

## 15.0 MANAGEMENT MEASURES

This chapter of the draft Safety Evaluation Report (DSER) contains the staff's review of management measures described by the applicant in Chapter 15 of the Construction Authorization Request (CAR). Management measures are defined 10 CFR 70.4 as functions, performed by a licensee, generally on a continuing basis, that are applied to items relied on for safety (IROFS) as identified in the Integrated Safety Analysis (ISA) Summary, to provide reasonable assurance that the items are available and reliable to perform their functions, when needed. Management measures include configuration management (CM); maintenance; training and qualifications; procedures; audits and assessments; incident investigations; records management; and other quality assurance (QA) elements. The objective of the review is to determine whether the management measures proposed will provide reasonable assurance that the applicant's principal structures, systems, and components (PSSCs), and eventual IROFS, will be available and reliable when needed and thus provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents. The staff evaluated the information provided by the applicant for management measures by reviewing Chapter 15 of the CAR, other sections of the CAR, supplementary information provided by the applicant, and relevant documents available at the applicant's offices but not submitted by the applicant. The review of management measures was closely coordinated with the review of accident sequences described in the Safety Assessment of the Design Bases (see Chapter 5.0 of this DSER). Since management measures be applied to IROFS, a more thorough evaluation of management measures will be performed as part of the review of the DCS application for a 10 CFR Part 70 operating license.

The staff reviewed how the information in the CAR addresses or relates to the following regulations:

- Part 21 of 10 CFR describes regulatory requirements for identifying, controlling, and reporting defects in a facility, activity, or basic component supplied to a facility, licensed under the Atomic Energy Act, which could create a substantial safety hazard.
- Section 70.23(b) of 10 CFR states, as a prerequisite to construction approval, that the design bases of the PSSCs and the quality assurance program be found to provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents. Section 70.23(b) of 10 CFR further states that the criteria in Appendix B of 10 CFR Part 50 will be used in determining whether the QA program provides reasonable assurance of protection against natural phenomena and the consequences of potential accidents.
- Section 70.64 OF 10 CFR requires that baseline design criteria (BDC) and defense-in-depth practices be incorporated into the design of new facilities. With respect to management measures, 10 CFR 70.64(a)(8) requires that inspection, testing, and maintenance be addressed as one of the BDC, to provide reasonable assurance that IROFS will be designed to allow them to be adequately inspected, tested, and maintained to ensure their availability and reliability to perform their function when needed.

The review of the applicant's description of management measures is addressed in the following sections in the order that the applicant presented them in the CAR, beginning with QA. The staff used Chapter 15.0 in NUREG-1718, "Standard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility," as guidance in performing the review.

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### 15.1 QUALITY ASSURANCE

#### 15.1.1 CONDUCT OF REVIEW

The staff reviewed the QA descriptions and commitments of the applicant's CAR for the Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF) in accordance with NUREG-1718. The purpose of this review is to establish that the applicant has a QA program that will provide reasonable assurance that PSSCs will be available and reliable to perform their safety function when needed and protect against natural phenomena and the consequences of potential accidents. To provide such assurance, the QA program is made applicable to the design, fabrication, and construction of the PSSCs. The following regulations apply specifically to QA:

- Part 21 of 10 CFR describes regulatory requirements for identifying, controlling, and reporting defects in a facility, activity, or basic component supplied to a facility, licensed under the Atomic Energy Act which could create a substantial safety hazard.
- Section 70.23(b) of 10 CFR states that the criteria in Appendix B of 10 CFR Part 50 will be used in determining whether the QA program provides reasonable assurance of protection against natural phenomena and the consequences of potential accidents.

In CAR Section 15.1, the applicant committed to implement its QA program as described in the MOX Project Quality Assurance Plan (MPQAP), Revision 2. As described in the QA Plan SER dated October 1, 2001, the staff accepted this MPQAP for MFFF construction activities.

