

Attachment 10

Ginna Station Procedure IP-DES-2
Ginna Station Procedure IP-DES-4



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PLANT CHANGE PROCESS

Responsible Manager

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Effective Date



1.0 PURPOSE

1.1 Introduction

This procedure describes the process for design, implementation, testing and administrative control of permanent modifications to Ginna Station. It establishes the administrative, engineering and safety requirements for a given plant change from design through close-out of the package. This interface procedure is meant to provide overall guidance for the plant change process. Guidance for activities specific to a certain area is incorporated by referring to lower tier procedures and specifications.

Implementation of this process will ensure that permanent plant hardware-related and setpoint changes are designed and processed in a controlled manner. (See Attachment 1 for process flow chart.)

1.2 Scope

This procedure describes the flow of engineering work, organizational responsibilities and implementing procedures for developing, reviewing and approving the engineering documents required for a plant change. Interfaces between design and implementing activities are also addressed including installation, testing and turnover.

- A. SCREENS (decision-making criteria checklists) provide guidance to categorize a given change, and to determine the administrative, engineering and safety requirements regardless of the safety classification of the given change.
- B. The interrelationships of those procedures required to develop engineering information for plant changes are described.
- C. The basic responsibilities for interfacing organizations are described.

1.2.1 This procedure covers the processing of a Plant Change Record (PCR), which is used to document plant changes.

The PCR provides flexibility in its use, to most effectively accommodate the needs of a specific plant change. Screens are used to develop each plant change package to the technical and administrative content commensurate with the nature of the change.



(Step 1.2.1 contd)

- A. For simple, smaller scope plant changes, the PCR may be used as a "stand-alone" document. It is used as a design "traveler" and the design activities are documented directly on the PCR to the extent practicable.
- B. For larger, more complex plant changes, the PCR is used primarily as a design record. It summarizes decisions made during the design process, and identifies the documentation which describes the plant change.
- C. The PCR form is intended to be elastic. That is, it can be expanded to include all necessary and applicable information to document and summarize the plant change, or it can be compressed to omit those topics or information which are not applicable. (The PCR form was developed as a WordPerfect document to facilitate such flexibility.) By use of screens, the content of each plant change package is defined and developed, based upon the specific requirements of the plant change. Unused sections of the PCR form should be marked as N/A.
- D. Prior to design approval by the Engineering Manager, the PCR is an in-process working document which is updated by the Assigned Engineer (AE) as necessary as the plant change design develops.

1.3 Definitions

- 1.3.1 Design Input - Those criteria, parameters, bases or other design requirements (including applicable regulatory guidance, codes, standards, etc.) upon which the detailed final design is based.
- 1.3.2 Design Output - Documents such as drawings, specifications, or other documents which define technical requirements of structures, systems, or components (including changes thereto).
- 1.3.3 Generic Modification - A modification that has provided common standard design solutions to repetitive identified issues.
- 1.3.4 Modification - A physical or functional change in the design or design basis of a plant structure, system or component; plant hardware-related design changes. Modifications may include setpoint and calibration changes.



- 1.3.5 Staged Modification - A modification that due to schedule or equipment availability/operability constraints needs to be performed in multiple evolutions. Outputs for these efforts are verified, released, and closed out as each phase is accomplished.
- 1.3.6 Standard Modification - A modification change that is processed from design through closeout in a continuous evolution.
- 1.3.7 Turnover - Process by which AE formally notifies the Shift Supervisor that the modification performed is acceptable for use. The tasks identified must be completed and signed off in the work order package per A-1603.3 prior to the Shift Supervisors formal acceptance.

2.0 REFERENCES

2.1 Source Documents

- 2.1.1 ND-CON, Configuration Management
- 2.1.2 ND-DES, Design Control
- 2.1.3 ND-ENV, Environmental Protection
- 2.1.4 ND-SAT, Surveillance and Testing

2.2 Developmental Documents

- 2.2.1 EPRI TR-103586, Guidelines for Optimizing the Engineering Change Process for Nuclear Power Plants
- 2.2.2 INPO 90-009 (Rev. 1, 2/92), Guidelines for the Conduct of Design Engineering

2.3 Use Documents

2.3.1 Administrative Procedures

- A. A-502, Plant Procedure Content and Format Requirements
- B. A-1101, Performance of Tests
- C. A-1303, Storage and Preservation of Materials and Equipment at Ginna Station
- D. A-1603.0, Overview of the Ginna Station Work Control System



(Step 2.3.1 contd)

- E. A-1603.1, Work Request/Trouble Report Initiation
- F. A-1603.3, Work Order Planning
- G. A-1603.5, Work Order Execution
- H. A-1603.6, Post Maintenance/Modification Testing
- I. TR-5.5.1, Plant Change Evaluation

2.3.2 Engineering Procedures

- A. EP-2-P-0111, CMIS & Fire Protection Program Databases, Data Input Guide
- B. EP-3-P-0121, Design Criteria
- C. EP-3-P-0122, Design Analysis
- D. EP-3-P-0123, Drawing Control
- E. EP-3-P-0124, Engineering Specifications
- F. EP-3-P-0131, ALARA Design Review
- G. EP-3-P-0132, Fire Protection/Appendix R Conformance Review
- H. EP-3-P-0133, Human Factors Review
- I. EP-3-P-0138, Erosion/Corrosion Control Program
- J. EP-3-P-0139, Environmental Qualification Program
- K. EP-3-P-0140, Modification Design Changes
- L. EP-3-P-0154, Review and Approval of Vendor Design Analyses
- M. EP-3-P-0161, Distribution and Control of Correspondence
- N. EP-3-P-0172, Document Update Form
- O. EP-3-P-0504, Electrical/I&C Analysis Impact Form
- P. EP-3-S-0301, EIN Naming Conventions
- Q. EP-3-S-0304, Work Prioritization
- R. EP-3-S-0306, Change Impact Evaluation
- S. EP-3-S-0125, Design Verification
- T. EP-3-S-0901, Records and Document Control

2.3.3 Interface Procedures

- A. IP-DES-1, Technical Staff Request
- B. IP-DES-4, Setpoint Change Process
- C. IP-IIT-1, ASME Section XI Repair, and Replacement Process
- D. IP-LPC-1, Commitment and Action Tracking
- E. IP-LPC-2, Technical Specification Associated Documents Control
- F. IP-LPC-3, License Amendment Requests
- G. IP-LPC-7, Updated Final Safety Analysis Report (UFSAR) Periodic and Continuous Updating
- H. IP-NPD-4, Nuclear Operations Group Work Prioritization



(Step 2.3.3 contd)

- I. IP-PES-2, Control of Procurement Documents Prepared for Ginna Station
- J. IP-QAP-1, Component Safety Classification
- K. IP-RDM-1, Drawing Change Request
- L. IP-RDM-2, Vendor Technical Document Change Request
- M. IP-SEV-1, Preparation, Review and Approval of 50.59 Applicability Determinations and 50.59 Screens
- N. IP-SEV-2, Preparation, Review, and Approval of 50.59 Evaluations
- O. IP-SQA-1, Software Quality Assurance
- P. IP-SQA-2, Software Change Process

3.0 INSTRUCTIONS

3.1.1 Responsibilities

1. Engineering Manager shall:
 - Assign Engineer(s) for proposed Plant Change
 - Review and approve the Plant Change package for issuance for implementation
 - Ensure preparers/reviewers of PCR input/outputs are qualified or have a qualified co-signature
 - Facilitation of multi-discipline PCR interfaces
 - Ensure all design activities associated with the change are completed satisfactorily
 - Perform Responsible Manager (RM) function for any System Modification (SM) or Non Safety-Related Station Modification (NSM) procedures developed for implementing the PCR
2. Assigned Engineer (AE) shall:
 - Initiate the Plant Change Record (PCR) and prepare in accordance with requirements specified in Section 3.0 of this procedure.



(Step 3.1.1 contd)

- Determine interfaces and support required for the plant change design development and ensure that support personnel are informed about and involved in the design (input selection and output development) as it is developed. The AE shall coordinate modification follow meetings.
- Perform a Change Impact Evaluation (CIE) to determine and identify the administrative, engineering and safety requirements for the plant change
- Develop the required design output documents (such as drawings, specifications, design analyses, bill of materials, and vendor documentation)
- Ensure a 50.59 Screening or, if required, 50.59 Evaluation of the plant change has been performed (this is transmitted separately to Records Management)
- Obtain required reviews, verification and approval of the plant change
- Develop modification testing requirements
- Support plant change work order package development activities, including:
 1. Ensuring work order is initiated
 2. Provide support for 50.59 Screening(s) for procedures developed or changed for modification installation
 3. Review of the planned work order package and any corresponding SM or NSM procedures
- Procure equipment that is not a normal stock item and requires engineering input
- Responsible for resolving engineering issues during the installation and testing phase of installation



(Step 3.1.1 contd)

- Update affected engineering documents to reflect the plant change per EP-3-P-0172, Document Update Form (DUF)
- Confirm that affected systems drawings have been updated and that new or revised systems plant procedures have been completed
- Coordinate with the Training Department any resulting training issues
- Determine overall modification cost including engineering, parts, vendor support, installation testing costs, and equipment removal (including radioactive waste disposal)
- Coordinate with NES Simulator Support Team to determine the components and/or changes needed for the simulator.
- Determination and coordination with Procurement Engineer and craft to ensure adequate spare parts are procured, including spare parts for the Simulator.

NOTE

Simulator instrumentation in many cases utilize different signal values.

- Shall provide to Operations at modification turnover a description of the plant change. Generally this will be the PCR cover sheet and any MDCNs that impact Operations. However, for modifications that have significant Operations impact a more detailed notice of the change shall be provided to Operations (consistent with Attachment 4). The content of the notice shall be determined with input from the Operations member of the modification follow group. For modifications that require training prior to turnover per TR-5.5.1, the AE is responsible for preparing the

Plant Change Description Notification Letter and providing to Operations at turnover. For all other modifications, the Training Modification Liaison will prepare a Plant Change Description Notification Letter and provide to Operations following turnover.



(Step 3.1.1 contd)

System Engineer shall:

- Assist the AE with determining applicable station support personnel
- Assist in specifying design input requirements
- Review final design to ensure design basis requirements have been met
- Facilitate the identification of reliability, operability, maintainability and testability issues for assigned systems
- Contribute system historical information for design consideration
- Contribute to post-modification system or component testing requirements
- Assess the impact of the plant change in the Maintenance Rule Program
- Review design outputs to confirm that details will not have an adverse effect on plant safety or operation
- Monitor progress of change installation
- Assist in the resolution of testing anomalies along with the AE
- Assist in identifying drawing, procedure and training needs

NOTE

The AE and System Engineer could be the same individual. The intent is to obtain System Engineer input.

4. Maintenance Planner shall:

- Prepare detailed work instructions, SM and NSM Procedures, and Procedure Change Notices (PCNs) to existing procedures. The intent is to provide clear and concise instructions to ensure the installation and testing are straightforward and easily followed. Administrative duties for



(Step 3.1.1 contd)

SM and NSM procedures shall be performed by Engineering Administrative Specialists.

- Prepare work order package
 - Procure modification commodity items (conduit, bolts, etc.)
 - Resolve non-engineering work order package issues during installation and testing phase of installation modification testing requirements
5. Maintenance Shop Foremen shall:
- Shall coordinate the overall installation phase of the modification with assistance from the Planner for work order package issues and Engineering for resolution of engineering issues.
 - Identifying resource requirements and with assistance from Maintenance Management bringing in outside resources as required to support installation and testing.
6. Support Personnel shall:
- Represent affected plant groups and ensure that group concerns are identified and incorporated into the design of the plant change
 - Review and comment on details of design, installation and testing documents for consistency to plant practices and impact on operability, maintainability, testability and ALARA
 - Assist in identification of need for training of specific groups
 - Identify spare parts needs
 - Assist in development of Work Order Package
 - Assist in identification of system related drawings, plant procedures and vendor documentation affected by proposed Plant Change



(Step 3.1.1 contd)

- Revise associate procedures maintained by their work group per the plant change
7. Engineering Administrative Specialist shall:
 - Obtain PCR Numbers from the Configuration Management Information System (CMIS) and enter applicable PCR information into the CMIS database
 - Performing administrative duties for SM and NSM procedures including obtaining PCN numbers
 8. Technical Process Specialist (TPS) shall:
 - Perform review of PCR package for completeness and consistencies
 - Forward PCR package to Records Management
 - Provide a copy of PCR package to NS&L for imaging
 9. Records Management shall:
 - Be responsible for distribution and/or retention of documents and records, as directed.
 10. Nuclear Safety and Licensing (NS&L)
 - Image completed PCR package for retrieval.

