

NRC INSPECTION MANUAL

NMSS/FCSS

MANUAL CHAPTER 2630

MIXED OXIDE FUEL FABRICATION FACILITY CONSTRUCTION INSPECTION PROGRAM

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2630-01 PURPOSE

The purpose of this Inspection Manual Chapter (IMC) is to define the Construction Inspection Program (CIP) for the Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF). Specifically, the CIP will:

01.01 Verify that the design bases of the principal systems, structures, and components (PSSCs) and the Quality Assurance (QA) Program are adequately implemented during construction to provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents.

01.02 Verify that the construction of the PSSCs and items relied on for safety (IROFS) have been completed in accordance with the construction authorization and the design basis as contained in the license application to possess and use special nuclear material in the MFFF.

01.03 To establish a record of the inspection and technical review activities, applicant/licensee actions taken and technical issues resolved to support the decision for authorizing the use of special nuclear material.

2630-02 OBJECTIVES

The primary objective of this manual chapter is to establish a CIP for inspecting PSSCs and IROFS and associated activities that are conducted by the applicant/licensee and their consultants, contractors, and suppliers, to support the decision on issuance of a license to possess and use special nuclear material in the MFFF. The following objectives are included in the CIP:

02.01 Provide reasonable assurance that regulatory requirements and applicant/licensee commitments for design bases, quality assurance, and management measures are adequately included in the design, procurement, and construction of the MFFF.

02.02 Provide reasonable assurance that the MFFF and the associated PSSCs and IROFS were constructed in accordance with the QA program, construction authorization, and the design basis sections in the license application to possess and use special nuclear material.

02.04 Verify the effective implementation of the QA program as specified in the MOX Project Quality Assurance Plan (MPQAP) and that it includes timely implementation of organizational staffing, procedures, instructions, QA activities, and administrative controls necessary to achieve quality objectives important to safety.

02.05 Verify that the applicant/licensee is identifying conditions that may adversely affect public and worker safety so that appropriate corrective actions can be taken.

02.06 Conduct risk-informed and performance based inspections across key functional areas to support the decision on issuance of a license to possess and use special nuclear material in the MFFF.

02.07 Provide guidance on disposition and documentation of inspection findings.

02.08 Provide guidance on a MFFF-specific assessment program to identify performance trends and determine if an expansion of U.S. Nuclear Regulatory Commission (NRC) inspections is necessary based on inspection findings.

02.09 To verify the operational readiness of the MFFF.

2630-03 APPLICABILITY

03.01 This IMC was developed to provide inspection program guidance for the MFFF CIP. The MFFF CIP applies to all construction activities, including, the design, procurement, fabrication, construction, and pre-operational testing and readiness activities. Implementation of this IMC began at the NRC issuance of the construction authorization, and will continue through facility construction activities, pre-operational testing and readiness activities.

03.02 As necessary, archived IMCs, inspection procedures (IP) and temporary instructions (TI) may be re-issued and used to perform the required inspections or reviews of outstanding design, licensing, and regulatory issues for the MFFF CIP.

03.03 The MFFF remains within the scope of the Commission's current Enforcement Policy for fuel cycle facilities in the construction phase. Traditional enforcement, i.e. the use of Severity Levels (SL), will be used for any SL IV and above non-compliances that are identified during inspections. SL IV violations identified by the NRC or applicant/licensee at the MFFF (under construction, including design, procurement, fabrication, construction, pre-operational testing, and readiness activities) will be dispositioned in accordance with the Commission's current Enforcement Policy for non-cited violations¹.

03.04 The transition of the MFFF to the full oversight provided by IMC 2600 will be a phased approach and is described in 2630-12 of this IMC.

2630-04 DEFINITIONS

04.01 Application. Application means the safety functions and design bases provided in the Construction Authorization Request (CAR) and further refined in the license application (LA) to possess and use radioactive material at the MFFF. Generally, those PSSCs defined in the CAR correspond to IROFS in the LA.

¹ Letter from USNRC to Shaw Areva MOX Services, dated February 14, 2013 (ML13030A333)

04.02 Completion of Construction. Completion of construction means that the system, structure, or component is able to perform its safety function as defined in the application, and can be verified by inspection or technical review².

04.03 Construction. 10 CFR Part 70.4 provides a definition for construction. *Construction* means the installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the regulations in this part that are related to radiological safety or security. The term "construction" does not include:

- a. Changes for temporary use of the land for public recreational purposes;
- b. Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;
- c. Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;
- d. Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this part;

For the purpose of this program, construction refers to the analysis, design, procurement, manufacture, fabrication, quality assurance, placement, erection, installation, modification, and inspection, of a system, structure, or component that has been defined as a PSSC.

04.04 Construction Authorization Request (CAR). Document(s) submitted by the applicant/licensee providing a description of the facility site; a description and safety assessment of the design bases of the PSSCs of the facility; and a description of the MPQAP.

04.05 Design Bases. Design bases are information which identifies the specific functions to be performed by a structure, system, or component of a facility, and the specific values, or ranges of values chosen for controlling parameters as reference bounds for design³. These values may be: (1) restraints derived from generally accepted "state of the art" practices for achieving functional goals, or (2) requirements derived from analyses (based on calculation and/or experiments) of the effects of a postulated accident for which a structure, system, or component must meet its functional goals to provide an acceptance level of safety.

² For the purpose of meeting 10 CFR 70.23(a)(8), testing and completion of activities supporting the startup of the facility are not necessary to make the staff's determination that the requirements of 10 CFR 70.23(a)(8) have been met. Pre-operational inspections and evaluations will be made during NRC's operational readiness review.

³ See NUREG 1718

04.06 DIAMOND. The Digital Information Archive for MFFF and Online Normalized Database (DIAMOND) is a tool that is used to manage, document, organize, and track the MFFF PSSC verification information obtained during inspections and technical reviews. The NRC staff (staff) uses DIAMOND to (1) plan their inspections, (2) access technical documents, (3) input inspection report (IR) data and staff reviews, (4) track progress toward inspection verification program completion, and (5) monitor status of open items. DIAMOND is discussed in Appendix G.

04.07 Independent Verification Plans (IVP). Inspection or technical review planning documents that describe the PSSCs identified in the CAR and prioritize the IROFS from the Integrated Safety Analysis Summary (ISAS). The IVPs also prioritize the IROFS components that are associated with the IROFS, and provide guidance to the inspection staff on the level of inspection effort.

04.08 In-Office (or Field) Review. Assessments, audits, or reviews conducted to assess licensing related activities.

04.09 Inspection. (1) An NRC activity consisting of examination, observation, or measurement to determine applicant/contractor/vendor (licensee/applicant oversight of vendors) conformance with requirements and/or standards. (2) Applicant/licensee/contractor/vendor activity consisting of examination, observation, or measurements to determine the conformance of materials, supplies, components, parts, systems, processes or structures, including IROFSs to pre-determined quality requirements.

04.10 Inspection Attribute. A specific element or area of applicant/licensee performance such as design control (please see Appendix E for a complete list of the inspection attributes) that can be inspected or assessed to identify, analyze, and document potential weaknesses or deficiencies that may result in a failure to comply with NRC requirements. Assessment or inspection of these attributes supports the intent of this IMC by reducing the likelihood of an undetected PSSC flaw that could adversely affect the public's health and safety. The inspection attributes specified in Appendix E are derived from the inspection procedures listed in Appendix A.

04.11 Items Relied on for Safety (IROFS). Structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in 10 CFR 70.61 or to mitigate their potential consequences. This does not limit the applicant/licensee from identifying additional structures, systems, components, or activities of personnel (i.e., beyond those in the minimum set necessary for compliance with the performance requirements) as IROFS.

04.12 Level of Inspection Effort (LOIE). A methodology that prioritizes the value of inspecting construction activities pertaining to PSSCs. This methodology determines the scope of each PSSC IVP and supports inspection planning and scheduling. This methodology will provide reasonable assurance that the construction of the PSSC has been completed in accordance with the application (as required by 10 CFR 70.23(a)(8)) by using a risk-informed approach to determine the LOIE value for each PSSC. The LOIE value is defined as the likelihood of an undetected construction error ("L" value) times the consequence of failure to detect the error ("C" value). The LOIE methodology is discussed in Appendix E.

04.13 Management Measures. The functions performed by the applicant/licensee, generally on a continuing basis, which are applied to IROFS, to ensure the items are available and reliable to perform their functions when needed. Management measures include configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other QA elements. Commitments related to management measures are contained in the LA.

04.14 MFFF Assessment and Review Group (MARG). An assessment group comprised of representatives from the Office of Nuclear Material Safety and Safeguards' (NMSS) Division of Fuel Cycle Safety and Safeguards (FCSS) MFFF project staff and the Division of Construction Projects in Region II, that has the responsibility to oversee the development and implementation of the program to verify that the construction of the MFFF PSSCs was completed in accordance with the application. The effort is focused on ensuring that the licensing and inspection programs will collect the information necessary for the Commission to make a determination that the requirements of 10 CFR 70.23(a)(8) for issuing a 10 CFR Part 70 license have been met. The MARG has the responsibility to oversee project completion and serve as the focal point for status of the project and for coordination between the Region and NMSS at Headquarters.

04.15 MFFF startup. Activities associated with the cold start-up or hot start-up of the MFFF as defined below.

- a. Cold Start-up. In-plant testing, inspection, or measurement activities not involving the use of licensed material on MFFF process systems or components. This phase also includes the reference period, as defined by the applicant/licensee, in which all safety and operations programs have been implemented.
- b. Hot Start-up. Pre-operational inspection, testing, or measurement activities involving the use of NRC licensed material in MFFF systems or components. This phase occurs after the reference period.

04.16 Mixed Oxide (MOX) Fuel. For the purposes of this manual chapter, a mixture of plutonium dioxide (PuO₂) in a depleted or natural uranium oxide (UO₂) matrix. Approximately 95% of the MOX material is composed of UO₂. The MOX fuel is characterized in terms of plutonium isotopics as reactor-grade or weapons-grade.

04.17 MOX Project Quality Assurance Plan (MPQAP). The applicant/licensee's plan that defines the actions taken by applicant/licensee management and personnel during the performance of quality-affecting activities on the project to ensure QA requirements are consistently met.

04.18 Operational Readiness Review (ORR). A disciplined, systematic, documented, performance-based examination of facilities, equipment, personnel, procedures, and management control systems to provide reasonable assurance that a facility will be operated safely within its approved safety envelope as defined by the facility safety basis. A graded approach will be used in defining the depth of the ORR based on these core requirements. In order to support a decision to possess and use special nuclear material, NRC will review and assess the state of readiness of facility operation based on the results of the ORR inspections.

04.19 Principal Systems, Structures, and Components (PSSCs). PSSCs are safety controls that are identified in the design bases as providing protection against the consequences of accidents or natural phenomena. PSSCs may be engineered controls (active or passive), or administrative (procedural) controls. Controls may be either preventive or mitigative. The PSSCs were defined by Shaw AREVA MOX Services (MOX Services or applicant/licensee) in the CAR and approved by the staff, in the safety evaluation report (SER) for the CAR (NUREG-1821).

04.20 PSSC Verification Program. The PSSC Verification Program is a process that incorporates one or more of the following activities: (1) PSSC field inspections; (2) technical staff reviews and evaluations; and (3) staff review of applicant/licensee PSSC completion bases. The verification of the construction of a PSSC will vary depending on the type and nature of the system, structure, or component. A sample of IROFS component types, procedures or documents should be selected and verified for each prioritized IROFS in the IVP in order to complete the PSSC verification process. This is necessary to provide reasonable assurance that the construction of the PSSCs has been completed in accordance with the application. In order to complete the IVP process for a particular PSSC or PSSC family, a minimum number of inspection attributes needs to be inspected or reviewed. The LOIE value lists provided in the IVPs correlate to a range of attributes that should be inspected or reviewed as part of the verification process.

04.21 Quality Assurance (QA) Program. The applicant/licensee's overall QA program to be applied to the design, fabrication, construction, testing, and operation of the PSSCs. This includes the MPQAP, QA procedures, and supporting procedures and program activities. The QA program also provides a management control system to assure the attainment of quality objectives.

04.22 Reference Period. A time frame defined by the applicant/licensee where the final step in the ORR is conducted. The following activities occur during the reference period: (1) simulated integrated operation of entire facility; (2) plant turned over to operations; (3) utilities and balance of plant systems running in normal mode; and (4) security and radiation/contamination boundaries enforced.

2630-05 RESPONSIBILITIES AND AUTHORITIES

05.01 Office of Nuclear Material Safety and Safeguards (NMSS).

- a. Responsible for regulatory oversight of the MFFF Project.
- b. Responsible for the overall safety inspection program policy, guidance, and approval.
- c. Responsible for preparing a Safety Evaluation Report Supplement that documents the overall finding of verification of construction of PSSCs as required in 10 CFR 70.23(a)(8).
- d. Lead responsibility for reviewing administrative controls in support of the PSSC verification program.

- e. Provides technical expertise, as needed, to support the inspection program of the MFFF.
- f. Responsible for the planning, performance, documentation, and enforcement associated with the aspects of the Headquarters' Material Control and Accounting inspection program.
- g. Assigns MFFF project staff to support the MARG for PSSC verification.
- h. Authorizes the possession and use of special nuclear materials at the MFFF.

05.02 Office of Nuclear Security and Incident Response (NSIR).

- a. Responsible for the overall safeguards inspection program policy, guidance, and approval.
- b. Concurs on the approval of this IMC and inspection procedures for activities relating to the safeguards aspects of the MFFF.

05.03 Director, Office of Enforcement (OE).

- a. Ensures consistent application of the enforcement process to violations of NRC regulations with the appropriate focus on the severity level of the finding.
- b. Provides representatives as necessary to support the Escalated Enforcement process in order to ensure consistent application of the enforcement process.

05.04 Regional Administrator, Region II (RII).

- a. Provides program direction for management and implementation of the inspection program elements performed by the regional office.
- b. Ensures, within budget limitations, that the regional office staff includes adequate numbers of inspectors in the various disciplines necessary to carry out the inspection program described in this chapter, including those needed for regional supplemental and reactive inspections.
- c. As necessary, directs the implementation of the supplemental inspection program.
- d. As necessary, applies inspection resources to deal with significant issues and problems at the MFFF.
- e. Makes the decision to authorize the commencement of operations at the MFFF with the concurrence of the Director, NMSS.

