INSPECTION PROCEDURE 88108

QUALITY ASSURANCE: CONTROL OF MATERIALS, EQUIPMENT, AND SERVICES (PRE-LICENSING AND CONSTRUCTION)

PROGRAM APPLICABILITY: 2630

88108-01 INSPECTION OBJECTIVES

01.01 To determine whether the procurement of Quality Level 1 (QL-1) and QL-2 material, equipment and services are controlled to assure conformance with specified technical and Quality Assurance (QA) requirements.

01.02 To determine whether the necessary controls have been established for QL-1 and QL-2, to ensure that only correct and accepted material, parts, and components are used or installed.

01.03 To determine that special processes that control or verify quality are controlled in accordance with U.S. Nuclear Regulatory Commission (NRC)-approved QA program requirements.

01.04 To determine that the handling, storage, cleaning, packaging, shipping, and preservation of items are controlled in accordance with requirements of the NRC-approved QA program, to prevent damage or loss and to minimize deterioration.

01.05 To determine that a process has been established for controlling items that do not conform to specified requirements and to prevent inadvertent installation or use. To determine that established controls provide for: (1) identification; (2) documentation; (3) evaluation; (4) segregation; when practical; (5) disposition of nonconforming items; and (6) for notification to affected organizations.

01.06 To determine if commercial-grade item dedication is appropriately defined and implemented to provide the necessary assurance of quality.

88108-02 INSPECTION REQUIREMENTS

Verify that selected elements associated with the applicant's systems for controlling purchased material, equipment, and services (as identified in an approved inspection plan) are in accordance with the applicant's approved QA Plan. Elements chosen for inspection may include three or more of the following:

02.01 Procurement Control System. Determine if the procurement of QL-1 and QL-2 material, equipment, and services are controlled to assure conformance with specified technical and committed QA Program and associated QA procedural requirements.

02.02 Identification and Control of Material, Parts, and Components. Determine if the QA program, and associated QA procedures, implement the necessary controls for QL-1 and QL-2, to assure that only correct and accepted material, parts, and components are used or installed. In addition, for QL-1, verify that procedures require that identification is

maintained on the items, or in documents traceable to the items, in a manner that assures that adequate identification and controls are established and maintained.

02.03 Control of Special Processes. Determine if the QA program and associated QA procedures establish the necessary requirements for the control of special processes, such as welding, heat treating, chemical cleaning, and nondestructive examination. Verify that these requirements include: (1) personnel qualification; (2) certification; (3) acceptable equipment; (4) environmental conditions; and (5) applicable codes, design specifications, and other established standards.

02.04 Handling, Storage, and Shipping. Determine if the QA program and associated QA procedures establish the necessary requirements to control the handling, storage, cleaning, packaging, shipping, and preservation of items, to prevent damage or loss and to minimize deterioration.

02.05 Nonconforming Materials, Parts, or Components. Determine if the QA program and associated QA procedures provide a process for controlling items that do not conform to specified requirements. Verify that these items are controlled to prevent inadvertent installation or use. Verify that the process for controlling items provides for: (1) identification; (2) documentation; (3) evaluation; (4) segregation when practical; (5) disposition of nonconforming items; and (6) notification to affected organizations.

02.06 Programmatic Review of Commercial-Grade Item Dedication.

a. Commercial-Grade Item Dedication Program Definitions. Determine if commercial-grade item program definitions are established and described, consistent with regulatory and QA plan requirements.

b. Dedication Activity Inspection. Determine if commercial-grade item dedication is appropriately performed in accordance with the QA plan.

88108-03 INSPECTION GUIDANCE

03.01 Procurement Control System.

a. Review the applicant's system for evaluating and selecting suppliers/subcontractors and their proposals/offers. Verify that evaluations are performed before subcontracts and/or purchase orders are awarded. Verify that the measures used for evaluating and selecting procurement sources are as specified in QA procedures and meet the requirements of the approved QA Plan. Verify that suppliers/subcontractors for QL-1 items have been placed on the approved supplier list and are periodically evaluated in accordance with the approved QA Plan.

b. Review the applicant's measures for evaluating supplier/subcontractor performance after contracts are awarded. Verify that such measures have been established and are in accordance with the approved QA Plan. Review a variety of procurement contractors (at least one each for materials, equipment, and services) associated with a QL-1 (SSCs) and verify that established evaluation measures are being followed.

c. Review the applicant's methods for accepting supplier-subcontractor-furnished material, equipment, or services. Verify that the supplier/subcontractor with an approved QA program has been placed on the applicant's Approved Suppliers List before the award of the subcontract. Verify that any certificate of conformance,

source verifications, receipt inspections, or post-installation testing (or other approved methods) used to accept QL-1, affecting materials, equipment, or services, have been performed per the approved QA Plan and associated implementing procedures.

d. Select two to three examples of purchased material, equipment, or services, to verify that the procurement process has been performed per the approved QA Plan and associated implementing procedures.

e. Review any reports of nonconformance from suppliers/subcontractors, and verify that the applicants have properly evaluated their effect on QL-1 safety controls.

f. Review the applicant's system for specifying, accepting, and receiving commercial-grade items. Verify that this system meets the requirements in the approved QA Plan and implementing procedures.

03.02 Identification and Control of Material, Parts, and Components.

a. Verify that the applicant has established and maintained an identification system on QL-1 items.

b. Verify that item identification methods make use of physical markings and ensure that traceability is established and maintained in a manner that allows an item to be traced to applicable design or other specifying documents. Verify that item traceability documentation ensures that the item can be traced from its source through installation or end use.