3.2 Plant Change Initiation (Attachment 2, Header)

1. The need for and scope of a Plant Change is primarily established by evaluations conducted in response to a Technical Staff Request (TSR).
2. The AE shall initiate a Plant Change Record (PCR) (Attachment 2) as follows:



(Step 3.2 contd)

- A. Enter the PCR Subject. The PCR subject shall provide a concise description of the plant change, not exceeding 62 characters in length.
- B. Enter the affected plant structure or system name(s) and number(s) (PSSL No.), if applicable. (For existing structures or systems, the PSSL Number may be obtained from IP-QAP-1 or from the Equipment Module of the CMIS database.)

NOTE A PCR may be initiated by the organization responsible for performing the change without the initiation of a TSR.

- C. Enter the affected Equipment Identification Number(s) (EIN), as applicable. If a new EIN is needed, refer to Reference 2.3.2(p).
- D. List applicable reference TSR, ACTION Report, etc. which initiated the plant change.
- E. Identify the lead engineering section, as applicable.

EXAMPLE: Primary Systems (NEP), Electrical/I&C (NEE), Balance of Plant (NEB), Configuration Support (NET), Strategic (NES), NS&L (NEL), Reliability (NERL), etc.

- F. Identify applicable System Engineer(s).
 - G. Identify the AE.
 - H. Obtain PCR Number from Administrative Specialist (the PCR Number is assigned/auto-generated by CMIS; PCR# (yyyy-nnnn) and assign the revision number.
 - I. Identify overall modification safety classification as described in Section 3.6.
3. Engineering Administrative Specialist personnel shall input applicable PCR information into the CMIS database.



- 3.2.1 The AE shall initiate (or verify one has been initiated) a WR/TR per A-1603.1 to allow the plant planning process to proceed with the installation and scheduling process. A common priority shall be assigned to the WR/TR and PCR per IP-NPD-4. If a PCR is subsequently canceled, a work cancellation checklist shall be attached to the PCR package. This checklist shall be signed by a NES manager.
- 3.3 Problem Identification (Attachment 2, Section 1.0)**
- Problem Statement - provide a sufficiently detailed description of the issue, problem or condition requiring a plant change; the reason for the plant change.
- 3.4 Change Description/Scope (Attachment 2, Section 2.0)**
- 3.4.1 Change Description - provide a sufficiently detailed description of the recommended or proposed plant change; define the scope of the plant change. This description should include documents which provided input requirements committed to be met such as regulatory guidance, codes and standards.
- 3.4.2 Identify the type of modification (standard, staged, generic or setpoint):
- A. Standard Modification - the AE shall determine the design inputs and outputs, etc. in accordance with this procedure. This effort is processed from design to closeout in one continuous evolution.
 - B. Generic Modification - the AE determines that the proposed design can be utilized as a standard approach to repetitive issues (such as ferrite beads for EMI suppression, pulse dampeners for pressure spikes, etc.) and completes the PCR as described within this procedure. Subsequent installation of this design will be invoked by the generation of a Work Order which references the generic design approach. The Work Order will have a step which requires that prior to Work Order closeout the AE updates that all configuration changes resultant from this work (drawings, procedures, CMIS, etc.) via the DUF have been updated per this effort. In addition, the PCR shall identify if a 50.59 Screening and Change Impact Evaluation (CIE) is required for each usage of the generic PCR. If the scope is specific enough such that a single CIE and 10 CFR 50.59 review can cover all installation, then check "No" in Section 7.3. If one is required, check "Yes."



(Step 3.4.2 contd)

NOTE For generic PCRs, the first usage will be transmitted and remain in construction status. If a change to the generic PCR methodology is required, a revision shall be processed per Section 3.15. Request Records Management to transmit a copy of generic PCR(s) to Planner(s), Training, and assigned individual (AI) as a minimum.

- C. Staged Modification - the AE develops the PCR package as described within this procedure, however, due to equipment availability/system operability/work scope it is recognized that the installation is to be performed in multiple evolutions. Any limitations or restrictions of the staged release are to be identified. Each staged release of the modification requires a revision to the PCR. Revisions shall include a description of the work performed from the prior release(s) with new information resultant for the stage annotated. Each revision should include a new CIE and/or 50.59. If the revision to the PCR does not change the existing CIE or 50.59, then it must clearly identify so on the PCR Form, Section 2.0.

Each Work Order package per stage will require that the documents affected be updated per a DUF for that effort (drawings, procedures, CMIS, etc). This shall be required via the Work Order by requesting a DUF be initiated at turnover of each state.

3.5 Interface Requirements (Attachment 2, Section 3.0)

3.5.1 Support Interfaces

The AE shall identify the support required from other organizations or groups and list the names of the individuals involved on the PCR Form. See EP-3-S-0306 for guidance in determining design support requirements. This should include groups which may:

- Provide input or recommendations for the design
- Be impacted by the plant change (Operations, Maintenance, and Training, as a minimum)
- Should review the plant change



(Step 3.5.1 contd)

- Install and test the plant change
- Specialty interfaces (such as Computer Group, GARD Committee, etc.)
- Program interfaces (MOV, EQ, PSA, AOV, IST, Erosion/Corrosion, etc.)

NOTE Training Department needs to be involved with modification from inception through closeout.

3.5.2 The AE shall coordinate the input from the identified groups throughout the Plant Change Process. This includes the formation of Modification Follow Teams to ensure that the design impact requirements are met, installed, tested and turned over successfully. The AE shall notify team members of these assigned responsibilities for the PCR. See Attachment 5 for recommended mod-follow agenda checklist.

3.5.3 The number of members on a modification group and the frequency of associated meetings depends on the scope and impacts of the modification, It is the expectation that all modifications will have an initial kick-off meeting during the preliminary design phase and another meeting following design completion (prior to PCR being issued for construction). In Section 3.2 of the PCR the specific meeting dates shall be documented. For PCRs that are minor in scope and have negligible impact on other plant groups, the applicable responsible manager can waive the requirements for a modification following meeting by documenting in Section 3.2 of the PCR form.

NOTE The AE is encouraged to perform a walkdown to ensure comprehensive project scope assessment.

3.6 Safety Classification (Attachment 2, Section 4.0)

3.6.1 The AE shall determine the safety classification of the plant change. For existing systems, structures or components (SSCs), the safety classification should be obtained from IP-QAP-1 or the Equipment module of the CMIS database, for the applicable system (PSSL No.) or Equipment Identification Number (EIN). Safety classification instruction is identified



(Step 3.6.1 contd)

per the Change Impact Evaluation (CIE). Identification of modification classification basis shall be explained for project which have multiple safety classifications.

3.6.2 The AE shall identify the safety class of the plant change on the PCR form. This determines the required process controls imposed on the modification. The overall safety classification shall be listed on the PCR form cover which represents the highest safety classification associated with the modification. For plant changes which involve multiple items with different safety classifications, PCR (Section 4) shall identify which portions of the modification relate to each classification and associated safety rules.

3.7 Design Inputs (Attachment 2, Section 5.0)

3.7.1 The AE shall identify or develop the Design Criteria which establish the design input requirements per one of the following methods:

- A. Project-specific Design Criteria shall be prepared, reviewed and approved in accordance with EP-3-P-0121. Detailed description of all identified parameters of the design criteria shall be provided to ensure clear design requirements are provided per ANSI N45.2.11 for the modification.
- B. Existing approved Design Criteria may be used. When doing so, list and explain any exceptions or deviations from the selected Design Criteria on the PCR and explain applicability to the current plant change as necessary.
- C. Utilize existing generic design criteria(s), when doing so, list and explain any exceptions or deviations from the selected Design Criteria on the PCR and explain applicability to the current plant change as necessary. The AE must include definition of modification related aspects per EP-3-P-0121 for the following:

1. Functional Requirements:

Outline the basic functions of each structure, system or component to be added or modified by the plant change. Include control functions and modes of operation, as applicable. Typical modes of operation to consider are:



(Step 3.7.1 contd)

- refueling
- cold shutdown
- hot shutdown
- normal operation
- standby
- off
- test
- automatic
- manual
- failure

2. Performance Requirements:

Performance requirements are the normal and/or bounding operating conditions (for all anticipated operating modes and events including transients) for systems, structures, or components associated with the change.

Typical performance requirements:

- capacity minimum 4 hour battery capacity for SBO condition
- rating 105 to 140 VDC voltage rating for new DC components
- output minimum 200 gpm flow to AFW system
- actuation time maximum 10 second stroke time for MFW reg. valve closure
- contiguous maximum 72 sq. in. gap in the vehicle barrier system
- UFSAR contains numerous examples of performance requirements (e.g. table 9.3-6)

(Step 3.7.1 contd)

3. Operational Requirements

Specify manual actions required for equipment under expected plant or system conditions.

- plant start-up
- normal plant operation
- plant shutdown (cooldown, hot standby, cold shutdown, etc.)
- plant emergency operation (accidents)
- plant special or infrequent operation (periodic, testing, refueling, system upset, etc.)
- specify any operating restrictions

4. Design Conditions

Design conditions are the design values or limits (excluding environmental) that systems, structures, or components associated with the change shall be ultimately capable of sustaining.

- pressure (transmitter, piping, tank)
- temperature (cable, components in enclosures)
- flow (pump, discharge canal)
- level (condenser, containment sump)
- velocity/speed (pump, motor)
- fluid chemistry (tank, piping)
- voltage (fuse, breaker)

5. Personnel Requirements

Specify new or changed personnel requirements and limitations including the qualification and number of personnel available for plant operation, maintenance, testing and inspection and permissible personnel radiation exposures for specified areas and conditions. Include specialized skills or training required to complete the change such as:



(Step 3.7.1 contd)

- NDE personnel qualifications
- welder qualifications
- system operation

3.7.2 Any regulatory guides or standards which initiate a PCR shall be clearly listed on the PCR. The AE shall keep current with evolving guidance as the modification progresses and ensure that the input requirements are reflected in the output documents resultant from the change.

3.8 Design Outputs (Attachment 2, Section 6.0)

3.8.1 The AE(s) shall develop, as applicable, the required design output documents for the plant change, including required design process controls and programmatic reviews as determined by the CIE per EP-3-S-0306. Industry operating experience shall be considered (and provided for design review/verification) when design and testing requirements are specified.

The required design output documents shall be identified on Section 6 of the PCR shall be forwarded to Records Management in accordance with EP-3-S-0901 and are summarized as follows:

- A. CIE required outputs (ALARA, Analyses, Human Factors, Appendix R Review, etc.) shall be prepared, reviewed and approved per the respective Engineering procedure.
- B. Drawings and circuit schedules, shall be prepared, reviewed and approved in accordance with EP-3-P-0123.
- C. Specifications shall be prepared, reviewed and approved in accordance with EP-3-P-0124.
- D. Calculations and Design Analyses shall be prepared, reviewed and approved in accordance with EP-3-P-0122.
- E. Bills of Materials shall be prepared per Attachment 3 or included on a drawing or sketch.



(Step 3.8.1 contd)

- F. Testing requirements, including purpose of testing, functions to be tested (functions affected by modification), acceptance criteria, data to be taken, test sequence, quality verification requirements, and test documentation requirements shall be defined in accordance with A-1101 and Nuclear Directive ND-SAT. Testing shall be sufficient to demonstrate that the change performs as designed. Tests shall demonstrate that all possible logic paths and failure modes are specified for validation. All circuit logic and functions upstream and downstream of the modified circuitry shall be tested to verify design function and operability prior to modification turnover. Test requirement documentation shall contain sufficient detail to allow test procedure development, if required (see Step 3.14.3).