05.05 Director, Division of Construction Projects, RII.

- a. Ensures that adequate resources necessary to carry out the inspection program described in this IMC are provided to the staff.
- b. Responsible for the planning, performance, documentation, and enforcement associated with the aspects of the inspection program that are performed by Region II.
- c. Responsible for coordinating with NMSS in the development and maintenance of the procedures to implement the CIP for the MFFF Project.
- d. Concurs on the approval of this IMC and inspection procedures for activities relating to the MFFF.
- e. Responsible for preparing a report for each PSSC or PSSC family requiring inspections that documents the completion of inspection activities in accordance with the IVPs.
- f. As requested by FCSS, assigns inspection staff to support the MARG for PSSC verification.
- g. Coordinates with the Division of Fuel Facility Inspection (DFFI) to ensure the transition from construction to operations.

05.06 Director, Division of Fuel Facility Inspection, RII.

- a. Ensures that adequate operational resources are assigned to support the ORR program and implement the operations inspection program described in IMC 2600.
- b. As requested by FCSS, assigns inspection staff to support for ORR inspections.
- c. Coordinates with the Division of Construction Projects (DCP) to ensure the transition from construction to operations.

05.07 MFFF Assessment and Review Group (MARG). The MARG is a working group comprised of representatives from the NMSS Division of Fuel Cycle Safety and Safeguards (FCSS) MFFF project staff and Region II, Division of Construction Projects. The MARG was formed and tasked with developing and implementing a program to verify that the construction of the MFFF PSSCs is/was completed in accordance with the license application. The MARG has responsibilities in the following areas:

- a. Oversees project completion.
- b. Serves as the focal point for status of the project and for coordination between the Region and the NMSS program office.
- c. Ensures that the licensing and inspection programs will collect, document, assess, and review the information necessary for the Commission to make a determination that the requirements of 10 CFR 70.23(a)(8) for issuing a Part 70 license have been met.

- d. Ensures that the IVP program for verifying the construction of PSSCs as it relates to the licensing process and compliance with 10 CFR 70.23(a)(8) has been implemented.
- e. Requests the participation of other Divisions on an as needed basis.
- f. Periodically reviews the information contained in DIAMOND (and supporting documents if needed) to support a determination of inspection attribute completion.
- g. A MARG-specific charter may be created to provide additional information for the group, including organization and reporting responsibilities.
- h. Recommends to management, with supporting documentation, when a PSSC has been verified to be constructed in accordance with the application.

2630-06 BACKGROUND AND OVERVIEW

Under a U.S. Department of Energy (DOE) initiative to determine options for the disposition of surplus plutonium from the weapons program, DOE selected an approach of fabricating mixed oxide fuel for use in commercial nuclear power plants, and selected the Savannah River Site for the MFFF. The Defense Appropriations Act of 1999, Section 202 of the Energy Reorganization Act of 1974, was amended to require NRC licensing of the facility for fabricating mixed plutonium-uranium oxide nuclear reactor fuel for use in commercial nuclear reactors. NRC will perform the licensing under the provisions of 10 CFR Part 70.

Before an applicant/licensee is granted a license to operate a plutonium processing and fuel fabrication plant, the Commission must verify that the construction of the PSSCs has been in accordance with the application (10 CFR 70.23(a)(8)). In addition, the LA includes a description of the applicant/licensee's safety program and a separate summary of the Integrated Safety Analysis (ISA). The safety program demonstrates that each IROFS will perform its intended function to limit risks at the facility. The safety program is composed of process safety information, the ISA, and management measures. The PSSCs for the facility were reviewed and approved by the NRC and are documented in the SER for the CAR (NUREG-1821) and the Construction Authorization. In addition, the staff reviewed the LA and issued an SER in December 2010.

06.01 Non-Reduction in Commitments and Changes to the MPQAP. Changes in commitments made to the ancillary codes, standards, and specifications identified in the American Society of Mechanical Engineers NQA-1-1994, Quality Assurance Requirements for Nuclear Facility Applications, Part II, are not necessarily a reduction in commitment. If the applicant/licensee can justify that a deviation or change to a code or standard is not a reduction in commitment and documents the basis justifying that the change or deviation provides an equivalent commitment, the change would not have to be reviewed by NRC staff prior to its implementation.

A footnote in Section 7, "Referenced Codes, Standards, and Specifications," of the Introduction to NQA-1-1994, Part II, states in part, that "Users of this part [Part II] should review the acceptability of the date or edition to be referenced with the regulatory and enforcement

authorities having jurisdiction at the nuclear facility.” NRC staff will have the opportunity to review all changes that are not reductions in commitments as discussed in the following section. Further, while this footnote may be interpreted by some to require NRC approval of codes, standards, and specifications included in NQA-1, Part II; NRC prior approval is only required for changes that reduce commitments. It is noted that this footnote was removed in a subsequent version of NQA-1, and that Regulatory Guide 1.28, Quality Assurance Program Criteria (Design and Construction) Revision 4, endorses a version of NQA-1 that does not contain this footnote.

Further, it is noted that several of the ancillary documents contained in NQA-1-1994, Part II, contain both technical and quality provisions for accomplishing work activities. Where the technical requirements in the NQA-1-1994, Part II may differ from the technical requirements contained in the MFFF licensing documents, the technical requirements in the licensing documents (MPQAP and LA) shall govern.

The staff may, at anytime, review changes to the MPQAP whether they are or are not reductions to commitments. Further, changes made by the applicant/licensee, identified as being a non-reduction in commitment change, may be subject to review during an inspection by the Region II staff or by the resident inspectors.

The applicant/licensee is required to submit all changes to the MPQAP in accordance with 10 CFR Part 70. NMSS/FCSS staff will review the updates to the MPQAP, including non-reduction in commitment changes. During this review, staff may sample or conduct a full review of all non-reduction in commitment changes. It is anticipated that these reviews will take place in conjunction with the annual MFFF LA update review submitted in accordance with 10 CFR 70.34.

06.02 Non-Conformance to Provisions Contained in NQA-1-1994, Part II. MFFF construction work activities can result in the identification of non-conformances to the provisions contained in the codes, standards, and specifications of NQA-1-1994, Part II. The processing of such non-conforming conditions should be in accordance with the applicable requirements of Appendix B to 10 CFR Part 50 and the provisions contained in the MPQAP, including the applicant’s procedures.

It should be noted that this discussion is applicable only to non-conforming conditions that arise due to circumstances such as worker errors, unexpected inspection and test results, and for material, equipment, parts, and/or services that do not conform to established technical and quality requirements. As a rule, for normal construction activities, the processing of these non-conforming conditions would not require NRC approval nor result in a change to the MPQAP. However, should there be instances where the nonconformance is significant enough that a change to the MPQAP or portions of the licensing application may be necessary, the applicant/licensee may need to interact with NRC licensing staff to determine the proper course of action.

Intentional departure from the technical and quality requirements contained in procurement documents, and provisions contained in the MPQAP, NQA-1, or other work-controlling documents without prior documentation, review, and approval is not applicable to the above discussion.

07.01 Inspection Planning and Scheduling Considerations. The MFFF construction phase inspection schedule should be based on the applicant/licensee's construction schedule and should be modified and updated periodically during the entire construction period.

Inspections should be coordinated and scheduled such that the efficiency and effectiveness of the inspection effort is enhanced and unnecessary burden to the applicant/licensee is minimized. To the extent practicable, the construction and pre-operational inspections should be coordinated with the applicant/licensee to ensure that key construction inspection activities are synchronized with the site construction project schedule.

Emphasis should be placed on early identification of problems. Inspections will be conducted periodically throughout construction. Inspections will be scheduled early in the implementation of individual construction activities to develop confidence that specific construction activities were adequately accomplished at all stages of construction.

Comprehensive construction program reviews aimed at determining underlying causes and extent of problem areas should be conducted if NRC management concludes significant deficiencies are occurring. Inspection depth and frequencies may be expanded to assure problem areas have been corrected. Corrective action programs are essential to effective resolution of individual deficiencies and programmatic issues. Inspection effort should be planned to specifically evaluate corrective action program effectiveness.

NRC RII DCP will develop, maintain and implement a Master Inspection Plan (MIP) and schedule for the MFFF construction inspection project. The MIP will include the targeted PSSC specific inspections identified in the IVPs, the programmatic inspections, and the inspection procedures that will be used for the inspections. The list of procedures for conducting inspections is provided in Appendix A of this IMC. The MIP will provide flexibility to address emerging issues that require additional inspection efforts, receipt of allegations, changes in funding activities by DOE or changes in scheduling activities by the applicant/licensee.

07.02 Inspection Procedures. A list of IPs for conducting inspections is provided in Appendix A of this IMC. Not all of the procedures or portions of the procedures listed in Appendix A will be applicable. The IPs are not a listing of applicant/licensee requirements and should not be used as such. The IPs provide inspection guidance to inspectors to help them develop their inspection plans. Inspectors should review the licensing basis documents (LA, MPQAP etc.) to identify the specific license requirements that should be included in the inspection plans.

The focus of this CIP is not completion of the IPs, but rather verification that IROFS sampled for inspection were constructed in accordance with license requirements, and that safety programs are effectively implemented. The IPs listed in Appendix A should be used in conjunction with the appropriate IVP found in DIAMOND. The completion of the CIP for the MFFF is not dependent on completion of the IPs listed in Appendix A. It should be noted that the NRC CIP for the MFFF will use the IVPs to verify that the construction of each PSSC listed in Table 5.6-1

of the MFFF CAR has been completed in accordance with the application and provide reasonable assurance that the design basis safety function can be met. For further information on the use of the IVPs, please refer to Appendix C of this IMC. The resource estimate in each IP is an estimate for planning purposes; it is not an expected level of inspection effort.

07.03 Resident Inspector Program. Resident inspector(s) may be assigned to the site during the various phases of construction. The senior resident Inspector would normally be the primary interface with the applicant/licensee for coordination of inspection scheduling for specific construction activities. The resident inspector(s) should also participate in inspections within their areas of qualification using the inspection procedures listed in Appendix A and coordinate the preparation of integrated IRs. Resident inspector(s) may be assigned to the site on a rotational basis during construction, and may be changed periodically, based on the type of construction activities being conducted. Length of service at the site will be in accordance with agency policy.

07.04 Inspection and Technical Personnel Considerations. Inspectors and technical representatives will be assigned responsibility for performing inspections consistent with their qualifications. In addition, inspectors performing MFFF inspection activities will either be provided familiarization training on this IMC and related procedures or become familiar with the requirements of this IMC and the applicable requirements of 10 CFR Part 70.

07.05 Findings Outside of Inspector's Qualifications. Inspectors sometimes identify issues or violations outside of the inspector's qualifications or expertise. In these cases, the inspector is responsible for (1) determining if an immediate threat to the public or worker health or safety exists, and if one does exist to notify applicant/licensee management immediately; and (2) determining if the issue is better addressed by an inspector with different qualifications (i.e., a specialist inspector).

07.06 Management Entrance and Exit Meetings. Inspectors are required to meet with applicant/licensee management as part of every inspection. Inspectors should hold an entrance meeting with the senior applicant/licensee representative who has responsibility for the areas to be inspected. Each inspection must include the discussion of inspection results with applicant/licensee management. At the conclusion of an inspection, inspectors must discuss their preliminary findings with the applicant/licensee's management at a scheduled exit meeting. Management entrance and exit meetings with applicant/licensee personnel should be scheduled to minimize the impact on other applicant/licensee activities necessary to assure the safe and proper construction of the facility.

07.07 Communication with Local Public Officials. As a matter of NRC philosophy, the NRC maintains an open door policy with regard to access by the public or federal, state and local officials to the NRC staff and to publicly available electronic documentation concerning an applicant/licensee's performance. The degree of interaction that is considered necessary to enhance public confidence in the NRC is expected to vary widely dependent upon the situation at each facility. Guidance pertaining to communication with stakeholders external to the NRC can be found in the latest revision of the Communication Plan for the MFFF and applicable regional office procedures.

08.01 General. The MFFF CIP provides the inspection requirements for selectively assessing the adequacy of the regulatory and safety-related programs, and verifying the construction of PSSCs and IROFS. This includes the implementation of the applicant/licensee's QA program and other management measures used to ensure the availability and reliability of safety and safeguards IROFS. Substantial emphasis is to be placed on the inspection of the IROFS that are most important for reducing the likelihood of high- and intermediate- consequence accidents through the implementation of commitments made by the applicant/licensee in the MPQAP and the LA.

Emphasis is also to be placed on the applicant/licensee's activities that assure principal contractors delegated authority to conduct activities related to safety are implementing an acceptable QA program in accordance with the applicant/licensee's QA program. The inspection program provides for the direct inspection throughout all stages of construction, including equipment fabrication, assembly and installation, and structural construction activities as may be necessary to ascertain whether elements of the QA program are effectively implemented.

The applicant/licensee is ultimately responsible for the safety of the nuclear facility. The NRC assures through an audit type of inspection program that the responsibility is carried out in an effective manner during the activities of facility construction. The CIP presented in this manual chapter is considered the minimum necessary to achieve an acceptable level of confidence as to the adequacy of construction at the facility.

This IMC emphasizes a systematic evaluation of the adequacy and effectiveness of the applicant/licensee's QA and construction programs and their implementation. NRC will perform inspections of selected activities at the applicant/licensee's project offices at the MFFF site and, as necessary, other project facilities. Inspections will also be performed, as necessary, at the facilities of the applicant/licensee's consultants, contractors, and suppliers. This IMC establishes priorities for inspection by planned sampling of IROFS and related activities consistent with their importance to safety and should consider the performance of the applicant/licensee in the areas inspected.

08.02 Program Areas. The specific areas to be inspected will include a sampling of the applicant/licensee's IROFS and regulatory and safety commitments as identified in the design basis section of the LA and the approved MPQAP. IROFS for inspection will be chosen based on information contained in the IVPs (discussion of IROFS prioritization can be found in Appendix E).

The NRC will periodically inspect the applicant/licensee's programs for adequate assurance that IROFS are designed, procured, fabricated, and installed in accordance with approved design bases. The inspections will also ensure that as-built construction meets the approved design. In addition, the applicant/licensee's design change and design control process will be reviewed to gain additional assurance that the design process used for the facility effectively implemented NRC requirements and other licensing design commitments made by the applicant/licensee. These reviews may be accomplished by multi-disciplinary technical review and/or inspection teams to verify the quality of design products and, inferentially, the entire facility design.

