

15.0 MANAGEMENT MEASURES

15.2 CONFIGURATION MANAGEMENT

15.2.1 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) system. The review should result in a determination that the applicant has described and committed to a CM system during design and construction (as described in the application for construction approval) and operations (as updated and described in the license application) that provides reasonable assurance that the applicant will maintain design information, safety information, and modifications (both temporary and permanent for design and operations) that might impact the ability of structures, systems, or components¹ (SSCs) (application for construction approval) or items relied on for safety (IROFS) (license application) to perform their function when needed in a consistent and up-to-date manner. The review should also result in a determination that the applicant's CM system captures formal documentation governing the design and continued maintenance of the SSCs (application for construction approval) or items relied on for safety (license application) and supporting management measures, as identified and described in the integrated safety analysis (ISA) programmatic commitments and ISA Summary (see Chapter 5.0). The review should ensure that the CM system is adequately coordinated and integrated with the other management measures such as maintenance, quality assurance, training and qualifications, procedures, and audits and assessments.

15.2.2 RESPONSIBILITY FOR REVIEW

Primary Project Manager

Secondary: Primary ISA Reviewer, Quality Assurance Reviewer, Records Management Reviewer, Organization and Administration Reviewer

Supporting: Fuel Cycle Facility Inspector

15.2.3 AREAS OF REVIEW

The applicant should submit a description of the CM system with the application for construction approval and should submit updated information with the license application. 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 SSCs (application for construction approval) or items relied on for safety (license application) and the supporting management

¹ "Structures, systems, and components" are, by definition, items relied on for safety (see proposed 10 CFR 70.4 or the glossary to this SRP).

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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) operational readiness review.

The following topics should be reviewed:

A. CM Policy

The review should cover the applicant's description of overall CM systems, including at least the following topics: (a) the scope of the SSCs (application for construction approval) or items relied on for safety (license application) to be included in the CM system, (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 design and construction (application for construction approval) and operations (license application), initially independent of the safety assessment of the design basis (application for construction approval) or the ISA results (license application), respectively. The review should also examine any reduced level of CM that the applicant may propose for certain SSCs (application for construction approval) or items relied on for safety (license application) based on the safety assessment of the design basis or ISA results, respectively.

Specifically, the primary reviewer should review the CM plan that provides management commitments and policy directives and defines key responsibilities, terminology, and equipment scope. The method for initiating immediate corrective actions should be examined. The secondary reviewers should examine the safety assessment of the design basis (application for construction approval) or the ISA Summary (license application) for the identification of dependence on CM of SSCs or items relied on for safety. Appropriate interfaces both within the CM system and with other facility organizations and functions should be examined. In particular, the quality assurance reviewer should assist in examining the functional interfaces with quality assurance (QA), maintenance, and training (including qualification). The reviewers should look for the applicant's identification of required databases and the rules for their maintenance. The reviewers should examine implementing procedures for the CM system.

B. 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 safety assessment of the design basis (application for construction approval) or the ISA (license application) should be evaluated. The review should be coordinated with the primary reviewer of Chapter 5.0.

C. Document Control

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

D. Change Control

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

E. Assessments

The review should examine the applicant's commitments to conduct initial and periodic assessments of the CM system to determine the system's effectiveness and to correct deficiencies, consistent with the acceptance criteria in SRP Section 15.6, "Audits and Assessments."

15.2.4 ACCEPTANCE CRITERIA

15.2.4.1 Regulatory Requirements

The staff's requirements applicable to CM are the following:

10 CFR 70.62(d), relating to the requirement that the applicant or licensee is to establish management measures to provide continuing assurance of compliance with the performance requirements.

10 CFR 70.64(a)(1), relating to the requirement that the design of new facilities or the design of new processes at existing facilities be developed and implemented in accordance with management measures.

10 CFR 70.65(a), relating to the requirement that the application is to include a description of the management measures.

10 CFR 70.72(a), relating to the requirement the licensee is required to establish a CM system.

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15.2.4.2 Regulatory Guidance

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

15.2.4.3 Regulatory Acceptance Criteria

The reviewers should determine that an applicant's CM system is acceptable if it satisfies the following criteria:

A. CM Policy

The applicant's description of its overall CM system describes at least the following topics: (a) the scope of the SSCs (application for construction approval) or items relied on for safety (license application) and supporting management measures to be included in the CM system (coordinate with reviewer of Chapter 5.0), (b) a description of each CM system activity, (c) the objectives of each CM system activity, (d) any reduced level of CM that the applicant may propose for certain SSCs (application for construction approval) or items relied on for safety (license application) based on the safety assessment of the design basis or the ISA results, respectively, and (e) the organizational structure and staffing interfaces.