EXAMPLE: Shall test to ensure unwanted AC, noise or ripple has not been introduced as a result of a modification or module replacement.

- G. Attached sketches and instructions may be provided to identify direction for installation and testing. They shall be reviewed and signed by the AE and a reviewer. PCR attachments shall be clearly labeled and identify PCR number and revision. Sheets shall be numbers 1 of N, 2 of N, etc. A subsequent revision of a PCR will require new attachments.
- H. Other documents which relate to design bases direction shall be prepared and referenced (alternate design verification calculations, letters, faxes, etc.)

3.9 50.59 Screening/Evaluation (Attachment 2, Section 7.0)

The AE shall ensure that a 50.59 Screening/Evaluation of the proposed plant change has been performed in accordance with IP-SEV-1 and IP-SEV-2.

3.10 Design Reviews/Verification(s) (Attachment 2, Section 8.1, 8.2)

- 3.10.1 For Non Safety Related plant design changes without Nuclear Regulatory Commission (NRC) commitments, a Technical Review shall be performed in a manner consistent with the guidance in EP-3-S-0125 to verify the adequacy of the design. Attachment B of EP-3-S-0125 shall be



(Step 3.10.1 contd)

completed and submitted as a record DESVER in accordance with EP-3-S-0901. The extent of the review required is a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs.

Signature of the reviewer shall be documented on PCR Section 8.1 as well as initialing the documents reviewed in Section 6.0.

- 3.10.2 For Safety Related, Safety Significant, or Non-Safety Related with NRC commitments (such as security), an independent Design Verification shall be performed in a manner consistent with the guidance in EP-3-S-0125 to verify the adequacy of the design. Attachment B of EP-3-S-0125 shall be completed and submitted as a record DESVER in accordance with EP-3-S-0901. The extent of the design verification required is a function of the importance to safety, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Signature of the verifier shall be documented on PCR Section 8.2 as well as initialing the documents reviewed in Section 6.0.
- 3.10.3 Open design verification items shall be listed on the PCR and included on the work order package. Open items shall be completed or deemed acceptable prior to turnover of the plant change for use.
- 3.10.4 Multi-discipline efforts require separate discipline specific review or verification using Attachment B of EP-3-S-0125. Additional verifiers/reviewers may co-sign or add additional signature lines, if desired.

NOTE PCR output documents prepared by a separate discipline shall be verified by an independent reviewer/verifier qualified in that discipline.

- 3.11 Integrated Assessment/Design Completion (Attachment 2, Section 8.3, 8.4)**
- 3.11.1 For multi-discipline design projects, the AE (or the project team, when applicable) shall review all of the design documents for the plant change to assure that the design outputs of all disciplines are consistent with the overall objectives of the plant change.
- 3.11.2 The AE shall document satisfactory completion of the Integrated Design Assessment on PCR (Section 8.3).



- 3.11.3 The AE shall sign the PCR Section 8.3 to certify that all required design activities and administrative controls for the plant change have been completed or listed as open items in Section 8.1 or 8.2. Unused sections of the PCR form should be marked as N/A.
- 3.11.4 The applicable Ginna Systems Engineer shall review the PCR package and sign the PCR Section 8.4 to verify that the proposed plant change design package adequately addresses and resolves the identified problem or condition. The System Engineer shall ensure that the modification satisfies the impacted systems design bases. For systems or components without an assigned Systems Engineer, contact the appropriate system engineering manager.

3.12 Plant Change Package Approval (Attachment 2, Section 8.5)

- 3.12.1 The Engineering Manager shall review the completed PCR package (PCR and applicable output documents) to assure that:
- The technical content is adequate and accurate
 - Open items have been reviewed and do not represent a commercial or safety risk.
 - The plant change adequately addresses and resolves the identified problem or condition
 - The PCR process has been properly applied
 - Ensure preparers/reviewers of PCR input/outputs are qualified or have a qualified co-signature

- 3.12.2 The Engineering Manager or designee shall indicate approval of the completed PCR package by signature and date on Section 8.5 of on the PCR.

3.13 PCR Construction Issuance

- 3.13.1 The AE shall forward the approved PCR package to the TPS for package review. TPS shall transmit approved PCR package to Records Management in accordance with EP-3-S-0901 and the package shall include as a minimum the following:



(Step 3.13.1 contd)

- PCR form
- CIE
- DESVER

NOTE When transmitting PCR packages to Records Management, specify the individuals you want to receive a copy of the package (such as Planner, Training, etc.). If not, Records Management will default to individuals listed on Section 3.1 of the PCR form.

3.13.2 If a design package is not complete (i.e., verification) it is possible to issue drawing and instructions which can allow pre-fabrication associated with the change. Outputs issued for pre-fab shall be statused as limited construction (LC) and construction work will be limited as noted.

3.13.3 For PCRs where rapid implementation is required, the AE may furnish an approved copy directly to a site individual(s). In this case, the AE shall note that a copy was given to the individual(s) on the Records Management transmittal form and shall forward the original PCR package to Records Management for distribution.

3.13.4 Records Management shall:

- Update related data in the CMIS database, and shall record any individuals that have received a copy.
- Transmit controlled copies of the PCR package per the established distribution.
- Retain the PCR package

3.14 Plant Change Implementation and Testing

3.14.1 Plant changes shall be implemented in accordance with the approved plant change package and applicable Ginna Station processes and procedures, including planning, installation, testing and turnover for use. PCR implementation shall be in accordance with the Work Order control system.



(Step 3.14.1 contd)

- A. Necessary items for plant changes shall be (or have been) procured and stored in accordance with IP-PES-2 and A-1303 respectively.
- B. Implementation activities shall be controlled in accordance with A-1603.5.
- C. The AE shall review the Work Order installation package prior to implementation.
- D. Testing activities shall be controlled in accordance with A-1603.6

3.14.2 The AE shall assist and support the implementation and testing as needed. Depending on the complexity of the implementation, this may require detailed job oversight.

3.14.3 The applicable planner shall prepare installation and testing instructions utilizing the following guidance per A-1603.3:

A. Safety-Related Plant Change

A safety related plant change requires an approved plant procedure as a minimum for implementation.

For simple changes, existing plant procedure(s) may be used. A PCN may be necessary to augment existing plant procedures with special instructions. Special instructions may include controls of turnover of drawings, procedures.

For complex changes, a Station Modification (SM) procedure shall be prepared in accordance with procedure A-502.

B. A non-safety related or safety significant plant change requires written instructions, as a minimum, for implementation.

For simple changes, work instructions with job steps or existing plant procedures may be used.

For a complex changes, a NSM shall be prepared. The procedure format shall be similar to the format of an SM procedure.



(Step 3.14.3 contd)

NOTE The SM or NSM procedures will be an attachment to the work order package. The completed procedure will be filmed with the work order package as part of the work order record.

3.14.4 After construction issuance, changes to approved design output documents shall be processed utilizing Modification Design Change Notices (MDCN) in accordance with EP-3-P-0140.

3.14.5 The AE and an independent reviewer (EM, Design Verifier, or System Engineer) shall annotate on the work order that all items identified per PCR open items list and A-1603.3 for turnover are acceptable prior to Shift Supervisor approval.

3.15 PCR Changes or Revisions

3.15.1 Once approved by the Engineering Manager, subsequent changes to the PCR shall require the PCR to be revised and reapproved. Prior revisions will become superseded.

NOTE Changes which are not bounded by the defined work scope of the PCR (Section 2.0) shall be processed via a new PCR or a revision to the PCR. If the change is within the scope of the PCR, a MDCN can be used to alter, clarify, or add information to approved outputs of the PCAR package.

3.15.2 If the revision to the PCR does not change the existing CIE or 50.59, then it must clearly identify so on the PCR Form, Section 2.0.

3.15.3 The AE shall:

- Make necessary changes to design inputs and/or outputs in accordance with applicable procedures
- Make the necessary changes to the PCR
- Change the revision level on the PCR
- Obtain applicable required reviews, verification and approval for the revised PCR, as described in Sections 3.8 - 3.12.



(Step 3.15.3 contd)

- Transmit the revised PCR and applicable revised and/or additional output documents to Records Management for issuance.
- Revise CIE
- Ensure that the 50.59 Screening/Evaluation has been revised
- Ensure that work order linkage in CMIS reflects the current revision level and status

3.16 Plant Change Closeout

3.16.1 The AE shall update, or request update of, applicable engineering documents and databases as necessary to reflect the plant change.

3.16.2 The AE shall summarize the documents, databases, programs, etc. which will be required to be updated as a result of the plant change using the DUF.

NOTE It is recommended that a set of markups (drawings, procedures, VTDs, CMIS, etc.) be developed early in the modification. Markups shall be based on mod-follow team input and the DUF. This will facilitate successful records updates.

3.16.3 The AE shall certify successful completion of the plant change or staged phases by signature on the DUF.

3.16.4 The design verifier/technical reviewer shall validate satisfactory completion of the plant change by signature on the DUF. This ensures that documentation requiring update prior to PCR closeout as identified in the Document Update Form has been revised, PCN'd or DCR'd or has an assigned tracking number.

3.16.5 DUF packages for PCR closure shall be forwarded through the Technical Process Specialist (TPS) to validate CMIS revisions and provide consistent interface with Records Management. DUF packages shall be assembled per EP-3-P-0172.



(Step 3.16.5 contd)

NOTE PCR packages issued to perform a modification shall be stasused construction (CN) and once the DUF is processed, changed to complete (CL) by Records Management.

- 3.16.6 It is expected that all records related to a modification or staged phase of a modification are closed out (updated or have change pending documents posted such as DCR, UCN etc.) within two months of turnover or assigned a CATS ID tracking number in accordance with IP-LPC-1.
- 3.16.7 If a SM procedure was created for the plant change, the AE shall initiate a PCN to delete it unless it will be used/ revised in the future.

4.0 RECORDS

- 4.1 The AE shall submit the completed PCR Document Update Form package through the TPS to Records Management (for retention) in accordance with EP-3-S-0901.
- 4.2 Documents developed in support of the PCR such as analyses, specifications, and reviews shall be transmitted separately as records in accordance with their use procedures (see Section 2.3 for examples).
- 4.3 TPS will forward a copy of the completed PCR package to Nuclear Safety and Licensing (NS&L) for imaging.