The MPQAP, Revision 2, was submitted as the required description of a QA program that meets the requirements of 10 CFR Part 50, Appendix B ("Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," referred to hereafter as Appendix B). The applicant has committed to compliance with the provisions of Parts I and II of American Society of Mechanical Engineers (ASME) NQA-1-1994, "Quality Assurance Program Requirements for Nuclear Facilities," as revised by the ASME NQA-1a-1995 Addenda, and U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 1.28 (Rev.3), "Quality Assurance Program Requirements (Design and Construction)." These ASME NQA-1 and Regulatory Guide provisions are hereafter referred to as NQA-1. The staff reviewed and compared and evaluated the MPQAP against the Appendix B requirements and the NQA-1 provisions, as well as NUREG-1718 guidance. The QA areas reviewed by the staff included the applicant's descriptions in the MPQAP for organization, QA function, design control, procurement document control, instructions, procedures, and drawings, document control, control of purchased items, identification and control of items, control of special processes, inspection, test control, control of measuring and test equipment, handling, storage, and shipping, inspection, test, and operating status, nonconformances, corrective action, QA records, audits and assessments, and the applicant's provisions for continuing QA. The results of this review are documented in the QAP SER dated October 1, 2001 (Reference 15.1.3.6). Additional discussions on the implementation and application of the applicant's QA program description in the MPQAP, Revision 2, as supplemented by requests for additional information (RAI) responses, were held during telephone meetings and in-office reviews, particularly on the Quality Level categorization commitments including classification criteria and the categorization process.

## 15.1.2 EVALUATION FINDINGS

In Chapter 15.1 of the CAR, DCS committed to implement its QA program at the proposed MFFF. Based on the staff's review of the applicant's QA program commitments in CAR Section 15.1, MPQAP, Revision 2, and the clarifications and commitments made by the applicant in response to NRC RAIs relevant to its QA program, the staff finds that DCS has met the applicable 10 CFR Part 21 requirements, and the QA requirements stated in 10 CFR 70.23(b). The staff concludes, pursuant to 10 CFR 70.23(b), that the QA program at the proposed MFFF will provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents. The scope of this finding pertains to the construction of the MFFF's SSCs, and includes all related design, procurement and fabrication activities, but does not include any start-up testing or operation of the MFFF.

## 15.1.3 REFERENCES

- 15.1.3.1 American Society of Mechanical Engineers (ASME). ASME–NQA–1–1994, "Quality Assurance Requirements for Nuclear Facility Applications," (as revised by the ASME NQA-1a-1995 Addenda). ASME: New York, New York. 1994/1995.
- 15.1.3.2 Code of Federal Regulations, *Title 10, Energy*, Part 21, "Reporting of Defects and Noncompliances."
- 15.1.3.3 Code of Federal Regulations, *Title 10, Energy*, Part 70, "Domestic Licensing of Special Nuclear Material."
- 15.1.3.4 Nuclear Regulatory Commission (U.S.), Washington, D.C. "Domestic Licensing of Special Nuclear Material (10 CFR Part 70)," *Federal Register*: Vol. 64, No. 146. pp. 41338-41357. July 30, 1999.
- 15.1.3.5 Nuclear Regulatory Commission (U.S.) (NRC). Regulatory Guide 1.28, Revision 3, "Quality Assurance Program Requirements (Design and Construction)," NRC: Washington, D.C. August 1985.
- 15.1.3.6 Persinko, A., U.S. Nuclear Regulatory Commission, letter to, Hastings, P., Duke Cogema Stone & Webster RE Duke Cogema Stone & Webster Quality Assurance Program for the Construction of the MFFF, October 1, 2001.

