

DPO Case File for DPO-2013-001

The following pdf represents a collection of documents associated with the submittal and disposition of a differing professional opinion (DPO) from an NRC employee involving [add title or brief description of case].

Management Directive (MD) 10.159, "The NRC Differing Professional Opinions Program," dated May 16, 2004, describes the DPO Program. <http://pbadupws.nrc.gov/docs/ML0417/ML041770431.pdf>

The DPO Program is a formal process that allows employees and NRC contractors to have their differing views on established, mission-related issues considered by the highest level managers in their organizations, i.e., Office Directors and Regional Administrators. The process also provides managers with an independent, three-person review of the issue (one person chosen by the employee). After a decision is issued to an employee, he or she may appeal the decision to the Executive Director for Operations (EDO).

Because the disposition of a DPO represents a multi-step process, readers should view the records as a collection. In other words, reading a document in isolation will not provide the correct context for how this issue was considered by the NRC.

The records in this are public and have been redacted prior to discretionary release.

Document 1: DPO Submittal

Document 2: Memo Forwarding DPO from DPOPM to Office Manager

Document 3: Memo from Office Manager Establishing DPO Panel

Document 4: DPO Panel Report

Document 6: DPO Decision

Document 1: DPO Submittal

NRC FORM 680 (11-2002) NRCMD 10.159		U.S. NUCLEAR REGULATORY COMMISSION		FOR PROCESSING USE ONLY	
DIFFERING PROFESSIONAL OPINION				1. DPO CASE NUMBER <div style="font-size: 1.2em; color: red;">DPO-2013-001</div>	
INSTRUCTIONS: Prepare this form legibly and submit three copies to the address provided in Block 14 below.				2. DATE RECEIVED <div style="font-size: 1.2em; color: red;">1/16/2013</div>	
3. NAME OF SUBMITTER Carl T. Jones		4. POSITION TITLE Sr. Construction Inspector		5. GRADE GG 14	
6. OFFICE/DIVISION/BRANCH/SECTION RII/DCI/B1/Electrical and Instrument		7. BUILDING 245 Pchtr Cntr	8. MAIL STOP 849	9. SUPERVISOR Anthony Masters	
10. DESCRIBE THE PRESENT SITUATION, CONDITION, METHOD, ETC., WHICH YOU BELIEVE SHOULD BE CHANGED OR IMPROVED. <i>(Continue on Page 2 or 3 as necessary.)</i>					
See attached discussion for Block 10.					
11. DESCRIBE YOUR DIFFERING OPINION IN ACCORDANCE WITH THE GUIDANCE PRESENTED IN NRC MANAGEMENT DIRECTIVE 10.159. <i>(Continue on Page 2 or 3 as necessary.)</i>					
See attached discussion for Block 11.					
12. Check (a) or (b) as appropriate: <input checked="" type="checkbox"/> a. Thorough discussions of the issue(s) raised in item 11 have taken place within my management chain; or <input type="checkbox"/> b. The reasons why I cannot approach my immediate chain of command are:					
SIGNATURE OF SUBMITTER <div style="font-family: cursive;">Carl T. Jones</div>		DATE JAN 16, 2013		SIGNATURE OF CO-SUBMITTER (if any) <div style="font-family: cursive;">Charles R. Foster</div>	
DATE JAN 16, 2013		DATE January 16, 2013			
13. PROPOSED PANEL MEMBERS ARE (in priority order): 1. Richard P. McIntyre, NRO/DCIP/CMVB 2. _____ 3. _____			14. Submit this form to: Differing Professional Opinions Program Manager Office of: Enforcement Mail Stop: O4H23		
15. ACKNOWLEDGMENT					
THANK YOU FOR YOUR DIFFERING PROFESSIONAL OPINION. It will be carefully considered by a panel of experts in accordance with the provisions of NRCMD 10.159, and you will be advised of any action taken. Your interest in improving NRC operations is appreciated.			SIGNATURE OF DIFFERING PROFESSIONAL OPINIONS PROGRAM MANAGER (DPOPM) <div style="font-family: cursive; color: red;">Renée Pedersen</div>		
PRE-CONDITIONS MET <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO			DATE OF ACKNOWLEDGMENT <div style="font-size: 1.2em; color: red;">1/24/2013</div>		

DIFFERING PROFESSIONAL OPINION
(Continued)

BLOCK 10

Describe the present situation, condition, method, etc., which you believe should be changed or improved.

The Program Office for Nuclear Material Safety and Safeguards has communicated guidance that indicates that 10 CFR 50 Appendix B Criterion VII, instead of Criterion III provides the regulatory requirements for the process of determining critical characteristics for dedication of commercial grade items that are placed into service as basic components. If the guidance is implemented as presented, dedications of commercial grade items at the Mixed Oxide Fuel Fabrication Facility will not comply with applicable provisions of the regulations in 10 CFR Part 21 and Part 50 Appendix B.

The discussion provided below describes the circumstances under which a differing opinion led to a formal request for regulatory guidance from the program office.

Circumstances Leading to Technical Assistance Request On February 13, 2012, Region II inspectors conducted an inspection of the program for commercial grade dedication at the Mixed Oxide Fuel Fabrication Facility (MFFF) near Aiken, South Carolina.¹ The inspectors identified that the applicant had not used design controls for the initial specification and a subsequent modification of critical characteristics for a safety-related epoxy adhesive. The applicant had proceeded to dedicate and install the adhesive as a basic component of the MFFF building structure based upon the identified critical characteristics. The inspectors' interviews with responsible personnel disclosed that the applicant did not believe that a requirement existed to use design controls in the process for specifying critical characteristics and verification criteria.

The applicant's procurement staff had defined the critical characteristics of the epoxy adhesive in a procurement program document referred to as a commercial grade item evaluation (CGIE).² The CGIE stated that the epoxy adhesive was an "item relied on for safety" with a safety function to maintain the structural integrity of wall and slab sections of safety-related plant structures during a postulated seismic event. Revision 2 of the CGIE established the following critical characteristics without reference to a design output document:

1. Bond strength equal to or greater than 1,800 psi with a 7 day cure time
2. Tensile strength equal to or greater than 6,310 psi with a 7 day cure time
3. Compressive strength equal to or greater than 12,000 psi with a 7 day cure time
4. Compressive modulus equal to or greater than 0.22×10^6 psi with a 7 day cure time

The inspectors verified in interviews with responsible procurement staff that the critical characteristics defined in the CGIE had not been derived from design calculations or any other design outputs that provided values for the forces that must be withstood by the epoxy adhesive. The applicant indicated

¹ ML12132A276, Inspection Report 070-3098/2012-001

² DCS01-WWJ-DS-CGD-M-65973, Revs. 2 and 3, Hilti HIT-RE-500 and HIT-RE-500-SD Epoxy Adhesives

DIFFERING PROFESSIONAL OPINION
(Continued)

the characteristics and acceptance parameters had been obtained by transcribing data contained in literature published by the commercial grade manufacturer.

Again, without referring to a design output document, the applicant subsequently issued revision 3 to the CGIE to delete the critical characteristics of bond strength, tensile strength, compressive strength, and compressive modulus. The revised CGIE established new critical characteristics of unspecified material composition and mechanical properties and did not provide criteria for verification. Instead, the CGIE stipulated that the commercial grade manufacturer would define and verify acceptable material composition and mechanical properties using the manufacturer's internal processes as observed in the applicant's quality assurance surveillance of the commercial grade supplier.³ The applicant had not approved the manufacturer's design control program as an Appendix B program.

The inspector's review of the applicant's quality assurance surveillance report established that the applicant's auditors had determined that the manufacturer did not have a program to verify the critical characteristics specified by revision 2 of the CGIE. Although revision 3 to the CGIE was issued to address the omission, the inspectors noted that the auditors had not provided sufficient information to support the provisions of revision 3. Specifically, their report had not documented any criteria for material composition and had reported that the only verification of mechanical properties was provided in a manufacturer's pull-out test. The inspectors determined that although the manufacturer's test could potentially be correlated to mechanical properties of bond strength or tensile strength, the survey report did not show that the test configuration was identical to the plant installation, and did not identify the acceptance criteria for the test.

Based upon the above observations, the inspectors concluded the applicant had not demonstrated that the commercially purchased basic component was capable of accomplishing its safety function. The forces that must be withstood by the epoxy adhesive had been defined by a non-Appendix B manufacturer and had not been shown to be the same forces that would result from a design basis earthquake.

In contrast, the applicant's quality assurance program, the Mixed Oxide Fuel Fabrication Facility Quality Assurance Plan (MPQAP), required them to demonstrate that the basic component was capable of performing its safety function by performing verifications of critical characteristics.⁴ Notably, the MPQAP incorporated the same requirements for dedication that are prescribed for nuclear power reactors in 10 CFR 21.⁵

The MPQAP requirements for dedication of commercial grade items specifically required the process to be conducted in accordance with the provisions of 10 CFR 50 Appendix B. Criterion III of Appendix B specifies that design control measures shall be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related

³ MFFF Commercial grade survey HIL-11-VE128, Hilti Entwicklungsgesellschaft MBH, dated 2/20/2011

⁴ ML112290010, MPQAP Section 7.2.8, requirement A.4

⁵ 10 CFR 21.3, "Dedication", definition (1)

DIFFERING PROFESSIONAL OPINION
(Continued)

functions of the structures, systems and components. In contrast, the applicant did not use design control to define the measures to determine suitability of the epoxy adhesive material that was essential to the safety-related function of structural walls and slabs.

The inspectors evaluated the potential for a programmatic deficiency by reviewing the applicant's procedure for commercial grade dedication.⁶ Their review determined that although the CGIE procedure contained a statement that the CGIE process did not perform design, the procedure actually implemented a design function of specifying and modifying critical characteristics without requiring the use of design controls. Specifically, in cases where design output documents did not provide sufficient detail, the CGIE writer was directed to develop the design basis information as part of the CGIE process.⁷ Under the CGIE procedure, applicant's procurement staff also implemented the design function of identifying and analyzing failure modes associated with the safety-related functions of basic components in order to determine the critical characteristics which were necessary to counter the failure modes.

Based upon the above results, the inspectors determined an apparent programmatic violation of Appendix B requirements for design control had occurred. However, responsible Region II management expressed a differing view that the MFFF was required to implement design control for specifying and modifying critical characteristics or the criteria for verifying them. Accordingly, the issue was documented as an inspection follow up item (IFI) in the inspection report.⁸ Resolution of the IFI was to be guided by a Technical Assistance Request (TAR) to the Nuclear Material Safety and Safeguards program office.

TAR and TAR Response

On May 30, 2012, Region II Division of Construction Projects issued a Technical Assistance Request to the Office of Nuclear Material Safety and Safeguards⁹ regarding the Mixed Oxide Fuel Fabrication Facility Quality Assurance Plan (MPQAP) requirements for Section 3, "Design Control," and Section 7, "Control of Purchased Material, Equipment and Services," pertaining to commercial-grade dedication.

The TAR problem statement was presented as follows:

"The inspection staff requests an interpretation of the MFFF MOX Project Quality Assurance Plan (MPQAP) as to whether the specification of critical characteristics of basic components and the development of criteria to be used for verification of these critical characteristics during the commercial grade dedication (CGD) process is (1) a 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."

⁶ PP9-18, Rev. 5, Commercial Grade Item Evaluations

⁷ PP9-18, Section 3.5.2.2, §2.3

⁸ IFI 70-3098/2012-001-004, Review the Applicability of Using Design Control to Define Critical Characteristics

⁹ ML12151A385, TAR on CGD at MFFF

DIFFERING PROFESSIONAL OPINION
(Continued)

The response to the Technical Assistance Request was communicated to regional management in a transmittal from the Office of Nuclear Material Safety and Safeguards on December 3, 2012.¹⁰

¹⁰ ML12200A124, Response to TAR on CGD at MFFF

DIFFERING PROFESSIONAL OPINION
(Continued)

BLOCK 11

Describe your differing opinion in accordance with the guidance presented in NRC Management Directive 10.159.