The scope of SSCs (application for construction approval) or items relied on for safety (license application) includes all those SSCs (application for construction approval) or items relied on for safety (license application) as defined by the safety assessment of the design basis or the ISA, respectively; furthermore, those items are included in the QA, maintenance, and training and qualifications programs. The functional interfaces with QA, maintenance, and training and qualification are of particular importance and should be addressed individually.

B. Design Requirements

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 safety assessment of the design basis (application for construction approval) or the ISA (license application) 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 design process leading to drawings and other statements of requirements proceeds logically from the design basis. Specific personnel are assigned the responsibility for maintaining the design bases and requirements. These may be the same personnel that maintain the safety assessment of the design basis (application for construction approval) or the ISA (license application) and controlled computer codes. SSCs (application for construction approval) or items relied on for safety (license application) 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 SSCs (application for construction approval) or items relied on for safety (license application) are required to function. The applicant should have indicated in the safety assessment of the design basis (application for construction approval) or the ISA (license application) what level of CM attributes are applied to a particular item. However, in the safety assessment of the design basis or 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.

C. Document Control

The applicant describes an acceptable method to establish and control documents within the CM system, 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.

The applicant's material shows that the CM system will capture documents that are relevant and important to safety. This includes design requirements; the safety assessment of the design basis (application for construction) or the ISA (license application); 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 system. 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 system should follow the guidance of "Records Management" discussed in SRP Section 15.8.

D. Change Control

The applicant demonstrates that the CM system will maintain strict consistency among the design requirements, the physical configuration, and the facility documentation. The applicant commits to an acceptable process for identifying and authorizing proposed changes; performing appropriate technical, management, and safety reviews of proposed changes in configurations of SSCs (application for construction approval) or items relied on for safety (license application); approving changes; tracking and implementing changes; and documenting changes (including placement of documentation in a document control center and dissemination to affected functions such as training, engineering, operations, maintenance, and QA). The applicant describes an acceptable process, within the CM system, for ensuring that the safety assessment of the design basis (application for construction approval) or the ISA (license application) is systematically reviewed and modified to reflect design or operational changes from an established safety basis, and that all documents outside the safety assessment of the design basis (application for

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construction approval) or the ISA (license application) that are affected by safety basis changes are properly modified, authoritatively approved, and made available to personnel.

Post-modification testing of items (or procedure drills or walk-throughs) may be performed in conjunction with periodic item performance monitoring and normal maintenance functions.

E. Assessments

The applicant confirms that assessments, including initial and periodic examinations of the CM system, will be conducted to determine the system'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 program as described by the applicant and reviewed by the NRC in accordance with Section 15.6 of this SRP.

Both document assessments and physical assessments (system walkdowns) will be conducted periodically to check the adequacy of the CM system. All assessments and follow-ups are documented. These reports can provide a supporting basis for future changes. Assessments will include reviews of safety systems from design requirements through implementation.

Also, the applicant should commit to update the CM system to reflect any changes between the application for construction approval and for a license.

15.2.5 REVIEW PROCEDURES

15.2.5.1 Acceptance Review

The primary reviewer should perform an acceptance review to determine if the application for construction approval or license application adequately addresses the items in Section 15.2.3, "Areas of Review."

Guidance specific to the application for construction approval and the license application is provided below.

A. Application for Construction Approval

The application for construction approval should address each item in Section 15.2.3 with an emphasis on the CM for managing the design basis during design and construction. This should include a reviewer determination that the applicant committed to a formal CM system for establishing the design basis and reviewing proposed changes to SSCs.

B. License Application

The license application should address each item in Section 15.2.3 with an emphasis on the CM for operation (e.g., procedures, maintenance, and training) and any new or changed material in the CM program that will arise as a part of the transition from design and construction (design basis) to operations (integrated safety analysis). This should include a reviewer determination that the applicant committed to a formal CM system for establishing and managing the ISA and reviewing proposed changes to items relied on for safety or items, procedures, and processes that may impact items relied on for safety.

