MANAGEMENT MEASURES
11.2 CONFIGURATION MANAGEMENT

11.2.1 PURPOSE OF REVIEW

The purpose of this review is to establish with reasonable assurance that the applicant has a plan for or has implemented an acceptable configuration management (CM) function. The review should result in a determination that the applicant has described and committed to a CM function over the life cycle of the facility that provides reasonable assurance that design information, safety information, and modifications (both temporary and permanent) that might impact the ability of items relied on for safety to perform their function when needed are maintained in a consistent and up-to-date manner. The review should also result in a determination that the applicant's CM function captures formal documentation governing the design and continued maintenance of those facility structures, systems, and components (SSCs) and supporting management measures, as identified and described in the ISA. The review should assure that the CM function is adequately coordinated and integrated with the other management measures such as maintenance, quality assurance, training and qualifications, procedures, and audits and assessments.

11.2.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: Primary ISA Reviewer, Quality Assurance Reviewer, Records Management Reviewer

Supporting: TWRS Site Representative

11.2.3 AREAS OF REVIEW

The applicant's descriptions and commitments for CM should be reviewed with an emphasis on the processes for documenting an established baseline configuration and controlling changes to it to preclude inadvertent degradation of safety. An examination should be conducted of the descriptions of the organizational structure responsible for CM activities and the process, procedures, and documentation required by the applicant for modifying the site, items relied on for safety, and the supporting management measures. The review should focus on the applicant's management level controls that ensure (a) the disciplined documentation of engineering, installation, and operation of modifications; (b) the training and qualification of affected staff, (c) revision and distribution of operating, test, calibration, surveillance, and maintenance procedures and drawings, (d) post-modification testing, and (e) readiness review.

The following topics should be reviewed:

Management Measures

1. CM Policy

   The review should cover the applicant's description of overall CM functions, including at least the following topics: (a) the scope of the SSCs to be included in the CM function (b) objectives of each CM activity, (c) a description of each CM activity, and (d) the organizational structure and staffing interfaces.

   The review should examine the applicant's establishment of a baseline CM policy applicable to all operations, initially independent of ISA results. The review should also examine any reduced level of CM that the applicant may propose for certain SSCs based on the ISA results.

2. Design Requirements

   The review should cover the applicant's demonstration that design requirements and associated design bases have been established and are maintained by an appropriate organizational unit. The applicant's CM controls on the design requirements and the ISA should be evaluated.

3. Document Control

   The review should include the applicant's methods used to establish and control documents within the CM function.

4. Change Control

   The review should examine the applicant's commitments to ensure that the CM function maintains strict consistency among the design requirements, the physical configuration, and the facility documentation. An important component of this review is the applicant's process, within the CM function, for ensuring that the ISA will be systematically reviewed and modified to reflect design or operational changes from an established safety basis, and that all documents outside the ISA that are affected by safety basis changes will be properly modified, authoritatively approved, and made available to personnel.

5. Assessments

   The review should examine the applicant's commitments to conduct initial and periodic assessments of the CM system to determine the function's effectiveness and to correct deficiencies, consistent with the acceptance criteria in SRP Section 11.7, "Audits and Assessments."

11.2.4 ACCEPTANCE CRITERIA

11.2.4.1 Regulatory Requirements

The requirement for CM 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.146. pp.41338--41357. July 30, 1999.

Specific references are as follows:

1. In § 70.4, “Definitions,” the term CM is defined.

2. In § 70.4, “Definitions,” the term management measures is defined. CM is included as a management measure.

3. In § 70.62(d), the applicant or licensee is required to establish management measures to provide continuing assurance of compliance with the performance requirements.

4. 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.

5. In § 70.65(a), the application is required to include a description of the management measures.

11.2.4.2 Regulatory Guidance

There are no regulatory guides that apply to CM for a new facility licensed under 10 CFR Part 70.

11.2.4.3 Regulatory Acceptance Criteria

The reviewers should determine that an applicant’s CM function is acceptable if it satisfies the following criteria.