(a) Summary of the prevailing staff view, the existing management decision or stated position, or the proposed or established agency practice involving technical, legal, or policy issues.

1. The NMSS response to the TAR contained numerous statements to the effect that Appendix B Criterion III, Design Control, does not apply to the specification or identification of critical characteristics of basic components and does not apply to the identification of criteria for verifying the critical characteristics. Some specific examples included the following:
 - "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." (response to Question 1, first paragraph, first sentence)
 - "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 not a design control process, but the decision should be based on design output documents." (response to Question 1, third paragraph, first sentence)
 - "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." (response to Question 1a, third paragraph)
2. The NMSS response to the TAR stated that, based upon MPQAP 7.2.8(B), the procurement organization staff (and by extension, not the design organization) must identify the critical characteristics that are necessary to assure basic components will perform their safety function. Example statements included the following:
 - "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 of the item including the intended items relied on safety (IROFS) safety function." (response to Question 1, second paragraph, first sentence)
 - "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." (response to Question 1a, second paragraph)

DIFFERING PROFESSIONAL OPINION
(Continued)

- "The extent of necessary engineering involvement is dependent on the complexity of the nature and use of the products involved." (Response to Question 1, fourth paragraph, last sentence)
3. The NMSS response to the TAR stated that the regulatory basis for commercial grade dedication is provided by Regulatory Guide 1.33, revision 2 (dated 1978), which in turn endorses ANSI N18.7/ANS 3.2 (Response to Question 1, fifth paragraph). In addition, the TAR response asserts that critical characteristics must include measures to assure purchased items and services conform to the procurement documents (response to Question 1, first paragraph, second sentence). Elsewhere, the TAR response stated that the characteristics must assure that purchased items meet catalogue or manufacturer's specifications (response to Question 1a, second paragraph, last sentence).
 4. The NMSS response to the TAR stated that design control does not always have to be implemented for modifications to previously specified critical characteristics and verification criteria (e.g. response to Question 1a, first paragraph). The TAR response asserted that the only time design control is to be implemented is to support the purchase of a replacement item that differs in form, fit, or function from the item originally specified by design (response to Question 1a, fourth paragraph). In one instance, the TAR response asserted that it was sufficient for the process of changing critical characteristics to follow Appendix B Criterion VI requirements for document control (response to Question 4, first paragraph). The response stated that the MPQAP requirement to provide written justifications for changes to design does not apply (response to Question 4, first paragraph).
 5. The NMSS response to the TAR stated that the CGIE process did not perform design; it asserted that the process required all of the required design information to be obtained from design specifications (response to Question 5, first paragraph).
 6. The NMSS response to the TAR and the transmittal letter stated that the commercial grade dedication process is highly dependent on the safety function of the item being dedicated, thus the correct application of the process must be evaluated for each individual item (Transmittal Letter, third paragraph; and Response, Page 1, second paragraph, final sentence).

(b) Description of the submitter's views and how they differ from any issues discussed in item (a) above.

The DPO submitter acknowledges that the guidance communicated by the response to the TAR may be entirely appropriate for some Part 70 fuel cycle facilities other than the Mixed Oxide Fuel Fabrication Facility; however, the guidance requested in the TAR was specifically directed to the enforceability of regulatory requirements for the MFFF.

DIFFERING PROFESSIONAL OPINION
(Continued)

1. The DPO submitter holds a differing opinion with this management position, and contends that Criterion III of Appendix B specifically applies to the measures used to identify critical characteristics of materials that are essential to safety-related systems, structures, and components. The DPO submitter contends that the critical characteristics and the criteria used to verify them are the design control measures necessary to accomplish the "review for suitability of application" that is identified in Criterion III, and by extension MPQAP Section 3.

The DPO submitter affirms that the TAR response accurately identified that 10 CFR 70.23(b) requires the MFFF to comply with Appendix B. The DPO submitter also asserts that the applicability of Appendix B is established in the applicant's MPQAP. Specifically, Section 7.2.8 of the MPQAP provides requirements for commercial grade dedication in Requirement A.4 which states that, in all cases the dedication process at MFFF must be conducted in accordance with the applicable provisions of 10 CFR 50, Appendix B.

The DPO submitter holds a differing opinion with the statement in the TAR response that the decision process for specifying critical characteristics should be based on design output documents. The DPO contends that this statement indicates that the process of specifying critical characteristics occurs after design output documents are finalized. As stated above, the DPO submitter contends that the process of specifying critical characteristics itself is a design control process, thus it cannot occur after the design is completed. The identification of the critical characteristics must be contained in verified and approved design output documents.

The DPO submitter asserts that the NRC has hosted industry workshops¹¹ and published generic communications, including GL 91-05¹² and IN 2011-01¹³, all of which have clearly communicated that Appendix B Criterion III requires the use of design controls to identify the items that are critical to accomplishing safety-related functions (i.e. critical characteristics). In addition, the communications have identified that the design control process must provide measures (i.e. criteria and methods) for determining suitability of the safety-related items. Criterion VII only applies to the measures to accomplish the verification and acceptance of purchased items.

Consistent with these communications, current inspection guidance in IP 43004¹⁴, Section 03.01, requires inspectors to verify the responsible engineering organization has performed technical evaluations that identify the necessary technical and quality requirements, including (4) the identification of the item's critical characteristics. The IP also

¹¹ ML090890707, NRC Responses to Commercial Grade Dedication and General Questions Received during the Vendor Workshop on New Reactor Construction In December, 2008

¹² ML031140508, Generic Letter 91-05, Licensee Commercial-Grade Procurement and Dedication Programs

¹³ ML103220180, Information Notice IN 2011-01, Commercial-Grade Dedication Issues Identified during NRC Inspections; discussion of Lack of Engineering Justification during the CGD Process

¹⁴ ML110871957, Inspection Procedure 43004, Inspection of Commercial-Grade Dedication Programs

**DIFFERING PROFESSIONAL OPINION
(Continued)**

requires inspectors to verify engineering has identified the acceptance criteria for the verification method used consistent with the plant-specific application.

Finally, the DPO submitter contends that recent enforcement history has enforced the requirement to use design controls at another Appendix B fuel facility. Specifically, a CY2011 inspection of the Louisiana Enrichment Services uranium enrichment facility issued a violation for failure to implement design controls for the process of changing specifications for critical characteristics and criteria for dedication.¹⁵

2. The DPO submitter holds a differing opinion with the guidance in the TAR response regarding the use of the procurement staff to perform design. As prescribed by MPQAP Section 2.2.6 and Appendix B Criterion II, the indoctrination, qualification, and training of personnel must be sufficient to assure suitable proficiency is achieved and maintained. The inspectors contend that the MFFF procurement staff has not been required to achieve or maintain proficiency in the various engineering disciplines necessary to perform design.

The DPO submitter holds a differing opinion with the implication made by the statements in the TAR response that MPQAP Section 7.2.8 provides a sufficient basis to permit the use of the procurement organization staff to perform the identification of critical characteristics and verification criteria without the use of design controls. The DPO submitter contends that qualified design personnel using design controls must identify the critical characteristics and criteria; otherwise, the MPQAP, as defined in the TAR response would not comply with applicable regulations and the process would represent a reduction in the level of quality assurance intended by the regulations.

The DPO submitter holds a differing opinion with the statement in the TAR response that the level of [design] engineering involvement in the procurement organization's process for determining critical characteristics is permitted to vary, depending upon the complexity of the basic component to be dedicated. The DPO submitter contends that design controls are always required for identification and modification of critical characteristics. Notably, the TAR response made a critical omission in its reference to GL 89-02¹⁶ as a basis for its position on the level of engineering involvement. The TAR response failed to identify that GL 91-05 subsequently clarified the discussion in GL 89-02 by stating that the 1989 guidance for "appropriate" engineering involvement was only intended to apply to the level of review necessary to determine whether substitute components were like-for-like or equivalent. The discussion was not intended to apply to the process for specification of critical characteristics. GL 91-05 specifically clarified that the identification of critical characteristics was a design control function.

¹⁵ ML11342A131, Louisiana Energy Services, L.L.C., National Enrichment Facility NRC Inspection Report No. 07003103/2011009 and Notice Of Violation; VIO 70-3103/2011-009-003

¹⁶ ML031140060, GL 89-02, Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products

DIFFERING PROFESSIONAL OPINION
(Continued)

3. The DPO submitter holds a differing regarding the appropriate regulatory basis for the commercial grade dedication process at the MFFF. The DPO submitter contends that the TAR response failed to identify that 10 CFR Part 21 and Appendix B provides the appropriate regulatory basis for dedication and control of commercial grade items. As an apparent consequence, the TAR response has provided a meaning for "critical characteristic" that substantially differs from the definition provided in Part 21. The differing definitions are provided below:

(Part 21) "When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, 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 safety function."

(TAR Response) "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 DPO submitter contends that the special definition provided by the TAR response, if applied at MFFF will not provide the necessary assurance that critical characteristics and verification criteria are based upon the safety function of the basic components.

The DPO submitter holds a differing opinion with the statement in the TAR response that a 1978 regulatory guide for quality assurance programs in operating facilities (i.e. RG 1.33¹⁷) provides an adequate regulatory basis for the commercial grade dedication process at MFFF. The DPO submitter contends that as described in the TAR response, the cited quality assurance standard is entirely concerned with the selection and procurement of spare and replacement items and does not address "dedication" of commercial grade items. Although the standard discusses the need to identify technical and quality requirements for replacement items, it does not address "critical characteristics." The only mention of measures to control purchases of commercial grade items is a vague requirement to assure the performance of commercial off-the-shelf replacement items is at least equivalent to the performance of the original items. The DPO submitter asserts that the appropriate regulatory guide for facilities under design and construction is RG 1.28.¹⁸ The construction program guidance provides a more explicit discussion of regulatory policy that is specifically applicable to Appendix B construction programs. Notably, the current revision of RG 1.28 endorsed quality assurance standard NQA-1 2008, with certain additions and modifications.

The DPO submitter affirms that the MFFF construction project has been authorized to implement the 1994 edition of NQA-1; however, the DPO submitter contends that Requirement 3 of NQA-1 2008 serves to provide necessary clarity to the NRC policy on the

¹⁷ ML003739995, RG 1.33, Rev. 2, Quality Assurance Program Requirements (Operation)

¹⁸ ML100160003, RG 1.28, Rev. 4, Quality Assurance Program Criteria (Design and Construction)

DIFFERING PROFESSIONAL OPINION
(Continued)

role of design control in the process for commercial grade dedication. The DPO submitter contends that the 2008 standard effectively contradicts the guidance in the NMSS response to the TAR. Specifically, the discussion of design control in Section 300 (c) of the standard states "The final design shall (3) identify assemblies and/or components that are part of the item being designed. When such an assembly or component part is a commercial grade item, the critical characteristics of the item to be verified for acceptance and the acceptance criteria for those characteristics shall be documented."

4. The DPO submitter affirms the TAR statements are accurate in stating that design controls are required to approve the installation of items that differ from their original designs. However, the DPO submitter contends that a discussion of changes to "items" was not pertinent to the TAR question. The TAR was concerned with changes to critical characteristics that are implemented without changing the items.

In addition, the DPO submitter holds a differing opinion with other statements in the TAR response concerning modifications to previously specified critical characteristics. The DPO submitter contends that MPQAP Section 3.2.5.A requires documented justifications to be provided for changes to previously approved final designs. This includes changes to previously approved design output documents that identify critical characteristics and the criteria for verifying the critical characteristics. Also, the implementation of MPQAP and Appendix B design controls requires that the previously specified design requirements be addressed as design inputs when changing, adding, or deleting requirements in design outputs. Documentation for the new or changed design must demonstrate that the previously verified and approved design solutions either were invalid or will be incorporated in an equivalent design. As guided by MPQAP 3.2.2.A, this design activity must be documented to the level of detail necessary to permit the design process to be carried out in a compliant and efficient manner.