08.03 Implementation. The RII DCP is responsible for managing and implementing the inspection program described in this IMC. This IMC is intended to provide the framework for managing the inspection effort. Where needed, sample sizes, frequencies of periodic inspections, and the time frame when certain inspection activities are to be performed are provided in the appropriate IP, IVP and/or inspection plan.

The inspection staff is expected to plan and conduct inspections based on risk considerations, current activities, and applicant/licensee performance. The DCP staff should develop, on at least an annual basis, a schedule of inspections to be conducted, based on the anticipated site activities that are to be performed in the upcoming year. The DCP staff should review and revise the schedule as needed to account for changes in site activities. The DCP staff should coordinate with FCSS on inspection program changes and document any changes from the planned inspections. The activities for conducting inspections should include the following:

- a. Developing and documenting detailed inspection plans.
- b. Scheduling and coordinating inspection activities in accordance with this IMC.
- c. Communicating inspection results, findings, and open items to appropriate NRC and applicant/licensee management.
- d. Documenting completed inspections, findings, and open items.

Inspection issues related to occupational health and safety should be evaluated in accordance with IMC 1007, Interaction Activities between Regional Offices of NRC and Occupational Safety and Health Administration (OSHA).

08.04 Inspection Requirements. Inspections will be based on 10 CFR Part 70 and other applicable regulations, commitments, conditions, the license application, MPQAP, and the construction authorization. Inspections will confirm that applicable regulations, requirements, and commitments have been met. Selection of inspection attributes will be based on safety considerations, status of work activities, and performance and are discussed in the IVPs.

08.05 Level of Effort. The level of effort will be determined by Region II by taking into account the total estimated resources allotted in the budget developed jointly by Region II and NMSS. Inspectors should charge to the IPs listed in Appendix A and other applicable TIs and activity codes provided by the DCP.

2630-09 INSPECTOR TRAINING AND QUALIFICATIONS

Only staff members who have been previously qualified as inspectors through IMCs 1245, 1246, 1247 or 1252 will be qualified to implement this IMC. The training completed by fully qualified inspectors combined with their field experience can be used, at management's discretion, to establish equivalency for many of the activities specified therein. The initial training and qualification requirements are divided into two phases: the construction phase and the post-construction phase. Refresher and continuing training activities are required as a means for

updating and maintaining qualification to keep up-to-date on changes to the inspection program and as a result of lessons learned from industry events and agency activities. Just-in-time training and additional specialized training may also be required to support critical inspection activities.

2630-10 INSPECTION FINDINGS AND ENFORCEMENT

10.01 Reports. Routine MFFF integrated construction IRs will normally be issued on a quarterly basis, unless otherwise determined by RII management. The inspection findings should be integrated into a single inspection report to encompass findings from resident inspections, in-office reviews, and/or one or more visits by regional or headquarters inspectors over a specific period of time (e.g., a 13-week period). Special inspections may be documented in a separate inspection report. IRs should identify specific PSSCs verification activities that are being inspected. During the construction of the PSSCs, Appendix B of this IMC will be used to evaluate and document construction inspection observations and to classify them as findings, if appropriate, after they have been placed in context and assessed for significance. Inspection findings identified during the pre-operational periods will be documented in accordance with Appendix B of this IMC, the IMC covering fuel facility inspection report writing (IMC 0616, Fuel Cycle Safety and Safeguards Inspection Reports), or any other format as directed by regional management, after they have been placed in context and assessed for safety significance. The findings will then be categorized as violations (VIO), non-cited violations (NCV), minor violations, inspector follow-up items (IFI), unresolved items (URI), or notice of deviations (NOD). The disposition of minor issues and minor violations will be in accordance with the screening guidance in IMC 0613, Power Reactor Construction Inspection Reports.

Traditional enforcement will be in effect for the construction of the MFFF as discussed in this IMC. Findings from inspections will be processed in accordance with 10 CFR Part 2 and applicable enforcement guidance using traditional enforcement tools, e.g., the use of severity levels and civil penalties as appropriate. The determination of the severity level of an apparent violation should consider its significance per Appendix B of this IMC and the Commission's current Enforcement Policy and Enforcement Manual.

10.02 Open Items. It is important to note that the applicant/licensee has been granted the authorization to construct the MFFF, and if the NRC determines that the construction is not in accordance with the applicant/licensee's commitments, then the operating license may be denied (see 10 CFR 70.23(a)(8)). The failure of the applicant/licensee to meet commitments specified in the LA shall be documented in the IRs as noted above. It is imperative that open items be appropriately documented in the IRs so that subsequent inspections can verify whether or not the applicant/licensee took the appropriate corrective actions. The failure of the applicant/licensee to take the appropriate corrective actions to address the open items by the end of the construction phase could result in either a denial to issue the operating license or a delay in the issuance of the operating license.

Any open items, and their closure, (e.g. violations, unresolved items, inspector follow-up items, allegations etc.) that affects PSSC verification, will be tracked in DIAMOND and will be monitored by DCP and NMSS staff. The DCP staff will work with the appropriate inspection staff to develop a plan to close any open items in the most efficient and effective method.

10.03 NRC Identified and Self-revealing NCVs. NRC identified and self-revealing NCVs will be documented in an IR. The description of the corrective actions taken or planned to take by the applicant/licensee, if known at the time the NCV is documented, should be in accordance with the Commission's current Enforcement Policy and Enforcement Manual. NCVs will be closed based on the applicant/licensee entering them into their corrective action program and their corrective actions will be sampled during NRC corrective action program inspections. The documentation should include the requirement(s) violated, describe how it was violated, identify the applicant/licensee's corrective action tracking number(s), and provide a very brief justification why the violation is greater than a minor violation and why the violation is not greater than SL IV. The following introductory paragraph should be included:

"This finding was determined to be a severity level (SL) IV violation using Section 6.5 of the Enforcement Policy. Because this was a SL IV violation and the example supporting the violation was entered into the applicant/licensee's corrective action program (corrective action tracking number(s)), this violation is being treated as a non-cited violation (NCV), consistent with the NRC Enforcement Policy."

10.04 Applicant/licensee-identified Violations. Applicant/licensee-identified violations are those items found through their own efforts rather than NRC inspections. The NRC will consider not issuing a Notice of Violation (NOV) for applicant/licensee-identified violations that would fall into the SL IV category and if the NCV criteria of the Commission's current Enforcement Policy are met. This consideration will be based on the results of the NRC's review of the applicant/licensee's corrective action program. Applicant-identified violations that are SL III or higher will be documented in an Inspection Report and a NOV will be issued.

Applicant/licensee-identified NCVs identified and corrected as part of the applicant/licensee's self assessment program will not normally be documented in the inspection report. When an applicant/licensee-identified SL-IV/NCV is documented in an inspection report, then the description of the corrective actions taken by the applicant/licensee in the inspection report should be in accordance with the Commission's current Enforcement Policy and the guidance in the current Enforcement Manual. The documentation should include the requirement(s) violated, describe how it was violated, identify the applicant/licensee's corrective actions that have been taken or plans to take and the corrective action tracking number(s), and provide a very brief justification why the violation is not greater than SL IV. The following introductory paragraph should be included:

"The following violation of low safety significance was identified by the applicant/licensee and is a violation of NRC requirements which meets the criteria of the NRC Enforcement Policy for being dispositioned as a Non-Cited Violation."

2630-11 ASSESSMENT

11.01 Overall Assessment Process. Typically, the regional office will conduct an applicant/licensee performance review (APR) using the inspection findings compiled over the previous 12 months (four quarters). This review should consider activities identified in the previous APR. The output of this review is an APR assessment letter to the applicant/licensee.

The 12-month assessment cycle will be from January 1 through December 31 of each year. The assessments will be based on the findings and conclusions documented in NRC IRs and any feedback on licensing performance received from the NMSS program office. Overall applicant/licensee performance will be based on the severity level and number of violations. The Agency's response and communication of applicant/licensee performance will follow the guidance in the Construction Action Matrix (CAM) (Exhibit 1 of this IMC).

11.02 Performance Reviews. The assessment process consists of a series of reviews which are described below.

- a. **Periodic Review.** The DCP staff, resident inspector(s), regional inspectors and the Branch Chiefs who participated in inspection activities during the quarter and the Chief, Construction Projects Branch 1 (CPB1) may optionally conduct a periodic review using the inspection findings and IRs conclusions compiled over the previous quarter. An assessment follow-up internal memo should be issued if the periodic review identified significant performance issues that resulted in changes to planned inspections. If applicant/licensee performance has declined resulting in changes to the planned inspections, an assessment follow-up letter to the applicant/licensee should be considered.
- b. **End-of-Cycle Review.** Region II will conduct an end-of-cycle review using documented inspection findings and inspection report conclusions compiled over the assessment period (typically a calendar year). This review incorporates activities from the periodic reviews.

In preparation for the end-of-cycle review, Region II will prepare a summary of inspection findings and documented conclusions related to applicant/licensee performance conducting special programs, a summary of allegations received and/or closed, and proposed inspections.

The end-of-cycle review is normally chaired by the Chief, CPB1 or his/her designee. If applicant/licensee performance has degraded to Column 2 or higher of the Construction Action Matrix (see Exhibit 1 of this IMC), then the end-of-cycle review should be chaired by the Division Director, Division of Construction Projects or, if appropriate, the Region II Deputy Regional Administrator for Construction or his/her designee. In cases of degraded performance, the DCI branch chiefs should coordinate with the Chief, CPB1, to provide adequate support for the presentation and development of the revised inspection plan. Other routine participants should include representatives from the NMSS/FCSS program office, applicable regional and resident inspectors, and any other additional participants deemed necessary by the regional office. The following representatives should also participate if there are pertinent performance issues that should be factored into the performance assessment: the regional Allegations Coordinator or the Agency Allegations Advisor, Office of Investigations, Office of Enforcement, and Office of Nuclear Security and Incident Response.

The assessment letter should be issued within nine weeks of the end of the assessment cycle.

11.03 Public Meeting with Applicant/licensee. Typically, Region II will conduct an end of cycle public meeting in the vicinity of the MFFF to communicate the results to the applicant/licensee and members of the public. Region II will coordinate with NMSS/FCSS for their participation in the meeting. If held, the meeting should be scheduled within 16 weeks of the end of the cycle. If a public meeting is conducted, Region II may consider using applicable portions of IMC 0305 or 2604 as guidance for conducting this meeting.

The involvement of the public in the results of the NRC's assessment of applicant/licensee performance is intended to provide an opportunity for the NRC to engage interested stakeholders on the performance of the facility and the role of the NRC in ensuring safe and quality conduct of construction activities.

The assessment letter provides the minimum performance information that should be conveyed to the applicant/licensee in a public meeting, if conducted. However, this does not preclude the presentation of additional facility performance information when placed in the proper context. The applicant/licensee should be given the opportunity to respond at the meeting to any information contained in the assessment letter. The applicant/licensee should also be given the opportunity to present to the NRC any new or existing programs that are designed to maintain or improve their current performance.

If a meeting is held with the applicant/licensee, it will be a Category 1 public meeting in accordance with the Commission's policy on public meetings, with the exception that the meeting must be closed for such portions which may involve matters that should not be publicly disclosed under Section 2.390 of Title 10 of the *Code of Federal Regulations* (10 CFR 2.390). Members of the public, the press, and government officials from other agencies are considered as observers during the conduct of the meeting. However, attendees should be given the opportunity to ask questions of the NRC representatives after the conclusion of the meeting.

Public involvement in the results of the NRC's assessment of applicant/licensee performance should focus on topics of interest to the public. In lieu of a public meeting, the format for the public involvement could include an open house, round table discussion, or poster board session. For higher-profile interactions, consideration should include NRC or non-NRC facilitators.

11.04 Assessment Areas. The following assessment areas and associated attributes should be used to assess MFFF performance. Depending on the stage of the construction project, not all assessment areas would be applicable during a given assessment period.

- a. Quality Assurance Program. The requirements of the QA program are effectively implemented, including design control. Design control activities are conducted in accordance with facility procedures and the QA plan. Engineering activities are effective in ensuring the plant is constructed in accordance with the approved design and authorized design changes.

- b. Construction Oversight.
 - 1. Construction Activities. Construction activities are conducted in accordance with the construction authorization and QA program. The applicant/licensee recognizes non-routine events affecting safety and effectively implements the corrective action program.
 - 2. Maintenance Activities. Maintenance activities, including PSSC maintenance activities (when applicable) are conducted in accordance with the applicant/licensee's maintenance procedures and the QA program. Activities are effective in preparing PSSCs and IROFS for operation.
- c. Pre-operational Oversight.
 - 1. Pre-Operational Activities. Pre-operational activities (when applicable) are effective and ensure systems and components important to the safety of the facility are fully tested to demonstrate that they satisfy design requirements. Management controls and procedures necessary for operation of the facility are effectively implemented.
 - 2. Startup Testing Activities. Startup testing activities (when applicable) are effectively implemented to provide for the safe startup testing of the facility during both routine and upset conditions, to recognize non-routine events affecting safety, use an internal reporting system, and to identify and execute corrective actions to return the facility to a safe and secure pre-operational condition after possible upsets.
 - 3. Training and Qualification of Plant Personnel. The training and qualification program (when applicable) is effective in training of personnel including managers, designers, technical staff, construction personnel, technicians, inspectors and other personnel whose level of knowledge is relied on for safety.
- d. Operational Readiness Activities. Activities completed during the operational preparedness phase to support the transition from construction to operation. The following performance areas should be coordinated with DFFI and NSIR to assess applicant/licensee performance:
 - 1. Safety Operations. The safety operations performance area includes the inspectable areas pertaining to plant operations, nuclear criticality safety, and fire protection.
 - 2. Safeguards. The safeguards performance area includes the inspectable areas pertaining to material control and accounting (MC&A), physical protection of special nuclear material, and classified material and information security.
 - 3. Radiological Controls. The radiological controls performance area includes the inspectable areas pertaining to radiation protection, environmental protection, waste management, and transportation.

4. Facility Support. The facility support performance area includes the inspectable areas pertaining to maintenance and surveillance of safety controls, management organization and controls, operator training, emergency preparedness, emergency exercise evaluation, and permanent plant modifications.
- e. Other Areas. This performance area is intended to include special issues that may arise on an occasional basis, but are not included in the review on a routine basis unless the significance of the issue rises to a level that is perceived to affect the quality of applicant/licensee performance. Examples include quality of licensing submittals, deviations from commitments in confirmatory action letters or confirmatory orders, licensing of new processes at an existing facility, and labor difficulties.

