INSPECTION PROCEDURE 88115

SUPPLIER/VENDOR INSPECTION (CONSTRUCTION PHASE)

PROGRAM APPLICABILITY: 2630

88115-01 INSPECTION OBJECTIVES

01.01 To determine if vendors of items relied on for safety (IROFS) comply with an established quality assurance (QA) program that satisfies the requirements of 10 CFR 70.22(f).

01.02 To determine if vendors that supply items relied on for safety, products, or services, have developed and implemented adequate programs to evaluate and correct conditions adverse to quality, including the reporting requirements of 10 CFR Part 21.

01.03 To determine that the corrective action program is in accordance with requirements of an established QA program and is adequately defined by effective procedures that identify and correct conditions adverse to quality and preclude recurrence of significant conditions adverse to quality.

01.04 To determine whether the applicant is providing acceptable oversight of the vendor's QA activities.

88115-02 INSPECTION REQUIREMENTS

02.01 Vendor/Supplier Inspection: Verify that procurement documents require that suppliers, contractors, and subcontractors implement documented QA programs with appropriate procedural controls, consistent with the requirements of 10 CFR70.22(f), before the initiation of work.

02.02 Procurement Document Control: Verify that applicable regulatory requirements, including controls for documenting and reporting deficiencies and maintaining adequate quality, are suitably included in procurement documents for material, equipment, and services, and that these requirements are appropriately implemented by the supplier.

02.03 Corrective Actions: Verify that nonconforming items and deficiencies were evaluated for potential adverse effects, including the performance of a root-cause analysis for

significant conditions adverse to quality, and that appropriate 10 CFR Part 21 evaluation and notification of defects and nonconformances were performed.

02.04 Inspection of Applicant's Surveillance of QA Program Implementation

a. Applicant Preparation. With the assistance of appropriate members of the applicant's organization, perform the following examinations:

1. Review the procurement documents related to scope of QA/Quality Control (QC) responsibilities delegated to the contractor.

2. Review applicant plans and activities relating to the attainment of overall (reviews, inspection, audits) contractor surveillance objectives.

3. Review information on previously identified deficiencies, including planned corrective actions.

4. Review surveillance plan with applicant.

5. Assess the adequacy of the plan, regarding the stated scope and overall surveillance objectives.

6. Review records related to qualifications of individuals assigned to perform the surveillance activity.

b. Audit of Applicant Surveillance Activities. Observe and evaluate the adequacy of QA program implementation relating to the applicant's conduct of the following contractor surveillance activities:

1. Pre-surveillance conference.

2. Execution of surveillance by members of the applicant's organization.

3. Identification and summarization of deficiencies.

4. The attainment of planned surveillance objectives.

5. Exit interview, as related to the attainment of required and timely contractor corrective actions.

88115-03 INSPECTION GUIDANCE

This inspection procedure applies to the implementation of the applicant's or licensee's QA program during the design and construction of a Mixed-Oxide Fuel Fabrication Facility (MFFF). The MFFF QA program is described in the Duke, Cogema, Stone and Webster, "Mixed-Oxide Fuel Fabrication Facility, MOX Project Quality Assurance Plan (MPQAP)", Docket Number 070-03098, under US Department of Energy Contract DE-AC02-99-CH10888. This inspection procedure applies to the principal structures, systems, and

components (PSSCs) and IROFS; as applied to the design, fabrication, construction, and preoperational testing of the structures, systems, and components (SSCs) of the plant; and to related activities described in the Integrated Safety Analysis (ISA).

Selection of areas for evaluation during inspections shall be based on the risk significance of the SSCs, related activities, and past performance. The scope of inspections should also consider the cumulative effect of failures related to low-risk-significant SSCs, regarding their potential effects on overall system performance and reliability.

For instances where first-of-its-kind components or equipment are used in specific applications, it may be necessary to perform an inspection of the manufacturer's facility, to gain confidence in the capability of the item to perform its intended safety function. Other instances that may prompt an inspection are those components or equipment, identified by 10 CFR Part 21 reports, or construction deficiencies reported pursuant to the applicant's or licensee's reporting requirements.

If the supplier/vendor is purchasing commercial-grade items and dedicating them as a basic component, for use as an IROFS, then the inspector should determine whether this process is in accordance with an approved quality assurance plan.

03.01 Vendor/Supplier Inspection: Verify that the applicable procurement documents require that contractors and subcontractors supplying Quality Level (QL-1) items and services have established and implemented an acceptable QA program. The vendor's documented QA program shall implement the applicable quality requirements specified in the applicant's MPQAP. The extent of the QA program applicability will depend on the scope, nature, or complexity of the item or service being procured. The procurement document shall also specify that the supplier incorporate the appropriate MPQAP requirements into any sub-tier supplier-issued procurement document.

Verify that the licensee has established the appropriate procedural controls to assure that procurement documents include a statement of work the contractor will perform, that identifies requirements such as: (1) applicable regulatory, design, technical, administrative, and reporting requirements; (2) drawings; (3) specifications; (4) codes and standards; (5) test and acceptance requirements; (6) access for audit or inspection by the purchaser; (7) identification of documentation to be submitted to the purchaser or retained by the supplier (including retention times); and (8) special process instructions that should be completed by the supplier(s)

03.02 Procurement Document Control: Verify that the applicable procurement documents require that contractors and subcontractors have established and implemented appropriate procedural controls for reporting and dispositioning of nonconformances.