1. CM Policy

   The applicant's description of overall CM functions describes at least the following topics: (a) the scope of the items relied on for safety (SSCs and management measures) to be included in the CM function (coordinate with the ISA Chapter reviewer for the application), (b) a description of each CM function activity, (c) the objectives of each CM function activity, and (d) the organizational structure and staffing interfaces. The scope of SSCs include all those items relied on for safety as defined by the ISA; furthermore, those items are included in the QA, maintenance, and training and qualifications programs. The functional interfaces with quality assurance (QA), maintenance, and training and qualification are of particular importance and should be addressed individually.

2. Design Requirements

Management Measures

The applicant demonstrates that design requirements and associated design bases have been established and are maintained by an appropriate organizational unit. The applicant demonstrates that the CM system provides for keeping design requirements and the ISA current and that suitable hazard/accident analysis methods, including controlled computer codes, if applicable, are available to evaluate safety margins of proposed changes. Technical management review and approval procedures are described. The specific items relied on for safety included in the CM function are identified within the ISA summary report.

3. Document Control

The applicant describes an acceptable method to establish and control documents within the CM function, including cataloging the document data base, the information content of the document data base, maintenance and distribution of documents, document retention policies, and document retrieval policies. A list of the types of documents controlled is established and includes key documents, such as drawings, procurement specifications, engineering analyses, operating procedures, training/qualification records, and maintenance procedures.

4. Change Control

The applicant demonstrates that the CM function will maintain strict consistency among the design requirements, the physical configuration, and the facility documentation. The applicant describes an acceptable process for identifying and authorizing proposed changes, performing appropriate technical and safety reviews of proposed changes, approving changes, implementing changes, and documenting changes. The applicant describes an acceptable process, within the CM function, for ensuring that the ISA is systematically reviewed and modified to reflect design or operational changes from an established safety basis, and that all documents outside the ISA that are affected by safety basis changes are properly modified, authoritatively approved, and made available to personnel.

5. Assessments

The applicant confirms that assessments, including initial and periodic examinations of the CM system, will be conducted to determine the program's effectiveness and to correct deficiencies. The applicant indicates that such assessments will be systematically planned and conducted in accordance with an overall facility audit and assessment function as described by the applicant and reviewed by NRC in accordance with Section 11.7 of this SRP.

11.2.5 REVIEW PROCEDURES

11.2.5.1 Acceptance Review

The primary reviewer should evaluate the application to determine whether it addresses the "Areas of Review" discussed in Section 11.2.3, above. If significant deficiencies are identified, the applicant should be requested to submit additional material before the start of the safety evaluation.

The reviewer should also determine that the applicant has committed to a formal CM function for establishing design bases and reviewing proposed changes to items, procedures, and processes that may impact SSCs relied on for safety.

11.2.5.2 Safety Evaluation

After determining that the application is acceptable for review in accordance with Section 11.2.1, above, the primary reviewer should perform a safety evaluation against the acceptance criteria described in Section 11.2.4. Review procedures for each criterion are discussed in the following:

1. CM Policy Management

   The primary reviewer should review the CM plan that provides management commitments, and policy directive, and defines key responsibilities, terminology, and equipment scope. The method for initiating immediate corrective actions should be examined. The secondary reviewers should examine the ISA for the identification of dependence on CM of items relied on for safety. Appropriate interfaces both within the CM function and with external organizations and functions should be examined. In particular, the quality assurance specialist should assist in examining the functional interfaces with QA, maintenance, and training (including qualification). The reviewers look for the applicant's identification of required databases and the rules for their maintenance. The reviewers examine implementing procedures for the CM function.

2. Design Requirements

   The primary reviewer should confirm that the design process leading to drawings and other statements of requirements proceeds logically from the design basis. The reviewers should verify that specific personnel are assigned the responsibility for maintaining the design bases and requirements. These may be the same personnel that maintain the ISA and controlled computer codes. The reviewers should verify that the items relied on for safety to be listed under CM are clearly defined in the requirements documents, along with the assignment of any grades or quality levels. The grades or quality levels, if specified, are based on the qualitative risk associated with postulated accident sequences in which the items relied on for safety are required to function. This part of the review should be coordinated with the ISA primary reviewer. The ISA specifies all items relied on for safety, and the applicant should have indicated in the ISA what level of CM attributes are applied to a particular item. However, in the ISA this indication may only consist of an index or

category designation. The definition of the multiple CM levels, if used, should be in the CM Chapter of the application. The primary reviewer for the CM Chapter is responsible to determine if the reduced levels the applicant would apply to safety items for lesser risk accident sequences are adequate.

