SECTION I

INSPECTION OBJECTIVES

Ascertain whether the licensee has developed and implemented a QA Program relating to the Control of Design Changes and Modifications that is in conformance with Regulatory requirements, commitments in the application and industry guides or standards.

SECTION II

INSPECTION REQUIREMENTS

1. Design Change Control

a. Program Review

(1) Determine that procedures have been established for control of design and modification change requests including:

(a) Method for initiating a design or modification change request.

(b) Design change request control form, or equivalent, with provisions for documenting completion of required reviews, evaluations, and approvals prior to implementing the change.

(c) Method for assuring that proposed change does not involve an unreviewed safety question as described in 10 CFR 50.59 or a change in the technical specifications.

(d) Method for assuring that applicable guidelines of R.G. 1.120, Fire Protection Guidelines For Nuclear Power Plants, or approved NRC alternate are included in design and procurement documents and that deviations therefrom are controlled.

(2) Determine that procedures and responsibilities for design control have been established including:

(a) Identification of organization(s) or person(s) responsible for performing design work.

(b) Responsibilities and methods for conducting safety evaluations.

(c) Procedures and responsibilities for identifying, reviewing, and approving design input requirements.

(d) Methods, procedures, and responsibilities for performing independent design verifications.

(e) If design responsibility is to be shared by more than one design organization verify that design interfaces (internal and/or external)

are established in writing.

(f) Responsibility for final approval of design documents.

(g) Review of design change is commensurate with the original design review.

(h) Procedures and responsibilities for assuring that proper inclusion of fire protection/prevention requirements delineated in R.G. 1.120 or NRC approved alternate.

(3) Verify that administrative controls for design document control have been established for the following:

(a) Controlling changes to approved design change documents.

(b) Controlling or recalling obsolete design change documents such as revised drawings and modification procedures.

(c) Release and distribution of approved design change documents.

(4) Verify that responsibility has been assigned in writing to assure implementation of the requirements in (3) above.

(5) Verify that administrative controls and responsibilities have been established commensurate with the time frame for implementation, to assure that design changes and modifications will be incorporated into:

(a) Plant procedures.

(b) Operator training programs.

(c) Updating plant drawings to reflect implemented design changes and modifications.

(6) Verify that controls have been developed that define channels of communication between design organizations

and the responsible individuals in (5) above.

(7) Verify that administrative controls require that design documentation and records which provide evidence that the design and review process was performed be collected and transmitted to records storage.

(8) Verify that controls require that implementation of approved design changes be in accordance with approved procedures.

(9) Verify that controls require that post modification acceptance testing be performed per approved test procedures and the results evaluated.

(10) Verify that responsibility has been assigned for identifying post modification testing requirements and acceptance criteria.

(11) Responsibility and method for reporting design changes/ modification to the NRC in accordance with 10 CFR 50.59.

b. Implementation

*(1) Review 20% (but not less than 10) of the design changes completed since issuance of the operating license. Verify the following for each:

*(a) The design change request was reviewed and approved as required.

*(b) Design input requirements were specified, reviewed, and approved.

*(c) Independent design verifications were performed as required.

*(d) Post modification acceptance tests were performed as required and designated acceptance criteria were met.

*(e) Any changes to the design documents were properly reviewed and approved.

*(f) Design reviews required by Technical Specifications were performed.

*(g) Plant drawings were updated to reflect the design change or modification.

*(h) Plant procedures have been updated to reflect the design changes.

*(i) The training organization was made aware of the modifications.

*(j) If an outside design organization was utilized, verify that interface documents have been prepared and implemented which identify lines of communication, responsibilities, and authorities of the organizations involved.

2. Verify that personnel who assign/designate safety related/non-safety related classifications are cognizant of the QA Program classification requirements (Select and interview 2).

2. Temporary Modifications Lifted Leads and Jumpers

a. Program Review

(1) Verify that controls require the review and approval of temporary modifications in accordance with Section 6 of the Technical Specifications and 10 CFR 50.59.

(2) Verify that the controls require the use of detailed approved procedures when performing temporary modifications.

(3) Verify that the control assign responsibility for approving procedures in (2) above.

(4) Verify that the controls require that a formal record be maintained of the status of temporary modifications, lifted leads and jumpers, temporary strainers, temporary trip points of control equipment, etc.

(5) Verify that the controls require evaluation of the need for independent verification where appropriate of installation and removal of temporary modifications, lifted leads and jumpers.

(6) Verify that the controls require functional testing of equipment following installation or removal of temporary modifications.