11.05 NRC Actions in Response to Applicant/licensee Performance Issues. The optional quarterly or the end-of-cycle assessment panels will determine the NRC response to significant performance issues. The staff may consider performance issues that extend across two or more performance areas and/or across two or more areas within a single performance area. Significant performance issues are defined as Severity Level I, II, and III violations.

- a. Description of the CAM. The CAM (Exhibit 1) was developed with the philosophy that, within a certain level of performance (i.e., Column I), applicant/licensees would address their performance issues without additional NRC engagement beyond the routine inspection program. Agency action beyond the routine inspection program will normally occur only if assessment input thresholds are exceeded. The CAM identifies the range of NRC and applicant/licensee actions and the appropriate level of communication for varying levels of applicant/licensee performance.

Overall response to applicant/licensee performance will be determined by the number and severity of violations. The CAM uses a graded approach in determining the response to the identified issues. This graded approach will result in an increase in sampling in the area(s) of concern, an increase in the IROFS being inspected, and/or the issuance of a Confirmatory Action Letter (CAL), Demand for Information, and/or the issuance of an Order. Increased inspection will be conducted through the use of supplemental construction inspections.

- b. Expected Responses for Performance in Each CAM Column. The CAM lists expected NRC and applicant/licensee actions based on the inputs to the assessment process. Actions are graded such that the agency becomes more engaged as applicant/licensee performance declines. Listed below are the ranges of expected NRC and applicant/licensee actions for each column of the CAM:
 1. CAM Column I. Violations that are not greater than SL IV. The applicant/licensee will receive only the routine inspection program and identified deficiencies will be addressed through the applicant/licensee's CAP.
 2. CAM Column II. There are no more than two SL III violations. The applicant/licensee is expected to place the identified deficiencies in its CAP and

perform an evaluation of the root and contributing causes. The applicant/licensee's evaluation will be reviewed during subsequent inspections. Following completion of the inspections, the branch chief or division director should discuss the performance deficiencies and the applicant/licensee's proposed corrective actions with the applicant/licensee, typically during an inspection exit meeting, at a periodic NRC management visit, or during a conference call with the applicant/licensee.

3. CAM Column III. A combination of three SL III violations or one SL II violation. The applicant/licensee is expected to place the identified deficiencies in its CAP and perform an evaluation of the root and contributing causes for both the individual and the collective issues.

The applicant/licensee's evaluation will be reviewed during subsequent inspections. Also, an independent assessment of the extent of condition will be performed by the region. Following completion of the inspections, the Deputy Regional Administrator for Construction (DRAC), or designee, should discuss the performance deficiencies and the applicant/licensee's proposed corrective actions with the applicant/licensee, typically during a public meeting with the applicant/licensee.

4. CAM Column IV. One SL I violation, multiple SL II violations, or a combination of the following: one SL II and a total of four SL III violations; or a total of seven or more SL III violations. The applicant/licensee is expected to place the identified deficiencies in its CAP and perform an evaluation of the root and contributing causes for both the individual and the collective issues. This evaluation may consist of a third party assessment.

Inspection(s) will be performed to review the breadth and depth of the performance deficiencies. The construction supplemental inspection plan must be approved by the appropriate regional division director with concurrence of the Director, FCSS.

Following the completion of the inspection, the Regional Administrator (or designee) and the Director, NMSS will decide whether additional agency actions are warranted. These actions could include additional construction supplemental inspection, a Demand for Information, a CAL, or issuance of an Order, up to and including a stop work order. At a minimum, the regional office will issue a CAL to document the applicant/licensee's commitments as discussed in their Performance Improvement Plan, as well as any other written or verbal commitments. The Regional Administrator should document the results of their decision in a letter to the applicant/licensee. Typically, these results will be discussed during a public meeting between the applicant/licensee and the Regional Administrator (or designee).

Note: Other than the CAL, the regulatory actions listed in this column of the CAM are not mandatory. However, the regional office should consider each of these regulatory actions when significant new information regarding applicant performance becomes available.

Due to the depth and/or breadth of performance issues reflected by a plant being in Column IV of the CAM, it is prudent to ensure that actual performance improvements have been made prior to closing out the violations and exiting Column IV of the CAM. In making this determination, the regional office should consider whether:

- (a) New site issues or violations do not reveal similar significant performance weaknesses;
- (b) The applicant/licensee's performance improvement program has demonstrated sustained improvement;
- (c) NRC supplemental construction inspections show applicant/licensee progress in the principal areas of weakness;
- (d) There were no issues that led the NRC to take additional regulatory actions beyond those already taken due to the applicant/licensee being in Column IV of the CAM. Additionally, the applicant/licensee has made significant progress on any regulatory actions that were imposed (e.g., CALs, orders) because of the performance deficiencies that led to the Column IV designation.

After the original violations have been closed out, the applicant/licensee will return to the CAM column that is represented by the other outstanding inputs to the CAM. Additionally, for a period of up to one year after the initial violations have been closed out, the regional office may use some actions that are consistent with Column III or Column IV of the CAM in order to ensure the appropriate level of agency oversight of applicant/licensee improvement initiatives. These actions, which do not constitute a deviation from the CAM, include senior management participation at periodic meetings/site visits focused on reviewing the results of improvement initiatives (such as efforts to reduce corrective action backlogs and progress in completing the applicant/licensee Performance Improvement Plan) and CAL follow-up inspections. The actions taken above those required by the CAM shall be discussed at the next APR meeting to ensure an appropriate basis for needing the additional actions to oversee the applicant/licensee improvement initiatives. These actions will also be described in subsequent performance review assessment letters until the NRC determines the actions have been completed in a satisfactory manner.

5. The regional office must convey the specific actions that the applicant/licensee needs to address to resolve the violations that caused the applicant/licensee to enter Column IV. Until the violations are addressed, the applicant/licensee will remain in Column IV.

2630-12 TRANSITION TO OPERATIONS ACTIVITIES

12.01 Operational Readiness Reviews. The NRC may consider the use of phased ORR inspections as a tool to provide input for NRC decisions regarding the operational readiness of MFFF areas or processes. In order to support a decision on issuance of a license to possess special nuclear material, NRC senior management reviews and assesses the state of readiness of facility operation based on the results of the ORR inspection(s). The status of previously identified inspection findings are also considered during the decision-making process. Appendix H provides guidance related to the ORR.

12.02 The overall approach for transitioning to operations activities will be in accordance with this IMC as stated below.

- a. The transition of the MFFF to operations will be a phased approach. The basis for why a certain program will be declared ready to be monitorable under IMC 2600 will be contained in the MFFF Transition Plan which shall be developed by Region II prior to the beginning of implementation of IMC 2600 at the MFFF.
- b. The Region II MFFF Transition Plan will adhere to the guidelines stated in this IMC and will be composed of transition tables. Each transition table will contain the records that verify that a program is fully monitorable (what inspection criteria were performed and when; whether inspection criteria were completed in their entirety or just in part with any exceptions or deviations noted; what significant open items, startup issues, licensing actions, or regulatory issues were resolved; the identified inspection findings and the corresponding applicant/licensee corrective actions). Based on the decision of Region II management with the concurrence of NMSS, that program will be placed under the oversight of IMC 2600.
- c. The MFFF Transition Plan should specify the required inspection procedures to be performed, when one or more programs are ready to be monitored by IMC 2600. The transition plan should also include a determination that startup issues, if applicable, have been resolved and confirm that the applicant/licensee's corrective actions were effective.
- d. The transfer of the MFFF to the full oversight of IMC 2600 will be by written approval of the Regional Administrator with the concurrence of NMSS. This transfer may occur even if all safety programs are not available, provided compensatory inspections are conducted as provided for by IMC 2600. Prior to this point in time, identifying the need for additional NRC inspections and determining the response to inspection findings or events will be by the assigned Region II branch chiefs in accordance with the

assessment process in Section 11 of this IMC. Subsequently, IMC 2600 will dictate what inspections should be implemented and what safety programs should be reviewed in determining the performance of the MFFF and also what will be the regulatory response for inspection findings or events.

2630-13 INTERFACE WITH RELATED PROGRAMS

13.01 Security and Safeguards Inspections. As with all other program areas, Region II will determine, as early as possible, when security program areas are ready to be monitored under the IMC 2600 baseline. NMSS and Region II will work closely with NSIR to ensure physical protection inspections are appropriate for any specific MFFF activities that are unique to the MFFF.

13.02 Operational Safety Inspections. Region II will determine, as early as possible, when the operational safety program areas are ready to be monitored under the IMC 2600 baseline. NMSS/FCSS and Region II/DCP will work closely with DFFI to ensure the operational safety inspections are implemented appropriately to ensure an effective transition from construction to operations (see Section 2630-12 of IMC 2630).

2630-14 REFERENCES

Duke, Cogema, Stone, and Webster, "Mixed-Oxide Fuel Fabrication Facility Construction Authorization Request," February 9, 2005 (latest revision accepted by NRC)

Shaw AREVA MOX Services, "Integrated Safety Analysis (ISA) Summary for the Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF)," Aiken, SC (latest version)

Shaw AREVA MOX Services, "License Application for the Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF)," Aiken, SC (latest version)

U.S. Code of Federal Regulations, Title 10, Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"

U.S. Code of Federal regulations, Title 10, Part 70, "Domestic Licensing of Special Nuclear Material"

U.S. Nuclear Regulatory Commission, "Enforcement Manual," Revision 9, September 9, 2013

U.S. Nuclear Regulatory Commission, "Enforcement Policy," (latest version)

U.S. Nuclear Regulatory Commission, "Standard Review Plan for the Review of an Application for a Mixed-Oxide Fuel Fabrication Facility," NUREG-1718, August 2000

U.S. Nuclear Regulatory Commission, "Final Safety Evaluation Report for the License Application To Possess and Use Radioactive Material at the Mixed Oxide Fuel Fabrication Facility in Aiken, SC," December 2010

U.S. Nuclear Regulatory Commission, "Final Safety Evaluation Report on the Construction Authorization Request for the Mixed Oxide Fuel Fabrication Facility at the Savannah River Site, South Carolina," NUREG-1821, March 2005

END

Appendix A

MIXED-OXIDE (MOX) FUEL FABRICATION FACILITY INSPECTION PROGRAM CONSTRUCTION PHASE INSPECTION PROCEDURES (INSPECTION PROCEDURES MAY BE ADDED OR DELETED TO THE INSPECTION PROGRAM AS REQUIRED)

QA Inspection Procedures

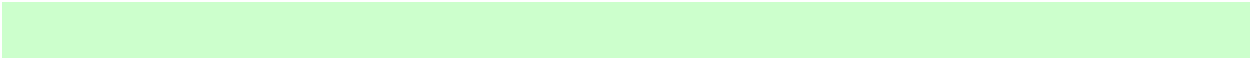
- IP 88106 Quality Assurance: Program Development and Implementation
- IP 88107 Quality Assurance: Design and Documentation Control
- IP 88108 Quality Assurance: Control of Materials, Equipment, and Services
- IP 88109 Quality Assurance: Inspection, Test Control, and Control of Measuring and Test Equipment
- IP 88110 Quality Assurance: Problem Identification, Resolution, and Corrective Action
- IP 88111 10 CFR Part 21 Inspection-Facility Construction
- IP 88112 Software Quality Assurance (under development)
- IP 88113 Control of the Electronic Management of Data
- IP 88114 Quality Affecting Item Procurement (10 CFR Part 21) and Commercial Grade Item Dedication Process (Reactive)
- IP 88115 Supplier/Vendor Inspection
- IP 88116 Inspection of Safety Function Interfaces for the Mixed Oxide Fuel Fabrication Facility (Pre-Licensing And Construction)
- IP 88117 Facility Change Process (under development)

Resident Inspector Procedures

- IP 88130 Resident Inspection Program for On-Site Construction Activities at the Mixed Oxide Fuel Fabrication Facility

Construction Inspection Procedures

- IP 88131 Geotechnical/Foundation Activities
- IP 88132 Structural Concrete Activities
- IP 88133 Structural Steel and Supports Activities
- IP 88134 Quality Assurance: Piping Relied on For Safety
- IP 88136 Mechanical Components
- IP 88137 Electric Cable

- IP 88138 Electrical Components and Systems
 - IP 88139 Ventilation and Confinement Systems
 - IP 88140 Instrumentation and Control Systems
 - IP 88143 Pipe Supports and Restraints
 - IP 55050 Nuclear Welding General Inspection Procedure
 - IP 55100 Structural Welding General Inspection Procedure
 - IP 88141 Fire Prevention and Protection
 - IP 88142 Underground Fire Water Loop and Equipment Installation
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Appendix B

Documenting Inspection Results

1. PURPOSE

To provide guidance for documenting Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF) construction inspection results.

2. BACKGROUND

The MFFF is a plutonium processing and fuel fabrication plant under construction that is currently inspected under the 10 CFR Part 70 construction inspection program. Inspectors should refer to Inspection Manual Chapter (IMC) 0616, Fuel Cycle Safety and Safeguards Inspection Reports, for guidance on inspection report (IR) content, format, and style. During the construction of the principal systems, structures and components (PSSCs), this appendix (Appendix B) will be used as supplemental guidance to evaluate and document construction inspection observations and findings after they have been placed in context and assessed for significance. In addition, the applicable portions of IMC 0613, Power Reactor Construction Inspection Reports, should be used to disposition minor issues and minor violations. For the purposes of this IMC, a minor violation is defined as a violation that is less significant than a Severity Level IV violation, is not the subject of formal enforcement action, and is not usually documented or described in an IR or inspection record.

With regard to the disposition of non-cited violations (NCVs), the Nuclear Regulatory Commission (NRC) Enforcement Policy was revised on January 28, 2013, and allows licensees and non-licensees to receive NCVs in lieu of cited violations, if certain criteria are met. The most significant of these criteria is that the licensee or non-licensee has a corrective action program (CAP) that has been inspected and found to meet regulatory guidance, industry standards, or both. In a letter dated February 14, 2013⁴, the NRC staff determined that Shaw AREVA MOX Services (MOX Services) had established a documented CAP as part of its NRC approved quality assurance (QA) program that complies with Appendix B to 10 CFR Part 50. The NRC has performed annual programmatic inspections of MOX Services' CAP, since nuclear construction began in 2007. Based on input from these inspections, the NRC staff determined that MOX Services has established a CAP that is consistent with the commitments in the NRC-approved QA program and meets Appendix B to 10 CFR Part 50. The change in the Enforcement Policy allows NRC identified Severity Level IV violations to be treated as NCVs at the MFFF.

