3.1 GENERAL REQUIREMENTS

A Quality Assurance Program shall be established for design-related activities. The design control program shall ensure that the design is defined, controlled and verified; that applicable design inputs are specified and correctly translated into design output documents; that design interfaces are identified and controlled; that design adequacy is verified by persons other than those who designed the item; and that design changes, including field changes, are governed by control measures commensurate with those applied to the original design.

Design records shall be developed to provide evidence that the design process and design verification were performed in accordance with the requirements of FPL's Quality Assurance Program.

Design records shall include design output documents and the important steps in the design effort. The intent of this documentation is to allow a technically qualified person to understand how the design was developed, and to allow that person to verify the design based on the design documentation and engineering data sources referenced therein.

Documents and databases designating safety related and quality related items and any revisions thereto shall be controlled in accordance with the FPL QA Program requirements.

3.2 IMPLEMENTATION

The controlling document for the identification of safety related items shall be the FSAR. Where the FSAR is not definitive for a specified plant, Nuclear Engineering shall develop and maintain documents/databases identifying those items which are safety related (e.g., plant equipment database, ~~Instrument List, Valve List, Line List,~~ drawings, etc). These documents/databases shall clearly identify the boundaries of safety related systems and may take the form of identifying boundaries on engineering drawings. For quality related items, Nuclear Engineering shall specify explicitly those aspects of design, manufacture, procurement, installation, and testing that shall be subject to the FPL QA Program requirements, as appropriate, in the design output documents (e.g., Plant Change/Modification package).

The design organization's Quality Assurance Program for design control shall be approved by the FPL Quality Assurance Department prior to the release of approved design output by the design organization. The design organization is the organization responsible for approval of design output. Quality Instructions shall be developed to delineate design control requirements governing design-related activities performed by Nuclear Engineering and for delegating activities to contractor organizations.

Design data approved by the design organization shall be transmitted in design output documents such as specifications, drawings, and other documents defining technical requirements or in correspondence which may reference these documents. Transmittals shall identify the status of design information or documents provided, and where necessary, identify incomplete items which require further evaluation, review, or approval.

A standard PC/M and numbering system shall be established and used at each plant to ensure that all PC/Ms are handled in a uniform manner and properly documented. Nuclear Engineering shall forward the approved PC/M to the applicable Plant Vice President. Internal plant coordination and review of design control documents shall be controlled by approved instructions.

3.2.1 Design Process

The design organization shall specify and document its design activities to the level of detail necessary to permit the design to be developed in a correct manner and to permit verification that design output documents satisfy design input requirements. Design methods, materials, parts, equipment and processes, including those associated with commercial grade items that are essential to the function of the item shall be selected, reviewed and approved for suitability of application by the design organization.

Design inputs shall be identified, documented, reviewed and approved by the design organization. They shall be specified to the level of detail necessary to permit the design activity to be carried out in a correct manner, and to provide a consistent basis for making design-related decisions, performing design verification and evaluating design changes. Changes to approved design inputs, including the reason for the changes, shall be approved, documented and controlled by the design organization.

The design organization shall identify aspects of manufacture, construction, inspection and testing critical to achieving the function of the item. Quality standards and quality requirements shall be specified on design output documents. Changes from approved quality- requirements specified in design output, including the reason for the changes, shall be approved, documented and controlled by the design organization.

Design analyses shall be controlled and documented. Approved design output documents and approved changes thereto shall be relatable to the design input by documentation in sufficient detail to permit verification. The design organization shall establish procedures to review industry design experience. As appropriate, this experience shall be made available to cognizant design personnel.

3.2.2 Design Change Control

Changes to approved design output documents, including field changes, shall be justified, subjected to control measures commensurate with those applied to the original design, and shall be reviewed and approved by the same design organization that approved the original design unless other organizations are specifically designated.

Where a significant design change is necessary because of an incorrect design, Nuclear Engineering shall determine the cause of the incorrect design. As necessary, design and verification procedures shall be reviewed and modified to correct the cause of the incorrect design.

Design changes shall be reviewed to ensure that implementation of the design change is coordinated with any necessary changes to operating procedures and practices, and required Nuclear Assurance activities, such as inspections and surveillances.

~~In accordance with plant technical specification requirements, nuclear safety-related design changes are reviewed by the Plant Nuclear Safety Committee (PNSC) or Facility Review Group (FRG) and the Company Nuclear Review Board (CNRB).~~

3.2.3 Design Interface Control

Quality Instructions shall establish interface controls between participating organizations and between the various technical disciplines within the design organization. These Quality Instructions shall include the assignment of responsibility, and be in sufficient detail to cover the preparation, review, approval, release, distribution and revision of design output documents.

For interdisciplinary design, approval documentation of each involved discipline of the design organization shall appear on the design output document or on a separate document directly traceable to the design output. The design organization shall designate a discipline(s) responsible for resolution of the comments of participating organizations. The designated discipline(s) approval of a design output shall also document resolution of the comments of participating organizations.

3.2.4 Design Verification

Design control measures shall be established to independently verify the design inputs, design process, and that design inputs are correctly incorporated into design output. The design organization shall develop instructions that govern design verification. These instructions shall require that the design organization identify and document the verification method utilized and that the documentation clearly identify those individuals performing the design verification.

Design verification shall be performed by technically qualified individual(s) or group(s) other than those who performed the design. The original designers and verifiers may both be from the design organization. Design verification by the designer's immediate supervisor shall be limited to those instances where the supervisor is the only qualified individual available within the design organization. These instances are further restricted to designs where the supervisor did not specify a singular design approach, or did not restrict design methods or alternatives, or did not specify design inputs (unless the specified design inputs have already been independently verified). Justification for verification by the designer's immediate supervisor should be documented along with the extent of the supervisor's involvement in the design.