The DPO submitter holds a differing opinion whether Appendix B Criterion VI controls are sufficient for the process of modifying critical characteristics and the criteria for verifying the characteristics. The DPO submitter contends the controls defined under Criterion VI are not sufficient because they do not require the following controls prescribed by Criterion III:

- Criterion VI does not identify a requirement for the process to address design inputs and does not specifically require implementation of measures to assure the design basis is translated into the design products.
- Criterion VI does not require provisions to assure that appropriate quality standards are specified and included in design documents. Criterion VI does not require deviations from such standards to be controlled.
- Criterion VI does not identify requirements for the identification and control of design interfaces and for coordination among participating design organizations.

DIFFERING PROFESSIONAL OPINION
(Continued)

- Criterion VI does not require measures that provide for verifying or checking the adequacy of design, including requirements for independence of verifiers.
 - Processes conducted under Criterion VI would not specifically require personnel performing the activity to be proficient in the applicable engineering disciplines.
5. The DPO submitter holds a differing opinion to the statement in the TAR response that asserted the CGIE process did not perform design. As described under Block 10 of this DPO, results obtained from a direct inspection in the plant contradict the NMSS response to the TAR. The inspection results were developed from procedure reviews, records reviews, and interviews with responsible plant personnel. The inspectors found that although the CGIE procedure contained a statement that the CGIE process did not perform design, the procedure actually implemented a design function of specifying and modifying critical characteristics without requiring the use of design controls. The DPO submitter contends that in contrast to the inspection results, the TAR response did not provide sufficient objective evidence or other adequate basis to support the contradictory statements.
6. The DPO submitter holds a differing opinion from the statements in the TAR response and the transmittal letter which assert that commercial grade dedications of some basic components do not require the same degree of control as others. The DPO submitter contends that this guidance is not consistent with MPQAP Section 2.2.2.G which requires the application of QL-1 quality controls for activities associated with all IROFS items. The TAR response did not indicate how the more safety significant IROFS items could be distinguished from the less safety-significant IROFS items. Also, the statements did not identify any regulatory guidance which would indicate how to determine which requirements for commercial grade dedication could be waived based upon different degrees of safety significance for IROFS.

(c) Assessment of the consequences if the submitter's position is not adopted by the agency.

Based upon the guidance in this TAR response, the inspector followup item identified in February 2012 would be closed without citing a violation of requirements for design control. In contrast, the DPO submitter contends that the identified condition represents a significant breakdown in a portion of the QA program for design control. As identified in the inspection exit with the applicant, and in the subsequent discussions with NRC management, the nonconforming methods being used to accomplish commercial grade dedications by the MFFF has resulted in actual installation of basic components that have not been verified to be capable of meeting their IROFS safety function. This programmatic deficiency has existed since the initial implementation of construction procurements and likely has remained out of compliance and unremediated since being identified in the exit meeting for the commercial grade dedication program inspection on February 13, 2012 (as of the date of this DPO, no follow up inspection has documented the status of the nonconforming condition). If the condition remains

**DIFFERING PROFESSIONAL OPINION
(Continued)**

uncorrected, procurements and subsequent installations of items of indeterminate quality can be expected to continue through operation of the facility.

In addition, the guidance provided by this TAR response is contradictory to guidance provided to the nuclear industry to date. If the TAR information is published or otherwise communicated, it will degrade the agency's efforts to clearly communicate requirements for commercial grade dedication.

- (d) The names of three potential ad hoc panel members, listed in priority order, or a statement that he or she will not provide names of potential ad hoc panel members.**

The DPO submitter has identified one individual (below) who meets the requirements for service as a member of the ad hoc panel. No other names will be provided.

[REDACTED]

- (e) Copies of relevant documents referenced in the DPO (documents that are available in ADAMS should not be attached to the DPO). The submitter should include only titles and accession numbers for such relevant documents, along with a brief statement regarding the relevance of the document to the issue being raised.**

- (Copy Attached) MFFF Procedure PP9-18, Rev. 5, Commercial Grade Item Evaluations
- (Copy Attached) MFFF Commercial grade survey HIL-11-VE128, Hilti Entwicklungsgesellschaft MBH, dated 2/20/2011
- (Copy Attached) MFFF Commercial Grade Item Evaluation DCS01-WWJ-DS-CGD-M-65973, Revs. 2 and 3, Hilti HIT-RE-500 and HIT-RE-500-SD Epoxy Adhesives
- ML003739995, RG 1.33, Rev. 2, Quality Assurance Program Requirements (Operation)
- ML031140060, GL 89-02, Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products
- ML031140508, Generic Letter 91-05, Licensee Commercial-Grade Procurement and Dedication Programs
- ML090890707, NRC Responses to Commercial Grade Dedication and General Questions Received during the Vendor Workshop on New Reactor Construction In December, 2008
- ML100160003, RG 1.28, Rev. 4, Quality Assurance Program Criteria (Design and Construction)
- ML103220180, Information Notice IN 2011-01, Commercial-Grade Dedication Issues Identified during NRC Inspections; discussion of Lack of Engineering Justification during the CGD Process
- ML110871957, Inspection Procedure 43004, Inspection of Commercial-Grade Dedication Programs
- ML112290010, MOX Project QAP
- ML11342A131, Louisiana Energy Services, L.L.C., National Enrichment Facility NRC Inspection Report No. 07003103/2011009 And Notice Of Violation; VIO 70-3103/2011-009-003
- ML12132A276, Inspection Report 070-3098/2012-001
- ML12151A385, TAR on CGD at MFFF

**DIFFERING PROFESSIONAL OPINION
(Continued)**

- ML12200A124, Response to TAR on CGD at MFFF

BLOCK 12

Thorough discussions of the issue(s) raised in Block 11 have taken place within my management chain

The DPO submitter has discussed this differing opinion with the management chain as follows:

- (March 5, 2012) Chief, RII/DCP/Branch 1; Chief, RII/DCI/Branch 2
- (March 13, 2012) Acting Chief, RII/DCI/Branch 1; Director, RII/DCI
- (March 21, 2012) Chief, RII/DCP/Branch 1; Acting Chief, RII/DCI/Branch 1
- (September 13, 2012) Deputy Director, RII/DCI
- (September 18, 2012) Region II Counsel and Acting Chief, RII/DCI/Branch 1; Chief, RII/DFFI/Branch 3; Deputy Director, RII/DCI
- (September 21) Acting Chief, RII/DCI/Branch 1
- (October 2012) RII Deputy RA, Construction
- (January 2013) Chief, DCI Branch 1; Director, RII/DCI

**Document 2: Memo Forwarding DPO from DPOPM to NMSS
Office Manager**

February 1, 2013

MEMORANDUM TO: Catherine Haney, Director
Office of Nuclear Materials Safety and Safeguards

FROM: Renée M. Pedersen, Sr. Differing Views Program Manager */RA/*
Office of Enforcement

SUBJECT: DIFFERING PROFESSIONAL OPINION INVOLVING COMMERCIAL
GRADE ITEMS AT MIXED OXIDE FUEL FABRICATION FACILITY
(DPO-2013-001)

The purpose of this memorandum is to advise you of a Differing Professional Opinion (DPO) that was submitted to me while serving as the Differing Professional Opinions Program Manager (DPOPM). I received the DPO on January 16, 2013, and in coordination with the Director, Office of Enforcement, screened it in accordance with the guidance included in Management Directive (MD) 10.159, "The NRC Differing Professional Opinions Program." On January 24, 2013, I notified senior management and the submitters that the preconditions for acceptance were met and that the submittal was accepted for review within the DPO Program as DPO-2013-001.

The DPO (Enclosure 1) raises concerns involving the regulatory requirements for the process of determining critical characteristics for the dedication of commercial grade items that are placed into service as basic components at the Mixed Oxide Fuel Fabrication Facility (MFFF).

Because the DPO takes issue with a position established by your organization, in accordance with section (D)(3)(c) of the Management Directive (MD) Handbook, I am forwarding this DPO to you for appropriate action.

MD 10.159-036 specifically addresses your responsibilities as an Office Director. In brief, you are required to:

- ☐ Establish an independent ad hoc panel (DPO Panel) to review the issue, draw conclusions, and make recommendations to you regarding the disposition of the issues presented in the DPO.

CONTACT: Renee M. Pedersen, OE/CRB
(301) 415-2742

Marge H. Sewell, OE/CRB
(301) 415-8045

- ☐ Provide appropriate oversight of and support to the DPO Panel to ensure a thorough and timely review of the DPO (while maintaining process independence).
- ☐ Review the DPO Panel's report to ensure that it clearly, accurately, and completely addresses the tasks outlined in your memorandum establishing the panel.
- ☐ Issue a DPO Decision to the submitters within the 120-day timeliness goal (May 24, 2013).
- ☐ Request approval from the Executive Director for Operations (EDO) for DPO extensions beyond the 120-day timeliness goal. (Requests should be forwarded thru the DPOPM with the reason for the delay and a new completion date.)
- ☐ Forward status updates during the disposition of the DPO and until the time that all follow-up actions are complete.
- ☐ Identify and assign appropriate follow-up actions and establish completion dates within 2 weeks of issuing the DPO Decision. (The DPOPM and submitter should be copied on any follow-up action memoranda or correspondence.)
- ☐ Notify the DPOPM of follow-up action schedule delays, including the reason for the delay and a revised completion schedule. (The DPOPM will subsequently notify the submitter and report it to the applicable Deputy EDO.)
- ☐ Forward a summary of the DPO to the DPOPM for inclusion in the Weekly Information Report. (In the event the DPO is appealed, the summary will be postponed until the DPO Appeal Decision is issued.)
- ☐ Take action to positively recognize the DPO submitters if the submitter's actions result in significant contributions to the mission of the agency.
- ☐ Review the DPO Case File for public release when the case is closed if the submitters request discretionary public release.

Disposition of this DPO should be considered an important and time sensitive activity. The timeliness goal included in the MD for issuing a DPO Decision is 120 calendar days from the day the DPO is accepted for review. The timeliness goal for issuing this DPO Decision is May 24, 2013.

Process Milestones and Timeliness Goals for this DPO are included as Enclosure 2. The timeframes for completing process milestones are identified strictly as goals—a way of working toward reaching the DPO timeliness goal of 120 calendar days.

Although timeliness is an important DPO Program objective, the DPO Program also sets out to ensure that issues receive a thorough and independent review. Therefore, if you or the DPO Panel determines that an extension beyond 120 calendar days is necessary at any time during the process, please send me an email with the reason for the extension request and a new completion date. I will subsequently forward this request to the EDO for approval.

In an effort to support effective implementation, the Office of the EDO will establish tracking to address the three key deliverables for the DPO process:

- (1) DPO Decision for DPO-2012-003 (May 24, 2012);
- (2) Follow-up action memorandum (2 weeks after DPO Decision); and
- (3) Weekly Information Report summary (2 weeks after DPO Decision);

Please ensure that all DPO-related activities are charged to Activity Code ZG0007.

Because this process is not routine, I will be meeting and communicating with all parties during the process to ensure that everyone understands the process, goals, and responsibilities. I will be subsequently sending you information intended to aid you, the DPO Panel, and support staff in implementing the DPO process.

An important aspect of our internal safety culture includes maintaining an environment that encourages, supports, and respects differing views. As such, all employees involved in the process should be instructed to exercise discretion and treat this as a sensitive matter. In an effort to preserve privacy, minimize the effect on the work unit, and keep the focus on the issues, employees should be instructed to simply refer to the employees as the DPO submitters. Managers and staff should be reminded to not engage in "hallway talk" on the issue and to refrain from behaviors that could be perceived as retaliatory and or are chilling the DPO submitters or creating a chilled environment for others.

On an administrative note, please ensure that all correspondence associated with this case include the DPO number in the subject line, be profiled in accordance with the Agencywide Document Access Management System (ADAMS) template OE-011, be identified as non-public with limited viewer rights to those included on distribution of correspondence and declared an official agency record when the correspondence is issued. Please email the ADAMS accession number for the record to DPOPM.Resource@nrc.gov and the record will be filed in the applicable DPO case file folder (DPO-2013-001) in the ADAMS Main Library. Following this process will ensure that a complete agency record is generated for the disposition of this DPO. If the submitters request that the documents included in the DPO Case File be made public when the process is complete, you will be provided specific guidance to support a releasability review.