⁴ Letter from USNRC to Shaw Areva MOX Services, dated February 14, 2013 (ML13030A333)

3. DEFINITIONS

Refer to IMCs 0616 and 0613 for applicable definitions of terms used in this appendix.

4. RESPONSIBILITIES

NRC inspectors conducting inspections at the MFFF are required to prepare IRs in accordance with the guidance provided in this appendix. General and specific responsibilities are listed below.

4.01 General Responsibilities. Each inspection of the MFFF should be documented in a report consisting of a cover letter, a cover page, an executive summary, and inspection details.

4.02 Report Issuance. The inspector's branch chief is responsible for the report content, conclusions, and overall regulatory focus. For integrated construction IRs, the Construction Projects Branch 1 (CPB1) branch chief is responsible for issuing the report to the applicant/licensee.

4.03 Report Timeliness.

- a. General Timeliness Guidance. Integrated construction IRs should be issued no later than 45 calendar days after inspection completion. RII management may provide additional guidance on IR issuance timeliness goals.

NOTE: Inspection completion is normally defined as the day of the exit meeting. For integrated IRs, inspection completion is normally defined as the last day covered by the inspection report.

- b. Reports Preceding Escalated Enforcement Actions. Timeliness goals should be accelerated for IRs covering potential escalated enforcement actions. For specific enforcement timeliness goals, see the NRC Enforcement Manual.
- c. Expedited Reports for Significant Safety Issues. Whenever an inspector identifies an issue involving significant or immediate public health and safety concerns, the first priority is facility and public safety; issues of documentation or enforcement action are secondary. Based on the circumstances of the case, an expedited inspection report may be prepared that is limited in scope to the issue, or expedited enforcement action may be taken before the inspection report is issued. The NRC Enforcement Manual provides additional guidance on matters of immediate public health and safety concern.

5. GUIDANCE - INSPECTION REPORT CONTENT

This section relates primarily to matters of content in the inspection report details. For guidance on the content of report cover letters, IR content, format, and style, refer to IMC 0616. The IR should include a paragraph for programmatic area(s) inspected; each principal system, structure, and component inspected; and inspection attributes. The IR should also list the inspection procedure, temporary instruction or generic communication inspected. The paragraphs should be organized in ascending order.

5.01 Narrative Report Details. The detailed discussion in the Narrative Report provides the information which forms the bases upon which the other sections of an inspection report are developed. In most cases, the detailed discussion will be organized into one or more sections, each addressing an area of inspection. Report details should be structured in terms of the areas inspected, as noted below.

The first section and subsequent sections should address the following:

1. Summary of Facility Status
2. Routine Resident Inspector Activities (list inspection procedure(s) used)
3. PSSC Related Inspections
 - a. PSSC-00x
 - (1)Attribute (and inspection procedure(s) used)
 - a) *Scope and Observations*
 - b) *Conclusions*
4. Programmatic Inspections
 - a. Program Area (and inspection procedure(s) used)
 - (1)Scope and Observations
 - (2)Conclusions
5. Follow-up of Previously Identified Items
 - a. (Item Status - Closed, Open, or Reviewed) Item Type (VIO, NCV, URI, or IFI), Item Tracking Number, Item Description
 - (1)Scope and Observations
 - (2)Conclusions
6. Exit Interviews

Normally, each following section should be divided into two parts: 1) Scope and Observations; and 2) Conclusions. Scope and Observations should consist of paragraphs that describe the scope of the inspection followed by the observations and resultant findings within the defined scope of that paragraph. Observations should be factual and not hunches, speculation, unsubstantiated hearsay, or unverified opinions and they should only be documented in the report when they are relevant to the inspection program or support a PSSC specific or programmatic conclusion. The section ends with a stated conclusion based on the inspector's observations and findings. In general, conclusions should focus on the capability of the program or activity to accomplish its design basis function. In assessing this capability, the conclusion statements may take various forms, but they should in all cases be concrete and supportable.

5.02 Thresholds of Significance. As part of maintaining a focus on safety, inspectors continually use NRC requirements, inspection procedures, industry standards (as required), regional and headquarters guidance, and their own training and insight to make judgments about which issues are worth pursuing and which are not.

To communicate effectively, IRs must give evidence of that judgment and prioritization, discussing significant safety issues in appropriate detail, treating less significant issues succinctly, and avoiding excess verbiage. To maintain some consistency in how minor issues are treated, report writers must recognize certain "thresholds of significance": that is, they must use similar criteria in deciding whether an issue is important enough to document, track or follow up.

The NRC Enforcement Policy acknowledges that some violations of minor safety, environmental, and regulatory concerns are below the level of significance of SL IV violations. Because of their minor nature, these minor violations are not the subject of formal enforcement action and are not usually documented in IRs.

NOTE: For additional guidance in this area, see the NRC Enforcement Manual and IMC 0613.

- a. Minor Violations--Determining Significance. Use IMC 0613 to determine the significance of the violations.
- b. Minor Violations--Determining Whether to Document. In general, minor violations should not be documented; however, certain exceptions apply. Documentation may be necessary as part of the resolution to an allegation. In other cases, while the violation itself is minor, the associated technical information may relate directly to an issue of agency-wide concern (e.g., the inspection was performed in response to an NRC Temporary Instruction . If, for these reasons or any other reason, the report writers and reviewers wish to document a minor violation, then it should be documented as a minor violation, with a reference to Section IV of the NRC Enforcement Policy. For example, "This failure constitutes a violation of minor significance and is not subject to formal enforcement action."
- c. Applicant/licensee Identified Violations. Under certain circumstances, even a violation that could be classified as SL IV ("more-than-minor") need not be documented. This is generally justified when the violation has been identified and corrected as part of an applicant/licensee self-assessment effort. As a matter of policy, NRC enforcement seeks to encourage applicant/licensee self-assessment efforts, and seeks to avoid the negative impact that can result from a redundant NRC emphasis on problems which the applicant/licensee's responsible action has already identified and corrected.

For example, suppose that while evaluating the applicant/licensee's QA efforts in the fire protection area, an inspector reviews relevant audits and surveillances conducted over the previous year. The review reveals that the audits have been probing and thorough; the findings are well-developed and technically sound, and include six noncompliance issues, four of which might be classified at SL IV.

In such a case, the inspector should follow up on the noncompliances and other audit findings to ensure that causes have been appropriately assessed, that appropriate and comprehensive corrective actions have been taken, and that no new examples of the violations exist. Normally, the inspector would not cite the four violations individually or report the details of those violations in the inspection report assuming that no new issues are revealed by this follow-up. Instead, the inspection report findings and conclusions should assess the adequacy of the applicant/licensee's QA efforts, including a clear reference to the name, dates, and general subject matter of the audit or self-assessment.

NOTE: This expectation only applies to SL IV violations. Even when identified through an applicant/licensee self-assessment, violations that could be categorized at SL III or above must be documented in the inspection report and given appropriate follow-up.

The violation must be clearly dispositioned in the report if, for any reason, the inspector decides to discuss a particular applicant/licensee's self-assessment or audit finding in the inspection report and that finding involves a violation. The SL IV violation should be documented as an NCV if the criteria of the latest revision to the NRC Enforcement Policy have been met (including applicant/licensee corrective action, etc.). Minor violations are not routinely documented in IRs. However, as stated in the Enforcement Policy and Enforcement Manual, there may be exceptions. Documenting a minor violation may be warranted as part of closing out a licensee event report (LER), unresolved item, or follow-up to an allegation. Licensees are required to correct minor violations. When it is necessary to document a minor violation, only minimal discussion is required. Briefly describe the issue of concern, state that the issue has been addressed by the applicant/licensee and include the following:

“This failure to comply with [requirement] constitutes a violation of minor significance that is not subject to enforcement action in accordance with the NRC's Enforcement Policy.”

NOTE: The NRC Enforcement Manual provides additional guidance on documenting and dispositioning violations.

5.03 Level of Detail. Just as inspectors must use judgment in determining what issues are worth including in the inspection report, they must also determine the appropriate level of detail for issues that are included. Some issues should be discussed in more detail than others, based on safety or regulatory significance, technical complexity, and other factors.

- a. Level of Detail on Inspection Scope and Observations.

The level of detail for the scope should include the following:

- 1) Identify how the inspection was conducted (i.e., the methods of inspection.)
Methods can include a walk-down, an in-office review, observation of test from the control room, or discussion with specific personnel.
- 2) Identify what was inspected. Include sufficient detail on which and how many samples were inspected. If more than six documents were reviewed, then list the items in an attachment and reference the attachment in the Scope and Observations section.

- 3) Identify the inspection objectives and the criteria that were used to determine whether the applicant/licensee is in compliance.
 - 4) Include inspection dates to clarify inspection scope context if it helps with understanding the scope. For example, inspection dates may be helpful when discussing event follow-up.
 - 5) If a substantive portion of the inspection activity was conducted at a location other than the plant, (e.g., an in-office review), then identify where the inspection took place.
- b. Once the inspector has decided that an observation or a finding is important enough to be included in the report, the same questions used in making that decision can assist in determining the appropriate level of detail. The following guidance applies for the level of detail:
- 1) The degree of actual or potential safety consequence associated with a finding should be a primary consideration in determining the level of appropriate detail. Items of higher significance generally merit more discussion.
 - 2) If the inspector has concluded that a finding has programmatic aspects (e.g., multiple examples of the problem, a related series of failures, an underlying procedure or training deficiency, or diverse effects resulting from the same root cause), enough detail should be given to support this conclusion.
 - 3) Findings of greater technical significance--that is, findings that give insights into items relied on for safety (IROFS) or human performance issues, or findings that could have generic significance--should be discussed in sufficient detail to communicate those insights.
 - 4) When initiating an unresolved item or inspection follow-up item, the issue description should provide enough background information that a different inspector, using that information, would be equipped to perform the follow-up inspection.

5.04 Documenting Noncompliances. When documenting noncompliances in the inspection report, the NRC staff will consider the use of four part write-ups. The primary guidance for matters related to enforcement, including documentation, is given in the NRC Enforcement Policy and the NRC Enforcement Manual. These documents can be found at <http://www.nrc.gov/about-nrc/regulatory/enforcement/guidance.html>. The following discussion summarizes certain aspects of that guidance related to IRs.

- a. Types of Noncompliances. The manner of documenting a noncompliance in the inspection report depends on how that noncompliance will be dispositioned. A noncompliance may be addressed as a non-escalated enforcement action (i.e., a SL IV violation or a nonconformance); as an escalated enforcement action (i.e., an apparent SL I, II, or III violation); or as an NCV.

A finding or observation is not discussed in the IR if a violation does not exist (e.g., no requirement exists for the area).

- 1) Non-Escalated Enforcement Actions. Most violations of very low significance (i.e., more than minor concerns) fall into the SL IV category. If at the time of issuing the inspection report a violation has been categorized at SL IV, and it does not meet the criteria for an NCV, then an NOV is generally sent out with the inspection report as a non-escalated enforcement action. The cover letter for reports that include non-escalated enforcement actions should follow the appropriate NRC Enforcement Manual guidance.
- 2) Potential Escalated Enforcement Actions. When an issue is being considered for escalated enforcement action, the inspection report narrative should refer to the potential noncompliance as an apparent violation. The report details should not include any speculation on the severity level of such violations nor on expected NRC enforcement sanctions. Potential escalated actions, by their nature, require further agency deliberation (and, usually, additional applicant/licensee input) to determine the appropriate severity level and NRC action.

Similarly, report narratives that discuss apparent violations should be carefully constructed to avoid making explicit conclusions (i.e., final judgments) about the safety significance of the issue. The report should include any available details that give evidence of safety significance, or that would help in making such a decision; however, since a potential escalated enforcement action automatically entails further evaluative steps, neither the inspection report details nor the accompanying cover letter should present a final judgment on the issue. The accompanying cover letter should include the escalated enforcement action (EA) number obtained from the Enforcement and Investigation Coordination Staff (EICS).

- 3) Non-Cited Violations. Per the most recent revision of the NRC Enforcement Policy, SL IV violations can be dispositioned as NCVs. When SL IV violations are dispositioned as NCVs, the report should briefly describe their circumstances and the description of the corrective actions taken or planned to be taken by the applicant/licensee, if known at the time the NCV was documented in the inspection report, and should be in accordance with the Commission's current Enforcement Policy. The report should clearly state what regulatory requirements were not met.
- 4) Minor Violations. Minor violations are not normally documented in IRs. However, to the extent that documentation is necessary, the standard language should be used: "This failure constitutes a violation of minor significance and is not subject to formal enforcement action;" and the report should clearly state why the violation was of minor significance.

END

Appendix C

Independent Verification Plans (IVPs)

1. PURPOSE

The purpose of the IVP is to provide an efficient, effective, and auditable method for implementing the Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF) Construction Inspection Program (CIP) as it relates to the licensing process and compliance with 10 CFR 70.23(a)(8) for the MFFF. 10 CFR 70.23(a)(8) states that an application for a license will be approved if the Commission determines that, where the proposed activity is the operation of a plutonium processing and fuel fabrication plant, construction of the principal systems, structures, and components (PSSCs) approved pursuant to 10 CFR 70.23 (b) has been completed in accordance with the application. Thus, in accordance with 10 CFR 70.23(a)(8), the staff has determined that the license to possess and use special nuclear material will not be issued before a determination that construction of the principal structures, systems, and components approved pursuant to section § 70.23(b) is in accordance with the application.”

2. IVP PROGRAM⁵

The verification of the construction of a PSSC will vary depending on the type and nature of the system, structure, or component. In some cases, a PSSC may be an administrative control (e.g., combustion loading controls for fire prevention), an active or passive engineering control, use of an approved item (e.g., 3013 transport cask approved under 10 CFR Part 71), or some combination of the above. Verification of PSSCs includes evaluations of procedures associated with administrative controls as well as engineered controls. To support the verification, inspection planning associated with PSSCs also includes construction scheduling provided by the applicant/licensee such as the installation of safety related tanks in process cells that will be inaccessible for inspection after process cells are sealed.