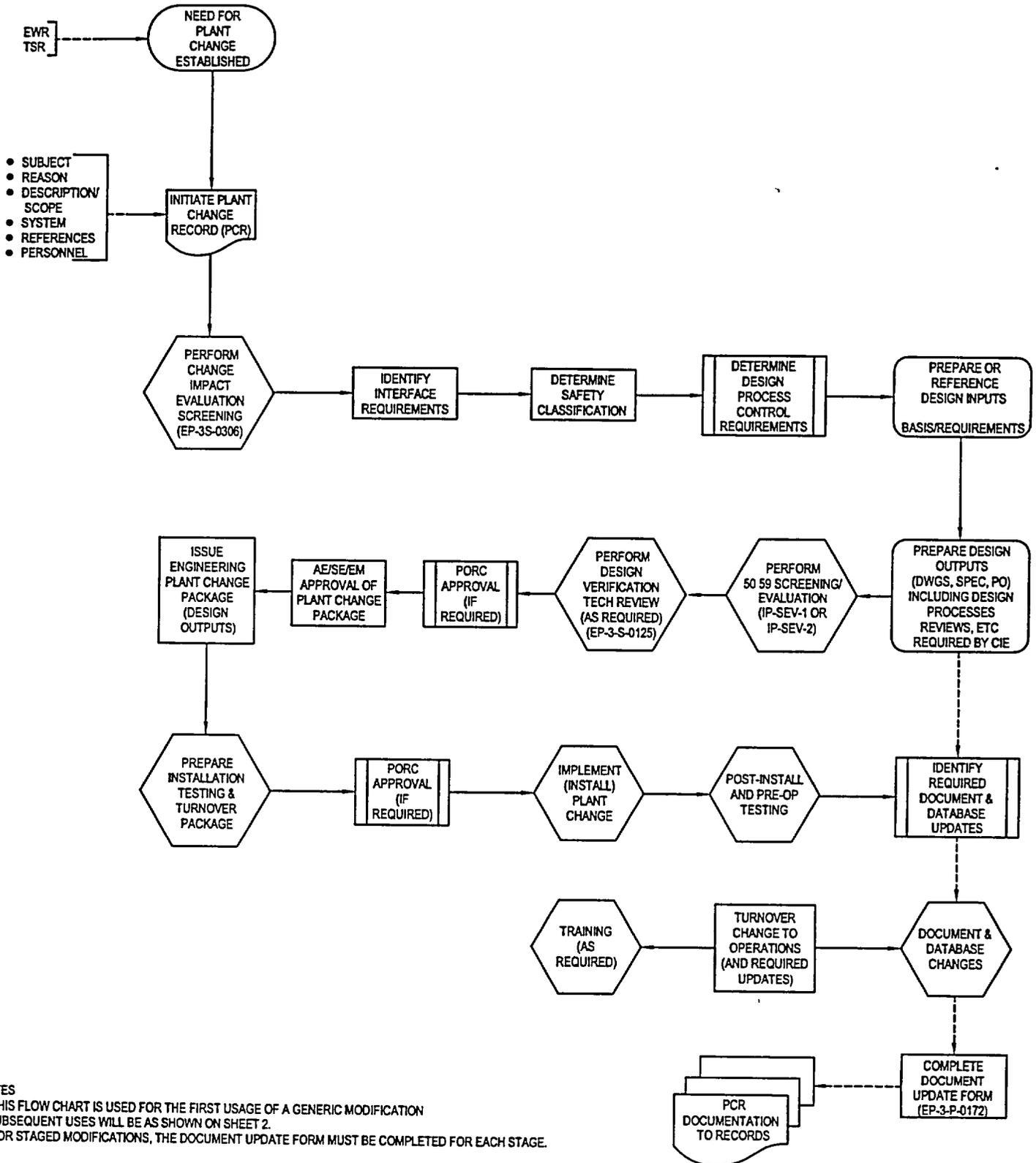
5.0 ATTACHMENTS

- 5.1 Attachment 1, Plant Change Process Flow Diagram
- 5.2 Attachment 2, Plant Change Record
- 5.3 Attachment 3, Modification Bill of Material
- 5.4 Attachment 4, Plant Change Description Notification Letter Format
- 5.5 Attachment 5, Mod-Follow Meeting Agenda Checklist

**ATTACHMENT I
PLANT CHANGE PROCESS FLOW DIAGRAM
(PAGE 1 OF 2)**

IP-DES-2
Rev. 16

PLANT CHANGE PROCESS FLOW DIAGRAM - STANDARD MODIFICATION
(SEE NOTES)

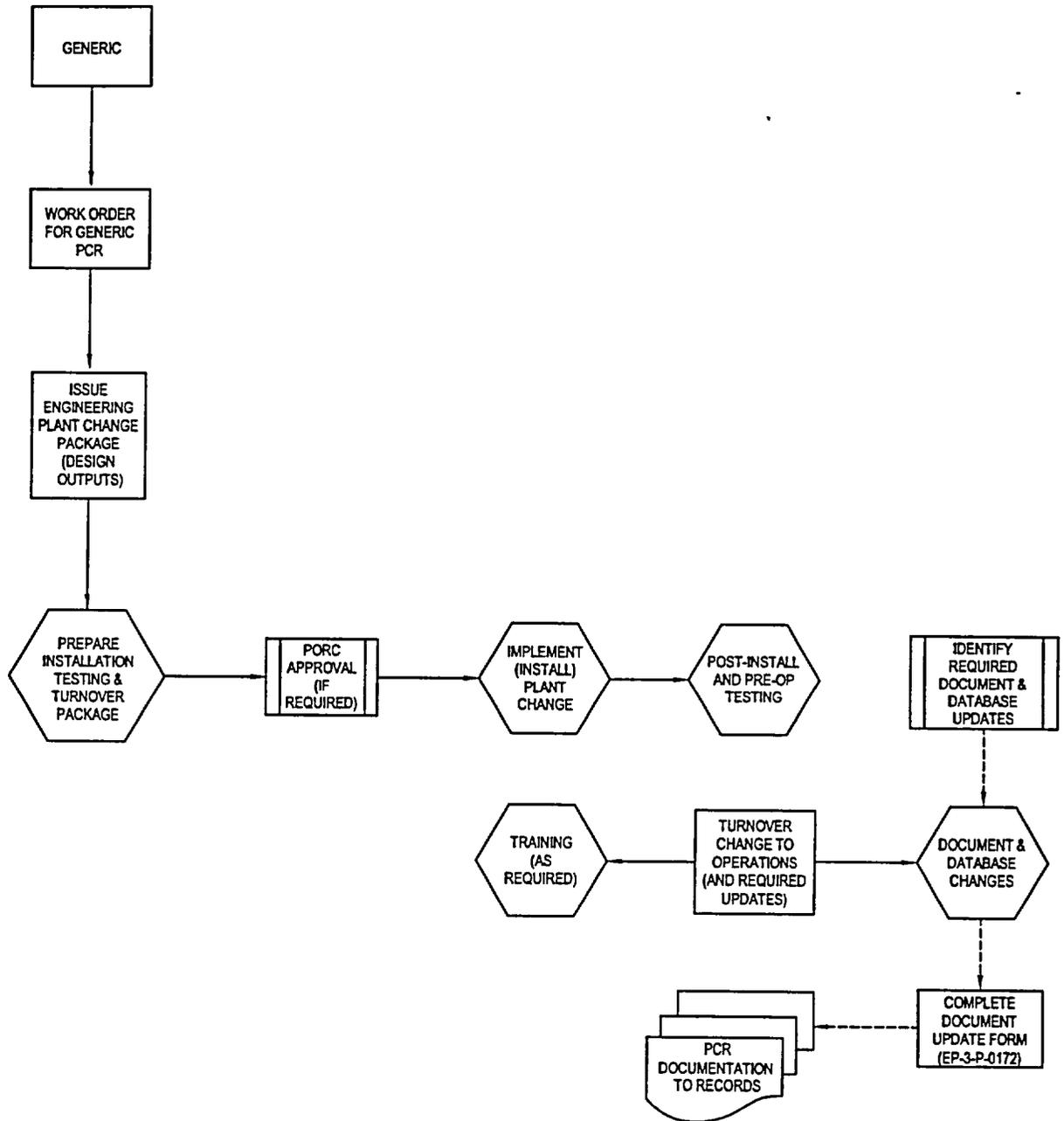


- NOTES**
- 1) THIS FLOW CHART IS USED FOR THE FIRST USAGE OF A GENERIC MODIFICATION SUBSEQUENT USES WILL BE AS SHOWN ON SHEET 2.
 - 2) FOR STAGED MODIFICATIONS, THE DOCUMENT UPDATE FORM MUST BE COMPLETED FOR EACH STAGE.

ATTACHMENT I (CONT'D)
PLANT CHANGE PROCESS FLOW DIAGRAM
(PAGE 2 OF 2)

IP-DES-2
Rev. 16

GENERIC MODIFICATION FLOW CHART - USE OF EXISTING GENERIC PCR FLOW CHART



Attachment 2
Plant Change Record
(Page 1 of 8)

IP-DES-2
Rev. 16

RG&E • GINNA STATION PLANT CHANGE RECORD (PCR)	PCR No. REV. W/O #	
SUBJECT:		
PSSL No.	SYSTEM NAME:	EIN:
LEAD ENGR. SECTION:		OVERALL PROJECT SAFETY CLASSIFICATION:
ASSIGNED ENGINEER:		SYSTEMS ENGINEER:
CIE # _____	REV _____	50.59 SCRIN/EVAL _____ Rev _____
1.0 <u>PROBLEM OR CONDITION/REASON FOR PLANT CHANGE:</u> 		
2.0 <u>CHANGE DESCRIPTION/SCOPE:</u> 		
MODIFICATION TYPE: <input type="checkbox"/> STANDARD <input type="checkbox"/> STAGED <input type="checkbox"/> GENERIC		

Record Category 4.32.2

Attachment 2 - Plant Change Record (contd)
 (Page 2 of 8)
 PLANT CHANGE RECORD (PCR)

IP-DES-2
 Rev. 16

PCR No.

Rev. No.

3.0 Interface Requirements

3.1 Design Interfaces

Identify all support disciplines. (Use CIE Checklist for guidance in determining support requirements).

Group	Individual(s)
I&C/Electrical	
Primary/Reactor Systems	
Balance of Plant Systems	
NS&L	
Nuclear Strategy/Procurement	
Reliability	
Nuclear Computer Systems	
Maintenance Planner	
Maintenance (Shops)	
Training	
Simulator Support	
Quality Control	
Operations	
RP/Chemistry	
Performance Monitoring	
Technical Performance/ Field Inspect Services	
Operational Review	
Scheduling	
Other	

PLANT CHANGE RECORD (PCR)

PCR No.

Rev. No.

3.2 Modification Following Meeting

Date(s)

Initial Design Phase _____

Completion of Design _____

Notes: _____

4.0 Required Process Controls

4.1 Safety Classification

Safety Related Rule #

Safety Significant Rule #

Non-Nuclear Safety Rule #

Explain: (if multiple classifications)

PLANT CHANGE RECORD (PCR)

PCR No. Rev. No.

5.0 Design Inputs

5.1 Modification Specific Design Criteria

_____ Reference #

_____ Rev.

5.2 Use existing modification specific design criteria

_____ Reference #

_____ Rev.

5.2.1 List and explain any deviations from the selected design criteria:

5.2.2 List any design input initiation references:

5.3 Invoke generic design criteria (EWR 10275 (Electrical/I&C),
10182 (Mechanical/Structural))

_____ Reference #

_____ Rev.

5.3.1 List and explain any deviations from the selected design criteria:

5.3.2 List any design input initiation references:

5.3.3 Function:

5.3.4 Performance Requirement:

5.3.5 Operational Requirement:

5.3.6 Design Condition:

5.3.7 Personnel Requirement:

PLANT CHANGE RECORD (PCR)

PCR No.

Rev. No.

6.0 Design Outputs (List all outputs for this change below, including revision, date, preparer)

6.1 CIE Related Documents CIE # _____

Documents	Rev	Date	Prepared By	Verifier/Reviewer Initials / Date

6.2 Drawings

Documents	Rev	Date	Prepared By	Verifier / Reviewer Initials / Date

6.3 Specifications

Documents	Rev	Date	Prepared By	Verifier / Reviewer Initials / Date

6.4 Analyses

Documents	Rev	Date	Prepared By	Verifier / Reviewer Initials / Date

PLANT CHANGE RECORD (PCR)

PCR No.

Rev. No.

6.5 Bill of Material

Documents	Rev	Date	Prepared By	Verifier / Reviewer Initials / Date

6.6 Testing Required (Spec., plan)

Documents	Rev	Date	Prepared By	Verifier / Reviewer Initials / Date

6.7 Attachment (Circuit schedules, sketches, etc.)

Documents	Rev	Date	Prepared By	Verifier / Reviewer Initials / Date

6.8 Other (correspondence, installation instructions, testing instructions, alternate design verification calculations, etc.)

Documents	Rev	Date	Prepared By	Verifier / Reviewer Initials / Date

PLANT CHANGE RECORD (PCR)

PCR No. Rev. No.

7.0 50.59 Screening/Evaluation

7.1 A 50.59 Screening of the proposed Plant Change has been completed.

_____ _____ _____
50.59 Screening # Rev. Date

7.2 A 50.59 Evaluation is required and has been approved.

_____ _____ _____
50.59 Evaluation # Rev. Date

7.3 If generic PCR, is a 50.59 screening and CIE required for each MDCN?

Yes No N/A

8.0 Design Reviews/Verifications

8.1 Technical Review (Non-safety changes w/o NRC commitments)

The PCR package has been reviewed for technical adequacy and accuracy. The proposed change will satisfactorily resolve the identified problem or condition, as stated in Section 1.0 of this PCR.

OPEN ITEMS

_____ _____
Technical Reviewer(s) Date

PLANT CHANGE RECORD (PCR)

PCR No.

Rev. No.

8.2 Design Verification (Safety-related/Safety Significant or non-safety change with NRC commitment changes)

An independent design verification has been made of this PCR in accordance with the guidance of EP-3-S-0125.