Verify that procurement document changes to the scope of work, technical requirements, QA program requirements, right of access, documentation requirements, nonconformances, and hold points are subject to the same degree of control as used in the preparation of the original documents. Verify that changes made as a result of proposal/bid evaluations or pre-contract negotiations are incorporated into the procurement documents.

For selected items, identify the attributes to be inspected to assure that procedures adequately describe and control the manufacturing process; that critical in-process tests adequately verify those attributes that cannot be verified after subsequent assembly operations; and that prescribed tests are performed on the product to confirm performance-based requirements.

03.03 Corrective Actions: Verify that procurement documents include requirements for the supplier to report nonconformances and purchaser approval of the disposition of nonconformances. Verify that the corrective action program also contains appropriate provisions to ensure that conditions adverse to quality are promptly identified and corrected. Verify that criteria for determining a significant condition adverse to quality are established and the responsible management evaluates significant conditions adverse to quality for their extent and impact. Verify that significant conditions adverse to quality, the cause of the condition, and the corrective actions to preclude recurrence are documented and responsible management determines the root cause of the problem and takes corrective action to prevent recurrence.

If applicable, verify that procurement documents include requirements for the supplier to establish and maintain a QA program that complies with the requirements of Part 21, regarding the reporting of defects and noncompliances. If it is known that a vendor/subcontractor has issued a Part 21 notification, verify the accuracy and completeness of the information submitted by the reporting party to the purchasers (for deviations, as defined by Part 21) and/or the U.S. Nuclear Regulatory Commission (NRC) (for deviations determined to be defects).

03.04 Inspection of Applicant's Surveillance of QA Program Implementation The inspector must keep in mind that this is an inspection of the applicant and not of the contractor. The primary purpose of the inspections will be to examine the implementation of applicant QA Program surveillance responsibilities.

The following conditions may warrant a more thorough examination:

1. Examination of applicant contractor-surveillance records discloses substantive deficiencies, or issues, relating to the adequacy of applicant execution of contractor surveillance responsibilities.

2. The results of applicant surveillance activities are insufficient to ascertain the general status of the contractor's implemented QA activities for the specific contract and where the general adequacy of his QA program has not been previously established by a Regional (routine or generic) inspection.

3. The applicant has identified numerous and substantive deficiencies relating to the implementation of the contractor's QA program for ongoing or near-future activities; but apparently neither the applicant nor the contractor has initiated timely corrective action in this regard.

4. Examination of applicant surveillance records discloses a substantive absence of execution of applicant QA program delineated surveillance responsibilities related to verifying contractor adherence to material, test,

inspection, and procurement document requirements prepared by the applicant.

88115-04 INSPECTION RESOURCES

An initial inspection of supplier/vendor programs may be conducted on issuance of the construction authorization, provided the applicant/licensee issued a purchase order, to the supplier/vendor, that invokes the requirements of Part 21. Depending on the work scope, this inspection will consist of one to two inspectors, at the supplier's facility, for 32-64 hours. The number and frequency of this inspection depend on the number of vendors/suppliers to be reviewed, and may be planned by NRC management for each contractor or vendor with QA/QC responsibilities, as the contracts are announced by the applicant, or routine examinations of the QA inspection identify substantive deficiencies in, or concerns relating to, the adequacy of applicant execution of contractor surveillance responsibilities.

88115-05 REFERENCES

Duke, Cogema, Stone and Webster, "Mixed-Oxide Fuel Fabrication Facility, MOX Project Quality Assurance Plan (MPQAP)", Docket Number 070-03098, under US Department of Energy Contract DE-AC02-99-CH10888, latest revision accepted by NRC.

Code of Federal Regulations, 10 CFR Part 21, "Reporting of Defects and Noncompliances."

Code of Federal Regulations, 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

U.S. Nuclear Regulatory Commission, Generic Letter 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products."

U.S. Nuclear Regulatory Commission, Information Notice 88-35, "Inadequate License Performed Vendor Audits."

U.S. Nuclear Regulatory Commission, Information Notice 89-70 and supplements, "Possible Indications of Misrepresented Vendor Products."

U.S. Nuclear Regulatory Commission, Information Notice 00-11, " Licensee Responsibility for Quality Assurance Oversight of Contractor Activities Regarding Fabrication and Use of Spent Fuel Storage Cask Systems."

U.S. Nuclear Regulatory Commission, NRR Office Letter No. 1300, "Procedures for Handling 10 CFR Part 21 and 10 CFR 50.55(e) Notifications of Defects, Noncompliances, and Construction Deficiencies."

END

ATTACHMENT 1

Revision History for IP 88115

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Accession Number
	10/25/06 CN 06-031 06-NMSS	IP 88115 is a newly issued procedure. Issued for MOX inspection program to improve effectiveness and efficiency by incorporating and consolidating vendor inspection requirements.	None	N/A	