As applicable to the specific type of PSSC, NRC construction inspection and/or the technical review programs will verify that the construction of each PSSC listed in Table 5.6-1 of the MFFF Construction Authorization Request (CAR) have been completed and the design basis safety function can be met. The item relied on for safety (IROFS) related to a specific PSSC can range from one to several thousand and will be inspected based on a prioritized sampling approach to assure that there is reasonable assurance that the PSSC construction is completed and is in accordance with the application.

Section 1 of the IVP contains a description of the PSSC or PSSC family (a table of PSSC families can be found in Appendix D of this IMC) including a discussion of the integrated safety analysis (ISA) events related to the PSSC and the safety functions as stated in the CAR and the license application (LA). The IVPs show the prioritized integrated safety analysis summary (ISAS) IROFS and the IROFS components from which a sampling will be inspected by regional inspectors or the resident inspectors, as appropriate. Additionally, a sampling of prioritized administrative control IROFS to be reviewed by headquarters technical reviewers is included.

⁵ The IVPs were categorized as, “Official Use Only – Security Related Information, Pre-Decisional” due to the proprietary and security related information contained in the ISAS.

Technical staff will use a specific administrative control review procedure for reviewing administrative controls associated with the PSSCs.

Section 4 of the IVP also provides the level of inspection effort (LOIE) values and appropriate attributes to select in the inspection or review for each PSSC within the family. The LOIE values are also maintained in the PSSC Central section in Digital Information Archive for MFFF and Online Normalized Database (DIAMOND). The LOIE for each PSSC indicates the number of attributes that should be inspected (see Appendix F of the IMC).

Sections 2 and 5 of the IVP discusses the inspection activities to be performed to verify the construction of the PSSCs has been completed in accordance with the application. The inspectors should select the corresponding inspection procedures based on the attributes selected from the LOIE section. The attributes listed in the IVP should be selected in the ranges provided for each PSSC.

Section 6 of the IVP contains information on the associated PSSC IROFS and families. There are several IROFS that are identified in the IVP which are associated with another IVP or IVPs. The inspection or review results from correlated IVPs needs to be documented and inspection or review information needs to be included or referenced in the verification documentation. The IVP also identifies where associated PSSCs or IROFSs have been evaluated.

Section 7 of the IVP is "Other Planning Considerations." The section states that, as applicable, inspection results from previously performed programmatic inspections, such as quality assurance (QA) program or correction action program, may be used or referred to during the conduct of the onsite inspections to inform inspections and support verification.

Section 8.1 of the IVP, entitled "Regional Inspections," includes the details of the type of inspections and IROFS component types that should be inspected as part of the verification activities. The list of inspections selected was based on the the Office of Nuclear Material Safety and Safeguards (NMSS)/Region II staff evaluation of the prioritization of IROFS components and a determination of the most appropriate inspection activities for regional inspectors. The IVPs leave flexibility for the inspectors as to the selection of inspection attributes and the sampling of prioritized IROFS or components.

Section 8.2 of the IVP, entitled "Resident Inspector Activities," discusses the inspection that the resident inspectors should perform onsite using applicable portions of the inspection procedures for IROFS or components that are not being inspected or attributes not evaluated as part of regional inspections. The resident inspectors should evaluate the appropriate number of attributes listed in Section 4 (LOIE). The inspectors should also examine, on a sampling basis, the IROFS and components listed in the IVP. The sampling should include at least one IROFS component from each prioritized ISAS IROFS.

The inspector should consider inspections for component receipt, comparing the design or installation drawings to the as-built condition, onsite component fabrication/construction (welding) activities and installation activities. Also, the resident inspectors should inspect the IROFS that may not be readily accessible during operation.

Section 8.3 of the IVP, entitled "Headquarters Activities," lists the prioritized administrative IROFS that can be sampled and reviewed by Headquarters using the specific administrative control review inspection procedure.

Section 8 of the IVP will also be used by the regional project inspector (RPI) to track the completion progress of PSSC inspection activities.

USE OF THE IVPs

The IVP is a summary planning document that the staff has developed to document what inspection or review activities of PSSCs are needed to make a finding with respect to 10 CFR 70.23(a)(8). The IVP documents the regional inspections that need to be performed, the inspection attributes that need to be selected, the IROFS components that are to be evaluated on a sampling basis by the inspection staff, and the administrative IROFS that will also be reviewed by technical staff.

The latest revisions of the IVPs are maintained in DIAMOND. The RPI is responsible for planning and developing the master inspection plan (MIP) for the MFFF. The scheduled inspections include those identified in the IVPs as well as programmatic inspections that support the PSSC verifications including the QA program and corrective action program. The MIP is designed to assure that the inspections identified in the IVPs are completed. These details and scheduling of the identified inspections are coordinated with the RPI, resident inspectors, and the applicant/licensee.

Once an inspection is scheduled by the RPI, a lead inspector will be identified to either conduct or lead a team inspection. This individual and his/her inspection team are chosen based on the technical expertise required to perform the inspection. The RPI will verify that the appropriate inspection as identified in the IVP and MIP will be performed.

The lead inspector should review the IVP and prepare the inspection plan based on the IROFS component types, inspection attributes and other information that is identified in the IVP. The lead inspector should also review the applicable portions of the PSSC scoping documents that were prepared by the applicant/licensee and are located in DIAMOND, as well as the other information related to verification of the specific PSSC. The lead inspector has the flexibility to scope out the inspection to include a sampling of the appropriate attributes for the particular inspection. The inspection plan should include a rationale for the selected attributes. Additionally, the IVP lists the ISAS IROFS and the IROFS component types that relate to the ISAS IROFS. The plan should consider an appropriate sampling of the IROFS components as identified in the IVP. The inspector has the flexibility to choose the appropriate IROFS components to be inspected. However, at least one IROFS component type should be selected for each ISAS IROFS.

The inspection plan and inspection reports (IRs) should identify the PSSCs that will be/was inspected and the inspection attributes that were selected. The documentation should include any conclusions (and basis for the conclusion) regarding the specific attribute that was inspected. For example, the reports should say the NRC has examined the installation attribute of the IROFS of PSSC-xxx (also include a brief description of the IROFS that was inspected). Based on the sampling and inspection findings, the staff has reasonable assurance that the IROFS was installed in compliance with applicant/licensee procedures and QA program and meets the requirements of 10 CFR Part 70 (identify any specific regulatory or QA requirement that has been met). The inspector or technical reviewer is only responsible for the conclusions

for the specific inspections that they have performed. The RPI will track the completion of the identified inspections for the overall PSSC verification program. This completion information will be tracked in DIAMOND. The RPI will be responsible for confirming that the required inspection activities have been completed in order to verify that the IVP has been completed.

The Resident Inspectors should perform onsite inspections using the applicable portions of the inspection procedures (IPs) for their assigned IROFS. Of the IROFS identified in Section 2 of the IVP, the resident inspectors should evaluate a sampling of the attributes provided in Section 4. Resident inspectors should inspect, using one or more of the specified attributes, a sampling of IROFS components from the list in Section 2 of the IVP. The sampling should include at least one IROFS component from each prioritized ISAS IROFS.

The inspectors should coordinate with technical staff in NMSS and RII to select the inspection sample if the inspector is not familiar with the IROFS or the components and their safety function or priority.

Headquarters reviewers will use the IVP to identify the prioritized administrative controls for review. The review of the administrative controls, generally facility procedures, will be performed using guidance from the administrative control review procedure. After review of the administrative controls, the Headquarters technical staff will document their review as specified in the procedure. The reviewer will forward the written evaluation to the NMSS project manager and the RPI for insertion into DIAMOND.

The evaluations prepared should include any conclusions (and the basis for the conclusion) regarding the procedure that has been reviewed. For example, the evaluations could say "the NRC has examined the xxx administrative control procedure. Based on the review of the document, the staff has reasonable assurance that the xxx administrative control procedure is in compliance with applicant/licensee QA program and meets the requirements of 10 CFR Part 70 (identify any specific regulatory of QA requirement that has been met)." The headquarters reviewer is only responsible for its conclusions for the review that they have performed. The RPI and NMSS Project Manager (PM) will track the completion of the identified inspections for the overall PSSC verification program. This completion information will be tracked in DIAMOND.

In some IVPs, there are specific verification activities that were identified in the technical review and were identified in the Safety Evaluation Report (SER). The technical reviewer will perform technical reviews/inspection activities to verify that items identified in the SER are verified. The reviews should be documented similar to that for administrative controls and will also be tracked in DIAMOND.

Occasionally, the inspection or technical review staff may identify issues or inconsistencies with the IVPs that would necessitate a revision. In order to capture feedback from the inspection or technical review staff, a feature has been added to DIAMOND under the "Knowledge Management" section to efficiently capture and track IVP change requests. This request should be made in DIAMOND under the "Knowledge Management" section and categorized as an "IVP Change Request."

It is anticipated that the MFFF Assessment and Review Group (MARG) will meet on a periodic basis to plan out the anticipated inspection activities based on actual construction progress. The MARG will also meet periodically to review the appropriateness of the LOIE values, revise the IVPs based on feedback from the inspection or technical review staff, review inspection and technical review data in DIAMOND, and monitor PSSC verification activities.

3. INSPECTIONS IDENTIFIED BY INSPECTION OR TECHNICAL REVIEW STAFF THAT ARE NOT CONTAINED IN AN IVP

In the event that an inspector or technical reviewer identifies that additional inspections or reviews, beyond those identified in the IVP, are needed in order to verify the construction of the PSSCs, then the additional recommended inspections should be documented along with the need and bases for the additional inspections. This request should be made in DIAMOND under the "Knowledge Management" section and categorized as a "MIP Change Request." The document should be transmitted to the RPI for consideration. The RPI will convene the MARG to evaluate whether the recommended inspections should be added to the IVP and MIP. The MARG will consider whether the additional inspection is needed to verify the PSSC. This evaluation will include the safety significance of the items proposed for inspection, as well as the overall resource implication.

4. ASSESSMENT

Requests for additional inspections or technical reviews will be evaluated as part of the continuous assessment process. It is expected that the basis for requesting the additional inspections will be discussed by the requestor or designee at the periodic assessment meeting. The review of the request by the MARG will also be discussed and a recommendation regarding the additional inspections will be made to regional management. A decision regarding the additional request will normally be made during the assessment meeting.

If it is determined that additional inspections are needed, with management concurrence, the IVP and the MIP will be revised to reflect the changes.

5. FOCUS OF INSPECTIONS

In order to effectively and efficiently allocate inspection resources, the NRC will perform sampling-type inspections to verify that the applicant/licensee is in compliance with NRC regulations. A combination of IROFS sample selection, statistical methods, risk-informed approaches, and inspections of the QA program, will be used to help determine the necessary level of inspection effort.

Inspection of all IROFS is not required for providing reasonable assurance that construction of the PSSCs was completed in accordance with the application. The NRC has historically relied on a sample-based inspection program to get a representative evaluation that can be applied across similar areas. The staff's chosen approach for a particular PSSC will be that which best fits the nature of the PSSC, can be practically performed, and will provide reasonable assurance that the PSSC can perform its safety function. In some cases, generic programmatic inspections will be performed to assess the implementation of key supporting programs supporting the performance of PSSCs, such as configuration management or quality assurance.

In a coordinated effort, the MARG considered the following attributes in selecting IROFS to be inspected in order to appropriately focus inspection resources: (1) safety significance; (2) propensity for errors; (3) construction and testing experience; and (4) opportunity to verify by other means. The NRC will focus its inspection resources on activities contributing to IROFS

determined to have higher inspection value. This inspection sample will include both observation of IROFS-related work at the MFFF construction site, vendor facilities, and review of calculations and analyses by NMSS technical staff including administrative controls. These inspection targets will define the minimum sample set the NRC will inspect. This will provide the staff with a comprehensive sample based on inspection and technical review for IROFS.

It should be noted that some of the PSSCs described in the MFFF CAR have only one safety function and have only a few IROFS associated with that safety function. In that scenario, the inspection target sample size may be equal to the number of IROFS. The verification process will incorporate one or more of the following methods: (1) PSSC field inspection results; (2) technical staff reviews and evaluations; and (3) staff review of applicant/licensee PSSC completion bases. For example, the inspections should include reviews of procedures; design verification and engineering reviews; vendor and procurement inspections; receipt inspections; installation inspections; reviews of inspection, test control, and control of measuring and test equipment; and control of materials, equipment, and services inspections.

The inspection program will also focus inspections on QA program implementation. Inspection activities should emphasize the early identification of problem areas. It is important that inspectors evaluate whether noted problems represent isolated cases or are symptomatic of more systemic problems.

6. PSSC VERIFICATION ACTIVITIES

a. Attribute Completion

In order to complete the IVP process for a particular PSSC or PSSC family, a minimum number of attributes should be inspected or reviewed. The LOIE value lists provided in the IVPs correlate to a range of attributes that should be inspected or reviewed as part of the verification process. For each PSSC, the minimum number of attributes identified should be evaluated through inspection or technical review. The attributes inspected should be identified in the IRs, and will be tracked in DIAMOND. The RPI will verify that the minimum number of attributes have been inspected for each PSSC. It should be noted that some attributes, such as the corrective action program and QA, will be evaluated by programmatic inspections of the MFFF programs and applied to all applicable PSSCs. DIAMOND will also be used to track these programmatic inspections, and credit will be taken in the verification of each PSSC, as applicable.

The MARG will periodically review the information contained in DIAMOND (and supporting documents if needed) to support a determination of attribute completion. The MARG will examine the inspection and technical review information on individual attributes against the IVP. The results of the MARG meetings will be contained in a summary document that will include the decision making process and basis for the completion of an attribute for a PSSC/PSSC family. This documentation will be included in DIAMOND and will be the basis for indicating the completion of attributes. Additionally, the number of attributes examined for each PSSC will be tracked and the MARG will verify that the minimum number of attributes have been evaluated for each PSSC.

b. Sample Selection

A sample of IROFS component types, procedures or documents should be selected and verified for each prioritized IROFS in the IVP in order to complete the PSSC verification process. This is necessary to provide reasonable assurance that the construction of the PSSCs has been completed in accordance with the application. The IVPs identify the ISAS level IROFS, IROFS component types, and in some cases specific parts of the facility (e.g., purification (KPA)) that should be examined. The inspection sampling should be selected from one or more (as appropriate) of the prioritized IROFS component types or specific components as identified in the IVP. The sample size of the inspection will vary depending on the complexity of the system, inspection findings, and inspector judgment.

c. Applicant/licensee's PSSC Completion Letter

It is the applicant/licensee's responsibility to complete the construction of each PSSC. The applicant/licensee has developed scoping documents that associates the ISAS IROFS with the 53 PSSCs described in the CAR. These scoping documents were prepared for each PSSC also correlate the events contained in the CAR to the ISAS. These documents also provide the ISAS events, ISAS IROFS, IROFS component types, and the specific IROFS components. The listing of administrative IROFS is separate and is not provided in the scoping documents.