If the primary reviewer verifies that CM is adequately addressed in the application for construction approval or the license application, the primary reviewer should accept the application for the safety evaluation in Section 15.2.5.2. If the primary reviewer identifies significant deficiencies in the material provided, the primary reviewer should request that the applicant submit additional information prior to the start of the safety evaluation.

15.2.5.2 Safety Evaluation

After determining that the application is acceptable for review in accordance with either Section 15.2.5.1(A) (application for construction approval) or 15.2.5.1(B) (license application), the primary reviewer should perform a safety evaluation against the acceptance criteria described in Section 15.2.4. On the basis of its review, the staff may request that the applicant provide additional information or modify the application to meet the acceptance criteria in SRP Section 15.2.4.

Guidance specific to the application for construction approval and the license application is provided below.

A. Application for Construction Approval

The primary reviewer should determine whether the applicant has adequately planned for CM to be accomplished during design and construction and whether necessary policies, personnel, procedures, and instructions will be in place to begin CM early, that is, during the safety assessment of the design basis and the design and construction of the SSCs. The secondary reviewers should confirm that the applicant's CM commitments are consistent with other sections of the application.

B. License Application

When the applicant updates the CM system for the license application, the primary reviewer should focus the review on any new or changed material. Particularly, the primary reviewer should ensure that the applicant has adequately planned for CM to be accomplished during operations and whether necessary policies, personnel, procedures, and instructions will be in place to transition from CM during design and construction to CM during operations, that is, from the safety assessment of the design basis and the design and construction of the SSCs to the ISA and the items relied on for safety.

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The primary reviewer should also confirm that the material presented remains consistent with the material provided in the license application in support of other chapters of this SRP.

The supporting reviewer (Fuel Cycle Facility Inspector) should become familiar with the applicant's CM commitments and determine whether ongoing activities are in agreement with them.

The license application review should result in a determination that there is reasonable assurance that the CM system will provide additional assurance that items relied on for safety will perform satisfactorily in service and that activities relied on for safety will be performed satisfactorily.

When the safety evaluation is complete, the primary staff reviewer, with assistance from the other reviewers, should prepare the CM input for the safety evaluation report (SER) as described in Section 15.2.6 using the acceptance criteria from Section 15.2.4.

15.2.6 EVALUATION FINDINGS

The primary reviewer should document the safety evaluation by preparing material suitable for inclusion in the SER. The primary reviewer should describe the review, explain the basis for the findings, and state the conclusions.

The staff could document a safety evaluation for the application for construction approval as follows:

The staff reviewed the Configuration Management (CM) system for (name of facility) according to Section 15.2 of NUREG-1718. [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.]

Based on its review of the application for construction approval, the NRC staff concluded that the applicant suitably and acceptably described its commitment to a proposed CM system, including the method for managing changes in procedures, facilities, activities, and equipment for SSCs identified in the safety assessment for the design basis. Management level policies and procedures, including an analysis and independent safety review of any proposed activity involving SSCs, are described that will ensure that the relationship between design requirements, construction, and facility documentation is maintained as part of a new design or change in an existing design. The administrative control will ensure that the organizational structure, procedures, and responsibilities necessary to implement CM are in place or committed to; that the design requirements and bases are documented and supported by analyses and the documentation is maintained current; that documents, including drawings, are appropriately stored and accessible; that drawings and related documents adequately describe SSCs; that procedures adequately describe how the applicant will achieve and maintain strict consistency among the design requirements, facility construction, and the facility documentation; that methods are in place for suitable analysis, review, approval, and implementation of identified changes to SSCs.

In situations where the applicant proposes a graded CM system based on risk significance the following can be added:

The applicant described its approach to applying at least two levels of CM attributes to SSCs and identified which SSCs 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.

The staff could document a safety evaluation for the license application using similar paragraphs as those used for the construction approval, but encompassing the new or updated material when compared to the safety evaluation for the construction approval, and addressing CM as applied to IROFS during operations, including controls to assure configuration verification, correct functional tests, accurate documentation for equipment and procedures, adequate methods or plans for initial and periodic examination of the CM system's effectiveness, and thorough assessments and follow-up reports of corrective actions.

15.2.7 REFERENCES

- A. Code of Federal Regulations, Title 10, Part 70, Domestic Licensing of Special Nuclear Material, U.S. Government Printing Office, Washington, D.C., 1999.
- B. 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.
- C. Department of Energy (U.S.) (DOE). DOE-STD-1073-93, "DOE Standard: Guide for Operational Configuration Management Function." Parts I and II, DOE: 1993.