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, plant safety committees, and program management for operational safety, radiation protection, fire protection, nuclear criticality safety (NCS), and quality assurance programs for all fuel cycle facilities. Plant safety, in the context of this procedure, refers to those areas which fall under the Nuclear Regulatory Commission's regulatory responsibilities. The objectives of this procedure are to determine whether management measures and other controls are established such that:

01.01 The licensee or certificate holder has implemented an organization in accordance with license or certificate requirements with defined qualifications, responsibilities, and functions to administer the safety programs.

01.02 The licensee or certificate holder has implemented governing policies for plant safety programs and management/staff understand their responsibilities and authorities under these policies.

01.03 The licensee or certificate holder has 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.

01.04 The licensee or certificate holder has implemented a system of internal reviews, self-assessments, and audits to identify, prioritize, and correct deficiencies related to regulated activities. The licensee or certificate holder has implemented a program for review of safety-significant events that meets license or certificate requirements.

01.05 Onsite and offsite plant safety committees (or their equivalents) are effective and functioning in accordance with license or certificate requirements.

01.06 The licensee or certificate holder is implementing a program for ensuring the quality and integrity of items relied on for safety (IROFS) and other equipment and systems important to safety.

88005-02 INSPECTION REQUIREMENTS

02.01 Organizational Structure. By discussions with licensee or certificate holder staff and management, and review of documentation, determine whether the licensee or certificate holder's organizational structure is in accordance with the license or certificate. By discussions with selected licensee or certificate holder managers who are new to their positions since the last Inspection Procedure (IP) 88005 inspection, and where appropriate, review of documentation, determine whether these managers meet the training and experience requirements for their positions as specified in the license or certificate.

02.02 Management and Administrative Practices for Operational Safety, Radiation Protection, Fire Protection, Chemical Safety, and NCS.

a. Plant Policy for Safety. By review of documentation, determine whether changes to the licensee or certificate holder's policy describing employee's responsibilities for operational safety, radiation protection, fire protection, chemical safety, and NCS are consistent with license or certificate requirements.

b. Management Responsibilities for Safety. By discussion, determine whether senior managers, operations managers, supervisors, radiation protection, and NCS function managers, engineers and technicians, operators, and support functions staff understand their responsibilities and authorities under the above policies.

c. Management Involvement in Administrative and Operating Procedures, Plant Safety Committees, and IROFS Failures Reports. By discussions with selected mangers and staff, determine whether the licensee or certificate holder meets requirements for management involvement in approving procedures, ensuring the plant safety committee (or equivalent) is operating in accordance with its charter, and reviewing IROFS and management measures failures that have been documented in accordance with 10 CFR 70.62(a).

02.03 Procedure Controls.

a. Procedure Content and Approvals. By reviewing a sample of recently changed procedures, determine whether the licensee or certificate holder's system for approving procedures complies with license or certificate requirements. Such procedures should include, but not be limited to, facility operations, maintenance, training, health physics, NCS, administrative, etc.

By reviewing procedures in use and discussions with licensee or certificate holder staff, determine whether procedure changes are:

1. Reviewed and approved as required by the license or certificate;

2. All personnel affected by a procedure are adequately and timely informed of changes in the procedures;

3. Only approved and current procedures are used; and

4. Whether any previously approved field changes have been incorporated into

the changed procedure within an established time period.

b. Procedure Revising and Updating. By reviewing a sample set of procedures, and by discussions with relevant plant staff, determine whether the licensee or certificate holder reviews and updates all safety-significant procedures on a periodic basis as required by the license, certificate, or method defined by licensee or certificate holder's procedure. By discussions, or by reviewing condition reports (or equivalent), determine whether revision and update of procedures is performed on a timely basis as a result of any procedural deficiencies found, regardless of the periodic review schedule.

02.04 Problem Identification and Resolution and Incident Investigations.

a. Program Implementation. Use direct observation of operations, discussions with relevant plant staff, and reviewing a sample of applicable documentation to determine the information below.

1. Determine whether equipment, human performance, and program issues are being identified by the licensee or certificate holder at an appropriate threshold and are being entered into the problem identification and resolution program.

2. Determine whether corrective actions commensurate with the significance of the issue have been identified and implemented by the licensee.

3. Determine whether the licensee or certificate holder is implementing a program for facility systems inspection (normally done on a shift or daily basis), or as otherwise required by the license or certificate conditions and implementing procedures.