The applicant/licensee's completion of a PSSC is based solely on the construction of the PSSC. The ability of the PSSC and its associated IROFS to function properly will be addressed as part of the operational readiness review (ORR). The detailed plan to perform the ORR at the MFFF will be documented separately from the PSSC verification program (see Appendix H). PSSC completion will vary based on the nature of the PSSC. The following are some unique aspects of completion for various PSSCs:

- 1) PSSC-002: 3013 Transport Cask - Completion of the 3013 transport cask is contingent upon the existence of a Certificate of Compliance, approved under 10 CFR Part 71, for transport of the 3013 canisters. The applicant/licensee would not be required to have the transport package constructed by the time of PSSC verification
- 2) PSSC-027: Hazardous Material Delivery Controls – This PSSC consists of administrative controls. For this PSSC to be completed, the applicable administrative controls and associated procedures would have to be completed and documentation issued by the applicant/licensee. A sampling of administrative controls will be reviewed by NRC technical reviewers as identified in the associated IVP.
- 3) For PSSCs that consist of engineered and administrative IROFS, the IROFS would have to be constructed and installed as part of PSSC completion. However, operational testing would not need to be performed at the time of

- 4) PSSC completion. For example, for one of the confinement systems, the fans and other IROFS components would need to be constructed and installed. The PSSC must be capable to perform its safety function even though operational testing had not yet been completed. This would mean that the confinement system that had been constructed has the capability to be balanced in order to perform its safety function of providing negative pressure. This would meet the requirements specified for verification of construction as part of PSSC verification. However, the verification of whether the system is indeed balanced would be part of the ORR. As noted in item b above, administrative controls and associated procedures will have been prepared and issued by the applicant/licensee as part of the PSSC verification.

Following completion of construction of the PSSC, the applicant/licensee has volunteered to submit a letter to the NRC NMSS program office stating that the PSSC is complete and ready for NRC to make a verification determination. This letter will contain the specific details for the staff to determine whether or not PSSC construction has been completed. It is expected that prior to such a letter being submitted, that the MARG and any additional inspection staff will meet, if necessary, with the applicant/licensee to identify whether there are any gaps in the applicant/licensee's PSSC completion that may impact the staff's ability to make a verification determination.

d. Review and Data Analysis

The MARG, with any additional staff resources as needed, will review and analyze the data stored in DIAMOND to assure that the required information has been collected to determine that construction of a PSSC is complete. Inspection records, supplemental information, and the verification activities summaries will be considered by the MARG. Technical reviewers, assigned to this review by their respective branch chiefs, may be required to provide input regarding the decision on the closure of verification activities of a PSSC.

This review process of inspection results and verification status will be performed continuously and will be the subject of meetings between the MARG and appropriate inspection staff.

Region II RPI and the RPI's Branch Chief will certify to NMSS the verification of construction completion for PSSCs subject to verification through inspection. The certification process will include the issuance of a PSSC construction completion report following this verification. This certification should indicate that there is reasonable assurance that the construction of the PSSC or PSSC family is complete based on a comprehensive inspection verification process that includes references to the relevant IRs.

NMSS will certify the verification of completion of PSSCs that are administrative in nature, as indicated in the IVPs. This includes those that reference an approved item such as the transportation package and other PSSCs that consist of only administrative controls. This certification should indicate that there is reasonable

assurance that the construction of the PSSC or PSSC family is complete based on the reviews that were performed and should include references to the evaluation reports.

Both NMSS and Region II RPI and the RPI Branch Chief will jointly certify the verifications of PSSC completions for those PSSCs (or families) that include both administrative controls and controls that were verified by inspections and will be documented as discussed above.

The verification of completion reports should reference the inspections and reviews that were performed to support the verification finding (this information should be in DIAMOND). The documents should include the basis for the staff's findings and should clearly state that construction of the particular PSSC has been verified. The report should follow a standard PSSC verification completion document format (under development). The verification documents should be signed by the branch chief in DCP responsible for the MFFF project. The individual PSSC verification documents should be submitted to the NMSS PM. The verification report may be prepared for individual PSSCs or a PSSC family as appropriate.

NMSS will maintain the status of the verification of construction completion for the PSSCs. NMSS will file a notice advising the Atomic Safety Licensing Board (ASLB) (if the record is still open) or the Commission (if the record is closed) once all information relevant to the verification of construction completion is before the agency and will prepare a Safety Evaluation Report Supplement following completion of the PSSC verification program.

e. Approval

Following receipt of the voluntary completion letter(s) for the PSSCs from the applicant/licensee, the staff will perform a final review and data analysis of the PSSCs. Additionally, a final walk down inspection by the resident inspector(s) and other appropriate staff may be performed if deemed appropriate. Additionally, in-office reviews between the MARG, the resident inspectors, and the applicant/licensee may be held to review the final aspects of the applicant/licensee's completion determination. In the event that the staff believes that it cannot make a positive verification finding regarding completion of construction of a particular PSSC, then staff will document the information that is still needed in the form of a request for additional information (RAI) which will be prepared by the NMSS PM. The staff will follow standard practices regarding resolving RAIs (i.e., written documentation, in-office reviews, inspections, etc.) prior to making a final determination.

Due to the expected length of time between the applicant/licensee's voluntary submittal of the first PSSC completion letter and the last PSSC completion letter, it is anticipated that the applicant/licensee will submit a final completion letter for all PSSCs to the NMSS program office. Following the applicant/licensee's voluntary submittal of the final PSSC completion letter and the staff's completion of the PSSC verification documents, the NMSS/FCSS PM will prepare an SER supplement which will summarize the documents and will provide the staffs overall finding regarding PSSC verification as per 10 CFR 70.23(a)(8).

END

Appendix D

Principal Systems, Structures, And Components (PSSCs) Families

IVP Number	Family (if applicable)	PSSC Number and Name
IVP-001	Process & Chemical Safety	PSSC-003: Backflow Prevention Features PSSC-007: Chemical Safety Control PSSC-038: Process Off-gas System PSSC-045: Process Safety Control Subsystem
IVP-002	Containment Systems	PSSC-004: C2 Confinement System PSSC-005: C3 Confinement System PSSC-006: C4 Confinement System PSSC-033: Material Maintenance & Surveillance Program PSSC-044: Process Cell Exhaust System
IVP-003	Fire Barriers and Control	PSSC-008: Combustible Loading Controls PSSC-021: Fire Barriers PSSC-022: Fire Detection and Suppression PSSC-043: Process Cell Fire Prevention PSSC-046: Seismic Monitoring and Associated Seismic Isolation Valves
IVP-004	Criticality Safety Controls	PSSC-009: Criticality Safety Controls PSSC-032: Material Handling Equipment
IVP-005	Process Vessels and Pipe	PSSC-010: Double Walled Pipe PSSC-023: Fluid Transport Systems PSSC-041: Process Cells
IVP-006	Electrolyzer Components	PSSC-011: Electrolyzer Structure PSSC-026: Guide Sleeves PSSC-039: PTFE Insulator
IVP-007	Emergency Systems	PSSC-012: Emergency AC Power System PSSC-014: Emergency Control System PSSC-015: Emergency DC Power System PSSC-018: Emergency Diesel Generator Fuel Oil System
IVP-008	Air Systems	PSSC-013: Emergency Control Room Air Conditioning System PSSC-017: Emergency Generator Ventilation System PSSC-028: Instrument Air System PSSC-050: Supply Air System
IVP-009	Building Structures	PSSC-016: Emergency Generator Building Structure PSSC-035: Missile Barriers PSSC-036: MFFF Building Structure
IVP-010	Facility Worker Action	PSSC-019: Facility Worker Action

IVP-011	Gloveboxes	PSSC-024: Glovebox PSSC-025: Glovebox Pressure Controls
IVP-012	MFFF Tornado Dampers	PSSC-034: MFFF Tornado Dampers
IVP-013	Sintering Furnace	PSSC-048: Sintering Furnace PSSC-049: Sintering Furnace Pressure Controls
IVP-014	Waste and Transfer container	PSSC-051: Transfer Container PSSC-052: Waste Containers
IVP-015	Waste Transfer Line	PSSC-053: Waste Transfer Line
IVP-016	3013 Canister	PSSC-001: 3013 Canister
IVP-017	3013 Transport Cask	PSSC-002: 3013 Transport Cask
IVP-018	Facility Worker Controls	PSSC-020: Facility Worker Controls
IVP-019	Hazardous Material Delivery Controls	PSSC-027: Hazardous Material Delivery Controls
IVP-020	Laboratory Material Controls	PSSC-029: Laboratory Material Controls
IVP-021	Maintenance Activity Controls	PSSC-030: Maintenance Activity Controls
IVP-022	Material Handling Controls	PSSC-031: Material Handling Controls
IVP-023	MOX Fuel Transport Cask	PSSC-037: MOX Fuel Transport Cask
IVP-024	Pressure Vessel Controls	PSSC-040: Pressure Vessel Controls
IVP-025	Process Cell Entry Controls	PSSC-042: Process Cell Entry Controls
IVP-026	Sintered Silicon Nitride Barrier	PSSC-047: Sintered Silicon Nitride Barrier

END

Appendix E

Prioritization of Items Relied on for Safety (IROFS)

1. PURPOSE

This section provides a discussion of the risk-informed methodology used for prioritizing IROFS. The overall objective of this prioritization is to define those IROFS that are most risk significant for each principal systems, structures and components (PSSCs). This prioritization was needed to optimize Nuclear Regulatory Commission (NRC) resources, while providing reasonable assurance that a significant flaw by the applicant/licensee does not go undetected.

2. BACKGROUND

Table 5.6-1 of the Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF) Construction Authorization Request (CAR) lists the 53 PSSCs and their associated safety functions. The PSSCs are identified as administrative controls, active engineered controls or passive engineered controls. Since the approval of the MFFF CAR on October 30, 2002, the applicant/licensee has identified, in the Integrated Safety Analysis Summary (ISAS), approximately 250 IROFS designated to perform the design basis safety functions of the PSSCs.

The staff's findings as documented in the MFFF construction authorization, stated "in accordance with 10 CFR 70.23(b), on the basis of information described in the CAR, as revised, and the additional statements and commitments heretofore made by DCS (now called Shaw Areva MOX Services), the design bases of the PSSCs for the proposed MFFF and the quality assurance (QA) program, provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents." The applicant/licensee submitted an License Application (LA) to possess and use special nuclear material on September 26, 2006 (as supplemented). The LA includes the detailed safety functions and design bases of the IROFSs for the MFFF. Additionally, the ISAS provides the IROFS for the facility that support the performance of the MFFF's safety functions. These IROFS perform the safety functions needed to satisfy the design bases defined in the CAR.

3. DISCUSSION

As part of the technical review of the MFFF LA and ISAS, the NRC staff performed a vertical and horizontal slice review of various aspects of the design. This first consisted of reviewing the LA and ISAS that were submitted by the applicant/licensee. The ISAS discussed the events that could cause a release of hazardous material or a radiation dose that could produce an intermediate or high consequence (as defined in 10 CFR 70.61) to affected workers or the public. The ISAS included over 200 IROFS which were applied by the applicant/licensee to make the identified events highly unlikely. The ISAS IROFS are more general in nature and include many categories of IROFS components (such as favorable geometry tanks, double walled pipe, and instrumentation). The ISAS did not discuss the specifics of each of the individual IROFS components. The specifics for IROFS components are provided in the process safety information required by the applicant/licensee to be maintained on site. For the

prioritization of IROFS for the MFFF, the staff used terms to identify IROFS which range from a) the general categories identified in the ISAS (ISAS IROFS); b) the categories of IROFS components types (i.e., tanks, valves, instrumentation, pipes, vessels, etc.); and c) specific IROFS components.

As part of the licensing review, the staff also reviewed a sampling of the applicant/licensees' process safety documents for the ISAS. These documents included Nuclear Safety Evaluations, Nuclear Criticality Safety Evaluations, calculations, what if checklists, drawings, etc. These reviews allowed the staff to have a good understanding of the types of events that could cause releases with intermediate or high consequences and which events were either determined by the applicant/licensee to be not credible or were determined to be of low consequence.

With this understanding, the staff selected the events that were determined to be of higher risk significance to perform a more detailed review. For example, in the review of chemical safety, the applicant/licensee outlined explosion events that could potentially occur at the MFFF and applied IROFS to make those events highly unlikely. Based on staff expertise and experience, knowledge of potential events at other fuel cycle facilities, potential consequences of the event, complexity of the system, and actual examples of incidents that have occurred around the world in the fuel cycle and chemical industry, the staff narrowed the list of events to review in more detail to the ones that were most significant. For these events of greater risk and significance, the technical reviewers performed detailed reviews of the calculational bases for the event. Known as horizontal and vertical slice reviews, these reviews looked at possible events in a general way (horizontal) and details of individual events (vertical) in a specific way. Specifically, for example, the chemical technical review staff spent more review effort on explosion events related to hydroxyl amine nitrate (HAN) and "Red Oil."

Following a similar approach as the technical reviewers, the staff used the same set of priorities to evaluate the ISAS IROFS. For the prioritized ISAS IROFS, the staff outlined the IROFS component types.. These IROFS component types provide the basis for the development of the staff's independent verification plans (IVPs) for PSSCs which are implemented via inspections and reviews of administrative controls.

The evaluation of the prioritization of the ISAS IROFS can be found in DIAMOND. This spreadsheet lists the ISAS IROFS associated with each PSSC. The document also shows the results of the staff review to identify the prioritized ISAS IROFS and provides a discussion of the prioritization bases by PSSC. The staff then took this document and prepared the IVP basis spreadsheet. This spreadsheet lists the prioritized ISAS IROFS by PSSC and includes the IROFS component types. These spreadsheets can be found in the reference section of DIAMOND. This document was used as the basis for development of the IVPs.

