QUALITY ASSURANCE: PROGRAM DEVELOPMENT AND IMPLEMENTATION (PRE-LICENSING AND CONSTRUCTION)

PROGRAM APPLICABILITY: 2630

88106-01 INSPECTION OBJECTIVES

01.01 To determine whether the applicant's quality assurance (QA) activities are conducted in accordance with U.S. Nuclear Regulatory Commission (NRC) approved QA program requirements.

01.02 To determine (at the appropriate time of the construction phase) that a process has been established to assure that structures, systems, and components (SSCs) have been characterized and classified in accordance with NRC-approved QA program requirements.

01.03 To determine that a process has been established to assure that the necessary indoctrination, training, and qualification of personnel performing or managing quality-affecting activities are identified and provided, and that suitable proficiency is achieved and maintained.

01.04 To determine that the applicant has established a system of management assessments to evaluate the effectiveness and implementation of QA program elements and other management measures for items relied on for safety (IROFS) and to address the technical adequacy of the items evaluated.

88106-02 INSPECTION REQUIREMENTS

Verify that selected elements associated with the applicant's functional organization and QA program structure (as identified in an approved inspection plan) are in accordance with the applicant's approved QA Plan. Elements chosen for inspection may include two or more of the following:

02.01 Organization. Applicant's organizational structure, functional responsibilities, and delegation authority;

02.02 Classification of Structures, Systems, and Components (SSCs). Quality Level categorization of SSCs commensurate with their safety significance;

02.03 QA Training. QA indoctrination, training, and qualification of personnel performing or managing quality-affecting activities are identified and provided to assure suitable proficiency is achieved and maintained; and

02.04 Management Assessments. Applicant management assessments and audits of QA program elements, to evaluate the effectiveness and implementation of QA program elements and other management measures for IROFS, and to address the technical adequacy of the items evaluated.

88106-03 INSPECTION GUIDANCE

03.01 Organization. Review the organizational requirements in the approved QA Plan. Verify that organizational structure, functional responsibilities, delegations of authority, and interfaces for those managing, performing, and assessing the work, have been properly established.

03.02 Classification of SSCs and IROFS.

a. Before the license application and associated Integrated Safety Analysis (ISA) have been reviewed and approved, the inspector should focus on any changes to the QL designations that would necessitate reevaluation of any QA grading applied. Specifically, the inspector should verify that:

    1. Changes in QA categorization are performed and documented in accordance with applicable QA project procedures.

    2. QA categorization changes require updating of the applicable design documents for the particular SSC that was changed and that these changes necessitated the review of applicable QA requirements for confirming or changing previously established graded QA controls.

    3. The licensee's QA Plan requirements for QLs assigned to SSCs are commensurate with their safety significance.

    The inspector should inform the NRC licensing function of any changes made to the QL designations.

b. After NRC's licensing function has reviewed and approved the license application and associated ISA, the inspector should review the licensee's QA program and pertinent implementing procedures and instructions in the steps below, and verify that the definitions of the various QLs are consistently applied throughout the program. Verify that the grading process is clearly described in procedures, and conducted, reviewed, and approved by the appropriately designated organizational functions.

    1. Review the SSCs identified in the applicant's safety analyses for the selected areas. Determine if the applicant has identified each SSC with the proper safety significance, by verifying that it has been properly categorized in the various QLs. Focus largely on those SSCs that are listed as less risk-significant, to ensure that the applicant is not underestimating the safety

significance. For example, would the failure of a control designated as QL-1b or lower, lead to loss of double contingency or cause 10 CFR 70.61 requirements to be exceeded.

2. Verify that the applicant applies a graded approach to the process by ensuring that the level of analysis, documentation, and actions used to comply with a requirement are commensurate with: (1) the relative importance to safety, safeguards, and security; (2) the magnitude of any hazard involved; (3) the life cycle stage of a facility; (4) the programmatic mission of a facility; (5) the particular characteristics of a facility; (6) the relative importance of radiological and non-radiological hazards; and (7) any other relevant factor.

