INSPECTION PROCEDURE 88005

MANAGEMENT ORGANIZATION AND CONTROLS

PROGRAM APPLICABILITY: 2600

88005-01 INSPECTION OBJECTIVES

This procedure addresses facility organization, procedure controls, internal reviews and audits, safety committees, and quality assurance programs for all fuel cycle facilities. The objectives of this procedure are to ensure that:

- 01.01 The licensee has an established organization with defined qualifications, responsibilities, and functions to administer the technical programs.
- 01.02 The licensee has established governing policies and procedures and implemented a system of operating procedures that ensures the use of only approved and current procedures, and that approved procedures exist for all plant functions affecting safety.
- O1.03 The licensee has established and implemented a system to perform internal reviews, self-appraisals, and audits.
- 01.04 The licensee has established onsite and offsite safety review committees (or their equivalents) that function in accordance with license conditions.
- 01.05 The licensee has established a quality assurance program for ensuring the quality and integrity of equipment and systems important to safety, where applicable.

88005-02 INSPECTION REQUIREMENTS

02.01 <u>Organizational Structure</u>. Verify that the licensee's organization or organizational structure addresses the qualifications of personnel for their assigned responsibilities, functions, and authorities.

Discuss with licensee representatives any organizational changes, structural changes, and/or changes in personnel responsibilities and functions, that have occurred since the last inspection. Also, with respect to these changes, ascertain whether a) the

individuals who made the changes were qualified to make them, and b) the changes were approved by NRC's appropriate licensing branch, or as otherwise required by the license or the licensee's procedures.

Examine licensee procedures that govern any of the types of changes specified above. Determine if these procedures were properly implemented to effect the

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changes made (particularly, whether the qualifications of personnel meet the requirements of the license, e.g., years of prior experience, educational background, training, required for the newly assigned responsibilities, as set forth in the license).

02.02 Procedure Controls

a. <u>Procedure Content and Approvals</u>. Verify that the licensee's system for approving procedures complies with license requirements. Such procedures should include, but not be limited to, facility operations, maintenance, training, health physics, nuclear criticality safety, administrative, etc.

Verify that the procedure control system requires 1) review and approvals by appropriate organizational units for significant changes made to procedures, and 2) document controls to ensure that all personnel affected by a procedure are adequately and timely informed of changes in the procedures, and 3) only approved and current procedures are used.

- b. <u>Procedure Change Reviews</u>. Review any safety-significant procedures that have been changed or modified since the previous inspection. For each such change:
 - 1. Verify that required approvals were obtained, signed off, and dated;
 - 2. Verify that the changed procedure received review and approval by the same individuals or functions that previously reviewed and approved the original procedure (or obtain justifications for changes in or departures from the original approval process);
 - 3. Verify that any previously approved field changes have been incorporated into the changed procedure within an established time period; and
 - 4. During a facility tour, note any changes in plant systems to verify that they conform to the procedural change reviewed.
- c. <u>Procedure Revising and Updating</u>. Verify that the licensee reviews and updates all safety-significant procedures on a periodic basis (usually annually), or as required by the procedures manual included in the license. Verify that revision and updating of the procedures is done as needed, whenever there are changes in equipment, or as a result of deficiencies found, regardless of the periodic review schedule.

02.03 <u>Reviews, Audits, and Assessments</u>

a. <u>Program Implementation</u>. Verify that the licensee is implementing a program for facility systems inspection

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(normally done on a shift or daily basis), or as otherwise required by license conditions and implementing procedures.

Verify that the licensee has performed periodic programmatic assessments to ensure that systems have been established to address meeting all safety commitments in the license.

Verify that a system exists for promptly reporting deficiencies to management and the NRC, for tracking corrective actions to completion, and for conducting self-appraisals of performance of plant safety systems.

Randomly select one or more internal facility system audits performed since the previous inspection, and examine the records documenting each audit to 1) verify that appropriate corrective actions were taken whenever deficiencies were found, and 2) verify that each record was properly signed and dated.

Determine, by interviewing the licensee representatives, whether they utilize a secondary (or followup) audit system on a periodic basis, conducted by a member of management or a senior technician not directly responsible for the system audited. (This is to determine if the licensee has attempted to verify that the findings of the primary audits were factual (although this may not be required by the license. Another effective approach to secondary audits, not normally required is to use a rotational audit system, i.e., avoid using the same individuals to perform the same audits on a continuous basis to decrease the chances that, in time, the auditor may overlook deficiencies due to over-familiarity with and rote acceptance of the way things are done).

Determine, by examination of a licensee self-appraisal report covering at least one functional area of process safety, that the licensee's self-appraisals of safety system performance reflect lessons learned from reported incidents, progress on ongoing corrective actions, and possible trends in safety system performance.