OPEN ITEMS

Design Verifier(s)

Date

8.3 Integrated Assessment/Design Completion

All discipline specific Inputs and Outputs for this change have been completed and reviewed by the AE. The undersigned has reviewed the design documentation and any required verification has been completed. All design inputs and outputs are listed in this PCR and will be included in the completed records package.

Assigned Engineer

Date

8.4 System Engineer concurrence

The proposed change adequately addresses and resolves the identified problem or condition, as stated in Section 1.0 of this PCR and meets the system design bases.

System Engineer

Date

8.5 Engineering Manager's approval and release for implementation.

Engineering Manager or Designee Date

ATTACHMENT 3
 MODIFICATION BILL OF MATERIAL
 Page 1 of 1

IP-DES-2
 Rev 16

PREPARED BY/DISCIPLINE		EXT		PLANT CHANGE, TSR, ETC		Page:	
REVIEWED BY: (8)				ACCOUNT # (5)		Revision: (6)	
PROCUREMENT ENGINEER		EXT		NEED DATE (4)		Date:	

ITEM (1)	QTY (2)	SAFETY CLASS (9)	DESCRIPTION (3)	MATERIAL I.D. (11)	PR NO (12)	EQ (10)	REMARKS (7)
					PO. NO		

Record Category 4 61.2

NOTES:

- (1) Items in sequential order
- (2) Preferred to include combined quantities
- (3) Description shall include rating of fittings
- (4) Need date should be completed consistent with project schedule
- (5) Ensure that account # is included
- (6) Revision gets changed when there is a change in description, quantity or new items
- (7) To include notes such as "this is an increase in quantity from revision 0"
- (8) Authorization to proceed with procurement (Assigned Engineer)
- (9) Safety class shall be provided
- (10) Environmental qualification shall be indicated
- (11) List material ID
- (12) List package requisition or order number

Plant Change Description Notification Letter Format

ROCHESTER GAS AND ELECTRIC CORPORATION

Inter-Office Correspondence

{ Date Prepared }

Subject: PCR ##-####, ".....PCR Subject....."

To: Training Modification Liaison

Turnover Date: _____

{ Letter Content }

Problem Statement - provide a sufficiently detailed description of the issue, problem or condition requiring the plant change.

Change Description - provide a sufficiently detailed description of the scope of the plant change. This description should include documents which provided input requirements committed to be met such as regulatory guidance, codes and standards.

Operational Impact - provide a sufficiently detailed description of changes in operational impacts such as the addition or removal of alarms, new/modified controls, indicating light changes, and/or modified control switches. In addition, details of changes in maintenance or repair activities should be outlined.

Document Impacts - provide a sufficiently detailed description of impacted plant documents such as plant [procedures and impacted CCDs.

Approved by: _____
Assigned Engineer Date

Mod-Follow Meeting Agenda Checklist
(Page 1 of 4)

Pre-Meeting Activities

- 1. Via Lotus Notes, invite appropriate organizational interfaces a minimum of two weeks (preferably four weeks) prior to meeting.

Mandatory invitees: Operations _____
 Training _____
 Planning _____

- 2. Develop conceptual mod description and sketches and mail out two weeks before meeting.
- 3. Review DUF for required document updates.
- 4. Assign an individual to take formal meeting notes, if desired.

Project Expectations

- 1. Verify that all appropriate mod follow team members are in attendance.

Training _____	Planning _____	Operations _____
Other _____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

- 2. Describe the scope of the work to be performed.
 - a. The briefing should start with a statement of the project title, reason the mod was initiated, conceptual design sketches and objective of the task (Whenever possible mail package two weeks prior to meeting.)
- 3. Discuss the project schedule and the expected plant/equipment that will be impacted
 - a. Discuss if the job is to be performed in separate phases or discrete work packages. If multi-discipline work order, have lead package with testing and turnover.
 - b. Project to be worked days/nights, both?
- 4. Review Project Output package
 - a. Using the drawings, sketches, and installation instructions to review the package for concerns relative to constructability and maintainability
 - b. Using the drawings, sketches, and testing instructions to review the package for concerns relative to testability.

Mod-Follow Meeting Agenda Checklist
(Page 2 of 4)

Division of Responsibility

1. Assign job functions, personnel required and responsibilities.
 - a. Ensure that all the appropriate personnel attend the briefing. This should include support groups such as RP, QC, Program Owners, Training, Ops, Craft, etc.
 - b. The assignment of team member positions ensures each member knows how they fit together and how their responsibilities for job completion interrelates.
 - c. Develop a list for all impacted programs and documents and establish each team member's responsibility. This includes assigning responsibility for the following:

	<u>Responsible Person</u>	<u>Due Date</u>
PCNs	_____	_____
DCRs	_____	_____
Labels	_____	_____
Others (UCN,s VTDCRS, etc)	_____	_____

2. Develop a list of constructability, maintainability, and testability issues and assign responsibility.
3. Discuss any lessons learned from previous experiences or applicable industry events.
4. Solicit input, questions and concerns from all team members.

Parts/Equipment/Tools

1. Discuss what tools and equipment are needed and who has responsibility for obtaining equipment and parts.
2. Discuss any parts that are needed for the job.
 - Purchases Order status
 - Documentation (C of Cs, Test Reports, etc.)
 - Delivery time
 - Spare parts
 - Simulator
 - Consumables (conduit, gaskets, fasteners, etc.)
3. Evaluate if the plant has experience with the equipment selected
4. Develop a list of modification parts and assign responsibilities for procuring (AE, Planner, Procurement Engineer, etc.).

Budget

- Account #s
- PE status

Mod-Follow Meeting Agenda Checklist
(Page 3 of 4)**Effect on Plant**

1. Discuss operational impact during construction and testing.
2. Discuss how the system/equipment will be returned to service to the Shift Supervisor.
3. Discuss and review any current tag-outs or temporary mods that may effect the job.
4. Evaluate potential effects on simulator.
5. Evaluate potential effects on Training.
 - Pre-Mod
 - Post-Mod
6. Evaluate potential effects on plant configuration – Use Document Update Form (DUF) as tool for review to consider items such as the following:
 - Drawings
 - Procedures
 - Database (CMIS,SAP)
 - UFSAR/TS
 - VTDS
 - Program Changes (MOV/AOV)

Schedule

1. Schedule next mod follow meeting prior to issuance of construction outputs (minimum)
2. Discuss when construction outputs are required to meet T-4 deadline
3. Establish any required input from plant for training material development such as PCNs and identify due dates.

Issuance of Meeting Minutes

1. Send copy to attendees and their manager.
2. Identify action items (AI) and expected completion dates to meeting minutes.
3. Stress that feedback subsequent to meeting is encouraged.

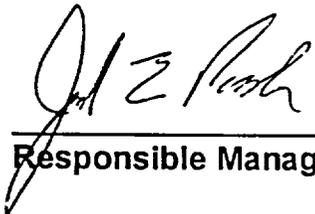


NUCLEAR OPERATIONS GROUP
INTERFACE PROCEDURE

IP-DES-4
Revision 2
Page 1 of 19

Controlled Copy # _____

SETPOINT CHANGE PROCESS


Responsible Manager


Robert C. Mecredy
Vice President
Nuclear Operations Group

8-13-02
Effective Date



1.0 PURPOSE

1.1 Introduction

This procedure establishes the process for evaluation, implementation, testing and administrative control of Setpoint Change Requests (SPCR) for Ginna Station. Adherence to this procedure will ensure that setpoints and limits will be maintained in a controlled manner and that the associated documents and databases impacted by the change will be updated accordingly.

NOTE SPCRs are not to be used if the setpoint change results in a hardware change. ~~If a hardware change (Plant Change Request - PCR) is needed, then SPCR sheets (without SPCR #) will become part of attachments to the PCR.~~

1.2 Scope

1.2.1 This procedure applies to all setpoints and limits associated with Ginna Station and are classified as follows:

- A. Category 1, 2, 3 (CAT-1,2,3) - Setpoints and limits as identified in IP-CON-3. These setpoints/limits are usually safety-related and are those typically specified in:
- Technical Specifications (TS)
 - Pressure and Temperature Limits Report (PTLR)
 - Updated Final Safety Analysis Report (UFSAR)
 - Core Operating Limits Report (COLR)
 - Technical Requirements Manual (TRM)
 - Emergency Operating Procedures (EOPs)
 - Acceptance Criteria Bases (ACBs)
 - NRC Regulatory Guide 1.97
 - Accident Analysis Program
 - Offsite Dose Calculation Manual (ODCM)
 - Abnormal Procedures (APs), except those specified for shift response consistencies

(Step 1.2.1 contd)

- B. Category 4 and 5 (CAT-4,5) - Setpoints and limits identified in IP-CON-3 which are not related to safety but are used to maintain system and process conditions within their functional limit (e.g. condenser hotwell level alarm level, BOP indication function and alarms, non-safety related setpoints not required for equipment protection, etc.).

1.2.2 SPCRs may be processed as part of a Plant Change Request (PCR) package. This will result in a SPCR form and design analysis being provided as outputs to the PCR. The PCR will have its own Change Impact Evaluation (CIE) and 50.59 Screening/Evaluation.

1.3 Definitions

1.3.1 Design Basis (10CFR50.2) - information which identifies the specific functions to be performed by a structure, system, or component (SSC) of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. The values may be (1) restraints derived from generally accepted "state of the art" practices for achieving functional goals, or (2) requirements derived from analysis (based on calculation and/or experiments) of the effects of a postulated accident for which a SSC must meet its functional goals.

1.3.2 Setpoint - a value at which a device changes state to perform an expected action or a value used to maintain system or process within functional limits. Refer to IP-CON-3, Section 1 for expanded definition.

NOTE A SPCR is not required for the following:

- PPCS setpoint variables that change during a cycle or from cycle to cycle and are controlled via approved procedure or
- PPCS setpoints used for temporary trending activities
- Setpoint is associated with core loading analysis. Update of setpoints will be accomplished by a TIF associated with revised design analysis
- ACB changes (processed via ACB Review Form)

1.3.3 Setpoint Class - CAT-1,2,3 or CAT-4,5 as defined in Section 1.2.



- 1.3.4 Setpoint Record - Configuration Management Information System (CMIS) category that provides platform to link setpoints to associated documents which need to be aligned to ensure configuration control between the physical and documented plant (source, used by, and verified by documents). Critical setpoint values, units, parameter types are captured within setpoint record type and related to Plant System and Structure List (PSSL) systems and equipment identification number (EIN). Setpoint record categories include both CAT-1,2,3 and CAT-4,5 setpoint records.
- 1.3.5 Setpoint Status - valid setpoint statuses within the CMIS record type are defined as follows:
- EF - Valid controlled setpoint is effective and will be maintained to ensure operation within established limits.
 - SS - Setpoint that has been superseded as a result of a SPCR. Record will show that a setpoint SP-XXXX has been superseded by SP-YYYY and related to the SPCR that authorized change.
 - UR - Setpoint is under review or has not been validated. When setpoint has been validated or setpoint change successfully turned over for acceptance, its status will convert to EF.
 - DE - Setpoint/device has been removed from service.
- 1.3.6 Source Document - document that provides basis for setpoint (such as RG&E Analyses, Vendor Analyses, Design Basis Correspondence (DBCOR), Vendor Manuals). (CMIS Setpoint Record, Page 4, Control Ref: Associated Stat - S, "Source")
- NOTE** A SPCR may be the source document for CAT-4,5 setpoints, whereas the Design Analysis is the source document for a CAT-1,2,3 setpoint and is related to the SPCR.
- 1.3.7 Turnover - process by which assigned individual formally notifies Shift Supervisor that a setpoint change performed in the field is acceptable for use. The tasks identified must be completed and signed off in the work order package per A-1603.3 prior to the Shift Supervisor's formal acceptance.