4. Perform a screening review of items entered into the corrective action program. The intent of this review is to be alert to conditions, such as repetitive equipment failures or human performance issues that might warrant additional follow-up through this inspection procedure or other core inspection procedures. It is not intended that the results of this review be documented or that inspectors follow-up each item, only that the inspector should be alert for trends and risk significant or repetitive failures.

5. Review a sample of issues to determine whether the licensee or certificate holder has appropriately classified the issue and has taken appropriate short- and long-term corrective actions.

6. Determine whether the licensee or certificate holder has conducted periodic reviews, audits, and assessments to assure that safety commitments in the license or certificate are assessed at an appropriate frequency.

b. Event Review and Incident Investigations. Determine whether the licensee or certificate holder has implemented a program of reviews that meets license or certificate requirements for evaluating safety-significant events. Review the safety-

significant events which have occurred since the last IP 88005 inspection to determine compliance with the license or certificate, as well as the adequacy of the licensee or certificate holder's evaluations of these events and resultant corrective actions.

02.05 Plant Safety Committees. Determine whether the plant safety committee (or equivalent) required by the license or certificate is operating per the associated charter and implementing procedures.

02.06 Quality Assurance Programs. Determine whether the quality assurance programs (or equivalent) required by the license or certificate are being implemented per the relevant procedures.

## 88005-03 INSPECTION GUIDANCE

General Guidance.

Although applicable requirements will be found in each specific facility license or certificate, the inspectors are expected to review the specified program areas for general safety information. The items selected for inspection should be based on the risk significance or as deemed appropriate.

03.01 Organizational Structure. Discuss with licensee or certificate holder representatives any organizational changes, structural changes, and/or changes in personnel responsibilities and functions that have occurred since the last IP 88005 inspection. Determine whether the individuals who made the changes were qualified to make them, and whether the changes were approved by NRC's appropriate licensing branch, or as otherwise required by the license, certificate, or the licensee or certificate holder's procedures.

Review licensee or certificate holder's procedures that govern the types of changes specified above. Determine whether these procedures were properly implemented to effect the changes made. Focus on whether the qualifications of involved plant staff meet the requirements of the license or certificate, including years of relevant experience, educational background, and training required for the newly assigned responsibilities.

Changes in organization and organizational structure need only be examined with particular attention to changes in personnel, qualifications of personnel, functions, responsibilities, and authorities. If no significant changes have occurred in the organization since the previous IP 88005 inspection, then the inspection report should state that there have been no significant changes in the organization since the previous IP 88005 inspection.

03.02 Management and Administrative Practices for Operational Safety, Radiation Protection, Fire Protection, Chemical Safety, and NCS.

a. Plant Safety Policy. By discussions with plant management, determine whether the written plant policy describing each employee's authority and responsibility for operational safety, radiation protection, fire protection, chemical safety, and NCS

remains unchanged. If changed, confirm that the changes do not adversely affect safety by reducing organizational and/or personal responsibility.

The plant safety policy should express the overall importance of safety in relation to production activities. Production activities shall not be allowed to compromise the plant safety policy. The plant safety policy should empower each employee to question the adequacy of safety requirements and should prohibit operations when safety questions cannot be immediately resolved. Furthermore, the plant safety policy should ensure that each individual, regardless of position, is ultimately responsible for safety in his or her own work area. If any changes are made to the plant safety policy, the inspector should confirm that the changes do not diminish personal or organizational responsibility for safety.

b. Management Responsibilities for Safety.

1. Plant Manager. By observation and discussion with various employees, determine whether the Plant Manager has empowered every employee with the authority, responsibility, and training to ensure safe operations. Determine whether the Plant Manager shows adequate knowledge and interest in safety issues and that the plant manager holds his or her staff accountable for safe operations.

   The Plant Manager should demonstrate overall responsibility for safety by showing continued interest in the various safety disciplines. The responsibility for establishing practices carrying out the radiation protection, fire protection, chemical safety, and NCS requirements should be delegated through instructions and procedures. The Plant Manager is also expected to monitor the safety program by instituting operational reviews and for periodic independent reviews of the safety organization. Determine the level of the Plant Manager's direct observations of on-the-floor safety conditions.