C. Haney

- 4 -

Finally, it would be helpful if you identify a point of contact (POC) who I can work with to support effective implementation of the DPO process. The POC can be the NMSS OCWE Champion (Beth Doolittle) or someone else.

Enclosures:

1. DPO Submittal
2. Milestones and Timeliness Goals

cc:

M. Weber, DEDMRT
N. Mamish, AO

C. Haney

- 4 -

Finally, it would be helpful if you identify a point of contact (POC) who I can work with to support effective implementation of the DPO process. The POC can be the NMSS OCWE Champion (Patty Doolittle) or someone else.

Enclosures:

1. DPO Submittal
2. Milestones and Timeliness Goals

cc:

M. Weber, DEDMRT
N. Mamish, AO

DISTRIBUTION:

SMoore
FBrown

EDoolittle
AMasters

DSeymour
DPO-2013-001 File

JYerokun
OE R/F

ADAMS ACCESSION NO.: (Package) ML13030A334

OFFICE	OE/CRB	OE/CRB	OE/CRB	OE: D
NAME	MSewell	RPedersen	DSolorio	RZimmerman
DATE	1/31/2013	1/31/2013	1/31/2013	2/1/2013

OFFICIAL RECORD COPY

**Document 3: Memo from NMSS Office Manager Establishing
Panel**

February 15, 2013

MEMORANDUM TO: Christopher G. Miller, Panel Chair
Robert J. Fretz, Jr., Panel Member
Richard P. McIntyre, Panel Member
Daniel J. Pasquale, Panel Member

FROM: Catherine Haney, Director **/RA/**
Office of Nuclear Material Safety
and Safeguards

SUBJECT: AD HOC REVIEW PANEL - DIFFERING PROFESSIONAL OPINION
INVOLVING COMMERCIAL GRADE ITEMS AT MIXED OXIDE FUEL
FABRICATION FACILITY (DPO-2013-001)

In accordance with Management Directive (MD) 10.159, ^AThe NRC Differing Professional Opinions Program,[@] I am appointing you as members of a Differing Professional Opinion (DPO) Ad Hoc Review Panel (DPO Panel) to review a DPO that was forwarded for me to disposition.

The DPO (Enclosure 1) raises concerns involving the regulatory requirements for the process of determining critical characteristics for the dedication of commercial grade items that are placed into service as basic components at the Mixed Oxide Fuel Fabrication Facility (MFFF).

I have designated Christopher Miller Chairman of this DPO Panel and Daniel Pasquale as a DPO Panel member. Richard McIntyre was proposed by the DPO submitters and serves as the third member of the DPO Panel. Because this issue addresses enforcement, Robert Fretz is serving as the fourth member. In addition to this panel, the Office of the General Counsel (OGC) has designated Michael J. Clark to assist in answering any legal questions that may arise in the Panel's deliberations, including serving as a liaison with OGC. Please feel free to consult with Mr. Clark as necessary.

In accordance with the guidance included in MD 10.159 and consistent with the DPO Program objectives, I task the DPO Panel to do the following:

- ☐ Review the DPO submittal to determine if sufficient information has been provided to undertake a detailed review of the issue.
- ☐ Meet with the submitters, as soon as practicable, to ensure that the DPO Panel understands the submitters' concerns and scope of the issues. (Normally within 7 days.)
- ☐ Promptly after the meeting, document the DPO Panel's understanding of the submitters' concerns, provide the Statement of Concerns (SOC) to the submitters, and request that the submitters review and provide comments, if necessary. (Normally within 7 days.)

CONTACT: Scott Moore, NMSS
(301) 492-4554

- ☐ Maintain the scope of the review to not exceed those issues as defined in the original written DPO and confirmed in the SOC.
- ☐ Consult with me as necessary to discuss schedule-related issues, the need for technical support (if necessary), or the need for administrative support for the DPO Panel's activities.
- ☐ Perform a detailed review of the issues and conduct any record reviews, interviews, and discussions you deem necessary for a complete, objective, independent, and impartial review. The DPO Panel should re-interview individuals as necessary to clarify information obtained during the review. In particular, the DPO Panel should have periodic discussions with the submitters to provide them the opportunity to further clarify their views and to facilitate the exchange of information.
- ☐ Provide monthly status updates on your activities via email to Renée Pedersen, Differing Views Program Manager (DVPM) about the last day of the month. This information will be reflected in the Milestones and Timeliness Goals for this DPO. Please provide a copy of email status updates to the submitters and to me.
- ☐ Issue a DPO Panel report, including conclusions and recommendations to me regarding the disposition of the issues presented in the DPO. The report should be a collaborative product and include all DPO Panel members' concurrence. Follow the specific processing instructions for DPO documents.
- ☐ Consult me as soon as you believe that a schedule extension is necessary to disposition the DPO.

Disposition of this DPO should be considered an important and time sensitive activity. The timeliness goal included in the MD for issuing a DPO Decision is 120 calendar days from the day the DPO is accepted for review. The timeliness goal for issuing this DPO Decision is May 24, 2013.

Process Milestones and Timeliness Goals for this DPO are included as Enclosure 2. The timeframes for completing process milestones are identified strictly as goals—a way of working towards reaching the DPO timeliness goal of 120 calendar days. The timeliness goal identified for your part of the process is 70 calendar days.

Although timeliness is an important DPO Program objective, the DPO Program also sets out to ensure that issues receive a thorough and independent review. The overall timeliness goal should be based on the significance and complexity of the issues and the priority of other agency work. Therefore, if you determine that your activity will result in the need for an extension beyond the 70 days, please send me an email with the reason for the extension request and a new completion date. If this delay will impact the overall 120-day timeliness goal, I will forward an extension request to the DVPM who will forward it to the EDO for approval. Please ensure that all DPO-related activities are charged to Activity Code ZG0007.

Because this process is not routine, the DVPM will be meeting and communicating with all parties during the process to ensure that everyone understands the process, goals, and responsibilities. The DVPM will be sending you information intended to aid you in implementing the DPO process.

An important aspect of our internal safety culture includes respect for differing views. As such, you should exercise discretion and treat this matter sensitively. Documents should be distributed on an as-needed basis. In an effort to preserve privacy, minimize the effect on the work unit, and keep the focus on the issues, you should simply refer to the employees as the DPO submitters.

As a final administrative note, please ensure that all correspondence associated with this case include the DPO number in the subject line, be profiled in accordance with ADAMS template OE-011, be identified as non-public with limited viewer rights to those included on distribution of correspondence and declared an official agency record *when the correspondence is issued*. Please email the ADAMS accession number for the record to DPOPM.Resource@nrc.gov and the record will be filed in the applicable DPO case file folder (DPO-2013-001) in the ADAMS Main Library. Following this process will ensure that a complete agency record is generated for the disposition of this DPO. If the submitters request that the documents included in the DPO Case File be made public when the process is complete, you will be provided specific guidance to support a releasability review.

I appreciate your willingness to serve and your dedication to completing an independent and objective review of this DPO. Successful resolution of the issues is important for NRC and its stakeholders. If you have any questions, you may contact me, Renée Pedersen, DVPM, at (301) 415-2742 or email Renee.Pedersen@nrc.gov or Marge Sewell, Safety Culture Specialist (301) 415-8045 or email Margaret.Sewell@nrc.gov.

I look forward to receiving your independent review results and recommendations.

Enclosures:

1. DPO-2013-001
2. Milestones and Timeliness Goals

cc: Submitter (include cover memo & Enclosure 2)
DVPM (just cover memo)

Because this process is not routine, the DVPM will be meeting and communicating with all parties during the process to ensure that everyone understands the process, goals, and responsibilities. The DVPM will be sending you information intended to aid you in implementing the DPO process.

An important aspect of our internal safety culture includes respect for differing views. As such, you should exercise discretion and treat this matter sensitively. Documents should be distributed on an as-needed basis. In an effort to preserve privacy, minimize the effect on the work unit, and keep the focus on the issues, you should simply refer to the employees as the DPO submitters.

As a final administrative note, please ensure that all correspondence associated with this case include the DPO number in the subject line, be profiled in accordance with ADAMS template OE-011, be identified as non-public with limited viewer rights to those included on distribution of correspondence and declared an official agency record *when the correspondence is issued*. Please email the ADAMS accession number for the record to DPOPM.Resource@nrc.gov and the record will be filed in the applicable DPO case file folder (DPO-2013-001) in the ADAMS Main Library. Following this process will ensure that a complete agency record is generated for the disposition of this DPO. If the submitters request that the documents included in the DPO Case File be made public when the process is complete, you will be provided specific guidance to support a releasability review.

I appreciate your willingness to serve and your dedication to completing an independent and objective review of this DPO. Successful resolution of the issues is important for NRC and its stakeholders. If you have any questions, you may contact me, Renée Pedersen, DVPM, at (301) 415-2742 or email Renee.Pedersen@nrc.gov or Marge Sewell, Safety Culture Specialist (301) 415-8045 or email Margaret.Sewell@nrc.gov.

I look forward to receiving your independent review results and recommendations.

Enclosures:

1. DPO-2013-001
2. Milestones and Timeliness Goals

cc: Submitter (include cover memo & Enclosure 2)
DVPM (just cover memo)

DISTRIBUTION:

RidsNmssOd

MClark, OGC

ML13045A991

OFFICE	NMSS	NMSS			
NAME	SMoore	Chaney			
DATE	02/ 13 /13	02/15 /13			

OFFICIAL RECORD COPY

Document 4: DPO Panel Report

April 25, 2013

MEMORANDUM TO: Catherine Haney, Director
Office of Nuclear Material Safety
and Safeguards

FROM: Christopher G. Miller, Panel Chair /RA/
Richard P. McIntyre, Panel Member /RA/
Daniel J. Pasquale, Panel Member /RA/
Robert J. Fretz, Jr., Panel Member /RA/

SUBJECT: DIFFERING PROFESSIONAL OPINION PANEL REPORT ON
COMMERCIAL GRADE ACTIVITIES AT THE MIXED OXIDE FUEL
FABRICATION FACILITY (DPO-2013-001)

In a memorandum dated February 15, 2013, you appointed us as members of a Differing Professional Opinion (DPO) Ad Hoc Review Panel (DPO Panel) to review a DPO regarding commercial grade dedication activities at the Mixed Oxide Fuel Fabrication Facility. The DPO Panel has reviewed the DPO in accordance with the guidance in Management Directive 10.159, ^AThe NRC Differing Professional Opinions Program.[@]

The DPO Panel's evaluation of the concerns raised in the DPO is detailed in the enclosed DPO Panel Report, and is enclosed for your consideration.

Please do not hesitate to contact us if you have any questions regarding the enclosed report.

Enclosure:
DPO Panel Report

cc: Submitter
Director, OE
DPOPM
OCWE Champion

MEMORANDUM TO: Catherine Haney, Director
Office of Nuclear Material Safety
and Safeguards

FROM: Christopher G. Miller, Panel Chair /RA/
Richard P. McIntyre, Panel Member /RA/
Daniel J. Pasquale, Panel Member /RA/
Robert J. Fretz, Jr., Panel Member /RA/

SUBJECT: DIFFERING PROFESSIONAL OPINION PANEL REPORT ON
COMMERCIAL GRADE ACTIVITIES AT THE MIXED OXIDE FUEL
FABRICATION FACILITY (DPO-2013-001)

In a memorandum dated February 15, 2013, you appointed us as members of a Differing Professional Opinion (DPO) Ad Hoc Review Panel (DPO Panel) to review a DPO regarding commercial grade dedication activities at the Mixed Oxide Fuel Fabrication Facility. The DPO Panel has reviewed the DPO in accordance with the guidance in Management Directive 10.159, ^aThe NRC Differing Professional Opinions Program.[@]

The DPO Panel's evaluation of the concerns raised in the DPO is detailed in the enclosed DPO Panel Report, and is enclosed for your consideration.