## **15.0 MANAGEMENT MEASURES**

### **15.2 CONFIGURATION MANAGEMENT**

#### **15.2.1 CONDUCT OF REVIEW**

This section of the draft Safety Evaluation Report (DSER) contains the staff's review of the configuration management system committed to by the applicant in Chapter 15, Section 15.2 of the Construction Authorization Request (CAR). The objective of this review is to verify that the applicant has adequately planned for the implementation of an acceptable configuration management (CM) system which will provide reasonable assurance that the principal structures, systems, and components (PSSCs) identified by the applicant will be available and reliable to perform their safety function when needed and will be adequate to protect against natural phenomena and the consequences of potential accidents. The review, for construction authorization, is to determine whether the applicant has adequately planned for CM to be accomplished during design and construction and whether necessary policies, personnel, procedures, and instructions will be in place to begin CM during the design and construction of the PSSCs.

NUREG-1718, Section 15.2.3, "Areas of Review," defines the review areas, and states that the description of the CM system should be reviewed with emphasis on the processes for documenting an established baseline configuration and controlling changes to it to preclude inadvertent degradation of safety. The review should include the applicant's descriptions of the organizational structure responsible for CM activities and the process, procedures, and documentation required for modifying structures, systems, and components (SSCs), PSSCs, and items relied on for safety (IROFS) and the supporting management measures. The review should focus on the applicant's management level controls that ensure (a) the disciplined documentation of engineering, installation, and operation of modifications; (b) the training and qualification of affected staff; (c) revision and distribution of operating, test, calibration, surveillance, and maintenance procedures and drawings; (d) post-modification testing; and (e) operational readiness review. The review topics should include CM policy, design requirements, document control, change control, and assessments.

##### **15.2.1.1 CM Policy**

The applicant describes its overall CM system in CAR Section 15.2, and presents its CM policy in Section 15.2.1, which states that CM is provided for PSSCs throughout the MFFF design, construction, testing, operation and deactivation, to provide the means to establish and maintain a technical baseline for the MFFF. The applicant's CM system during design and construction is the responsibility of the Deputy Project Manager - MFFF Engineering and Construction. The CM system controls documents in accordance with quality assurance (QA) procedures for design control, document control, and records management. During the design and construction phases, the applicant's CM is, and will be, based on Section 3, "Design Control" of the Mixed Oxide (MOX) Project Quality Assurance Plan (MPQAP) and associated MPQAP requirements and procedures for design and construction documents and activities that establish and maintain the technical baseline. The staff reviewed these MPQAP commitments and requirements for CM, and determined that they were acceptable for construction activities, including design, procurement and fabrication. The staff review and conclusion were documented in a SER, on October 1, 2001 (Reference 15.2.3.4). Design documents and changes undergo interdisciplinary review and verification. Proper implementation is verified and reflected in the design basis documentation. The applicant will update the CM description to include details of the operational

configuration management program in the license application for possession and use of special nuclear material (SNM). If the MFFF is licensed to operate, any changes to the CM program would be governed by 10 CFR 70.72, "Facility Changes and Change Process."

Section 15.2 of the CAR states that CM is applied to PSSCs. The applicant provided supplemental information in which it discussed its CM program requirements, addressing its commitment to CM application during design and construction (Reference 15.2.3.5). It specifically discussed: (1) establishing and controlling the design bases to include all SSCs, not just PSSCs and IROFS, (2) how the CM process functions for documenting the baseline configuration and controlling all changes, and (3) how it provides for change control during construction (i.e., that the same design control procedures are to be used for all SSCs, not just PSSCs and IROFS). During construction all field changes, as-built configurations, and non-conformances will be reviewed for impact to the design basis.

The applicant describes the design documents under CM, which include calculations, safety analyses, design criteria, engineering drawings, system descriptions, technical documents, and specifications that establish design requirements. The scope of CM expands throughout the design process. During construction, startup and operations, the scope of documents under CM expand to include vendor, test, and inspection data, startup, test, operating and administrative procedures, and nonconformance reports. These documents will include those generated through functional interfaces with QA, maintenance, and training and qualifications of personnel. The applicant discusses how the CM system is implemented through or related to other management measures and describes these interfaces and relationships (Reference 15.2.3.5, RAI 239).

