

MANAGEMENT MEASURES

11.5 PLANT PROCEDURES

11.5.1 PURPOSE OF REVIEW

The purpose of this review is to establish that there is reasonable assurance that the applicant is capable and committed to providing management control of facility operations through the development, review, control, and implementation of written procedures, that will protect the workers, the public and the environment during testing, startup, and full-scale operation of the facility.

11.5.2 RESPONSIBILITY FOR REVIEW

Primary: License Project Manager

Secondary: Primary staff reviewers in all operating areas

Supporting: TWRS Site Representative

11.5.3 AREAS OF REVIEW

The review should address the process the applicant has developed for the production, use and management control of written procedures. This should include the basic elements of identification, development, verification, review and comment resolution, approval, validation, issuance, change control, and periodic review. This should include two general types of procedures:

1. Procedures used to directly control process operations, commonly called "operating procedures". These are procedures for workstation operators and should include directions for normal operations as well as off-normal events caused by human error or failure of equipment. Procedures of this type include required actions to ensure nuclear criticality safety, chemical safety, fire protection, emergency planning, and environmental protection; and,
2. Procedures used to effect activities that support the process operations, that are commonly referred to as "management control procedures". These are procedures used to manage the conduct of activities such as configuration management, radiation safety, maintenance, human-systems interface, quality assurance, design control, test control, startup, training and qualification, audits and assessments, incident investigations, record-keeping and reporting.

11.5.4 ACCEPTANCE CRITERIA

Management Measures

11.5.4.1 Regulatory Requirements

The requirement for Management Measures/Procedures is addressed in the following:

Nuclear Regulatory Commission (U.S.), Washington, D.C. "Domestic Licensing of Special Nuclear Material (10 CFR Part 70)." *Federal Register*: Vol. 64, No. 145. pp. 41338-41357. July 30, 1999.

Specific references are as follows:

1. In § 70.4, "Definitions," the term *management measures* is defined. Procedures are included as a management measure.
2. In § 70.62(d), the applicant or licensee is required to establish management measures to provide continuing assurance of compliance with the performance requirements.
3. In § 70.64(a)(1), the design of new facilities or the design of new processes at existing facilities is required to be developed and implemented in accordance with management measures.
4. In § 70.65(a), the application is required to include a description of the management measures.
5. In § 70.22(a)(8), the application is required to include procedures that protect health and minimize danger to life.

11.5.4.2 Regulatory Guidance

None.

11.5.4.3 Regulatory Acceptance Criteria

The reviewers should determine that the applicant's process for developing and implementing procedures is adequate if the process satisfies the following:

1. Procedures should be written or planned for the conduct of all operations involving controls identified in the ISA as activities relied on for safety and for all management control systems supporting those controls.
2. Operating procedures contain the following elements:
 - a. purpose of the activity;
 - b. regulations, polices, and guidelines governing the procedure;
 - c. type of procedure;
 - d. steps for each operating process phase;
 - e. initial startup;
 - f. normal operations;

- g. temporary operations;
 - h. emergency shutdown;
 - i. emergency operations;
 - j. normal shutdown;
 - k. startup following an emergency or extended downtime;
 - l. hazards and safety considerations;
 - m. operating limits;
 - n. precautions necessary to prevent exposure of hazardous chemicals or licensed special nuclear material;
 - o. measures to be taken if contact or exposure occurs;
 - p. safety controls associated with the process and their functions;
 - q. time frame for which the procedure is valid.
3. Management control procedures contain elements reflecting the important elements of the functions described in the applicable chapters of this SRP. Procedures should exist to manage the following activities:
- a. configuration management;
 - b. radiation safety;
 - c. maintenance;
 - d. human-systems interface;
 - e. quality assurance;
 - f. training and qualification;
 - g. audits and assessments;
 - h. incident investigations;
 - i. records management;
 - j. criticality safety;
 - k. fire safety;
 - l. chemical process safety;
 - m. design control;
 - n. test control;
 - o. startup;
 - p. reporting requirements.
4. The applicant's method for identifying the procedures includes using ISA results to identify needed procedures. Process operating procedures should provide specific direction regarding administrative controls to ensure process operational safety.
5. The application should describe the method for identifying, developing, approving, implementing, and controlling procedures. This method should include, as a minimum, that:
- a. operating limits and controls are specified in the procedure;
 - b. procedures include required actions for off-normal conditions of operation as well as normal operations;
 - c. if needed, safety checkpoints are identified at appropriate steps in the procedure;