3. Review changes in QA categorization to verify they have been performed in accordance with QA procedures, and that applicable design documents were changed accordingly.

4. Review the applicant's procedure for classifying SSCs and IROFS according to their importance to safety. Verify that the process described in the procedure is consistent with the requirements in 10 CFR Part 70, the Mixed Oxide Project Quality Assurance Plan (MPQAP), and the Construction Authorization Request (CAR). Verify that the current listing of Principle Structures, Systems and Components and Items Relied on for Safety (PSSCs) and IROFS important to safety is documented on a (Q-List). Select a number of PSSCs/IROFS not on the Q-list and verify that the engineering basis for not including them is adequately documented.

5. Select several Q-list items and verify that adequate analysis was performed to demonstrate that the SSCs and IROFS meet the design basis established in the CAR, license, engineering documents, system descriptions, applicable regulatory requirements, or other design basis documents.

6. Verify that requirements for the Q-list items are adequately translated into specifications, drawings, procedures, and instructions.

7. Verify that design work for the Q-list items selected is completed and documented on a timely basis and to the level of detail to support the overall design process, fabrication, construction, and operation. Verify that the design documents have sufficient detail, regarding purpose, method, assumptions, design input, references, and units to enable a person technically qualified in the subject to understand the documents and verify their adequacy without recourse to the originator. Verify that documentation of design analysis includes: (1) the definition of the objectives of the analysis; (2) definition of design inputs and their sources; (3) results of literature searches; (4) identification of assumptions; (5)identification of computer calculations; and (6) identification of the originator, reviewer, and approver for the Q-list items selected. Verify that the design analysis

documents are legible and in forms suitable for reproduction, filing, and retrieval.

8. Verify that procedures are established that require documented verification of dimensional accuracy and completeness of design drawings and specifications. Verify that procedures are established requiring design drawings and specifications to be reviewed by the QA organization, to assure that the documents are; (a) prepared, reviewed, and approved in accordance with documented procedures; and (b) contain the necessary QA requirements such as inspection and test requirements, acceptance requirements, and the extent to which inspections and test results are required to be documented.

9. Verify that design procedures are prepared, reviewed, and approved in accordance with the document control program.

10. Select several calculations completed to support the design of SSCs and IROFS on the Q-list. Verify that the calculations are identified by subject (including the SSC and IROFS to which the calculations apply), originator, reviewer, and date – or by other designators, – such that the calculations are traceable.

03.03 QA Training.

a. Review the QA indoctrination of personnel performing quality-affecting activities, to verify that it includes the elements specified in the approved QA Plan and implementing procedures. Verify that all personnel performing quality-affecting activities have received QA indoctrination.

b. Review the procedures for qualification and certification of Nondestructive Examination personnel, inspection and test personnel, and/or Audit and Lead Audit personnel, to verify that these qualification and certification programs meet the requirements in the approved QA Plan. Verify that periodic reevaluation of job performance and record-keeping of qualifications and certifications are in accordance with the QA Plan. Verify that personnel have completed the qualification/certification program(s) before performing these examinations, inspections, and tests.

03.04 Management Assessments. Management assessments should include the following levels of activities to evaluate the effectiveness of the QA program:

Audits - independent planned and documented evaluations performed by the QA organization. Audits evaluate the scope, status, adequacy, programmatic compliance, and implementation effectiveness of quality-affecting activities.