(7) Verify that the controls require periodic reviews of lifted lead and jumper records including a check of outstanding entries.

b. Implementation

*(1) Review the temporary modification log and verify the following for three log entries.

*(a) The log reflects the actual status of items involved.

*(b) Approved procedures covering the modification are available.

*(c) Independent verification, where appropriate, that installation and removal was performed.

* (2) Select two cabinets in each of the following systems and determine if any jumpers are installed or leads lifted. If so, verify that such jumpers or lifted leads are properly logged and approved.

(a) Reactor Protective System

(b) Emergency Safety Features

(c) Emergency Diesel Generators

* (3) Determine that reviews and checks of 2.a.(7) are being implemented.

SECTION III

INSPECTION GUIDANCE

References: ANSI N45.2.11-1974; ANSI N18.7-1976; 10 CFR 50.59; Section 17 of the FSAR; Section 6 of the proposed Technical Specifications.

1. Design Change Control

The quality assurance program for design control should be described in Section 17.2.3 of the FSAR. Requirements for the plant and corporate safety committees to review proposed design changes and modifications are defined in Section 6.5 of the Technical Specifications. 10 CFR 50.59 further defines requirements for evaluation of proposed design changes and modifications. Section 5.2.7.2 of ANSI N18.7-1976, specifies that modifications of safety-related structures, systems, and components shall be accomplished in accordance with ANSI N45.2.11-1974. RG 1.120 or NRC approved alternative identify requirements which should be established to assure that applicable fire prevention/protection measures are included in design documents.

a. The inspection requirements identified under "Program Review" are intended to determine that the licensee has established a design control program consistent with his commitments to the documents described above.

a.(2)(b) This should include responsibility for assuring that appropriate attention is given to cold weather protection of all fluid systems or components whose failure could result in degradation of safety-related systems or components. Operating experience has shown that failure of systems important to safety was caused by freezing of impulse lines, blockage of equipment with ice, etc.

a.(2)(g) Determine that when it is undesirable or impractical for the original design organization to approve the change/modification the licensee

will specify another organization that: a. has access to the pertinent background information, b. have demonstrated competency in the specific design area of interest, and c. have adequate understanding of the requirements and intent of the original design.

a.(5)(c) The inspector should assure that interim measures have been provided for temporary updating of drawings pending formal issuance.

a.(9) Section XI of the ASME, articles IWP 3000 and IWV 3000 require that operational readiness testing of pumps and valves following modification or replacement be performed to confirm that system performance parameters were not affected. Section XI is identified in 10 CFR 50.55a.(g).

b.(1) The inspection requirements identified here are intended to verify that the licensee's program for control of design changes and modifications has been adequately implemented. If problems are identified in review of the implemented program the inspector should determine the source of the problems: lack of familiarity on the part of the plant staff, or documented program inadequate or not clear. The

inspector should determine that responsibilities between participating design organization are clearly defined. However, if design organizations such as the corporate or architect engineering staffs are involved and their respective design control programs were previously inspected by NRC it is not intended that their programs be reinspected.

2. Temporary Modifications, Lifted Leads and Jumpers

The installation of a jumper or the lifting of a lead on a nuclear safety circuit constitutes a modification to the circuit. Formal control of such jumpers is required according to Section 5.2.6 of ANSI N18.7-1976. Section 6.5 of the Technical

Specifications; and 10 CFR 50.59. The use of mechanical devices such as dutchmen, temporary strainers, blind flanges or piping bypasses also constitute system modifications and must be controlled.

It is not intended that the inspection requirements identified in paragraph 2.a be applied to test leads used in the performance of routine surveillance testing. Installation and removal of such test leads should be controlled by the respective test procedure.

In addition, it is not intended that the inspection requirements identified in paragraph 2.a be applied to hand-held jumpers used for trouble shooting or maintenance checks on equipment that has been removed from service. However, if a jumper or lifted lead is physically installed, even temporarily, it shall be controlled and accounted for. Control may be accomplished via steps in properly approved

procedures, such as maintenance procedures, or by use of a jumper control log and related administrative procedures. Independent verification of jumper installation and removal is required by Section 5.2.6 of ANSI N18.7-1976.

Note: 1. Only single * requirements need to be inspected when the reactor facility for which the application is being made for an operating license is located at the same site and will use the same site management that was inspected within the previous 24 months.

2. The program review function should be completed during the operational preparedness phase of MC 2513.

3. A Design Changes and Modifications procedure for plant operations is not required until the facility license is issued. Therefore, inspection of program implementation may be deferred if necessary, but should be completed within the first six-month period of operation.

4. For record keeping purposes, the program review and program implementation phases of the inspection will be assigned 50% of the total inspection effort.