END

Appendix F

Level of Inspection Effort (LOIE) Methodology

1. PURPOSE

The staff developed a process called LOIE to prioritize the level of inspection effort and the number of inspection attributes that will be used to verify completion of each principal systems, structures and components (PSSCs).

2. METHODOLOGY

LOIE is a methodology that prioritizes the value of inspecting construction activities pertaining to PSSCs. This methodology determines the scope of each PSSC Independent Verification Plan (IVP) and supports inspection planning and scheduling. This methodology will provide reasonable assurance that the construction of the PSSC was completed in accordance with the application (as required by 10 CFR 70.23(a)(8)) by using a risk-informed approach to determine the LOIE value for each PSSC. The LOIE value is defined as the likelihood of an undetected construction error (“L” value) times the consequence of failure to detect the error (“C” value). The Mixed Oxide (MOX) Fuel Fabrication Facility Assessment and Review Group (MARG), consisting of staff from the Office of Nuclear Material Safety and Safeguards’ Division of Fuel Cycle Safety and Safeguards (NMSS/FCSS) and the Region II Division of Construction Projects (RII/DCP) determined both the “L” values and “C” values. The “C” values were determined by considering the impact of the loss of the PSSC’s safety function and on the following:

- Impacts public (C = 3; high consequence)
- Impacts off-site workers and facility workers (C = 2; medium consequence)
- Impacts only facility workers (C = 1; low consequence)
- No consequence (C = 1; low consequence)

The consequence value was obtained from the review of the applicant/licensee’s Integrated Safety Analysis Summary (ISAS). The ISAS presents the events that could cause either an intermediate or high consequence event (radiation dose or chemical exposure) as required by 10 CFR Part 70. The events are shown in areas such as explosion events, criticality, loss of confinement, et al. The ISAS further discussed the potential consequences of the events, the items relied on for safety (IROFS) applied to make the event highly unlikely, the applicable codes and standards, the application of quality assurance (QA) requirements, and the use of management measures. The events related to individual PSSCs were identified in the staff’s technical review and were used in the development of LOIE values for each PSSC.

For the determination of likelihood, the MARG used the considerations listed below to determine the “L” values as part of the LOIE calculation.

- Error propensity
- Complexity of construction
- Fabricator/vendor performance

- Quality of materials
- One-of-a-kind item
- Commercial grade dedication process
- Construction testing experience
- Licensee oversight
- QA organization
- Defense in depth
- Operating experience
- Likelihood that the error would be detected by other means (self revealing, pre-op testing, etc.)

The MARG examined the individual PSSCs and the IROFS that relate to the PSSCs. The MARG used the above factors in order to determine the likelihood for an undetected PSSC error. The values used in the determination are:

- High likelihood (L=3)
- Moderate likelihood (L=2)
- Low likelihood (L=1)

Table 1 shows the relationship between likelihood, consequence, and the LOIE value. Note that a LOIE value of “1” would necessitate the least amount of inspection resources, while a LOIE value of “9” would require the greatest amount of inspection resources. By definition, a LOIE value of “0” would not be possible.

Table 1- LOIE value prioritization matrix

	Consequence		
Likelihood	Low (C=1)	Medium (C=2)	High (C=3)
High (L=3)	3	6	9
Medium (L=2)	2	4	6
Low (L=1)	1	2	3

The LOIE value for each PSSC was translated into inspection attributes. Refer to Table 2 to obtain the correlation between the LOIE value and the number of inspection attributes. The inspection attributes are units that allow meaningful comparison of PSSCs. The inspection attributes were derived from the inspection procedures listed in Appendix A of this IMC and will determine the scope of the verification activities. The inspection attributes are defined below:

- Quality Assurance
- Design Control
- Control of Materials, Equipment, and Services
- Test Control
- Corrective Action Program
- Installation
- Procurement
- Fabrication
- Procedures
- Vendor Oversight / Inspection
- Software Quality Assurance Program
- Quality Assurance Interfaces
- As-built / Functional Arrangement of IROFSS
- Special Processes (e.g. welding)
- 10 CFR 21 – Construction

Depending on the LOIE value for each PSSC; the number of inspection attributes is shown in Table 2.

Table 2- Correlation of LOIE Value to Inspection Attributes

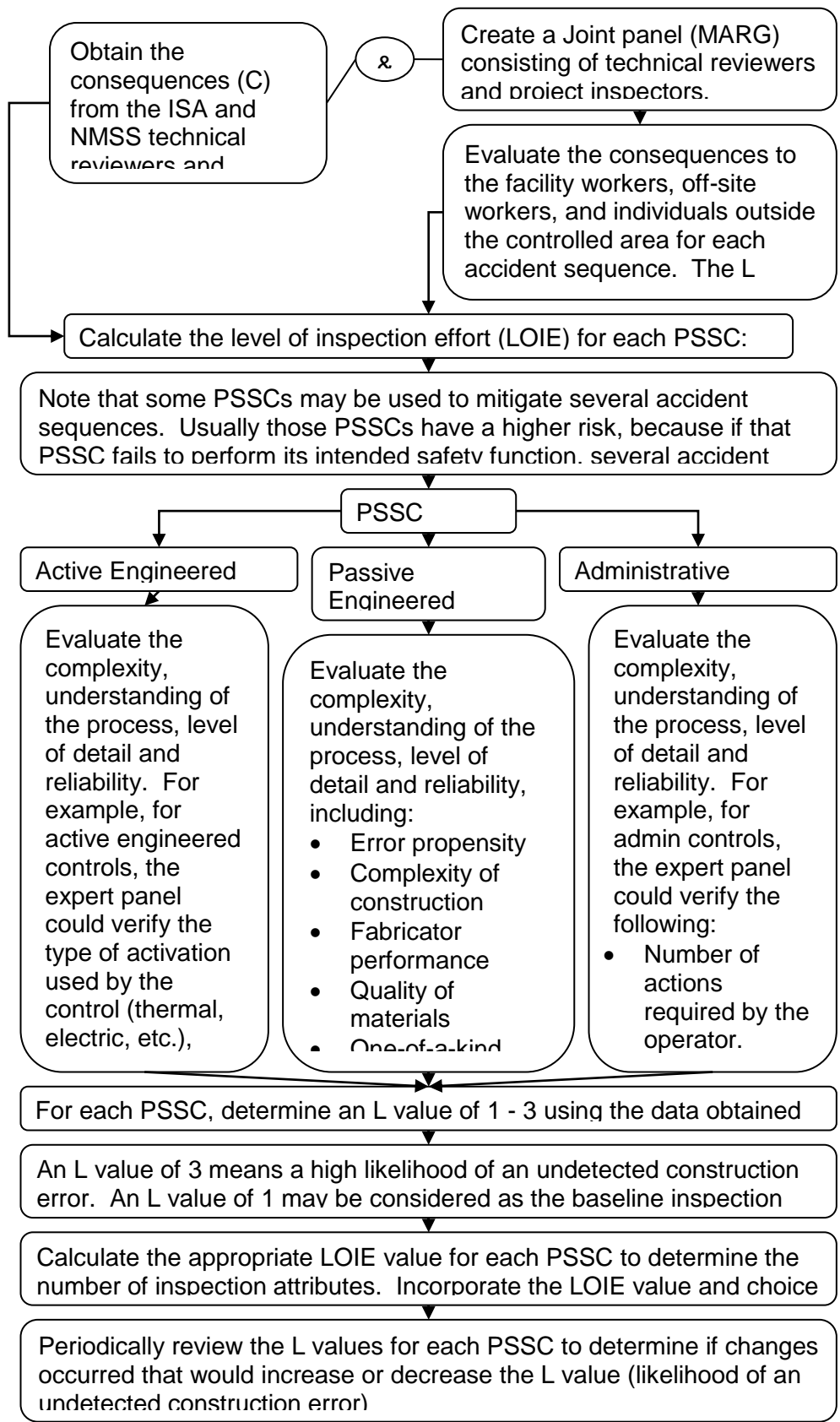
LOIE	# of Attributes (Determines the Scope of the IVP)
1	1-5
2	2-6
3	3-7
4	4-8
6	6-11
9	10-15

Additionally, to ensure that the scope of the inspection program evaluates all PSSCs, C=0 and L=0 were not considered. This is conservative and ensures that each PSSC is assigned a non-zero LOIE score and will receive an inspection of at least one attribute.

3. REVIEW AND ASSESSMENT

Periodically, the MARG will review the LOIE values as described in Figure 1 and determine if the likelihood values need to be revised based on inspection experience, new information received from the applicant/licensee, vendor performance, or operating experience. The basis for revising the likelihood values will be documented in DIAMOND as well as any subsequent changes to the LOIE. Changes to the LOIE value will result in adjusting the number of inspection attributes and the scope of the inspections described in the IVP. The MARG will determine if the IVP and the Master Inspection Plan (MIP) should be revised to reflect the changes. The inspection staff should be kept apprised of any adjustments to the LOIE as well as changes to the IVP or MIP.

Figure 1: Level of Inspection Effort (LOIE) Flowchart for MFFF PSSCs



Appendix G

Digital Information Archive for the Mixed Oxide Fuel Fabrication Facility (MFFF) and Online Normalized Database (DIAMOND)

1. PURPOSE

This section provides general information regarding DIAMOND and how it will be used to document and track the principal systems, structures and components (PSSCs) verification activities. These activities include inspections and reviews by regional and resident inspectors and headquarters technical staff. This documentation will be used as the basis for the determination that the applicant/licensee was met the requirements of 10 CFR 70.23(a)(8).

2. BACKGROUND

DIAMOND is a tool that will be used to input and manage inspection data, as well as track the progress of the completion status of the MFFF PSSC verification inspection program. Staff will use DIAMOND to (1) plan their inspections, (2) access technical documents, (3) document inspection reports and staff reviews, (4) track progress toward inspection verification program completion, (5) allocate inspection resources, (6) monitor status of open items, and (7) prepare status reports.

Access to this tool is located on the Office of Nuclear Material Safety and Safeguards' internal SharePoint Site and access is controlled. Only authorized inspectors and personnel can access DIAMOND. This tool has been designed specifically for the verification program for the MFFF. Since this is a SharePoint site, it is relatively easy to use, and assistance can be provided by the Agency-wide SharePoint Help-Desk. The SharePoint Help Desk may be reached by dialing 301-415-1234, option #5- "EPM and SharePoint" or by email: SharePoint.Help@nrc.gov.

3. Documentation in DIAMOND

Proper documentation of the verification activities is essential to accomplish an effective implementation of the MFFF inspection program and provide documentation for demonstrating compliance with 70.23(a)(8). Once an inspection report has been prepared and declared in ADAMS, it will be added to DIAMOND. A summary of the verification activities for each PSSC will be entered to the system. Inspection items (e.g. open, closed and discussed items) must be added (or updated) into DIAMOND as well. The information entered in DIAMOND should be concise and precise. The user should keep in mind that the information in DIAMOND will be used to make the final licensing decision for the MFFF. The regional project inspector is responsible for entering information into DIAMOND.

If LOIE values are updated or require change (based on inspection experience), the LOIE value information should be promptly updated in DIAMOND. The basis for the changes will be documented and approved by the Mixed Oxide (MOX) Fuel Fabrication Facility Assessment and Review Group (MARG) prior to any changes being made. When the verification activities have been completed for a particular PSSC, staff will update DIAMOND to show that the PSSC has been verified.

Specific details about DIAMOND can found in the DIAMOND User's Guide which can be accessed in the "Reference" section of DIAMOND.

END

Appendix H

**Mixed Oxide Fuel Fabrication Facility
Operational Readiness Review**

RESERVED

Exhibit 1: Construction Action Matrix

		Column I	Column II	Column III	Column IV
RESULTS		Only Severity Level (SL) IV violations or non-cited violations NRC requirements fully met	One or two SLIII violations NRC requirements met with some challenges to applicant/licensee	Three SL III violations or one SL II violation, or a combination of the above. NRC requirements met with some significant challenges to applicant/licensee (Degraded Performance)	One SL I violation, multiple SL II violations, or a combination of the following: one SL II and a total of four or more SL III violations; or a total of seven or more SL III violations Loss of confidence to construct within NRC requirements in areas of concern (Unacceptable Performance)
	Regulatory Performance Meeting	None	Branch Chief or Division Director meets with applicant/licensee	Deputy Regional Administrator for Construction (DRAC) or designee meets with senior applicant/licensee management	Regional Administrator (RA) or designee meet with senior applicant/licensee management
RESPONSE	Applicant/licensee Action	Applicant/licensee corrective actions	Applicant/licensee root cause evaluation and corrective action with NRC oversight	Applicant/licensee cumulative root cause evaluation with NRC oversight	Applicant/licensee Performance Improvement Plan and independent inspection with NRC oversight
	NRC Inspection	Routine inspection program	Limited increase in NRC oversight of area(s) of concern.	Expanded NRC oversight in area(s) of concern. Inspection sample increased as appropriate. .	Reactive team inspection in area(s) of concern.
	Regulatory Actions	None Additional actions considered for sites exiting Column III or Column IV.	Additional inspection only. Additional actions considered for sites exiting Column III or Column IV.	Additional inspection only. (Additional actions considered for sites exiting Column IV).	At minimum, issue confirmatory action letter. Evaluate need for Demand for Information and/or Order.
	Assessment Letters	If needed, Branch Chief or Division Director reviews/signs assessment report	Division Director reviews/signs assessment report	DRAC or designee reviews/signs assessment report	Regional Administrator reviews/signs assessment report
COMMUNICATION	Annual Public Meeting	Senior Project Inspector or Branch Chief meets with applicant/licensee	Branch Chief or Division Director discusses performance with applicant/licensee	DRAC or designee discusses performance with applicant/licensee	Regional Administrator or designee discusses performance with applicant/licensee
	Commission Involvement	None	None	None	Consider Commission meeting with senior applicant/licensee management
	INCREASING SAFETY/REGULATORY SIGNIFICANCE →				

Attachment 1 - Revision History for IMC 2630

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment and Feedback Resolution Accession Number
N/A	ML051450201 05/18/05 CN 05-013	New Inspection Manual Chapter	None	N/A
N/A	ML14028A249 05/09/14 CN 14-011	Completely revised to incorporate inspection documentation requirements for inspections of principal systems, structures, and components; assessment process; independent verification plan process; level of inspection effort methodology; use of inspection data management tools; and prioritization of items relied on for safety.	None	ML14055A375