Assessments - management-directed evaluations of the scope, status, adequacy, programmatic compliance, and implementation effectiveness of QA and other management measures in its area of responsibility.

a. Verify that written procedures for conducting management assessments and audits have been established and approved per the QA Plan.

b. Verify that management assessments and audits are being scheduled, performed, and reported in accordance with these approved procedures.

c. Verify that management assessments and audits are conducted in accordance with written procedures that include the following elements:

    1. Identification of training and qualification requirements for assessment and audit personnel;

    2. Authorization for the assessment team to investigate any aspect of the items under evaluation, with access to relevant information;

    3. Provision for immediate corrective actions with appropriate documentation;

    4. Review of assessment results by management having responsibility for the area evaluated;

    5. Documentation and distribution of assessment findings and recommendations to appropriate management for review and response; and

    6. Interface to the corrective action program to ensure timely and effective corrective action.

d. Review the applicant's audit program and verify that the following program elements have been implemented in accordance with the applicant's approved QA plan:

    1. Internal Audit Schedules: Internal audits should be scheduled in a manner to provide coverage, consistency, and coordination with ongoing work, and at a frequency commensurate with the status and importance of the work, and performance history.

    2. Audit Plans: An audit plan should be developed for each scheduled audit.

    3. Audit Teams: Auditors shall be independent of any direct responsibility for performing the work being audited. Audit personnel should have sufficient authority and organizational freedom to ensure the audit process is effective.

    4. Audit Performance: Elements that have been selected for the audit should be evaluated against specified requirements; audits should be performed in accordance with written procedures or checklists; audit results should be documented by auditing personnel, and reported to, and reviewed by, management having responsibility for the area audited. Conditions requiring prompt corrective action should be reported immediately to management of

the audited organization; conditions adverse to quality should be documented according to the requirements of the applicant's approved QA plan; minor audit findings, if corrected during the audit, shall be documented and verified by the audit process.

5. Reporting Audit Results: The audit report should be issued to the management of the audited organization and participating organizations. If applicable, the audit report should include a response due date for conditions adverse to quality and minor adverse conditions.

6. Responding to Audits: The management of the audited organization should respond to conditions adverse to quality according to the requirements of the applicant's approved QA plan.

7. Evaluating Audit Responses: The adequacy of corrective actions for conditions adverse to quality should be evaluated in accordance with the requirements of the applicant's approved QA Plan.

8. Closing an Audit: Follow-up action should be taken to verify that corrective actions are accomplished in accordance with the requirements of the applicant's approved QA Plan.

9. Audit Team Qualification Requirements: Auditors should have appropriate orientation, current applicable training, and demonstrated competency. The lead auditor should be certified in accordance with the applicant's approved QA Plan, as being qualified to lead audits.

88106-04 RESOURCE ESTIMATE

Inspection resources necessary to complete this inspection procedure are estimated to be 32 to 40 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 Organization. This section should be inspected once per year or when significant organizational or management changes occur. Estimated effort is 4 to 8 hours per occurrence.

04.02 Classification of SSCs. This section should be inspected once per year or when significant additions or changes to SSCs occur. Before ISA approval, the resource estimate for this section is 4 to 8 hours per occurrence. After ISA approval, the resource estimate for this section is 12 to 16 hours per occurrence.

04.03 QA Training. This section should be inspected once per year or when significant additions or changes to personnel or qualification requirements occur. The resource estimate for this section is 8 to 12 hours per occurrence.

04.04 Management Assessments. This section should be inspected once per year or when significant QA program deficiencies are identified. The resource estimate for this section is 4 to 8 hours per occurrence.

88106-05 REFERENCES

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

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

3. 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.

4. 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 1, 2, and 18).

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

6. The American Society of Mechanical Engineers, NQA-1-1994 Edition with NQA-1a-1995 Addenda.

7. U.S. Nuclear Regulatory Commission, "Quality Assurance Program Requirements (Design and Construction)," (Rev. 3), Regulatory Guide 1.28.

END

ATTACHMENT 1

Revision History for IP 88106

Commitment Tracking Number	Issue Date	Description of Change	Training Needed	Training Completion Date	Comment Resolution Accession Number
	02/07/07 07-006 06-NMSS	IP 88106 is a newly issued procedure. Issued for MOX inspection program to improve effectiveness and efficiency by incorporating and consolidating quality assurance program development inspection requirements during pre-licensing and construction.	None	N/A	ML070090078