QUALITY ASSURANCE: PROBLEM IDENTIFICATION, RESOLUTION and CORRECTIVE ACTION (PIRCA)
(CONSTRUCTION, PRE-OPERATION AND OPERATION)

PROGRAM APPLICABILITY: 2630

88110-01 INSPECTION OBJECTIVES

01.01 To determine that the corrective action program is in accordance with requirements of the NRC-approved 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.

01.02 To verify that the licensee reports to management the results of reviews conducted on audit reports, internal surveillance reports, corrective action reports, and management assessments and initiates corrective actions as necessary.

01.03 To determine that significant conditions adverse to quality are evaluated for reportability and, if warranted, reported in accordance with 10 CFR 21, Reporting of Defects and Noncompliance."

88110-02 INSPECTION REQUIREMENTS

Verify selected elements associated with the applicant's program for PIRCA (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 Procedures. Determine if procedures pertaining to the corrective action program are approved and adequately implemented. Determine if procedures contain provisions for identifying, reporting and documenting conditions adverse to quality. Determine if procedures exist that describe the follow-up, closure and trending processes and ensure implementation in a timely manner.

02.02 Identification and Classification of Conditions Adverse to Quality. Determine if measures are established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances and significant conditions adverse to quality are promptly identified. Verify that conditions adverse to quality are appropriately classified according to their significance and corrective actions are taken accordingly.

02.03 Documentation and Reporting of Conditions Adverse to Quality. Determine if a process and instructions exist for documenting and reporting conditions adverse to quality to appropriate levels of management responsible for the conditions, and to the organization responsible for tracking. Verify that the licensee reports to management the results of reviews conducted on audit reports, internal surveillance reports, corrective action reports, or management assessments and initiates corrective actions as necessary.

02.04 Follow-up, Closure and Trending. Determine if proper implementation and closure of corrective action are completed in a timely manner. Determine if criteria are established for quality trending. Determine if trending information is distributed to affected organization management and used to identify significant conditions adverse to quality.

88110-03 INSPECTION GUIDANCE

This inspection procedure applies to the implementation of the applicant's Quality Assurance Plan and to the structures, systems, and components (SSCs) important to safety; and the design, fabrication, construction, testing and operation of the SSCs and barriers of the plant.

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.

03.01 Procedures. Verify that procedures are established that describe the corrective action program. Verify that the procedures have been reviewed and approved by the affected organizations. Verify that procedures describe a process for follow-up and closure of issues, including requirements for documenting closure.

Verify that a process and instructions exist for documenting and reporting conditions adverse to quality to appropriate levels of management responsible for the conditions and to the responsible organization for tracking.

Verify that criteria are established and a process described for identifying and tracking adverse quality trends.

03.02 Identification and Classification of Conditions Adverse to Quality. Verify that criteria for determining a significant condition adverse to quality are appropriately established. Select a sample of documented problems and verify the following:

a. The problems are adequately described and labeled with unique identifiers.

b. The problems are classified by significance and identify, as a minimum:

    1. Conditions adverse to quality, such as:

        a. failures;
        b. malfunctions;
        c. deficiencies;
        d. deviations;
        e. defective material and equipment; and
        f. state of noncompliance with quality assurance program requirements

    2. Significant conditions adverse to quality, such as:

a. Deficiencies that would seriously impact an item from performing its intended function of assuring public health and safety;

b. Deficiencies in design that have been approved for fabrication or construction where the design deviates extensively from design criteria and bases;

c. Deficiencies in the fabrication or construction of, or significant damage to, structures, systems or components that require extensive evaluation, re-design or repair in order to establish the adequacy of the structure, system or component to perform its intended function of assuring public health and safety;

d. Deviations from performance specifications that require extensive evaluation, re-design, or repair to establish the adequacy of the structure, system or component to perform its intended function;

e. A significant error in a computer program used to support activities affecting quality after it has been released for use;

f. Loss of essential data required for activities or items subject to the applicant's QA Program;

g. Repetitive problems indicating programmatic failures or precursor of significant technical deficiencies;

h. A condition that, if left uncorrected, has the potential to have a serious negative impact on activities or items subject to the applicant's QA Program.

03.03 Documentation and Reporting of Conditions Adverse to Quality. Select a sample of completed conditions adverse to quality, and;

a. Verify that for conditions adverse to quality that management has determined the extent of the adverse condition, completed remedial action as soon as practical, and documented the results.

b. Verify that significant conditions adverse to quality are documented and reported to management responsible for the condition, their upper management, and to the QA organization for tracking. Verify that the QA organization concurred with the proposed corrective action, including remedial action. For significant conditions adverse to quality, verify that corrective actions for root causes have been taken and are effective. Ensure that the QA requirements described in the licensee's corrective action procedures are being implemented.

c. Select several problems that have been resolved and verify that proper implementation of corrective actions and closures were completed in a timely manner.

d. Verify that the cause of the significant conditions adverse to quality are determined by qualified personnel using approved methods and corrective action taken is adequate to preclude recurrence.

e. Verify that significant conditions adverse to quality were evaluated for a stop work condition by the QA organization to determine if stopping work was warranted. Verify that appropriate action was taken by QA management to issue stop work orders to the responsible management in a timely manner after a stop work condition was identified. Verify that appropriate action was taken to lift and close (in part or total) the stop work issued by the QA organization based on the resolution of the related significant condition adverse to quality.

03.04 Follow-up, Closure, and Trending. Verify that reports are generated to identify conditions adverse to quality and significant conditions adverse to quality, and to provide management with a tool for identifying root causes. Verify that nonconformance documentation including reports are periodically analyzed by the QA organization to identify quality trends. Verify that trend evaluations are performed in a manner and at a frequency that provides for prompt identification of adverse quality trends. Verify that trend evaluations are distributed to affected organization management. Verify that identified adverse trends are reported to the management of the organization responsible for corrective action. Verify that the documentation for closure of the adverse condition has been generated and is complete, signed off, and properly filed and logged into a system to allow for retrieval.

88110-04 INSPECTION RESOURCES

Inspection resources necessary to complete this inspection procedure are estimated to be 8-16 hours of inspection per facility visit. It is anticipated that the resources need to complete the initial inspection would be approximately 16 hours. Once the construction authorization is issued, the basics of this inspection procedure should be conducted during the construction phase on an annual basis.

88110-05 REFERENCES

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

NUREG-1718, Standard Review Plan for the Review of an Application for a Mixed Oxide Fuel Fabrication Facility, August 2000.

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 (Section 16).

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

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