Please do not hesitate to contact us if you have any questions regarding the enclosed report.

Enclosure:
DPO Panel Report

cc: Submitter
Director, OE
DPOPM
OCWE Champion

Distribution:

C. Haney, NMSS
C. Miller, RI, DRS
R. McIntyre, NRO, DCIP
D. Pasquale, NRO, DCIP
R. Fretz, OE, ES
M. Clark, OGC

DOCUMENT NAME: DPO-2013-001 Panel Report FINAL.docx

Non-Public Designation Category: MD 3.4 Non-Public B.1 (A.3 - A.7 or B.1)

ADAMS ACCESSION NUMBER: ML13115A234

<input checked="" type="checkbox"/> SUNSI Review		<input checked="" type="checkbox"/> Non-Sensitive <input type="checkbox"/> Sensitive		<input type="checkbox"/> Publicly Available <input checked="" type="checkbox"/> Non-Publicly Available	
OFFICE kah	OE:ES	NRO/DCIP	NRO/DCIP	RI/DRS	OGC
NAME	RFretz	RMcIntyre	DPasquale	CMiller	MClark
DATE	04/09/2013	04/09/2013	04/09/2013	04/25/2013	04/24/2013

OFFICIAL RECORD COPY

**Differing Professional Opinion (DPO)
Regarding Commercial Grade Dedication
Activities at the
Mixed Oxide Fuel Fabrication Facility
(DPO-2013-001)**

DPO Panel Report

/RA/

Christopher G. Miller, Panel Chair

/RA/

Richard P. McIntyre, Panel Member

/RA/

Daniel J. Pasquale, Panel Member

/RA/

Robert J. Fretz, Jr., Panel Member

Date: April 25, 2013

Introduction

On January 16, 2013, two members of the Region II staff involved in construction inspection activities at the Mixed Oxide (MOX) Fuel Fabrication Facility submitted a differing professional opinion (DPO). The DPO raised concerns involving regulatory requirements for determining critical characteristics in conjunction with commercial grade dedication activities. On February 15, 2013, the Director, Office of Nuclear Material Safety and Safeguards, appointed members of a panel to review the DPO. The DPO Panel met with one of the two submitters in order to determine the specific concerns to be addressed. Those concerns are described below. The second DPO submitter was initially unavailable to be interviewed because she was in an extended leave status; however, the DPO Panel shared the Statement of Concern and background information with the second submitter, and received agreement that it captured the concern properly. The panel then met several times to review materials included as part of the DPO, referenced in the DPO, or recommended by others interviewed by the Panel.

Statement of Concern(s)

The DPO submitters are concerned that, based on a December 3, 2012 NMSS response to a Technical Assistance Request (TAR) from Region II, certain inspection findings related to design problems at MOX may not be addressed properly as either inspection or enforcement matters. The submitters are concerned that this could lead to continuing violations of 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."¹ The submitters are particularly concerned that this could lead to violations during construction of the facility and, potentially, improper construction of the facility.

Basis for Statement of Concern

In their DPO, the submitters provide a detailed critique of NMSS's December 3, 2012 TAR response. After a detailed review of the documents relating to the DPO submission, as well as discussions with the submitter, the Panel concludes that the submitters agree with much of the TAR response, but do not believe the TAR response properly addressed their concerns. In particular, the submitters do not believe the TAR response adequately addressed how certain inspection findings related to design and commercial dedication of components could be cited as violations of Appendix B.

In support of their position, the DPO submitters provided specific details regarding the applicant's apparent failure to properly demonstrate the design basis for specifications made for a critical component needed to fulfill a safety function. The DPO submitters contend that the applicant did not have sufficient engineering details to ensure that an epoxy used to hold structural rebar would perform its safety function. The submitters believed this constituted a violation of Appendix B, Criterion III, Design Control. Others in Region II believed this was not a violation of Criterion III, but rather a violation of Criterion VII, Control of Purchased Material, Equipment and Services. Region II managers generated a TAR on May 30, 2012, in order to guide any enforcement action related to this inspection.

¹ The NRC's regulations require that MOX describe its quality assurance program. These regulations further state that this description "should include a discussion of how the criteria in appendix B of part 50 of this chapter will be met." *Id.* In its application, MOX discusses the Appendix B criteria and states that its quality assurance plan will meet these criteria. MOX Project Quality Assurance Plan (June 22, 2000) (ADAMS Accession No. ML010450086).

Because of an apparent incomplete communication of the issues raised by the DPO submitters, the questions Region II submitted as part of the TAR did not completely reflect the submitters' concerns. In addition, NMSS's TAR response was not created with the benefit of complete communication with the submitters. Both of these factors appear to have contributed to the TAR response not fully addressing the DPO submitters' concerns.

Evaluation

To most effectively respond to the DPO submitters' concerns, the DPO Panel first attempted to understand the full extent of the TAR request and the subsequent TAR response. The DPO Panel believes that the overarching issue that needs to be resolved is whether the commercial grade dedication process can be considered a quality activity related to only *one* Appendix B criterion—for example, Criterion III or Criterion VII—or whether multiple criteria should be considered as appropriate. Because 10 CFR 50 Appendix B was the focus of the DPO submitter's concern, the DPO panel based its assessment on implementation of those requirements rather than ones contained within the MOX MPQAP, as the TAR response often did. By focusing on Appendix B rather than the MOX-specific requirements imposed by the MPQAP, the DPO Panel also hopes to provide general insights that will better enable staff to characterize inspection findings as part of the enforcement process.

Background

Over the years, the nuclear industry has experienced a steady decrease in the number of suppliers opting to obtain or maintain a quality assurance program that meets the requirements of Appendix B. To help offset these diminishing resources, in the mid-1980's NRC staff endorsed an alternate procurement method known as commercial grade dedication (CGD). During the late 1980's and early 1990s both the NRC and the nuclear industry issued several guidance documents to help address this change in nuclear procurement practices.

NRC Generic Letter (GL) 91-05, "Licensee Commercial-Grade Procurement and Dedication Programs" explains the basic premises that support the commercial grade dedication process. As explained in the "Background" section of GL 91-05, Appendix B contains the NRC's regulations for procurement quality assurance (QA) and quality control (QC) for products to be used in safety-related applications. These requirements, if properly implemented, provide a measure of assurance for the suitability of equipment, including commercial-grade items for use in safety-related systems. For example, Criterion III of Appendix B (Design Control) requires licensees to select and review for suitability of application materials, parts, equipment, and processes that are essential to the safety-related functions of the structures, systems, and components. Criterion IV (Procurement Document Control) requires that procurement documents specify the applicable requirements necessary to ensure functional performance. Criterion VII (Control of Purchased Material, Equipment and Services) requires licensees to ensure that the following are sufficient to identify whether specification requirements for purchased material and equipment have been met: source evaluation and selection, objective evidence of quality, inspection of the source, and examination of products upon delivery.

The process used to meet Appendix B requirements when upgrading commercial grade items for safety-related applications is commonly called "dedication." The process of ensuring compliance with Appendix B must include all those activities necessary to establish and confirm the quality and suitability of commercially procured and dedicated items intended for safety-related applications. As stated in GL 91-05, the licensee is responsible for identifying the important design, material, and performance characteristics for each part, material, and service

intended for safety-related applications. The licensee is also responsible for establishing acceptance criteria and providing reasonable assurance of the conformance of items to these criteria.

As GL 91-05 makes clear, dedication is a process that can encompass several different criteria of Appendix B, depending upon what specific quality activity is being performed. GL 91-05 did not attempt to tie the dedication process to one specific Appendix B criterion or activity; rather, GL 91-05 made clear that commercial-grade procurement and dedication programs must comply with existing NRC requirements in Appendix B, such as Criterion III (Design Control), Criterion IV (Procurement Document Control), Criterion VII (Control of Purchased Material, Equipment and Services), or Criterion XVIII (Audits). Although the language in GL 91-05 is in some cases prescriptive, it cannot reasonably be interpreted to limit the use of any of the 18 Criteria in Appendix B.

Another NRC generic letter, GL 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," discusses commercial-grade dedication in terms of engineering involvement in the procurement process, product acceptance, and the dedication process. It also endorsed (conditionally) the use of EPRI NP-5652, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety Related Applications (NCIG-07)." GL 89-02 emphasized that involvement of the dedicating entity's engineering staff in an effective procurement process would normally include (1) development of specifications to be applied during 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 engineering involvement needed depends on the complexity of the nature and use of the products involved. This engineering involvement is typically performed by the dedicating entity as part of the Technical Evaluation (TE) process that is conducted to identify the safety function, failure modes and effects analysis (FMEA), critical characteristics, and the acceptance methods and acceptance criteria for the commercial-grade item being dedicated.

The commercial grade dedication process, including engineering involvement during the TE process, is also described in NRC Inspection Procedure (IP) 38703, "Commercial-Grade Dedication"; NRC IP 43004, "Inspection of Commercial-Grade Dedication Programs"; ASME NQA-1, Subpart 2.14, Quality Assurance Requirements for Commercial Grade Items and Services"; and EPRI NP-5652, "Commercial Grade Item Guidance." In addition, the NRC has issued regulatory guides addressing issues relevant to commercial grade dedication. For example, Regulatory Guides 1.28, 1.33, and 1.123 provide guidance on quality control measures used in facility design, construction, and operation.

In sum, these guidance documents are relevant to the questions the DPO Panel addresses in this report. Based on the requirements of Appendix B, and taking into the NRC's relevant guidance, the DPO Panel provides the following responses and conclusions.

DPO Evaluation

The DPO Panel believes that the nine specific questions presented in the TAR can be best addressed by grouping them under three general issues. By addressing these general issues, the Panel provides the clarification needed to address the TAR questions.

1. **Is the Commercial Grade Item (CGI) process, including the technical evaluation, a design engineering activity or a procurement activity?**
 - a. RTAR Question #1: Is the specification of critical characteristics of basic components and the development of criteria used for verification of these critical characteristics during the commercial grade dedication 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?
 - b. RTAR Question #1a: Is the process for identifying and modifying specified critical characteristics for basic components and the criteria for verifying the critical characteristics subject to the requirements of Section 7, *Control of Purchased Material, Equipment and Services*?
 - c. RTAR Question #2: Is a revision to a commercial-grade item evaluation (CGIE) (e.g., change of critical characteristics) considered a design change?
 - d. RTAR Question #3: What requirements from MPQAP Section 3, *Design Control*, are applicable to CGIEs (e.g., specification of the critical characteristics and acceptance methods) and revisions to CGIEs?
 - e. RTAR Question #7: Is it an acceptable approach to include commercial-grade dedication requirements in MPQAP Section 7, *Control of Purchased Material, Equipment, and Services*, instead of MPQAP Section 3, *Design Control*?
 - f. RTAR Question #8: Is it an acceptable approach to consider the applicant's CGD program as an acceptance, procurement, and verification process (MPQAP Section 7, *Control of Purchased Material, Equipment, and Services*) with engineering involvement?

Appendix B requires a licensee (or applicant) to incorporate managerial and administrative controls to ensure safe operation of the facility as documented in its final safety analysis report (FSAR) or integrated safety analysis (ISA). The implementation of the 18 quality assurance criteria in Appendix B provides assurance that structures, systems, and components (SSC) documented in a facility's FSAR or ISA will perform satisfactorily while in service (i.e., will perform their safety functions). Appendix B also requires that quality assurance actions related to the physical characteristics of an SSC provide a means to control quality to predetermined standards. These quality assurance requirements from Appendix B apply throughout the entire lifecycle of a facility. They are expected to control the licensed safety basis for all safety-significant SSCs from design through procurement, installation and operation of the facility.