1.3.8 Used by Documents - documents that utilize the setpoint (such as UFSAR, TS, PTLR, TRM, COLR, ACBs, EOPs, APs, ODCM, P-procedures, other analyses). Refer to CMIS setpoint records related documents and records. (CMIS Setpoint Record, Page 4 or 5, Control Ref or Related Record, Associated Stat - U)

1.3.9 Verified by - documents that validate the successful testing of a setpoint (e.g. CPI, PT, and RSSP procedures). (CMIS Setpoint Record, Page 4, Control Ref: Associated Stat - V)

2.0 REFERENCES

2.1 Source Documents

2.1.1 ND-CON, Configuration Management

2.1.2 ND-DES, Design Control

2.1.3 ND-RDM, Records

2.2 Development Documents

2.2.1 EPRI TR-103586, Guidelines for Optimizing the Engineering Change Process for Nuclear Power Plants

2.2.2 INPO 90-009 (Rev. 1, 2/92), Guidelines for the Conduct of Design Engineering

2.2.3 Ginna Calculation Control Project, Project Plan No. 98-002, Rev 1, dated April 1999

2.3 Use Documents

2.3.1 Administrative Procedures

- A. A-502, Plant Procedure Content and Format Requirements
- B. A-1101, Performance of Tests
- C. A-1603.0, Overview of the Ginna Station Work Control System
- D. A-1603.1, Work Request/Trouble Report Initiation
- E. A-1603.3, Work Order Planning
- F. A-1603.5, Work Order Execution



(Step 2.3.1 contd)

- G. A-1603.6, Post Maintenance/Modification Testing

2.3.2 Engineering Procedures

- A. EP-3-P-0122, Design Analysis
- B. EP-3-P-0140, Modification Design Changes
- C. EP-3-P-0154, Review and Approval of Vendor Design Analyses
- D. EP-3-P-0161, Distribution and Control of Correspondence
- E. EP-3-P-0172, Document Update Form
- F. EP-3-S-0306, Change Impact Evaluation
- G. EP-3-S-0505, Instrument Setpoint/Loop Accuracy Calculation Methodology
- H. EP-3-S-0901, Records and Document Control

2.3.3 Interface Procedures

- A. IP-DES-1, Technical Staff Request
- B. IP-LPC-2, Technical Specification Associated Documents Control
- C. IP-LPC-3, License Amendment Requests
- D. IP-LPC-7, Updated Final Safety Analysis Report (UFSAR) Periodic and Continuous Updating
- E. IP-PRO-3, Procedure Control
- F. IP-RDM-1, Drawing Change Request
- G. IP-RDM-2, Vendor Technical Document Change Request
- H. IP-RDM-3, Ginna Records
- I. IP-SEV-1, Preparation, Review and Approval of 50.59 Applicability Determination and 50.59 Screens
- J. IP-SEV-2, Preparation, Review and Approval of 50.59 Evaluations
- K. IP-SQA-1, Software Quality Assurance
- L. IP-SQA-2, Software Change Process
- M. IP-CON-3, Setpoint and Instrument Uncertainty Control and Verification Process



3.0 Instructions

3.1 Responsibilities

NOTE A SPCR may be initiated by the organization (NES, RP, etc) responsible for performing the change without initiation of a TSR.

- A. A SPCR may be requested by anyone in NOG. The need for a setpoint change shall be identified by completing a Technical Staff Request (TSR) per IP-DES-1. If the TSR is accepted, a SPCR will be created by the responsible organization.
- B. The Responsible Manager (RM) or designee shall:
- Evaluate TSR and process per IP-DES-1
 - Assign individual to perform SPCR
 - Assign an Independent Reviewer
 - Facilitate multi-program owner review/interface
- C. Assigned Individual (AI) (SPCR originator) shall:
- Perform Setpoint Evaluation (SPCR, Attachment 1).
 - Perform Design Analysis for CAT-1,2,3 Setpoints in accordance with EP-3-S-0505 for analyses which require instrument loop uncertainty evaluations.
 - Form a mod-follow team based on change complexity.
 - Perform Program/Document Impact determination by completing CIE per EP-3-S-0306.
 - Perform Design Analysis for CAT-1,2,3 Setpoints in accordance with EP-3-P-0122 for analyses or generate a Design Bases Correspondence (DBCOR) (CAT-3a,b,c only) in accordance with EP-3-P-0161 supported by technical justification.
 - Complete Technical Input Form (TIF) for Analysis or DBCORS for CAT-1,2,3 setpoint



(Step 3.1 contd)

- Complete Setpoint Input Form (SIF) for all setpoints associated with change.

NOTE

For CAT-4,5 setpoint changes a design analysis is not required. However, if a prior design analysis has been performed and is pertinent to the change, it shall be updated and stasured accordingly.

- Support plant change work order package development activities, of setpoint changes including:
 1. Ensure work order is initiated
 2. Provide support for 50.59 Screening(s) for procedures developed or changed for modification installation
 3. Review of the planned work order package and any corresponding SM or NSM procedures
- Coordinate with the Training Department to perform Training Input Evaluation (TIE) to determine required training.
- Ensure that a 50.59 Screening and if required, a 50.59 Evaluation of the setpoint change is performed.

NOTE

Transmitted separately to Records.

- Identify Setpoint Change and testing instructions as part of SPCR or include as an attachment.
- Resolve engineering issues that arise during the installation and testing phase of the setpoint change.
- Transmit completed SPCR package to Records Management through the Technical Process Specialist (TPS) for construction(CN).
- Complete Document Update Form relative to Setpoint change per EP-3-P-0172 after turnover.



(Step 3.1 contd)

- D. Independent Reviewer (IR) shall:
- Review SPCR Setpoint Evaluation and associated Design Analyses or DBCOR (CAT-3a,b,c SPCR only).
- E. Maintenance Planner shall:
- Prepare detailed work instructions, SM and NSM Procedures, and Procedure Change Notices (PCNs) to existing procedures per Reference 2.3.3. The intent is to provide clear and concise instructions to ensure the installation and testing are straightforward and easily followed. Administrative duties for SM and NSM procedures shall be performed by Engineering Administrative Specialists.
 - Prepare work order package.
 - Resolve non-engineering work order package issues during installation and testing phase of in-field setpoint change.
- F. Maintenance Shop Foremen or Technical Support Group Leader shall:
- Coordinate the overall installation phase of the setpoint change with assistance from the Planner for work order package issues and Engineering for resolution of engineering issues.
- G. Program Owners shall:
- Assess program impact as a result of CIE for pending setpoint change and assist in identification of setpoint change impact (such as databases, drawings, procedures).
- H. Technical Process Specialist
- Perform review of SPCR package for completeness and consistency



(Step 3.1 contd)

- Forward SPCR Package to Records Management
 - Provide copy of SPCR package to NS&L for imaging
 - Provide SIF to Engineering Administrative Specialist
- I. Nuclear Safety and Licensing (NS&L) shall:
- Image completed SPCR package for retrieval
 - Assist in identification of setpoint change impact (such as databases, drawings, and procedures).
- J. Records Management shall:
- Distribute SPCR package for implementation and testing
 - Closeout SPCR documentation in accordance with EP-3-S-0901.
- K. Engineering Administrative Specialist
- Update CMIS Setpoint Record per SIF

3.2 Instructions

3.2.1 Initiating a SPCR

1. SPCRs forms may be completed by engineers or analysts within NOG who have the associated area of responsibility as defined in IP-CON-3.
2. Attachment 3 provides a flow chart depicting the SPCR process.
3. SPCR form, Attachment 1, sections are identified in () throughout following instructions:



(Step 3.2.1 contd)

4. The AI shall:

A. Complete a SPCR form (Attachment 1) as follows:

- Obtain a SPCR number (1) as auto-generated by CMIS (record type SPCR). Additional sheets shall have the SPCR number indicated at the top or bottom of each page. The following are the minimum fields that shall be entered in CMIS (see Records Management or Engineering Administrative personnel if assistance is needed).

NOTE

Numbers in parenthesis are locators which help related instructions to sample SPCR Form (Attachment 2).

1. To add a record:

Record Type: SPCR
Status: IP

2. Enter the following on Page 1:

Revision level: 0
Subject: (up to 62 characters max)
Date: (Date initiated)

3. Enter the following on Page 2:

Assigned Individual (3): (person assigned)
Planner (planner assigned)
WO (work order number)
Planners W/O



(Step 3.2.1 contd)

- B. Reference any initiating document (2) such as; Technical Staff Request (TSR), Abnormal Condition Tracking Initiation or Notification (ACTION) Report, Commitment and Action Tracking System (CATs), Nuclear Regulatory Commission (NRC) Information Notices, etc. Place this on CMIS page 4 or 5, as applicable for the SPCR record.
- C. Provide a setpoint change problem statement (4). Place this on CMIS page 7 under text.

3.2.2 Dispositioning SPCRs

- Classify the SPCR setpoint type (CAT-1,2,3 or CAT-4,5) (5). IP-CON-3 may be used to provide additional information.

1. For CAT-4,5 setpoint changes, document setpoint basis evaluation (6) on SPCR Form (Attachment 1).

NOTE Enter setpoint value, tolerance, and setpoint ID number in space provided. If setpoint is replacing an existing setpoint also list superseded setpoint. (7)

2. For CAT-1,2,3 setpoint changes, document setpoint basis evaluation (6) on SPCR Form (Attachment 1) and perform Design Analysis (DA) (or DBCOR (CAT-3a,b,c only) in accordance with EP-3-S-0505, EP-3-P-0122, or EP-3-P-0161 as applicable. Place reference to Design Analysis on form (5).
 3. For both CAT-1,2,3 and CAT-4,5 setpoint changes, ensure that a 50.59 Screening, and if required, a 50.59 Evaluation of the setpoint change per IP-SEV-1 or IP-SEV-2 has been performed and document on SPCR. (8)
- Perform CIE per EP-3-S-0306 and document on SPCR (8)



(Step 3.2.2 contd)

- Provide testing instructions (attach additional page if needed) (9).

NOTE Check test instructions attached if testing requirements are not included within disposition.

3.2.3 SPCR Review

1. Program owners shall document their concurrence with the setpoint change during CIE review.
2. AI sign completed by line (10).
3. For CAT-4,5 setpoint changes, an independent reviewer shall verify the adequacy of the setpoint change. This includes concurrence with setpoint change basis, impact evaluation, and that the 50.59 Screening/Evaluation is attached. Signature of the reviewer shall be documented on the SPCR form (11).

NOTE Program owners are responsible for update of program documents in accordance with the setpoint change.

4. For CAT-1,2,3 setpoint changes an independent reviewer shall verify the adequacy of the setpoint change. This includes concurrence with setpoint change basis as documented on a formal design analysis, change impact evaluation and that the 50.59 Screening/Evaluation is attached. Signature of the reviewer shall be documented on the SPCR form (11).

3.2.4 SPCR Package Approval

1. The Responsible Manager or designee of SPCR shall review the completed SPCR package (SPCR and applicable output documents) to assure that:
 - The technical content is adequate and accurate
 - The setpoint change adequately addresses and resolves the identified problem or condition



(Step 3.2.4 contd)

- The SPCR process has been properly applied
 - Ensure preparers/reviewers of SPCR are qualified or have a qualified co-signature
2. The Responsible Manager or designee shall indicate approval of the completed SPCR package by signature (12).

3.2.5 SPCR Construction Issuance

1. The AI shall forward the approved SPCR package to the TPS for issuance to Records Management in accordance with EP-3-S-0901 and the package shall include as a minimum the following:

- SPCR form with installation and testing requirements attached (including SIF)
- Design Analysis, or DBCOR if SPCR is related to CAT-1,2,3 setpoint change (including TIF)
- CIE

NOTE SPCR packages which do not result in a "physical" change to a setpoint ("Analytical Only") shall be processed directly for closure (i.e., no construction). The status shall be stated as complete (CL) by RM upon receipt of entire package.

2. When transmitting SPCR packages to Records Management (RM), standard distribution is as follows, specifying other package recipients, if desired:

- Planner
- Training
- Operations
- AI

NOTE RM shall change SPCR status to Construction (CN)



3.2.6 SPCR Implementation and Testing

1. Setpoint changes shall be implemented in accordance with the approved plant change package and applicable Ginna Station processes and procedures, including planning, installation, testing and turnover for use. SPCR implementation shall be in accordance with the Work Order control system.
 - A. Implementation activities shall be controlled in accordance with A-1603.5.
 - B. The AI shall review the Work Order installation package prior to implementation.
 - C. Testing activities shall be controlled in accordance with A-1603.6
2. The AI shall assist and support the implementation and testing as needed. Depending on the complexity of the implementation, this may require detailed job oversight.
3. The applicable planner shall prepare installation and testing instructions utilizing the following guidance per A-1603.3:
 - A. **Safety-Related Plant Change**

A safety related plant change requires an approved plant procedure as a minimum for implementation.