2. Operations Management. Interview selected operations managers as to how they implement their responsibility for the various safety disciplines such as operational safety, radiation protection, fire protection, chemical safety, and NCS. By interviews and document reviews, determine how safety-related responsibilities have been conveyed to individuals in each manager's organization. Based on the manager's knowledge of the plant safety policy, and actions taken to monitor its implementation in the various safety disciplines, determine whether the overall management involvement is effective.

   Determine through interviews with the selected operations managers the degree of ownership they take for ensuring operational safety, radiation protection, fire protection, chemical safety, and NCS. Determine through interviews that the managers ensure their employees receive adequate training and qualification for the assigned tasks. Determine the degree to which managers monitor and enforce procedural compliance. Determine whether the managers ensure the adequacy of written procedures to ensure that considerations for operational safety, radiation protection, fire protection,

and NCS are adequately addressed for all operations under their supervision. Determine whether the managers are aware of and follow the licensee or certificate holder's configuration control policies and procedures for their assigned areas. Determine the level of the managers' direct observations of on-the-floor safety conditions.

3. Operations Supervisors. Interview selected operations supervisors to determine the adequacy of their understanding of their roles in implementing the plant safety policy. Supervisors should demonstrate an appropriate level of knowledge of operational safety, radiation protection, fire protection, chemical safety, and NCS for operations under their management. Determine the degree to which supervisors participate in the development and maintenance of procedures affecting their areas. Determine whether the supervisors expect and enforce procedural compliance. Supervisors should ensure that employees in their areas receive the required initial and periodic safety training.

4. Support Function Management. Support functions are those areas which are not directly involved in production activities, such as engineering, maintenance, quality assurance, quality control, construction, etc. Determine whether the managers in support functions are effectively involved in ensuring the effectiveness of the plant safety policy. Support function managers should carry out their responsibilities for operational safety, radiation protection, fire protection, chemical safety, and NCS in a manner similar to operations management. Safety responsibilities should be conveyed to individuals in each manager's organization in written documents and covered in training programs.

c. Management Involvement in Administrative and Operating Procedures and Plant Safety Committees.

1. Management Involvement in Administrative and Operating Procedures. Determine whether administrative procedures exist to ensure that the operational safety, radiation protection, fire protection, chemical safety, and NCS functions are consulted whenever a change or new activity affects the functions. Determine whether revised operating procedures are approved by the functions whenever process changes are made.

   Requirements should be established for developing, approving, and updating administrative and operating procedures for activities involving operational safety, radiation protection, fire protection, chemical safety, and NCS. Biennial review of operating procedures should be conducted.

2. Plant Safety Committee. Determine whether the plant safety committee (or equivalent) meets in accordance with its governing charter and procedures. Determine whether designated plant managers attend these Committee meetings regularly.

03.03 Procedure Controls. 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 reviewed by the licensee or certificate holder. Several of the changed procedures should be randomly selected by the inspector and a determination made by direct observation of activities that the changed procedures reflect the activities being performed. Determine whether the review and approval process was in accordance with program requirements.

03.04 Problem Identification and Resolution and Incident Investigations. A fundamental goal of the NRC's fuel cycle oversight process is to establish confidence that each licensee or certificate holder is detecting and correcting problems in a manner that limits the risk to members of the public. One key component of this process is event review and/or incident investigation.

Problem identification and resolution (PI&R) reviews are done by individual specialists while inspecting components of the overall safety program, such as during NCS inspections (PI&R in the NCS area), radiation protection (PI&R or radiation protection issues), etc. The PI&R review is to determine whether the overall PI&R program is operating effectively and in accordance with requirements.

a. Program Implementation. To the extent possible, this inspection should follow a performance based approach. Emphasize the products and results of the licensee's PI&R program. Inspections performed under this procedure should concentrate on the identification of problems and the effectiveness of corrective actions for risk significant issues (IROFS and management measures) rather than on reviewing the administrative aspects of the corrective action program and associated procedures.

   The inspector should examine, in part, a sample of licensee or certificate holder corrective action issues to provide an indication of overall problem identification and resolution performance.

   In selecting issues for inspection, the inspectors should seek examples of issues in operational safety, radiation safety, fire protection, chemical safety, and NCS, using the following criteria:

   1. Licensee or certificate holder identified issues (e.g., issues identified during audits or self assessments) including a sample of the highest significance level licensee corrective action items.