The commercial grade dedication process was introduced as an alternate procurement process to the one described in Appendix B to 10 CFR 50. 10 CFR Part 21.3 defines dedication as "an acceptance process undertaken to provide reasonable assurance that a commercial grade item

to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, appendix B, quality assurance program.” While the use of the term “acceptance process” could conceivably be interpreted as meaning that commercial grade dedication is exclusively a procurement activity, the more reasonable interpretation, borne out by the Part 21 definition of “dedication,” is that upon completion of the dedication process an item is *deemed equivalent to an item designed and manufactured under an Appendix B program*. When procuring replacement items, equivalent performance is confirmed by conducting a technical evaluation to ensure specified items meet the licensee’s or applicant’s design basis requirements.

This alternate method of procurement is intended to encompass and rely upon all of the QA/QC requirements presented in the 18 Criteria of Appendix B. Meeting all criteria is, therefore, necessary to deem an item “equivalent” to one designed and manufactured under an Appendix B program. The dedication process was never intended as an alternate process for modifying a facility’s design basis. The design requirements of the item must be established prior to initiating procurement activities. In other words, the technical evaluation and acceptance activities involved in dedication are not substitutes for design. They cannot be used to change the design basis associated with the item’s safety function, nor are they a means to approve the adequacy of an item’s safety basis. If a facility’s use of the dedication process leads to a determination that the selected item or component would result in a change in fit, form, or function of a SSC contained in a facility’s licensing basis, the licensee or applicant must use appropriate design change control processes to authorize the change.

It should also be noted that, just as an Appendix B supplier could violate multiple Appendix B criteria, the same is true for the dedicating entity. This basic premise has been supported by numerous staff inspection findings at licensee and supplier facilities alike, where one or more of the 18 criteria were cited against a dedicating entity’s commercial grade dedication process. The DPO Panel recognizes that historically the majority of cited violations and non-conformances have been written against Criterion III, “Design Control”, or Criterion VII, “Control of Purchased Material, Equipment, and Services.” This is not a limitation imposed by Appendix B, however, but a result of the inherent similarities that the dedication process shares with supplying a component that meets a required safety function, and with the steps involved in providing reasonable assurance that the procured item will perform the intended safety function.

Potential violations and non-conformances associated with commercial grade dedication should be based on the individual circumstances of each inspection finding and cited against the specific regulatory requirements that are not met. If a single finding results from more than one regulatory requirement not being met, all appropriate regulatory requirements may be cited in the inspection finding to properly capture and describe the actual nature of the violations.

2. What is meant by engineering involvement in the commercial grade dedication process?

- a. RTAR Question #9: What is meant by engineering involvement as described in NRC Generic Letter 91-05?

Beginning with GL 89-02, the staff has consistently emphasized that engineering involvement in the commercial grade dedication process is essential for a CGD program to be effective. This guidance is not prescriptive as to how the engineering organization should be organized and what engineering qualifications, if any, are needed to satisfy this recommendation. Instead, that determination is left up to each dedicating entity, with the expectation that the individuals

performing these activities are technically capable to perform them consistent with the complexities of the item being dedicated. What is evident from the current CGD guidance is that engineering involvement is essential throughout the entire process.

This engineering involvement is typically performed by the dedicating entity as part of the technical evaluation process that is performed to identify a SSC's safety function, failure modes and effects analysis (FMEA), critical characteristics, acceptance methods, and acceptance criteria. This technical evaluation is commonly referred to as an engineering activity, and it is conducted and documented by the responsible engineering organization. This evaluation may, however, be performed by anyone meeting the dedicating entity's documented threshold of "engineering involvement." GL 91-05 re-emphasizes the role of engineering in the CGD process without being prescriptive as to what credentials are necessary to perform a particular activity. Specifically, GL 91-05 states that engineering involvement "is important" because the technical evaluation identifies the critical characteristics, acceptance criteria, and methods for verification.

3. What is an appropriate process for revising a CGIE?

- a. RTAR Question #4: Is a documented technical justification required by the MPQAP when issuing a revision to a CGIE (e.g., change in critical characteristics) or can the technical evaluation in the CGIE stand on its own merit?
- b. RTAR Question #5: Is a CGIE considered a design (output) document?
- c. RTAR Question #6: Is it permissible to revise critical characteristics once they are established?

As stated above, engineering involvement is typically performed by the dedicating entity as part of the technical evaluation process. This process includes the identification of critical characteristics, their acceptance methods, and the acceptance criteria. The technical evaluation process has always been considered the appropriate mechanism for addressing critical characteristics. If a revision to the CGIE results in a change in fit, form, or function of an SSC, the appropriate design control change process must be used to evaluate, authorize and document the change. Similarly, if the revision to a CGIE could potentially reduce the margin of safety in the item's critical characteristics, that change should also be addressed as potentially impacting fit, form, or function associated with the facility's design basis. Accordingly, the revision should be entered into the appropriate design engineering change process that evaluates, authorizes, and documents the change. It should be noted, however, that even though a CGIE does not constitute a design change document, it is still a quality record as described in Appendix B, and as such must be maintained in order to furnish evidence of activities affecting quality. This includes documenting changes which prescribe all activities affecting quality. The process for identifying critical characteristics, determining the appropriate verification methods for each critical characteristic, and identifying acceptance methods is clearly described in IP 43004.

December 17, 2012, Letter to Shaw AREVA MOX Services

In a letter dated December 17, 2012, NMSS provided MOX with specific guidance relative to the Appendix B criteria associated with performing commercial grade dedication activities. The guidance was directed at two specific questions:

- 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?
- 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?

Based on its review, the DPO Panel concludes that, while the content of the December 17, 2012 letter was not technically incorrect, it failed to provide the needed program clarification and may have provided information that could be misinterpreted by dedicating entities and inspectors. Furthermore, the letter appears to have missed a significant opportunity to reaffirm to the applicant the requirement to both maintain the licensed design basis through successful implementation of all 18 Appendix B criteria and implement a robust commercial grade dedication program as described in GL 91-05. Instead, the letter could lead a reader to infer that Appendix B, Criterion VII, "Control of Purchased Material, Equipment, and Services," is the only criterion used to document non-conformances associated with commercial grade dedication. The DPO Panel believes this letter would have been more effective had it emphasized that the primary purpose of commercial grade dedication, as defined in 10 CFR Part 21, is to provide reasonable assurance that a commercial grade item used as a basic component will perform its intended safety function and, in this respect, is equivalent to an item designed and manufactured under an approved Appendix B quality assurance program. In other words, the NMSS letter missed the opportunity to emphasize that the adequacy of an applicant's commercial grade dedication program depends upon the successful implementation of *all* 18 criteria in Appendix B.

Communication of Inspection Findings and TAR Process Issues

During discussions with the DPO submitters and others involved in the TAR, the Panel members noted an apparent gap in communication on some of the issues related to both the TAR and to previous applicant performance regarding commercial grade dedication activities and issues. More than one branch in the Region and a number of inspectors and supervisors had some involvement, but it seemed from the discussions that a thorough knowledge of the inspection findings was not commonly understood. This led to problems in writing the TAR, because the basic questions of some inspectors were not captured. This also led to problems in responding to the TAR, because those same inspectors were not sufficiently consulted to obtain information that would have clarified the purpose of the original questions. The current issue of substance in the DPO submission is characterized as Inspector Follow-up Item 70-2098/2012-002-003. The DPO Panel recognizes the significant inspection and enforcement capabilities present in the Region, as well as the well-defined enforcement processes and support services available to resolve issues of this type, and would expect these processes to be used to address MOX commercial grade dedication issues, including this Inspector Follow-up Item.

Documentation of Apparent Violations and Non-conformances

During its review and discussions with individuals involved with the TAR and the DPO, the DPO Panel heard varying comments relating to documenting violations and non-conformances in inspection reports. Some members of the staff hold the view that only one NRC requirement may be cited in a violation (e.g., Appendix B, Criterion VII). While the general practice is to simplify the write-up as much as possible, citations must establish a link between the licensee's performance deficiency and a failure to comply with legally binding NRC requirements, such as a regulation (e.g., 10 CFR Part 50, Appendix B), a license condition, an order, or a statute (e.g., the Atomic Energy Act).

Documenting violations typically involves two steps: (1) summarizing the facts leading to the violations, and (2) providing a "contrary to" statement that relates those facts to the NRC requirements that are not being met. In many cases, a licensee's performance deficiency may involve the failure to comply with multiple NRC requirements. Additionally, the inspector may need to refer to commitments in licensee documents and explain why those commitments are legally binding. For example, if the underlying violation relates to the failure to follow a specific licensee procedure, such as the MPQAP or a procedure implementing the commercial grade dedication program, the inspector will need to identify the regulation or license condition requiring that the licensee adhere to the procedure. In either case, the "restatement of requirements not met" portion of a citation often refers to more than one NRC requirement.

In the Hilti epoxy adhesives/rebar example associated with this DPO, it appeared that the applicant failed to follow MOX implementing procedures associated with commercial grade dedication and that multiple regulatory requirements were not met. These requirements include Criterion III and Criterion VII in Appendix B, as well as regulations in 10 CFR Part 21. Assuming this is the case, it may have been appropriate for the inspectors to have referred to multiple regulations as the "lead-in regulatory requirements" for any procedure-related violations described in their inspection report. The overarching goal is to ensure that the citation is able to clearly describe the licensee's failure to meet a legally binding requirement.

The DPO submitters also suggest that the possible violations associated with the epoxy adhesive commercial grade dedication constitute a programmatic breakdown in MOX's QA/QC program. The DPO Panel finds no support for concluding that the violations identified here constitute a programmatic breakdown as defined in the NRC's Enforcement Policy. Typically, enforcement issues that invoke the term "programmatic breakdown" are associated with violations of NRC requirements involving multiple licensee organizations and multiple root causes. Based on the information reviewed by the DPO Panel, that is not the case here. However, the DPO Panel recognizes that additional information and examples regarding the MOX QA/QC program may lead the Region to evaluate this aspect further.

Conclusion(s)

As previously noted in this report, the NRC has traditionally cited violations and non-conformances associated with commercial grade dedication activities against Criterion III (Design Control) or Criterion VII (Control of Purchased Material, Equipment, and Services) in Appendix B. These two criteria describe a wide range of quality assurance measures that must be established to ensure that the licensing basis is maintained at a nuclear facility, whether under construction or in operating status. This may have led to a tendency of the staff to be less mindful that licensees and applicants are responsible for implementing all 18 Appendix B

criteria, and that commercial grade dedication activities are governed by the entirety of Appendix B, as well as other regulatory requirements, including 10 CFR Part 21.

Striving for precision in classifying certain commercial grade dedication activities as either “design control” or “procurement” activities is less important to the oversight process than maintaining a focus on uncovering potential violations and ensuring applicants and licensees take adequate corrective actions. The DPO Panel understands that the specific issues surrounding the dedication of epoxy adhesives for safety (QL-1) applications at the MOX facility remain open and are the subject of a current inspection follow-up item. The best way to resolve that item is to use the established processes for inspection and enforcement, as aided by collegial review and support from the program office and the Office of Enforcement. As such, the DPO Panel has purposely avoided presenting an exhaustive analysis of the resolution of the specific issue.

The panel members have the following observations and conclusions:

- (1) The DPO submitters were correct in raising an issue about the apparent lack of an engineering basis in the “selection of application” of the Hilti epoxy adhesive as part of construction specifications for “post-installed” reinforcing bars. MOX does not appear to have established a nexus between applicable design basis requirements (e.g., seismic loadings) and use of the epoxy adhesive dating back to the original design change authorized in 2008. This has led to what could potentially be a series of inadequate commercial grade dedication activities that may be directly attributed to improper implementation of design controls. The DPO Panel also understands that there may be other design basis-related issues that need to be resolved associated with the post-installed reinforcing bars and the ongoing corrective action effort at MOX.
- (2) The DPO Panel finds that, given the information provided to the Panel, there does not appear to be a sufficient basis to conclude that the possible violations associated with the epoxy adhesive commercial grade dedication rise to the level of a programmatic breakdown of MOX’s QA/QC program.
- (3) NMSS’s December 17, 2012, letter to MOX and the TAR response would have been more effective had they emphasized that (a) the primary purpose of commercial grade dedication is to determine whether a commercial grade item is equivalent to an item designed and manufactured under an approved Appendix B quality assurance program; and (b) for that reason, whether a commercial grade dedication program is adequate depends on whether it satisfies all 18 criteria of Appendix B.
- (4) Once an applicant or licensee determines a critical characteristic is necessary to support a design basis safety function, that characteristic must be verified. It was not apparent from the DPO Panel’s review that, for those safety functions identified by the DPO submitters, MOX had verified all the specified critical characteristics. Specifically, the DPO Panel did not find any documented justification for why previously identified critical characteristics had been removed.
- (5) There appear to be a number of issues resulting from the extensive use of commercial grade dedication at new construction facilities. Close coordination and communication of these issues and the resulting decisions on specific issues is paramount for the NRC to approach this growing area in a consistent manner. This communication can be enhanced by training on difficult topics and sharing information through collaborative processes such

as Enforcement Panels or Significance Determination Process and Enforcement Review Panels, in which the Regions and the Office of Enforcement regularly participate. Frequent discussions between inspection branches and projects branches dealing with these issues would be beneficial in ensuring NRC staff is aligned on the paths forward for some of the more difficult issues.

