dedicating entity.

Dedication. When applied to MOX Services MFFF licensed pursuant to 10 CFR 70, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended IROFS function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR 50, appendix B, quality assurance program. This assurance is achieved by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, appendix B. The process is considered complete when the item is designated for uses as a basic component.

The ability to employ the proposed definition of commercial grade item along with associated definition clarifications would provide MOX Services with increased flexibility to apply the commercial grade item procurement and dedication strategy for equipment procurements where the equipment would not meet the present definition applicable for Part 70 licensees. This flexibility is particularly necessary in situations in which few or no suppliers are available with appropriate Appendix B QA Programs and Part 21 procedures. The proposed definition would remove unnecessary restrictions and allow MOX Services to employ an equally controlled and safe approach to item procurement.

The Requested Exemption is Authorized by Law

The NRC has the authority under the Atomic Energy Act to grant exemptions from its regulations if doing so would not violate the requirements of law. This exemption is authorized by law as is required by 10 CFR 21.7. No law exists that precludes the activities covered by this exemption request. The provisions of 10 CFR 21.3, "Definitions,"

Commercial grade item, paragraph (2) were adopted at the discretion of the Commission consistent with its statutory authority. No statute required the NRC to adopt the specific provisions from which MOX Services seeks an exemption. Rather, the NRC may determine that alternative means are adequate to provide reasonable assurance of safety.

The Requested Exemption Will Not Endanger Life, Property, or the Common Defense and Security

In adopting the revised definition of commercial grade item for nuclear power plants in 1995, the Commission determined that a commercial grade item, when properly and successfully dedicated, is deemed by the NRC to be equivalent in its safety function performance to the same or similar item designed and manufactured under a Part 50 Appendix B quality assurance program. 60 Fed Reg. 48,372 (Sept. 19, 1995). Since then, procurement of commercial grade items using the more flexible definition of commercial grade item has been successfully implemented by Part 50 licensees. As a result, implementation of a similar procurement process by MOX Services also will not endanger life, property, or the common defense and security.

The Requested Exemption is in the Public Interest

The requested exemption is in the public interest because it will allow MOX Services to implement a controlled and safe approach to item procurement that will support MOX Services' goal of constructing the MFFF in a timely and cost efficient manner. The overall result of not granting the exemption will be the delayed completion of procurement activities, and associated economic losses, without any safety benefit. Therefore, granting the requested exemption is in the public interest.

Conclusion

As demonstrated above, the requested exemption is authorized by law, will not endanger life, property, or the common defense and security, and is otherwise in the public interest. Since the provisions of 10 CFR 21.7 are satisfied, the requested exemption should be granted.