   2. Issues identified through employee concerns programs, if any.

   When evaluating the effectiveness of licensee or certificate holder corrective actions for a particular issue, the licensee's or certificate holder's actions must be viewed against the nature and significance (or potential significance) of the identified problem. While licensee or certificate holder corrective action programs may appropriately consider monetary, plant production, and other concerns as factors in determining significance, risk should be a primary factor in the licensee's or certificate holder's significance determination. Attributes to consider during review of licensee or certificate holder's actions associated with individual issues

include:

1. Complete and accurate identification of the problem in a timely manner commensurate with its significance and ease of discovery.

2. Evaluation and disposition of operability and reportability issues.

3. Consideration of extent of condition, generic implications, common cause, and previous occurrences.

4. Classification and prioritization of the resolution of the problem commensurate with its safety significance.

5. Identification of root and contributing causes of the problem.

6. Identification of corrective actions which are appropriately focused to correct the problem (may be deferred to biennial inspection).

7. Completion of corrective actions in a timely manner commensurate with the safety significance of the issue. If permanent corrective actions require significant time to implement, then determine whether interim corrective actions and/or compensatory actions have been identified and implemented to minimize the problem and/or mitigate its effects, until the permanent action could be implemented.

It is not expected that the inspectors assess each attribute for every issue selected for followup during these routine reviews. Rather, inspectors may choose to assess licensee or certificate holder performance against selected attributes, as necessary to be most effective.

Routine inspections of operations or equipment may be done by senior technicians or shift supervisors on a shift and/or daily basis. Discuss with the licensee or certificate holder any identified shortcomings from these activities. By discussions with operators, engineers, and maintenance staff, and reviewing records, determine whether the licensee or certificate holder staff is promptly reporting deficiencies to management, and adequately tracking corrective actions to completion.

Randomly select internal or contracted audits performed since the previous IP 88005 inspection, and examine the records documenting selected audits to determine whether there was a written plan for the audit, the audit adequately reviewed the audited area, appropriate corrective actions were taken whenever deficiencies were found, and whether there was a check of the effectiveness of the corrective action.

Determine by interviewing the licensee or certificate holder representatives, how the licensee or certificate holder assures the effectiveness of audits, such as by use of contractor audits, use of 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.

Part 70 licensees are required to maintain records of IROFS or management measures that have failed to perform their function upon demand or has degraded such that the performance requirements are not satisfied. These records should be readily retrievable and inspected. These records should identify the IROFS or management measure that has failed and the safety function affected, the date of discovery, date (or estimated date) of the failure, duration (or estimated duration) of the time that the item was unable to perform its function, any other affected IROFS or management measures and their safety function, affected processes, cause of the failure, whether the failure was in the context of the performance requirements or upon demand or both, and any corrective or compensatory action that was taken. A failure should be recorded at the time of discovery and the record of that failure updated promptly upon the conclusion of each failure investigation of an IROFS or management measure. (10 CFR Part 70.62(a)(3)).

b. Event Review and Incident Investigations. Review the events occurring since the last IP 88005 inspection to determine compliance with the license or certificate including, as appropriate;

1. The prompt review and evaluation of non-routine events and unusual occurrences;

2. Assessing the significance of non-routine events and unusual occurrences, and reporting them, both internally, and to the NRC;

3. Evaluation of extent of condition of findings; and

4. Assuring completion of corrective actions related to non-routine events and unusual occurrences.

The licensee or certificate holder's incident investigation program should identify and evaluate root and contributing causes, identify and evaluate recommendations to reduce the probability of recurrence and/or mitigate potential consequences, and ensure resolution of recommendations. There should be an extent of condition review. The root cause and extent of condition reviews and corrective actions should be sufficient to prevent reoccurrence of any violations of NRC requirements. The following should be addressed.

1. Determine whether all incidents have been reported to plant management (and NRC, if appropriate).

2. Categorization of incidents (e.g., as near-miss, minor, medium, and major). Each category should have its own level of investigation specified (e.g., such as no further action required, or setting up (or activating) an investigation committee with one or more experts). A system should be set up to investigate near-misses that might indicate the potential for the occurrence of significant incidents.

   The inspector should determine whether the licensee or certificate holder has a procedure in place to determine the cut-off points for investigating near-

misses. Based on the safety-significance, the inspector should look at the selected events to determine whether they were properly classified and addressed by the licensee or certificate holder. In addition, the licensee or certificate holder should have a procedure (such as trending analysis) to review events that fall below the threshold (i.e., below the cut-off for full-fledged investigation). This could provide useful information on inherent deviations from design intent, that exist within the system, which can then be rectified.