The QA program, described in the MPQAP in CAR Section 15.1, establishes the framework for the applicant's configuration management system and other management measures for PSSCs. CM system records are generated and processed in accordance with the requirements of the MPQAP. Maintenance requirements are established as part of the design basis which is controlled under CM, and records provide evidence of compliance with preventative and corrective maintenance schedules. Training and qualification of personnel is controlled in accordance with the MPQAP provisions, and will be considered part of the design basis controlled under CM. Corrective actions and changes resulting from audits, assessments, and incident investigations, will be evaluated and controlled in accordance with provisions of the MPQAP and QA procedures. Plant procedures will be controlled in accordance with the MPQAP and QA procedures, and will be reviewed for impact to the design basis.

The applicant's description of CM includes the designation of PSSCs under the QA classification and grading provisions of Section 2 of the MPQAP. The grading approach to SSC includes applying the most stringent QA controls to SSCs with the highest safety significance. All controls for all PSSCs are controlled under CM and documented in the same manner. The QA classification and grading process of the applicant was clarified in response to requests for additional information (RAIs) (Reference 15.2.3.5) on the MPQAP, as well as CAR RAI 234. The applicant's responses were considered adequate to describe appropriate commitments for SSC classification and the grading process. The responses and staff review of these areas are discussed in the QAP SER (Reference 15.2.3.4).

### **15.2.1.2 Design Requirements**

The applicant stated that the organization structure and staffing interfaces for the CM system, for design and construction, will be administered by the MFFF Engineering organization. The lead discipline engineers will have primary technical responsibility for the work performed by their disciplines, and will be responsible for the conduct of interdisciplinary reviews. Reviews are also conducted by construction management, operations, QA and procurement personnel. The design control process will also interface with document control and records management processes controlled by QA procedures. PSSCs are designated as Quality Level-1 (QL-1) (IROFS) using the MPQAP classification process, and their associated design documents will be subject to review and verification. Analyses constituting the safety assessment of the design bases, and later the Integrated Safety Analysis (ISA), are subject to these same requirements, and changes are evaluated to ensure consistency with the design bases. Design bases documented in CAR Chapters 5 through 11 will be consistent with those in, and flowed down from, the design requirements and basis of design documents, analyses, specifications and drawings. The CM system will capture these requirements and resulting design bases in accordance with design control, document control and records management procedures.

SSCs will be classified based on their safety significance and role in preventing or mitigating design basis accidents in accordance with the categories of QA classification described in Section 2 of the MPQAP and in the staff's review documented in Reference 15.2.3.4.

### **15.2.1.3 Document Control**

Document control will be implemented in accordance with Section 6 of the MPQAP. These provisions were reviewed by the staff and found to be adequate for design and construction of the MFFF (Reference 15.2.3.4).

### **15.2.1.4 Change Control**

The applicant's description for control of changes to the technical baseline identifies that they are controlled under Section 3, "Design Control," of the MPQAP and associated procedures. The change control process includes technical, management and safety reviews prior to implementation. The review process includes reviews to ensure consistency with the approved safety assessment of the design bases of principal SSCs and the ISA, and include provisions for appropriate reviews at the design, construction, and operations phases.

### **15.2.1.5 Assessments**

The applicant confirms that assessments, including initial and periodic examinations of the CM system, will be conducted to determine the system's effectiveness and to correct deficiencies. The applicant committed that such assessments will be systematically planned and conducted in accordance with an overall facility audit and assessment program as described by the applicant in CAR Section 15.6.

The applicant also committed to updating the CM system to reflect any changes between the construction approval review and application for a license.