Recommendation(s)

Based on its review, the DPO Panel recommends the following:

1. Because the DPO Panel understands that the epoxy dedication issue raised by the DPO submitters remains an open inspection follow-up item, the Panel recommends that the Region's inspection team continue its normal oversight of related corrective action activities. The Panel notes that the following concerns should be addressed by the applicant before the NRC closes out the corrective actions associated with this issue:
 - a. The Region should review actions to ensure MOX addresses the remaining design issues associated with post-installed epoxy-grouted rebar. The DPO Panel understands that the current design documents may not meet applicable requirements of the American Concrete Institute (ACI) Code, which is a design basis requirement.² This could lead to other concerns about the epoxy adhesive and post-installed rebar design.
 - b. The technical evaluation associated with commercial grade dedication of the Hilti epoxy adhesive, if used in structural applications, will need to identify those critical characteristics that support the determination that the adhesive will perform its intended safety function and that it is equivalent to an item designed and manufactured under an Appendix B quality assurance program.
 - c. While evaluating the applicability of materials from Hilti as they pertain to use at the MOX facility, regional staff should be aware that Hilti quality control processes regarding epoxy may be limited to verifying batch consistency and other chemical process controls, and may not support their published catalog data (tensile strength, bond strength, etc.) needed to justify use in safety-related applications at the MOX facility without further testing.
2. NMSS should amend its December 17, 2012, letter to MOX Services in order to clarify that commercial grade dedication involves the implementation of multiple regulatory requirements, including all Appendix B criteria.
3. The DPO Panel recommends rescinding or modifying the TAR response issued by NMSS. Existing NRC guidance is sufficient to address the issues discussed in the TAR response at a high level. While the TAR response attempts to provide more detailed guidance, certain statements in the TAR response could lead to confusion in identifying and citing violations. In particular, the TAR response primarily addresses the applicability of Criterion VII in Appendix B, but other criteria in Appendix B may also apply.

² During the interviews, the DPO Panel learned that there may be other issues beyond the commercial grade dedication, such as whether the actual embedment depth of the rebar in some installations meets requirements specified by Hilti. In addition, the panel members learned that there may be unresolved ACI Code issues in some instances.

4. The Region should take steps to enhance communication of existing inspection issues related to commercial grade dedication, particularly those related to MOX. For example, the Region might consider forming a collaborative panel with experts in commercial grade dedication.
5. The NRC should develop formal training to consistently address the oversight of commercial grade dedication activities for licensees, applicants, and vendors
6. Since Part 21 is currently being revised, the DPO Panel's report should be provided to members of the staff responsible for the Part 21 rulemaking activities.
7. The DPO Panel's report should be provided to members of the staff working on the endorsement of a revision to EPRI-NP-5652. This Panel's report may be relevant to these staff members because the revision to EPRI-NP-5652 will likely include additional guidance for effectively applying the Appendix B criteria to a commercial grade dedication process.

Persons Contacted by the DPO Panel

<u>Name</u>	<u>Position</u>
Larry Campbell	Senior Project Manager, NMSS
Bill Gloerson	Senior Fuel Facility Inspector, Region 2
Elaine Heher	Construction Inspector (DPO submitter)
Carl Jones	Senior Construction Inspector (DPO submitter)
Joel Munday	Director, Division of Construction Projects, Region 2
Deborah Seymour	Chief, Construction Projects Branch 1, Region 2
Mel Shannon	Senior Resident Inspector, MOX Facility

DPO-2013-001 Timeline

Date	Event
February 5, 2008	<p>MOX Services approved Engineering Change Request (ECR) 000563 "Post-Installing Reinforcing and Anchor Bolts." The ECR requested, in part, a revision to DCS01-BKA-DS-SPE-B-09330, specification section 03301, "Placing Concrete and Reinforcing Steel," to include post-installation of reinforcement and anchor bolts by drilling and grouting using a structural epoxy adhesive.</p> <p>Page 3 of 3 authorized a revision to construction specification 03301 to allow "post-installed rebar." The revised specification required that the epoxy gel "be a two component, moisture insensitive structural epoxy adhesive that conforms to the requirements of ASTM C-881." Acceptable epoxy gels included HIT RE 500 epoxy adhesive manufactured by Hilti North America.</p>
September 22, 2010	<p>CR-10-513 (Condition Report) identified issues relating to the commercial grade dedication of epoxy material used at MOX. The Commercial Grade Item Evaluation (CGIE) addressed the use of this material as a "grout" and, thus, listed compressive strength as the only critical characteristic. The CR originator stated that it may not be the only critical characteristic needed based upon the use of the epoxy on site. The CR originator surmised that the problem may have been caused by the improper identification of this product as an "epoxy grout" rather than its correct classification as an "epoxy adhesive." Actions relating to CR-10-513 included:</p> <ol style="list-style-type: none"> (1) placed a hold on all procurements and material release of the epoxy until all issues related to the use of the material were resolved (10/26/2010); (2) required a revision to the commercial grade dedication plan (DCS01-WWJ-DS-CGD-M-65828-1) to add additional critical characteristics related to physical properties and tensile strength (completed 12/21/2010); (3) revised specification DCS01-BKA-DS-SPE-B-09330 to include limitations and requirements for use (completed 04/28/2011); (4) identified specific locations and conditions where the epoxy was used on post installed rebar. The list provided input to CR-09-399/AT-11-1041 for evaluation of the credited anchorage capacity and completion of the cumulative analysis action (completed 12/30/2011). <p>The DPO Panel understands that the engineering evaluation to determine the anchorage capacity credit is on-going.</p>
October 1 through December 31, 2010	<p>A routine NRC inspection was conducted at the MOX facility. During this time, inspectors observed that post-installed rebar had been installed on structures designated as an "item relied on for safety (IROFS)" using the design change approved under ECR 000563. The inspectors concluded that MOX Services failed to specify and/or perform the necessary inspection and/or testing to verify that the epoxy adhesive gel, used for installing steel reinforcing bars in hardened concrete, met the requirements of ASTM C881. Specifically, MOX Services did not adequately verify that the physical properties, including bond strength and tensile strength, were in accordance with the ASTM C881 Standard along with other requirements. The commercial grade dedication for the epoxy adhesive gel only addressed compressive strength tests. The inspectors were subsequently informed by MOX Services that the epoxy issue had been previously identified in CR-10-513. Based on a review of the CR, the inspectors concluded that MOX Services developed adequate corrective actions.</p>

Date	Event															
December 10, 2010	<p>MOX Services issued Revision 2 to a new CGIE (DCS01-WWJ-DS-CGD-M-65973-2) for Hilti HIT-RE 500 and HIT-RE-500 SD Epoxy as an “epoxy adhesive.” The sampling plan included testing the epoxy material for bond strength, compressive strength, compressive modulus, and tensile strength consistent with ASTM C881. The critical characteristic acceptance requirements, however, were more stringent than required by ASTM C881:</p> <table><tr><td><u>Critical Characteristic</u></td><td><u>CGIE Requirements</u></td><td><u>ASTM C881</u></td></tr><tr><td>Bond Strength</td><td>1,800 psi</td><td>1,500 psi</td></tr><tr><td>Compressive Strength</td><td>12,000 psi</td><td>8,000 psi</td></tr><tr><td>Compressive Modulus</td><td>>0.22 x 10⁶</td><td>> 0.15 x 10⁶</td></tr><tr><td>Tensile Strength</td><td>6,310 psi</td><td>6,000 psi</td></tr></table> <p>The CGIE requirements in Revision 2 to the CGIE are consistent with Hilti technical product information, and appear to meet ASTM C881.</p>	<u>Critical Characteristic</u>	<u>CGIE Requirements</u>	<u>ASTM C881</u>	Bond Strength	1,800 psi	1,500 psi	Compressive Strength	12,000 psi	8,000 psi	Compressive Modulus	>0.22 x 10 ⁶	> 0.15 x 10 ⁶	Tensile Strength	6,310 psi	6,000 psi
<u>Critical Characteristic</u>	<u>CGIE Requirements</u>	<u>ASTM C881</u>														
Bond Strength	1,800 psi	1,500 psi														
Compressive Strength	12,000 psi	8,000 psi														
Compressive Modulus	>0.22 x 10 ⁶	> 0.15 x 10 ⁶														
Tensile Strength	6,310 psi	6,000 psi														
January 24 through January 25, 2011	<p>MOX Services conducted a commercial grade survey of Hilti’s test facility in Kaufering, Germany, in support of Revision 2 to the CGIE. The survey team sought to determine if testing performed by Hilti could address the tests required by the CGIE. The survey team noted that Hilti does not consider the testing required by the CGIE as critical characteristics; rather, Hilti considers various process controls, chemical testing of each batch, daily “pull tests” and other quality control methods representative of the quality of epoxy shipped. Bonding strength is validated by daily pull tests utilizing a threaded stud as opposed to using deformed steel reinforcing bars (rebar) used in the “post-installed rebar” design. The survey report also stated that “none of the tests noted in the product literature are performed during receipt or batching operations.”</p>															
February 10, 2011	<p>NRC Inspection Report No. 70-3098/2010-004 documented the issues surrounding the commercial dedication of epoxy gel used for installing reinforcing bars in hardened concrete. Inspectors concluded that MOX Services failed to specify and/or perform the necessary inspection and/or testing to verify that the epoxy adhesive gel, used for installing steel reinforcing bars in hardened concrete, met the requirements of ASTM C881. This conclusion applied to the epoxy purchased prior to Revision 1 and 2 of the CGIE. Region II issues NCV 70-3098/2010-004-006 on the basis that corrective actions associated with CR-10-513 (dated 09/22/2010) will adequately address issue.</p>															
February 23, 2011	<p>MOX Services issued Revision 3 to Commercial Grade Item Evaluation for Hilti Epoxy Adhesives. Revision 3 changed the procurement strategy from including special testing and inspection to accepting the commercial grade survey conducted at Hilti on January 24 - 25, 2011. The sampling plan and the critical characteristics previously listed in Revisions 1 and 2 were revised. The CGIE noted that “engineering shall establish appropriate procedures or guides for the selection of this material [epoxy] for specific applications and controls required for the installation process which shall be in accordance with the manufacturer’s recommendations.” Suppliers will provide a certificate of conformance to certify that the product supplied have the properties stated in the supplier’s published data.</p>															
January 1 through March 31, 2012	<p>A routine NRC inspection was conducted at the MOX facility. The inspection scope included a review of commercial grade dedications conducted in accordance with CGIE DCS01-WWJ-DS-CGD-M-65973, Commercial Grade Item Evaluation for Hilti HIT-RE-500 and HIT-RE-500-SD Epoxy Adhesives.</p>															

Date	Event
February 12, 2012	MOX Services initiates CR-12-056 to document outcome of NRC inspection regarding Commercial Grade Dedication, concluding that MOX did not provide adequate technical justification for changes (i.e., removal of) to critical characteristics associated with the dedication of Hilti epoxy adhesives (Revision 2 to Revision 3).
May 11, 2012	NRC Inspection Report No. 70-3098/2012-001: The inspectors determined that further review by the NRC staff will be necessary to evaluate the applicability of requirements to use design control for the definition of critical characteristics. IFI 70-3098/2012-001-004, Review the Applicability of Using Design Control to Define Critical Characteristics, was opened to further evaluate this condition.
May 30, 2012	Region II submits TAR to NMSS.
December 3, 2012	NMSS response to Region II TAR.
December 17, 2012	NMSS letter to Shaw AREVA MOX Services providing information on commercial grade dedication activities.
January 16, 2013	DPO Submitted.