3. Establishment of an investigation team comprising, as a minimum; one expert, all persons involved in the incident, as well as other experts necessary to conduct a thorough investigation. Training, both initial and refresher, should be provided to the incident investigation team on techniques, methodology, and protocol.

4. Initiation of the incident investigation within 48 hours (within 24 hours of incident stabilization) to allow collection of evidence (such as fluid samples, values of critical process parameters before and after incident), and interviews with personnel while the incident is still fresh in their minds, etc. This information is often invaluable in correctly determining the root cause of an incident.

5. Determine whether an incident report, including date of incident, description of incident, contributing factors, root cause analysis, findings, and recommendations, has been provided to plant management and NRC, if appropriate.

6. Establishment of a system to promptly address and resolve findings and recommendations of the investigation team. Documentation of resolutions and corrective actions is required.

7. There should be an implementation schedule available for intended corrective actions. The schedule should be based on a prioritization of actions.

8. There should be a system for tracking recommendation, implementation, and closure on a plant-wide basis. Progress, status, and milestone reports should be generated at regular intervals. (The inspector should ask for documented evidence that all management-approved recommendations from previous incident investigations were implemented in a timely manner.)

9. The inspector should conduct a field check to determine implementation of recommendations. If any of the management-approved recommendations have not been implemented (or scheduled for implementation), then the inspector should ascertain the reason. The lack of a schedule is an indication of the lack of management commitment.

10. Relevant investigation findings should be reviewed with all affected personnel, including contractors.

11. Standard operating procedures, safety practices, training, configuration management, maintenance and inspection, emergency procedures, and planning should be updated as required to prevent recurrence of the incident.

12. Incident investigation reports should be retained for a period specified in the license or certificate, or as stated in the licensee or certificate holder's policy.

03.05 Plant Safety Committees. Review changes since the last inspection to the membership, charter, and procedures for the onsite and/or offsite plant safety committees (or equivalent) to determine whether changes meet the license or certificate requirements. Determine whether meetings have been held at the required frequencies specified in the license or certificate. Examine the minutes of select meetings held by the plant safety committees since the previous IP 88005 inspection to determine whether the committees' agenda items are in accordance with its charter. For recommendations made since the last IP 88005 inspection, determine whether management has accepted or rejected the advisory recommendations and that, for the accepted recommendations, implementing actions and schedules have been assigned to specific plant organizations. For rejected recommendations, the basis for rejection should be documented.

Determine whether the licensee or certificate holder has in place a process to designate alternate committee members when regular members are unavailable, as well as a stipulation as to what constitutes a quorum.

If the license or certificate does not stipulate the membership or duties of the plant safety committees, determine whether:

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.

03.06 Quality Assurance Programs. Determine whether the quality assurance (QA) program is being conducted in accordance with the license or certificate requirements (if the license or certificate contains requirements for QA program). In any case, examine QA records to determine that the licensee or certificate holder is performing tests on systems and components important to safety (including those used in transportation), and determine verification of approval.

**NOTE**: Some licensee or certificate holder's have a QA program for transportation only. Some licensee or certificate holder's use 10 CFR Part 71, Subpart H, "Quality Assurance" for transportation, or have an NRC approved program combining the quality assurance of 10 CFR Part 71 and 10 CFR Part 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

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

Determine whether documentary evidence includes sign-offs attesting to overall conformance to requirements for component design, testing, and installation requirements. If the license or certificate 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 or certificate.)

## 88005-04 RESOURCE ESTIMATE

An inspection performed using this inspection procedure is estimated to require 16 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

10 CFR 70, “Safety Program and Integrated Safety Analysis”

NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Facility," dated March 2002

NRC Regulatory Guide 3.52, "Standard Format and Content for the Health and Safety Sections of License Renewal Applications for Uranium Processing and Fuel Fabrication," Revision 1, dated November 1986

END

ATTACHMENT 1

Revision History for IP 88005

| Commitment Tracking Number | Issue Date | Description of Change | Training Needed | Training Completion Date | Comment Resolution Accession Number |
|---|---|---|---|---|---|
| | 09/05/06 CN 06-020 | This document has been revised to: (1) emphasize the risk-informed, performance-based approach to inspection, (2) impose changes to the core inspection program based on operating experience, and (3) remove completed or obsolete MCs and incorporate other fuel cycle MCs into a central location. | None | N/A | ML061800405 |
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