The design organization shall be responsible for determining the extent of design verification and methods to be employed. The methods may include one or more of the following: the performance of design reviews, the use of alternate calculations, or the performance of qualification tests. This shall apply to original design and to changes to approved design output.

Where reverification is not required for a design change, the bases shall be documented by the design organization. Cursory supervisory reviews and mathematical checks for calculation accuracy do not satisfy the independent design verification requirement. Design verification shall normally be completed prior to release of design output for procurement, manufacture or release by the design organization for use in design activities by a participating organization. Verification shall be conducted based on the status of design at the time of release of design documents. Where this timing cannot be met, verification may be deferred provided that the unverified portion of the design output, and all design output documents, structures, systems and components based on the unverified

portion of design are identified and controlled. In all cases verification shall be completed prior to relying on any affected items to perform their design functions.

3.2.5 Computer Programs/Software

Organizations **developing software** or utilizing purchased or FPL developed computer programs/software in the performance of activities affecting quality as defined in the TQAR, shall maintain instructions or procedures to effect the following:

a. That such programs/software within the scope of the quality assurance program are identified and included in a computer software index. The controlled distribution of this index, electronic **or hard copy,** shall include the ~~Manager~~ Director Information ~~Management (IM)~~ **Technology (IT)** Operations. The method for determining which programs/software fall within the scope of the QA program shall be described in these procedures or instructions;

b. That such programs/software are verified for their particular use using benchmark problems, alternate calculations, comparison with other code or experimental results, **requirements and/or** design ~~review~~ **reviews** or similar methods;

c. That such programs/software have been qualified for their specific application sufficient to ensure valid results;

d. That such programs/software are provided with user instructions sufficient for a technically competent individual to follow;

e. That configuration controls are provided to assure that such programs/software changes or modifications are documented and controlled;

f. That errors in such programs/software are identified, evaluated, provided with a disposition and corrected.

3.3 RESPONSIBILITIES

3.3.1 The Vice President Nuclear Engineering ~~and Licensing~~ is responsible for:

a. Determining and documenting which items are nuclear safety related or quality related;

b. The review and coordination of design interfaces;

c. Assuring that design documents are reviewed for possible design interfaces, that interface problems are resolved and that design criteria and design interface changes are reviewed by participating organizations prior to approval of design documents;

d. Preparing design documents, including performing the safety evaluation or screening to determine if the proposed design change involves an Unreviewed Safety Question or a change to the Technical Specifications;

e. Performing design verification, including evaluation of the effects of proposed design changes on overall design adequacy (design integration);

f. Providing Nuclear Engineering approval of design documents;

g. Updating design documents and drawings according to applicable procedures;

h. Coordinating the NRC interface for 10 CFR 50.59 reports.

3.3.2 The Plant ~~Site~~ Vice President is responsible for:

a. Reviewing, tracking the status of, and maintaining a file on proposed PC/Ms;

b. Reviewing proposed PC/Ms for inclusion of appropriate quality criteria, standards, and hold points, including human factors considerations for design changes involving the Control Room or Remote Shutdown Panel;

c. reviewing completed PC/Ms, after implementation for compliance with governing procedures, including a review of all endorsements, sign-offs, completion of required acceptance testing/inspection, and any necessary changes to operating practices and procedures;

d. maintaining design documents as Quality Assurance records.

e. assuring that all plant design changes and drawing changes are coordinated through Nuclear Engineering;

f. determining whether or not a proposed design change affects nuclear safety;

g. approving or disapproving implementation of the proposed design change after receipt of a recommendation from the Plant Nuclear Safety Committee (PNSC) or Facility Review Group (FRG);

h. ensuring ~~the~~ Environmental ~~Affairs Department~~ **Services** is included in the proposed PC/M review if the design change may have an adverse impact on the environment;

i. reviewing design changes to ensure that the implementation of the design change is coordinated with any necessary changes to operating practices and procedures.

3.3.3 The Plant Nuclear Safety Committee (PNSC) or Facility Review Group (FRG) is responsible for:

a. Reviewing all proposed PC/Ms for plant systems or equipment related to nuclear safety;

b. Rendering a determination in writing (PNSC/FRG meeting minutes) as to whether or not the proposed design change constitutes an Unreviewed Safety Question.

3.3.4 The Director Nuclear Assurance is responsible for:

RR917 a. reviewing PC/Ms **and other FPL originated design specifications** for inclusion of appropriate quality criteria, standards, hold points, and Nuclear Assurance activities.

3.3.5 The Company Nuclear Review Board (CNRB) is responsible for:

a. Reviewing Safety Evaluations for design changes to verify that the design changes did not constitute an Unreviewed Safety Question. CNRB review of evaluations involving screening rather than Safety Evaluation is not mandatory;

b. Reviewing proposed design changes which involve an Unreviewed Safety Question or a change in Technical Specifications or License.

3.3.6 Each direct report to the President, Nuclear Division and Department Heads of organizations supporting the Nuclear Division shall be responsible for:

a. identification of computer programs/software used to accomplish activities affecting quality;

b. establishment of departmental instructions which prescribe the methods and techniques used to meet the QA program requirements for control of computer programs/software.

3.3.7 ~~The Manager Corporate~~ **Director** Information ~~Management (IM)~~ **Technology (IT)** Operations is responsible for evaluating all hardware or operating system software changes or problems occurring on computer systems under ~~IM~~ **IT Operations** control to determine if the answers produced or the integrity of data maintained in databases may be affected. If ~~the Manager~~ ~~IM~~ **IT** Operations determines applications may be affected, then ~~he/she~~ ~~IM~~ **IT Operations** is responsible for notifying user departments.