Document 5: DPO Decision

October 31, 2013

MEMORANDUM TO: Carl T. Jones, Senior Construction Inspector
Construction Inspection Branch 1
Division of Construction Inspection
Region II

FROM: Catherine Haney, Director **/RA/**
Office of Nuclear Material Safety
and Safeguards

SUBJECT: DIFFERING PROFESSIONAL OPINION DECISION INVOLVING
COMMERCIAL GRADE DEDICATION ACTIVITIES AT THE
MIXED OXIDE FUEL FABRICATION FACILITY (DPO-2013-001)

On January 16, 2013, in accordance with Management Directive 10.159, "The NRC Differing Professional Opinions Program," you and Elaine Heher, formerly with NRC's Region II office, submitted a differing professional opinion (DPO) regarding commercial grade dedication activities at the Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF) near Aiken, South Carolina. Specifically, your DPO raised concerns involving regulatory requirements, and related guidance, for determining critical characteristics in conjunction with commercial grade dedication activities. The purpose of this memorandum is to notify you of the decisions that I have made in response to your DPO.

On February 15, 2013, I established a DPO Ad Hoc Review Panel (the Panel) and tasked it to meet with you, review your DPO submittal, and issue a DPO report, including conclusions and recommendations regarding the disposition of the issues presented in your DPO. The Panel met with you, in order to determine your specific concerns, and shared their Statement of Concern and background information with Ms. Heher, who was initially unavailable to be interviewed because she was in an extended leave status. After conducting a records review, conducting interviews with relevant individuals, and completing its own deliberations, the Panel issued its report to me (enclosure) on April 25, 2013.

The Panel concluded that a number of your concerns have merit. For example, the Panel concluded that you were correct in raising an issue about the apparent lack of an engineering basis in the "selection of application" of the Hilti epoxy adhesive as part of construction specifications for "post-installed" reinforcing bars. In addition, the Panel found that this Office's letter to MFFF and the Technical Assistance Request (TAR) response on this topic would have been more effective had they emphasized other points. Also, the Panel emphasized close

CONTACT: Catherine Haney, NMSS
(301) 287-9243

coordination and communication, in ensuring NRC staff is aligned on the paths forward for some of the more difficult issues. On the other hand, the Panel found that, given the information provided to the Panel, "there does not appear to be a sufficient basis to conclude that the possible violations associated with the epoxy adhesive commercial grade dedication rise to the level of a programmatic breakdown of MOX's QA/QC program." The Panel was careful to point out that the specific issues surrounding the dedication of epoxy adhesives for safety applications at the MOX facility remain open [as of the Ad Hoc Panel report date] and are the subject of a current inspection follow-up item.

In addition to its conclusions, the Panel made seven specific recommendations, ranging from the epoxy dedication issue to the TAR response to training. My decisions regarding the Panel's recommendations are addressed below.

Following receipt of the Panel's report, I met with you on October 2, 2013, by telecon, to discuss the Panel's report and recommendations. At my request, Region II management and Office of Nuclear Material Safety and Safeguards (NMSS) managers also participated in that telecon, and assisted in the technical discussions. On October 3, 2013, I met with Christopher Miller, Ad Hoc Panel Chair, to discuss the Panel's report and recommendations. I also asked NMSS staff and Region II for feedback on the report and recommendations.

After reviewing the Panel's report, considering the information provided in my meetings with you and the Panel Chair, and considering associated background information, I agree with most of the Panel's recommendations, as follows:

Recommendation 1: I agree with the main recommendation that the NRC should continue with normal oversight of MFFF's corrective action activities. While Region II will be aware of the issues raised by the Panel in items a), b), and c), some of the issues raised in these subparagraphs are actions for MFFF, rather than NRC staff, so subparagraphs a), b), and c) are not included in this decision.

Recommendation 2: I will task NMSS staff to clarify the December 17, 2012 letter. The manner of clarification will be left for NMSS' Division of Fuel Cycle Safety and Safeguards (FCSS) to decide.

Recommendation 3: I agree that the TAR response should be supplemented. I will task FCSS to work closely with Region II and any other applicable Offices in developing supplementary TAR guidance.

Recommendation 4: I agree that the Region should take steps to enhance communication of existing inspection issues related to commercial grade dedication, and think that this can be broadened to include other Offices such as my own. While we may want to consider a collaborative panel, I will not direct that, as it is but one of a number of ways to enhance communications.

Recommendation 5: I agree that NRC should develop training focused on MOX commercial grade dedication and the specific related requirements and enforceable standards for the MOX facility, but I do not think that it needs to be "formal." In fact, rapid, informal training may be more solution-oriented right now than waiting too long for classroom training to be developed.

Recommendation 6: I agree that the Panel's report [and this Director's Decision] should be shared with the Part 21 rulemaking staff, with the caveat that the Ad Hoc DPO Panel's report should be characterized as just that, and understood that it is not Agency policy.

Recommendation 7: I agree to share the Panel's report [and this Director's Decision] with the staff working on the EPRI-NP-5652 revision, with the same caveat as Recommendation 6.

As a result of the Panel's recommendations and these decisions, I will be issuing a separate memorandum tasking the Director, Division of Fuel Cycle Safety and Safeguards, and others, to develop, track, and implement follow up actions to address the decisions summarized above. You will receive a copy of the memorandum and will be kept informed of the completion for the follow up actions.

Thank you for raising your DPO concerns and for your participation in the DPO process. By examining issues such as these, we strengthen our regulatory process and ensure that our regulatory programs remain strong and effective. A summary of the DPO and the DPO decision will be included in the Weekly Information Report to advise interested employees of the outcome when the case is closed. If you have any questions or would like to discuss the matter further, please do not hesitate to contact me.

Enclosure:
DPO Panel Report

cc: Renee Pedersen, DPO Program Manager, OE
Christopher Miller, Panel Chair, FSME
Richard McIntyre, Panel Member, NRO/DCIP
Daniel Pasquale, Panel Member, NRO/DCIP
Robert Fretz, Panel Member, OE
Michael Clark, OGC

Recommendation 6: I agree that the Panel's report [and this Director's Decision] should be shared with the Part 21 rulemaking staff, with the caveat that the Ad Hoc DPO Panel's report should be characterized as just that, and understood that it is not Agency policy.

Recommendation 7: I agree to share the Panel's report [and this Director's Decision] with the staff working on the EPRI-NP-5652 revision, with the same caveat as Recommendation 6.

As a result of the Panel's recommendations and these decisions, I will be issuing a separate memorandum tasking the Director, Division of Fuel Cycle Safety and Safeguards, and others, to develop, track, and implement follow up actions to address the decisions summarized above. You will receive a copy of the memorandum and will be kept informed of the completion for the follow up actions.

Thank you for raising your DPO concerns and for your participation in the DPO process. By examining issues such as these, we strengthen our regulatory process and ensure that our regulatory programs remain strong and effective. A summary of the DPO and the DPO decision will be included in the Weekly Information Report to advise interested employees of the outcome when the case is closed. If you have any questions or would like to discuss the matter further, please do not hesitate to contact me.

Enclosure:
DPO Panel Report

cc: Renee Pedersen, DPO Program Manager, OE
Christopher Miller, Panel Chair, FSME
Richard McIntyre, Panel Member, NRO/DCIP
Daniel Pasquale, Panel Member, NRO/DCIP
Robert Fretz, Panel Member, OE
Michael Clark, OGC

DISTRIBUTION:

S. Moore, NMSS	J. Andersen, FCSS	G. Tracy, NRO	M. Sewell, OE
M. Bailey, FCSS	G. Holahan, NRO	A. Masters, Rgn. II	R. Zimmerman, OE
F. Brown, Rgn. II	V. McCree, Rgn. II		

ML13304B839

OFFICE	NMSS		
NAME	CHaney		
DATE	10/ 31 /13		

OFFICIAL RECORD COPY

October 31, 2013

Elaine Heher


Dear Ms. Heher,

On January 16, 2013, when you formerly worked for the U.S. Nuclear Regulatory Commission, you and Carl T. Jones submitted a Differing Professional Opinion (DPO) in accordance with Management Directive 10.159, "The NRC Differing Professional Opinions Program." Your DPO was in regard to commercial grade dedication activities at the Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF) near Aiken, South Carolina. The purpose of this letter is to notify you of the decisions that I have made in response to your DPO.

Enclosed is a more detailed memorandum that I provided to Mr. Jones that explains my decisions on the DPO. I hope that the memorandum provides a thorough explanation of the process used to evaluate your DPO, the recommendations made by an Ad Hoc Panel that reviewed your DPO, the decisions I am making on the Panel's recommendations, and the tasking that I will be making to develop, track, and implement follow up actions in response to your DPO and the Panel's recommendations.

Thank you for raising your DPO concerns and for your participation in the DPO process, as an NRC employee. By examining issues such as these, we strengthen our regulatory process and ensure that our regulatory programs remain strong and effective. A summary of the DPO and the DPO decision will be included in the Weekly Information Report to advise interested employees of the outcome when the case is closed. If you have any questions or would like to discuss the matter further, please do not hesitate to contact me at 301-287-9243 or Renee Pedersen, NRC's DPO Program Manager, at 301-415-2742.

Enclosure:
DPO Decision

Sincerely,

/RA/

Catherine Haney, Director
Office of Nuclear Material Safety
and Safeguards

Elaine Heher

Dear Ms. Heher,

On January 16, 2013, when you formerly worked for the U.S. Nuclear Regulatory Commission, you and Carl T. Jones submitted a Differing Professional Opinion (DPO) in accordance with Management Directive 10.159, "The NRC Differing Professional Opinions Program." Your DPO was in regard to commercial grade dedication activities at the Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF) near Aiken, South Carolina. The purpose of this letter is to notify you of the decisions that I have made in response to your DPO.

Enclosed is a more detailed memorandum that I provided to Mr. Jones that explains my decisions on the DPO. I hope that the memorandum provides a thorough explanation of the process used to evaluate your DPO, the recommendations made by an Ad Hoc Panel that reviewed your DPO, the decisions I am making on the Panel's recommendations, and the tasking that I will be making to develop, track, and implement follow up actions in response to your DPO and the Panel's recommendations.

Thank you for raising your DPO concerns and for your participation in the DPO process, as an NRC employee. By examining issues such as these, we strengthen our regulatory process and ensure that our regulatory programs remain strong and effective. A summary of the DPO and the DPO decision will be included in the Weekly Information Report to advise interested employees of the outcome when the case is closed. If you have any questions or would like to discuss the matter further, please do not hesitate to contact me at 301-287-9243 or Renee Pedersen, NRC's DPO Program Manager, at 301-415-2742.

Enclosure:
DPO Decision

Sincerely,
/RA/
Catherine Haney, Director
Office of Nuclear Material Safety
and Safeguards

cc: Carl T. Jones, RII
Renee Pedersen, OE

DISTRIBUTION: (w/o Enclosure)

S. Moore, NMSS	M. Bailey, NMSS	J. Andersen, NMSS	M. Sewell, OE
R. Fretz, OE	R. Zimmerman, OE	G. Tracy, NRO	G. Holahan, NRO
R. McIntyre, NRO	D. Pasquale, NRO	V. McCree, RII	F. Brown, RII
A. Masters, RII	M. Clark, OGC	C. Miller, FSME	

ML13304C005

OFFICE	NMSS			
NAME	Chaney			
DATE	10/ 31 /13			

OFFICIAL RECORD COPY