03.03 Control of Special Processes.

a. Verify that the applicant has established and maintained a list of special processes that each organization will perform, or will be responsible for performing.

b. Verify that special processes (such as welding, heat treating, chemical cleaning and nondestructive examination) that control or verify quality are controlled in accordance with the approved QA Plan and implementing procedures.

03.04 Handling, Storage, and Shipping.

a. Verify that the applicant controls the handling, storage, cleaning, packaging, shipping, and preservation of items, in accordance with established work and inspection procedures, shipping instructions, or other specified documents, as required by the approved QA Plan.

b. If required for particular items, verify that the applicant has specified and provided special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas and specific moisture and/or temperature levels). Verify that the applicant adequately maintains the tools and equipment in accordance with the approved QA Plan and implementing procedures.

03.05 Nonconforming Materials, Parts, or Components.

a. Verify that the applicant has an established process for controlling items that do not conform to specified requirements. Verify that nonconforming materials, parts, or components are controlled to prevent inadvertent installation or use.

b . Verify that the process for controlling nonconforming items includes the following requirements, as specified in the approved QA Plan:

1. Identification - Verify that nonconforming items are identified by marking, tagging, or other methods that do not adversely affect their end uses.

2. Documentation and evaluation - Verify that nonconformance documentation clearly identifies and describes the characteristics that do not conform to specified criteria. Verify that the responsibility and authority for reviewing, evaluating, approving the disposition, and closing nonconformances is specified.

3. Segregation - Verify that the applicant has made provisions to segregate nonconforming items by placing them in a clearly identified and designated hold area, until properly dispositioned, or if segregation is impractical, employ other precautions to preclude inadvertent use.

4. Disposition - Verify that the disposition of "use-as-is," "reject," "repair," or "rework," for nonconforming materials, parts, or components, is clearly identified and documented. Verify that items that do not meet the original design requirements and are dispositioned "use-as-is" or "repair" are subject to design control measures commensurate with those applied to the original design. Determine that the disposition of an item to be reworked or repaired includes a requirement to reexamine the item, to verify acceptability.

03.06 Programmatic Review of Commercial Grade Item Dedication. 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 also should consider the cumulative effect of failures related to low-risk-significant SSCs, regarding their potential effects on overall system performance and reliability.

Specific Guidance:

a. Commercial-Grade Item Dedication Program Definitions.

Verify that definition of "commercial-grade item" meets the requirements of 10 CFR Part 21.

1. Verify that preferred definitions of critical characteristics, dedicating entity, and dedication are adopted.

2. Verify that the licensee commits to comply with all provisions associated with the commercial-grade-item dedication definitions.

3. Verify that the QA program describes the responsibilities and requires instructions and procedures for commercial-grade item dedication.

b. Dedication Activity Inspection.

1. Verify that commercial-grade items are identified as such in approved design output documents.

2. Verify that the original intended function and design requirements are met for substituted commercial-grade items.

3. Verify that commercial-grade item supplier evaluation and selection are based on the complexity and importance to safety, when applicable.

4. Verify that the basis for sampling plans used for commercial-grade-item dedication activities are documented; and

   (a) Sampling plans for high-safety-risk-significant activities use criteria that provide a 95-percent confidence that only 5 percent of the items in a lot are defective (95/5).

   (b) Lots sampled are essentially homogeneous.

5. Verify that commercial-grade items are identified in the procurement documents by the manufacturer's published product descriptions.

6. Verify that, after receipt of a commercial-grade item, the purchaser confirmed the following:

   (a) Damage was not sustained during shipment.

   (b) The item received was the item ordered.

88108-04 INSPECTION RESOURCES

Inspection resources necessary to complete this inspection procedure are estimated to be 24-36 hours of inspection per facility visit. Once the construction authorization is issued, the basics of this inspection procedure should be conducted annually, during the construction phase.

04.01 Procurement Control System. This section should be inspected once per year or when significant design control changes occur. Estimated effort is 16 to 20 hours per occurrence.

04.02 Identification and Control of Material, Parts, and Components. This section should be inspected once per year or when significant additions or changes occur. The resource estimate for this section is 2 to 4 hours per occurrence.

04.03 Control of Special Processes. This section should be inspected once per year or when significant additions or changes occur. The resource estimate for this section is 2 to 4 hours per occurrence.

04.04 Handling, Storage, and Shipping. This section should be inspected once per year or when significant additions or changes occur. The resource estimate for this section is 2 to 4 hours per occurrence.

04.05 Nonconforming Materials, Parts, or Components. This section should be inspected once per year or when significant additions or changes occur. The resource estimate for this section is 2 to 4 hours per occurrence.

04.06 Programmatic Review of Commercial Grade Item Dedication. This section should be inspected once per year or when significant additions or changes occur. The resource estimate for this section is 2 to 4 hours per occurrence.

8108-05 REFERENCES

U.S. Code of Federal Regulations, Title 10, Part 70, “Domestic Licensing of Special Nuclear Material.”

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 (Sections 7, 8, 9, 13, and 15).

Duke, Cogema, Stone and Webster, “Mixed-Oxide Fuel Fabrication Facility Construction Authorization Request,” latest revision accepted by NRC.

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

END

ATTACHMENT 1

Revision History for IP 88108

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Accession Number
	02/07/07 CN 07-006	IP 88108 is a newly issued procedure. Issued for MOX inspection program to improve effectiveness and efficiency by incorporating and consolidating quality assurance requirements for the control of materials, services, and equipment and the associated inspection requirements.	None	N/A	ML 070110343