For simple changes, existing plant procedure(s) may be used. A PCN may be necessary to augment existing plant procedures with special instructions. Special instructions may include controls of turnover of drawings, procedures.

For complex changes, a Station Modification (SM) procedure shall be prepared in accordance with procedure A-502.
 - B. A non-safety related or safety significant plant change requires written instructions, as a minimum, for implementation.



(Step 3.2.6 contd)

For simple changes, work instructions with job steps or existing plant procedures may be used.

For complex changes, a non-safety related station modification procedure (NSM) shall be prepared. The procedure format shall be similar to the format of an SM procedure.

NOTE The SM or NSM procedures will be an attachment to the work order package. The completed procedure will be filmed with the work order package as part of the work order record.

4. Changes resulting from setpoint installation and testing shall be processed utilizing a Modification Design Change Notice (MDCN) per EP-3-P-0140.

- 3.2.7
1. Once approved by the Engineering Manager, subsequent changes not bounded by SPCR scope shall require a revision to the SPCR. Prior revisions shall be superseded.

NOTE Contact Records Management to defeat CMIS auto-generation feature for revisions.

2. If the revision of the SPCR does not change the existing CIE or 50.59, it must be clearly identified on the SPCR Form, Section 2.0.
3. SPCR revision may be issued based on the magnitude of changes resultant from MDCN.

NOTE The "as-built" final revision of the SPCR shall be linked to the appropriate DUF, CIE and 50.59 screen or evaluation.

3.2.8 SPCR Closeout

1. The AI shall update, or request update of, applicable documents and databases as necessary to reflect the plant change.



(Step 3.2.8 contd)

NOTE Analyses that were issued and status of approved (AP) for construction will need to be updated to design basis (DB) or historical status (HS) status in accordance with EP-3-P-0122.

2. The AI shall summarize the documents, databases, programs, etc. which will be required to be updated as a result of the plant change using the Document Update Form (DUF) per EP-3-P-0172.

NOTE It is recommended that a set of markups (drawings, procedures, VTDs, CMIS, etc.) be developed early in the modification. Markups shall be based on program owner input and the DUF. This will facilitate successful records updates.

3. The AI shall certify successful completion of the SPCR by signature on the DUF. The AI is responsible to ensure all records and databases shall be updated within two months or at turnover.
4. An independent reviewer shall validate satisfactory completion of the plant change by signature on the DUF. This ensures that documentation requiring update prior to SPCR closeout as identified in the Document Update Form has been revised, PCN'd or DCR'd or has an assigned tracking number.
5. DUF packages for SPCR closure shall be forwarded through the TPS to validate CMIS revisions and provide consistent interface with Records Management. DUF packages shall be assembled per EP-3-P-0172 and will result in SPCR status change to complete (CL) by RM.
6. If a SM procedure was created for the change, the Assigned Individual shall initiate a PCN to delete it unless it will be used/revised in the future.
7. The AI shall forward the completed SPCR and DUF (if applicable) to TPS for closeout review. TPS will validate CMIS input and provide consistent interface with Records Management.



(Step 3.2.8 contd)

8. The TPS shall:

- Perform a closeout review of action taken for impact on documentation or records
- Update the SPCR record in CMIS

Enter the following on Page 1:

Status: IC (In closeout)
Date: (current date)

Enter the following on Page 7:

Text: Enter text from SPCR Setpoint change basis text (6), enhance setpoint record and document links, and image related records.

- Forward reviewed SPCR and DUF packages (if applicable) to Records Management for closeout in accordance with EP-3-S-0901.
 - Forward a copy of completed SPCR package to NS&L for imaging.
 - Forward SIF to Engineering Administrative Specialist.
9. Records Management
- Change SPCR record status to complete (CL).

4.0 RECORDS

1. Completed SPCR and appropriate supporting documentation shall be forwarded through TPS by AI to Records Management in accordance with EP-3-S-0901.
2. TPS will forward a copy of SPCR package to NS&L for imaging.



5.0 ATTACHMENTS

5.1 Attachment 1, Setpoint Change Process (SPCR) Form

5.1 Attachment 2, Sample Setpoint Change Process (SPCR) Form

5.3 Attachment 3, Setpoint Change Process Flow Diagram

~~5.4 Attachment 4, Setpoint Input Form~~

~~5.5 Attachment 5, Setpoint Input Form Instructions~~

Setpoint Change Request (SPCR)

SPCR # _____	Rev. _____
TSR / ACTION / CATS #: _____	
Assigned Individual: _____	W/O _____
Problem statement: 	
Evaluation:	
Classification: <input type="checkbox"/> CAT-1,2,3	Design Analysis or DBCOR: _____
<input type="checkbox"/> CAT-4,5	
Setpoint change basis: 	
Setpoint value _____	Tolerance _____
	Setpoint ID _____
<input type="checkbox"/> 50.59 Screening # _____	<input type="checkbox"/> 50.59 Evaluation # _____ Rev. _____
	<input type="checkbox"/> CIE _____ Rev. _____
Testing instructions (list below or check box) <input type="checkbox"/> Attached	
Completed by: _____	Date: _____
Assigned Individual	
Reviewed by: _____	Date: _____
Independent Reviewer	
Responsible Manager: _____	Date: _____

Sample Setpoint Change Request (SPCR)

SPCR # _____ (1) Rev. _____

TSR / ACTION / CATS #: _____ (2)

Assigned Individual: _____ (3) W/O _____

Problem statement: _____ (4)

Evaluation:

Classification (5): CAT-1,2,3 Design Analysis or DBCOR: _____
 CAT-4,5

Setpoint change basis: _____ (6)

Setpoint value _____ Tolerance _____ Setpoint ID _____ (7)

50.59 Screening # _____ 50.59 Evaluation # _____ Rev. _____ CIE _____ (8) Rev. _____

Testing instructions (list below or check box) Attached (9)

Completed by: _____ Date: _____ (10)
Assigned Individual

Reviewed by: _____ Date: _____ (11)
Independent Reviewer

Responsible Manager: _____ Date: _____ (12)

Attachment 3
Setpoint Change Process Flow Diagram

IP-DES-4

Rev. 2

See G:\Procedur\IP\IP-DES-4-Att. 3.vsd

**Attachment 4
Setpoint Input Form**

IP-DES-4

Rev. 2

(CMIS Record Type: Setpoint)

1. Description (CMIS page 1)

2. Status (CMIS page 1)	UR	EF	DE	Setpoint ID # _____ <input type="checkbox"/> Supersedes Existing Setpoint# _____
--------------------------------	----	----	----	---

3. Setpoint Type/Value (CMIS page 2)	OD-nom	DV-min	DV-max	DV-nom	NS-max	AV-min	AV-max	AL-min	AL-max
---	--------	--------	--------	--------	--------	--------	--------	--------	--------

Setpoint Value: _____ Cat. 1, 2, 3 Yes No # of Source Docs _____

4. Setpoint Parameter (CMIS page 2)	5. Setpoint Units (CMIS page 2)
--	--

6. EINS (CMIS page 3)

7. "Source" Document (CMIS page 4 or 5)	DA	DBCOR	VTD	SPCR	Other
--	----	-------	-----	------	-------

ID: _____

8. "Used By" Doc (CMIS Page 4 or 5)	UFSAR	TS	COLR	TRM	EOP	ACB	ANL	Other
--	-------	----	------	-----	-----	-----	-----	-------

Doc ID: _____ Doc ID: _____ Doc ID: _____

9. Verified By (CMIS page 4 or 5)	CP	CPI	RSSP	PT	Other
--	----	-----	------	----	-------

Doc ID: _____ Doc ID: _____ Doc ID: _____

10. Othe References (CMIS Page 4 or 5)	SPCR	ACTION	SEV	Other
---	------	--------	-----	-------

Doc ID: _____

11. Comments (CMIS page 7)

Originator Signature

Data Entry By

Attachment 5
Setpoint Input Form Instructions

IP-DES-4

Rev. 2

1. The Setpoint Input Form (SIF) shall be submitted to an engineering administrative specialist as required in this procedure.
2. Complete all applicable fields, except as stated below. Write "N/A" in any field which is not applicable to the setpoint. If more room is required, continue writing outside the border, expand the form or use an additional form.
3. The Setpoint Input Form (SIF) shall be completed for each setpoint generated by the initiative.
4. The engineering administrative specialist will contact the preparer of the Setpoint (SIF) if entries for any fields are not compatible with the CMIS data requirements.

FIELD-SPECIFIC INSTRUCTIONS

1. Setpoint Description
 - Provide a clear description of setpoint's purpose (e.g. VITAL BATTERY MONITOR ALARM ON HIGH DISCHARGE CURRENT)
2. Setpoint Status
 - Provide appropriate status (UR - Under Review, EF-Effective, DE-Deleted)
3. SETPOINT TYPE /Value
 - Type (min, max, nominal) See Setpoint example on following pages of this attachment for visual aid as well as setpoints use definitions.
4. Setpoint Parameter
 - (Flow, level, Current) - Refer to Setpoint Parameter List for choices
5. Setpoint Units
 - (degrees F, mR/Hr, feet, inches, etc.) - Refer to typical unit list (of this attachment) for choices
6. EINs
 - List EINs associated with setpoint value
7. Source Document
 - Identify Setpoint Source Document - Note: The Source Document is the design analysis, DBCOR, VTD, or SPCR which establishes the setpoint

Attachment 5 (contd)
Setpoint Input Form Instructions

IP-DES-4

Rev. 2

8. Used by:

- Check applicable setpoint used by choice and identify related docs/sections or tables as follows:
 - For UFSAR record types identify relationships via UV Tags (UFSARTAG record type) as follows:
 - 00002086
 - For COLR, PTLR, TS, and TRM record types identify via Tech Spec Tags (TSTAG record type) as follows:
 - 10003458
 - For EOP record types identify as follows:
 - E.1
 - For ACB record types identify as follows:
 - 1999-0086
 - For analyses or other documents that use the identified setpoint, identify associated Doc ID.

9. Verified by:

- Check applicable setpoint verified by choice and identify related document ID.

10. Other References:

- Identify other references that should be linked to setpoint record (e.g. SPCR, ACTION, SEV, etc.)

11. Comments:

- Provide additional comments as deemed necessary. Note: Comments field is text searchable

Attachment 5 (contd)
Setpoint Input Form Instructions

IP-DES-4
Rev. 2

Setpoint Type definitions (Ref. IP-CON-3):

Operator Decision/Action Point (OD) - A setpoint whose value is set to initiate an alarm, light, or other indication (but not a trip function or mechanical action) to elicit operator action. These operator decision points may be reflected in standard operating procedures, Abnormal Operating instructions, Abnormal Response Procedures and the EOP's. Valid Type - OD-Nom.

Design Value (DV) - The process limit of a measured or calculated variable as established by the system's design requirements or actual installed configuration, independent of environmental and Measuring and Test Equipment considerations. Valid Types - DV-Min, DV-Max, and DV-Nom.

Nominal Setpoint (NS) - The Nominal Setpoint is the value that a person observing a control room indicator would expect to see when the action corresponding to the Setpoint occurs. It is the value contained within the Technical Specifications (if applicable) or plant procedures (e.g., this value is the nominal value to which a bistable/relief valve, etc. is set). Valid Type - NS-Nom.

Analytical Limit (AL) - Limit of a measured or calculated variable established or used by the safety analyses to ensure that a safety limit (UFSAR Chapter 15) Accident Analyses is not exceeded. Valid Types - AL-Max, and AL-Min.

Allowable Value (AV) - A Limiting Value that the trip setpoint may have when tested periodically, beyond which appropriate action shall be taken (e.g., channel should be declared inoperable). Valid Types - AV-Max, AV-Min.