## 15.2.2 EVALUATION FINDINGS

In Chapter 15.2 of the CAR, DCS committed to implement and update its CM system at the proposed MFFF. Management-level policies and procedures, including an analysis and independent safety review of any proposed activity involving SSCs, are described that will ensure that the relationship between design requirements, construction, and facility documentation is maintained as part of a new design or change in an existing design. The administrative control will ensure that the organizational structure, procedures, and responsibilities necessary to implement CM are in place or committed to; that the design requirements and bases are documented and supported by analyses and the documentation is maintained current; that documents, including drawings, are appropriately stored and accessible; that drawings and related documents adequately describe SSCs; that procedures adequately describe how the applicant will achieve and maintain strict consistency among the design requirements, facility construction, and facility documentation; and that methods are in place for suitable analysis, review, approval, and implementation of identified changes to SSCs. The applicant described its approach to QL categorization and grading of controls for SSCs and identified the process, criteria and control to be applied. The applicant's proposed approach is found adequate to provide adequate assurance of the reliability and availability of the PSSCs identified in the CAR. The staff concludes, pursuant to 10 CFR 70.23(b), that the CM system will provide reasonable assurance of protection against natural phenomena and the consequences of potential accidents

## 15.2.3 REFERENCES

- 15.2.3.1 Code of Federal Regulations, *Title 10, Energy*, Part 70, "Domestic Licensing of Special Nuclear Material."
- 15.2.3.2 Department of Energy (U.S.) (DOE). DOE-STD-1073-93-Pt.1 and -Pt.2, "DOE Standard Guide for Operational Configuration Management Program." DOE: Washington, D.C. 1993.
- 15.2.3.3 Nuclear Regulatory Commission (U.S.), Washington, D.C. "Domestic Licensing of Special Nuclear Material (10 CFR Part 70)." *Federal Register*: Vol. 64, No.146. pp. 41338-41357. July 30, 1999.
- 15.2.3.4 Persinko, D., U.S. Nuclear Regulatory Commission, letter to P. Hastings, Duke Cogema Stone & Webster RE DCS Quality Assurance Program for Construction of the MFFF, October 1, 2001.
- 15.2.3.5 Hastings, P., Duke Cogema Stone & Webster, letter to U.S. Nuclear Regulatory Commission, RE Response to Request for Additional Information (DCS-NRC-000059), August 31, 2001.

## **15.0 MANAGEMENT MEASURES**

### **15.3 MAINTENANCE**

#### **15.3.1 CONDUCT OF REVIEW**

This section of the draft Safety Evaluation Report (DSER) contains the staff's review of the maintenance program committed to by the applicant in Chapter 15, Section 15.3 of the Construction Authorization Request (CAR). The objective of this review is to determine whether the facility will have a maintenance program for principal structures, systems, and components (PSSCs) and eventual items relied on for safety (IROFS) (other than personnel activities) which will provide reasonable assurance that the PSSCs/IROFS will be available and reliable to perform their safety function when needed and will adequately protect against natural phenomena and the consequences of potential accidents. Section 70.64(a)(8) of 10 CFR requires that inspection, testing, and maintenance be addressed as one of the Baseline Design Criteria (BDC) to provide reasonable assurance that IROFS will be designed to allow them to be adequately inspected, tested, and maintained to ensure their availability and reliability to perform their function when needed.

##### **15.3.1.1 Maintenance Program**

In CAR Section 15.3, the applicant describes and commits to implementation of a maintenance program including safety controls, surveillance/monitoring, corrective maintenance, preventive maintenance, functional testing, and work control methods, and describes the relationship of the maintenance elements to other management measures. The applicant will describe its maintenance program in more detail in the license application for possession and use of special nuclear material (SNM). Preventive maintenance activities, surveillance, and performance trending will be done to provide reasonable and continuing assurance that IROFS will be available and reliable to perform their safety functions.

##### **15.3.1.2 Safety Controls**

The applicant commits to providing safety controls by specifying maintenance requirements for calibration frequency, functional testing requirements, and replacement of specified components for IROFS.

##### **15.3.1.3 Maintenance Elements**

The applicant's description requires that surveillance and monitoring of IROFS, including instrument calibration and testing be performed at specified intervals to measure the degree to which IROFS meet performance specifications. The results of surveillances will be trended and when indicated by potential performance degradation, preventive frequencies adjusted or other corrective action taken. Incident investigations may also identify root causes of failures related to maintenance type or frequency, and lessons learned these investigations will be factored into the maintenance program. Procedures will prescribe compensatory measures for surveillance tests that can be performed only while equipment is out of service.