Management Measures

- d. procedures are validated through field tests;
 - e. procedures are approved by management personnel responsible and accountable for the operation;
 - f. a mechanism is specified for revising and reissuing procedures in a controlled manner;
 - g. the quality assurance and configuration management programs at the plant ensure that current procedures are available and used at all work locations; and
 - h. the plant training program ensures that the required persons are trained in the use of the latest procedures available.
6. The application should include the following statement regarding procedure adherence: "Activities involving special licensed nuclear material will be conducted in accordance with approved procedures".
 7. The application should describe the types of procedures used by the facility. These should typically include management control, operating, maintenance, and emergency procedures. The application should provide information regarding the procedure categories used at the facility. An acceptable identification discussion should clearly state areas for which a procedure is required. The application should provide a listing of the types of activities that are covered by written procedures. This should include the topics of administrative procedures; system procedures that address startup, operation, and shutdown; abnormal operation/alarm response; maintenance activities that address system repair, calibration, inspection and testing; and emergency procedures. Appendix D to this SRP provides an acceptable listing of the items to be included under each topic.
 8. The application should indicate that following unusual incidents, such as an accident, unexpected transient, significant operator error, or equipment malfunction, or following any modification to a system, a review of written procedures will take place, as needed.
 9. The application should indicate how technical accuracy of procedures will be ensured as written. The discussion should identify who is responsible for verification.
 10. The application should indicate how documents will be distributed in accordance with current distribution lists. A process limiting the use of outdated procedures should be addressed.
 11. The application should describe how formal requirements governing temporary changes will be developed and implemented.
 12. The application should have formal requirements for Design Control for items that are important to safety, and should identify who is responsible for design inputs, processes, outputs, changes, interfaces, and records.
 13. A description of the Test Control program should be provided, and should indicate that an effective test program has been established for tests, including commissioning and preoperational tests. Acceptable test control program procedures should provide criteria for determining when a test is required or how and when testing activities are performed.

- a. Tests should be performed under conditions that simulate the most adverse design conditions, as determined by analysis.
 - b. Test results should be documented, evaluated, and their acceptability determined by a responsible individual or group.
14. Maintenance procedures involving safety controls should commit to the topics listed below for corrective, preventive, functional testing after maintenance, and surveillance maintenance activities:
- a. Pre-maintenance activity involving reviews of the work to be performed, including procedure reviews for accuracy and completeness.
 - b. Steps that require notification of all affected parties (operators and supervisors) prior to performing work and upon completion of maintenance work.
 - c. Control of work by comprehensive procedures to be followed by maintenance technicians.
15. The application should contain a commitment to conduct periodic reviews of procedures to ensure their continued accuracy and usefulness and establishes the time frame for reviews of the various types of procedures. At a minimum all procedures should be reviewed every 5 years and emergency procedures should be reviewed every year.
16. The application should describe the use and control of procedures.
17. A pre-operational testing (startup) program should be described. Information pertaining to how, and to what extent, the plant operating, emergency, and surveillance procedures will be user-tested during the test program should be provided.

Section 5, "Instructions, Procedures, and Drawings," of SRP Appendix C, provides criteria for other procedures.

11.5.5 REVIEW PROCEDURES

11.5.5.1 Acceptance Review

The primary reviewer should evaluate the application to determine whether it addresses the "Areas of Review" discussed in Section 11.5.3, above. If significant deficiencies are identified, the applicant should be requested to submit additional material before the start of the safety evaluation.

11.5.5.2 Safety Evaluation

Management Measures

After determining that the application is acceptable for review in accordance with Section 11.5.5.1, above, the primary reviewer should perform a safety evaluation against the acceptance criteria described in Section 11.5.4. The safety evaluation forms the basis for staff findings, and supports the reviewers' conclusions that the applicant has committed to:

1. Controls that are identified in the ISA for safety procedures (i.e., procedures that constitute administrative controls for safety).
2. The independent verification and validation of procedures before use.
3. The review and approval by an independent multi-disciplinary safety review team and control by the configuration management function of any change to operating, management control, or maintenance procedure
4. Following approved procedures while processing licensed special nuclear material.
5. Having procedures for the notification of operations personnel before and after maintenance is performed on safety controls.

Secondary staff reviewers should review the management measures/procedures section of the application to ensure that there is no contradiction between it and their primary review areas. They should also ensure that the scope of the applicant's procedures program includes the operating and management control procedures listed in paragraph 11.5.4.3., above.

The supporting staff reviewer should become familiar with the applicant's management control and operating procedures, and determine whether ongoing activities are in agreement with them.

11.5.6 EVALUATION FINDINGS

The staff's evaluation should verify that the license application provides sufficient information to satisfy the regulatory requirements of Section 11.5.4.1 and that the regulatory acceptance criteria in Section 11.5.4.3 have been appropriately considered in satisfying the requirements. On the basis of this information, the staff should conclude that this evaluation is complete. Each reviewers should write material suitable for inclusion in the SER prepared for the entire application. The primary reviewer should have primary responsibility for specific input to the SER. The SER should include a summary statement of what was evaluated and the basis for the reviewers' conclusions.

The staff can document the evaluation as follows:

The application has described suitably detailed processes for the development, approval, and implementation of procedures. [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] Special attention has been paid to items relied on for safety, as well as to systems important to the health of plant workers and the public and to the protection of the environment.

11.5.7 REFERENCE

U.S. Nuclear Regulatory Commission, (U.S.), Washington, D.C. "Guidance on Management Controls/Quality Assurance, Requirements for Operation, Chemical Safety, and Fire Protection for Fuel Cycle Facilities." *Federal Register*: Vol. 54, No. 53. pp. 11590-11598. March 21, 1989.