- b. <u>Responsibilities</u>. Verify that the licensee has included some essential elements to be audited (not all inclusive) during its inspections of facility systems, as follows, or as otherwise described in the license:
 - Whether responsibilities have been assigned for the review of planned and unplanned maintenance and testing activities,
 - Whether responsibilities have been assigned for the prompt review and evaluation of non-routine events and unusual occurrences,
 - 3. Whether responsibilities have been assigned for assessing the significance of non-routine events and unusual occurrences, and reporting them, both internally, and to the NRC,

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- 4. Whether responsibilities have been assigned for assuring completion of corrective actions related to nonroutine events and unusual occurrences, and
- 5. Whether audits have been conducted using written procedures and checklists.

O2.04 <u>Safety Committees</u>. Verify that the onsite and offsite safety committees (or equivalent) required by the license have been formally appointed and chartered, that their membership meets the terms and conditions stipulated in the license, and that meetings have been held at the required frequencies specified in the license. Examine the minutes of all meetings held by the safety committees since the previous inspection. Note any recommendations the committees have made and verify that the licensee has implemented or otherwise appropriately addressed those recommendations.

(If the license does not stipulate the membership or duties of the safety committees, verify that:

- a. their membership consists of managers or individuals with expertise in the areas of safety over which their committee has responsibility,
- b. their functions are clearly specified as those of approval, recommendation, fact-finding, etc., and
- c. the composition of the committee is sufficiently broad, and its working rules are appropriately constituted, that the committee can function independently without undue influence from line management.)

02.05 Quality Assurance Programs

a. Major Components Important to Safety

Verify that the quality assurance (QA) program is being conducted in accordance with license requirements (if the license contains require-ments for a QA program). In any case, examine QA records to determine that the licensee is performing tests on systems and components important to safety (including those used in transportation), and determine verification of approval.

Verify by discussions with licensee personnel whether components manufactured at vendor facilities are inspected at the vendor shops and/or upon receipt.

Verify that documentary evidence includes signoffs attesting to overall conformance to requirements for component design, testing, and installation requirements. If the license does contain certain requirements for the QA program, ascertain that changes have been approved by the appropriate authority. (Whether changes require approval will depend on the wording in the license.)

Verify that configuration control procedures and systems exist to ensure that changes in equipment, systems, and procedures important to safety are not reduced in their effectiveness as a result of unauthorized or unanalyzed changes that affect the safety of the subject or neighboring plant areas.

Other Quality Assurance Procedures. All essential activities conducted at the licensee's facility are reflected in numerous procedures that include quality controls in calibrations, sample preparation, sample counting, personnel dosimetry handling, laboratory equipment adjustments, etc. However, the various procedures for other QA activities may be changed from time to time and not require licensing approval. It should be verified that required procedures are being followed. Randomly select procedures for examination that have been changed as determined by discussions with licensee personnel. Verify by direct observation in chosen areas of interest how these changes improve the quality of operations and attendant results. Examples of improvement include procedural changes and modifications to facility areas that result in reduced airborne radioactivity and/or radiation exposure, internal review and audit followup that may result in the discovery of deficiencies and in the taking of corrective actions, and adjustments of analytical counting equipment and techniques that result in a higher degree of confidence and precision.

88005-03 INSPECTION GUIDANCE

General Guidance

Although applicable requirements will be found in each specific facility license, the inspectors are expected to review the specified program areas for general safety information.

O3.01 Organizational Structure. Changes in organization and organizational structure need only be examined with particular attention to changes in personnel, qualifications of personnel, functions, responsibilities, and authority; otherwise, if no changes have occurred in the organization since the previous inspection, there is no need to pursue the issue in any depth, except to state in the report that there have been no changes in the organization since the previous inspection.

03.02 Procedure Controls

a. Procedure Content and Approvals. Although periodic updating and revising of procedures are performed as the need arises; e.g., the discovery of deficiencies in some procedures, all changes in those procedures should be examined. Several of the changed procedures should be randomly selected and a determination made by direct observation of activities that the changed procedures reflect the activities being performed. Ensure that the review and approval process was in accordance with program requirements.

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O3.03 <u>Internal Reviews and Audits</u>. Routine inspections of operations, safety equipment, etc., may be done by senior technicians or shift supervisors on a shift and/or daily basis and these personnel do have direct responsibilities in the areas audited. Discuss with the licensee identified shortcomings of the system (if they exist) and express other ways to better accomplish the task with more confidence, such as the utilization of someone not directly involved in the activity to perform followup audits, perhaps on a weekly basis.

88005-04 RESOURCE ESTIMATE

An inspection performed using this inspection procedure is estimated to require 24 hours of inspector resources. This estimate is only for the direct inspection effort and does not include preparation for and documentation of the inspection.

88005-05 REFERENCES

Reg. Guide 3.52 "Standard Format and Content for the Health and Safety Sections of License Renewal Applications for Uranium Fuel Fabrication Plants," Revision 1, November 1986.

NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Facility," Draft, March 1995 and later.

END

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