3. Document Control

The primary reviewer should evaluate the applicant's material showing that the CM system will capture documents that are relevant and important to safety. This includes design requirements, the ISA, as-built drawings, specifications, all safety-important operating procedures, procedures involving training, QA, maintenance, audits and assessments, emergency operating procedures, emergency response plans, system modification documents, assessment reports, and others, as necessary, that the applicant may deem part of the CM function. The primary reviewer should determine whether a controlled document database is used to control documents and track document change status. Rules of storage for originals or master copies of documents within the CM function should follow the guidance of “Records Management” discussed in SRP Section 11.9.

4. Change Control

The primary reviewer should ensure that the description of change control within the CM function commits to acceptable methods in place for: (a) the identification of changes in configurations relied on for safety; (b) technical and management review of changes, and (c) tracking and implementing changes, including placement of documentation in a document control center and dissemination to affected functions such as training, engineering, operations, maintenance, and QA. Post-modification testing of hardware (or procedure drills or walk-throughs) may be done in conjunction with periodic equipment performance monitoring and normal maintenance functions.

5. Assessments

The primary reviewer should ensure that both document assessments and physical assessments (system walkdowns) will be conducted periodically to check the adequacy of the CM function. The primary reviewer should ensure that all assessments and follow-ups are documented. These reports can provide a supporting basis for future changes. The primary reviewer should assure that assessments will include reviews of safety systems from design requirements through implementation.

11.2.6 EVALUATION FINDINGS

The staff's evaluation should verify that the license application provides sufficient information to satisfy the regulatory requirements of Section 11.2.4.1 and that the regulatory acceptance criteria in Section 11.2.4.3 have been appropriately considered in satisfying the requirements. On the basis of this information, the staff should conclude that this evaluation is complete. The reviewers should write material suitable for inclusion in the SER prepared for the entire

application. 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 staff has reviewed the Configuration Management (CM) function for (name of facility) according to Section 11.2 of the Standard Review Plan. [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.]

The applicant has suitably and acceptably described its commitment to a proposed CM system, including the method for managing changes in procedures, facilities, activities, and equipment for systems important to safety. Management level policies and procedures, including an analysis and independent safety review of any proposed activity involving systems important to safety, are described that will ensure that the relationship between design requirements, physical configuration, and facility documentation is maintained as part of a new activity or change in an existing activity involving licensed material. The administrative control will include (or does include) the following elements of CM.

1. Configuration Management

The organizational structure, procedures, and responsibilities necessary to implement CM are in place or committed to.

2. Design Requirements

The design requirements and bases are documented and supported by analyses and the documentation is maintained current.

3. Document Control

Documents, including drawings, are appropriately stored and accessible. Drawings and related documents adequately describe systems important to safety.

4. Change Control

Responsibilities and procedures adequately describe how the applicant will achieve and maintain strict consistency among the design requirements, the physical configuration, and the facility documentation. Methods are in place for suitable analysis, review, approval, and implementation of identified changes to systems important to safety. This includes appropriate CM controls to assure configuration verification, functional tests, and accurate documentation for equipment or procedures that have been modified.

5. Assessments

Management Measures

Methods or plans are in place to perform initial and periodic examination of the effectiveness of the CM system itself. In the case of existing facilities, assessments and follow-up reports of corrective actions are documented.

In situations where the applicant proposes a graded CM function based on risk significance the following can be added: the applicant has described its approach to applying at least two levels of CM attributes to items relied on for safety, and has identified which safety items involve lower risk and may receive the reduced level of CM requirements. The applicant's proposed reduced CM features are found adequate to contribute to the reliability and availability of the lesser risk items relied on for safety identified in the application.

11.2.7 REFERENCES

1. Nuclear Regulatory Commission (U.S.), Washington, D.C. "Domestic Licensing of Special Nuclear Material (10 CFR Part 70)." *Federal Register:* Vol. 64, No.146. pp. 41338--41357. July 30, 1999.

2. Department of Energy (U.S.) (DOE). DOE-STD-1073-93, "DOE Standard: Guide for Operational Configuration Management Function." Parts I and II, DOE: 1993.