Preventive maintenance measures described by the applicant include preplanned and scheduled periodic refurbishment, overhaul, or replacement of IROFS to ensure their continued safety function. Planning will include results of surveillance and monitoring, and instrument calibration and testing.

Corrective maintenance will be performed for repair or replacement of equipment that has unexpectedly degraded or failed. Corrective maintenance will restore IROFS to acceptable performance through a planned, systematic, controlled, and documented approach for the activities.

Following initial installation, functional testing of IROFS will be performed as part of the applicant's periodic surveillance testing, and, also, after corrective or preventive maintenance or calibration to ensure that the item is capable of performing its safety function when required. The functional testing will be conducted using approved procedures, that will include compensatory measures that may be necessary while the test of equipment or systems is being conducted.

#### **15.3.1.4 Work Control Methods**

The applicant commits to maintenance-related work control methods including maintenance management and tracking, which will involve integration of maintenance activities with ongoing operations activities. Work control methods will also include appropriate interfaces with radiation protection and associated work permits, lockout/tagout requirements, and procedures.

#### **15.3.1.5 Maintenance Relationship to Other Management Measures**

The applicant's committed maintenance function will interface with the configuration management and procedure systems by obtaining the approved and controlled drawings, specifications and procedures. Personnel will be trained in the maintenance of IROFS through the training program, and records of performance trends and maintenance history will be maintained.

### **15.3.2 EVALUATION FINDINGS**

In Chapter 15.3 of the CAR, DCS described and committed to implement its maintenance program to be used on PSSCs and associated activities at the proposed MFFF. Based on that information and the discussion provided in the sections above for maintenance, the staff finds that the applicant has adequately described its maintenance program. The applicant will describe its maintenance program in more detail in its application for a 10 CFR Part 70 operating license. The staff concludes, pursuant to 10 CFR 70.64(a)(8), that the maintenance program provides reasonable assurance that IROFS will be designed to allow them to be adequately inspected, tested, and maintained to ensure their availability and reliability to perform their function when needed. The staff further concludes, pursuant to 10 CFR 70.23(b), that the maintenance program set forth in the CAR will provide reasonable assurance that the PSSCs identified by the applicant will protect against natural phenomena and the consequences of potential accidents.

### **15.3.3 REFERENCES**

- 15.3.3.1 Code of Federal Regulations, *Title 10, Energy*, Part 70, "Domestic Licensing of Special Nuclear Material."
- 15.3.3.1 ———. *Title 10, Energy*, Section 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants."
- 15.3.3.1 ———. *Title 29, Labor*, Section 1910.119, "Process Safety Management of Highly Hazardous Chemicals."

- 15.3.3.1 ———. *Title 40, Protection of Environment*, Part 68, "Risk Management Program for Chemical Accidental Release Prevention."
- 15.3.3.1 Nuclear Regulatory Commission (U.S.), Washington, D.C. "Guidance on Management Controls/Quality Assurance, Requirements for Operation, Chemical Safety, and Fire Protection for Fuel Cycle Facilities." *Federal Register*: Vol. 54, No. 53. pp. 11590–11598. March 21, 1989.
- 15.3.3.1 ———. "Domestic Licensing of Special Nuclear Material (10 CFR Part 70)," *Federal Register*: Vol. 64, No. 146. pp. 41338-41357. July 30, 1999.
- 15.3.3.1 Nuclear Regulatory Commission (U.S.) (NRC). Inspection Manual, Procedure 88025, "Maintenance and Surveillance Testing." NRC: Washington, D.C. May 23, 1984.
- 15.3.3.1 ———. Inspection Manual, Procedure 88062, "Maintenance and Inspection." NRC: Washington, D.C. January 1996.
- 15.3.3.1 ———. Regulatory Guide 1.160, Rev. 2, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants." NRC: Washington, D.C. March 1997.