Setpoint Type Example

PZR HIGH PRESSURE TRIP SETPOINT			
-----	2750 PSIA SAFETY DESIGN LIMIT (DV-Max)	-----	
-----	2437 PSIA ANALYTICAL LIMIT (AL-Max)	-----	Increasing
-----	2385 PSIA T/A ALLOWABLE (Operability) VALUE (AV-Max)	-----	Pressure
-----	2378 PSIA CALCULATED SP (NS-Nom)	-----	Values
-----	2335 PSIA PRE-TRIP ALARM (OD/AP-Nom)	-----	
-----	2250+25 PSIA NORMAL OPERATION (DV-Nom)	-----	

NOTES

1. Max type is used if setpoint value identified is increasing relative to reference value.
2. Min type is used if setpoint value identified is decreasing relative to reference value.
3. Nominal type is used if setpoint is an established absolute value.
4. Analytical Values (AV) and Allowable Values (AL) are determined with respect to Nominal Trip Setpoint (NS) reference value.
5. Nominal Trip Setpoints (NS) and Operator Decision (OD) are used with respect to Normal Operation (DV)-Nominal.
6. Normal Operation (NO) is the system "expected" baseline value, therefore (DV) nominal.

Attachment 5 (contd)
Setpoint Input Form Instructions

IP-DES-4

Rev. 2

SETPOINT ENGINEERING UNITS LIST

Setpoint Engineering Units	Abbreviation
ATMOSPHERES	ATM
BRITISH THERMAL UNITS	BTU
BRITISH THERMAL UNITS PER HOUR	BTU/HR
HEAT TRANSFER COEFFICIENT	BTU/HR-FT ² -F
BRITISH THERMAL UNITS PER POUND MASS	BTU/LBM
CUBIC CENTIMETERS	CU CM
CUBIC FEET	FT ³
CUBIC INCHES	IN ³
DEGREES CELSIUS	DEG C
DEGREES FAHRENHEIT	DEG F
FOULING FACTOR	F-FT ² -HR/BTU
FEET	FT
GALLONS	GAL
GALLONS PER MINUTE	GPM
GALLONS PER DAY	GPD
GALLONS PER DAY/HR	GPD/HR
INCHES	IN
INCHES OF MERCURY	IN OF HG
KILOGRAM	KG
KILOWATT	kW
KILOWATTS PER HOUR	Kw/HR
POUND MASS PER HOUR	LBM/HR
LITERS	LTR
MEGA VOLT AMPS REACTIVE	MVAR
MEGAWATT	MW
MICRO CURIES PER CUBIC CENTIMETER	MCCC
MICRO MHOS (CONDUCTIVITY)	UMHO
MILES PER HOUR	MPH
MILLIAMPS	mA
MILLIAMPS DIRECT CURRENT	mADC
MILLION CYCLES PER SECOND (MEGAHERTZ)	MHZ
MILLIREM PER HOUR	mRHR
MILLIVOLTS	MV
MILS (ONE THOUSAND INCH)	MIL

Attachment 5 (contd)
Setpoint Input Form Instructions

IP-DES-4

Rev. 2

MINUTES	MIN
OHM (RESISTANCE)	OHM
PARTS PER BILLION	PPB
PARTS PER MILLION	PPM
PERCENT	%
PERCENTAGE HYDROGEN (PH)	PH
POUNDS	LB
POUNDS PER HOUR	PPH
POUNDS PER SQUARE INCH	PSI
POUNDS PER SQUARE INCH - ABSOLUTE	PSIA
POUNDS PER SQUARE INCH - DIFFERENTIAL	PSID
POUNDS PER SQUARE INCH - GAUGE	PSIG
RAD PER HOUR	R/HR
REVOLUTIONS PER MINUTE	RPM
SECONDS	SEC
STANDARD CUBIC FEET PER HOUR	SCFH
STANDARD CUBIT FEET PER MINUTE	SCFM
STEPS (REACTOR CONTROL ROD POSITION)	STEP
SQUARE CENTIMETER	SQ CM
SQUARE FEET	FT2
SQUARE INCHES	IN2
TON	TON
VOLTAMP	VA
VOLTAMPS REACTIVE	VAR
VOLTS	VOLT
VOLTS ALTERNATING CURRENT	VAC
VOLTS DIRECT CURRENT	VDC
WATT	WATT

Attachment 5 (contd)
Setpoint Input Form Instructions

IP-DES-4

Rev. 2

Setpoint Parameter Types

Name	Description
Acceleration	G's
Area	square feet, etc.
Capacity	A-H, VA
Concentration	%, specific gravity, Ph, enrichment, hydrogen generation, etc.
Current	mA, A, etc.
Dimensionless	number, ratio, efficiency, DNBR, etc.
Dose	rem/hour, etc.
Energy Deposition	calories/gram
Flow	volume per unit time
Frequency (electrical)	Hz
Hydrogen Generation	cu ft/hr
Impedence	ohms
Inertia	16 - ft ²
Leakage	gpm, drops per minute, includes leak rate, etc.
Level	%, inches, feet, gal./%, etc
Linear Dimensions	length, height, circumference, diameter, etc.
Oxidation	mils/period, %
Power	megawatts, kilowatts, watts, V-A, VAR, QPTR, etc.
Pressure	psig, psia, psid, in hg, etc.
Probability	number, %
Reactivity	Keff
Reliability	failure rate
Rotary Motion (mechanical)	rpm, degrees
Temperature	units primarily involving deg F, deg C
Thermal Performance	units involving BTU
Time	seconds, minutes, hours, etc
Velocity	mph, feet/second, etc.
Vibration	mils, in/sec etc.
Voltage	mV, V, etc.
Volume	gallons, cubic feet, etc.
Weight	include mass here

Attachment 11

Syncor QA Manual

QSP-100 Version 004

Rev. 1/2/02

Implemented MAR 14 2002

Syncor

Radiation Management

Quality Assurance Manual

ISO 9001: 2000

FDA 21 CFR Part 820

Energy 10 CFR Part 50 Appendix B

ISO 13485:1996

EN 46001:1996

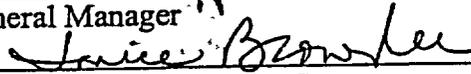
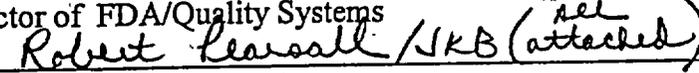
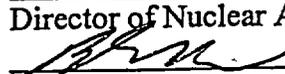
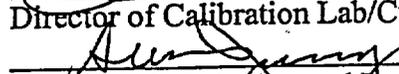
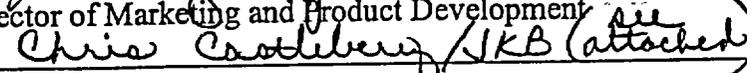
ISO 17025 (parts)

ROCHESTER GAS & ELECTRIC
QA REVIEWED
REVIEWER <i>A.R. Pizzo</i>
DATE <i>4-2-02</i>
Company Identifications
Changed. No significant
changes

Controlled Copy Number	<i>56</i>
---------------------------	-----------

Syncor Radiation Management Quality System Manual Approval Sheet

Approved by:

 General Manager	2/15/02 Date
 Director of FDA/Quality Systems	3/11/02 Date
 Director of Nuclear Associates	3/12/02 Date
 Director of Operations	1-11-02 Date
 Director of Calibration Lab/Customer Services	1/15/02 Date
 Director of Marketing and Product Development	3/5/02 Date
 RA/QA Manager	3/12/02 Date
 Engineering Manager	2/19/02 Date

Rev. date 1/2/02

QSP-100 Version 004

Page 1

Syncor Radiation Management Quality System Manual Approval Sheet

Approved by:

<u><i>T. B. Hansen</i></u>	<u>2/15/02</u>
General Manager	Date
<u><i>Janice Browlee</i></u>	<u>3/11/02</u>
Director of FDA/Quality Systems	Date
<u><i>Robert J. Pearsall</i></u>	<u>3/12/02</u>
Director of Nuclear Associates	Date
<u><i>[Signature]</i></u>	<u>1-11-02</u>
Director of Operations	Date
<u><i>[Signature]</i></u>	<u>1/15/02</u>
Director of Calibration Lab/Customer Services	Date
<u><i>[Signature]</i></u>	<u>3/5/02</u>
Director of Marketing and Product Development	Date
<u><i>[Signature]</i></u>	<u>3/12/02</u>
RA/QA Manager	Date
<u><i>Bill [Signature]</i></u>	<u>2/19/02</u>
Engineering Manager	Date

**Syncor Radiation Management
Quality Assurance Manual**

SECTION 0.0 TABLE OF CONTENTS

Section	Description
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4.12	Inspection , Test and Operating Status
4.13	Control of Nonconforming Product
4.14	Corrective and Preventive Action
4.15	Handling, Storage, Packaging, Preservation and Delivery
4.16	Control of Quality Records
4.17	Quality Audits
4.18	Training
4.19	Servicing
4.20	Statistical Techniques

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SECTION 0.1 QUALITY POLICY STATEMENT

COMPANY MISSION STATEMENT

Syncor Radiation Management is dedicated to providing the highest quality radiation measuring and detection products, accessories and services, with particular attention to cost-effectiveness and timely distribution.

SYNCOR RADIATION MANAGEMENT QUALITY POLICY STATEMENT

The personnel of Syncor Radiation Management are committed to achieving quality through the following objectives:

- Focusing on the customer by applying innovation and flexibility to meet their needs
- Fostering a controlled atmosphere for continuous improvement and problem prevention
- Identifying the need for, and providing appropriate training to ensure the development and qualification of our personnel
- Communicating the mission and objectives to our personnel and customers
- Developing relationships with our customers that emphasize continuous improvement in product quality, service and support
- Promoting a supportive work environment that facilitates the delivery of a quality product on a consistent basis

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SECTION 0.2 COMPANY BACKGROUND

Syncor Radiation Management (SRM) is located at 6045 Cochran Rd., Cleveland, Ohio 44139-3313 and has a distribution office at 120 Andrews Rd., Hicksville, NY, 11801.

SRM is a new division of Syncor International Corporation in Woodland Hills, CA. and was formerly called Inovision Radiation Measurements (IRM) and Nuclear Associates. IRM was the result of the combining of two companies, Keithley Instruments Radiation Measurements Division and Victoreen L.L.C. in 1999. Products may carry the name Victoreen, Inovision, Nuclear Associates, Syncor, or the name of the original manufacturer.

SRM's primary customers are the medical diagnostic x-ray industry, the radiation therapy industry, nuclear medicine, health physics and the nuclear energy industries. The devices which SRM manufactures are used for calibration and maintenance of x-ray generators, radiation treatment devices such as linear accelerators, and for radiation detection and measurement in health physics applications, nuclear medicine and nuclear energy systems. SRM, through its Global Calibration Laboratory (GCL) and service department, also provides calibration and repair services to radiation detection and measurement instruments.

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0.3 AMENDMENT RECORD

This quality assurance manual (QAM) contains only the pages issued by this facility; the Management Representative (MR) will process all authorized changes, issuing amendment pages for the official distribution copies. The MR will see that all down level and/or obsolete pages are withdrawn from use and archived to prevent unintentional usage. This QAM is a controlled copy document. The Master of this QAM is maintained by the MR; this Master shall be used as the final authority regarding the latest revision level and amendment status for the Syncor Radiation Management QAM.

Section/ Page	Date	Description of Revisions	Approval
All	5/20/99	Inovision Radiation Measurements Quality Assurance Manual QSP-100	See approval sheet with Master document
Appx. B	6/14/99	Change structure of documentation reference of AOP's to QSP's and add reference of CSOP's ; Update amendment record-page 4 of 39 of the Quality Manual	See DCR #10 for sign-off
All	12/7/99	Added additional requirements for EN46001/ISO 13485 and incorporated personnel changes to responsibilities sections	See DCR# 82 for sign-off and approval sheet with Master document
All	10/9/00	Reflect changes in organizational responsibilities	See DCR# 159 for sign-off and approval sheet with Master document
All	12/28/01	Change name of company to Syncor Radiation Management to reflect acquisition by Syncor, change authorities and responsibilities to reflect organizational restructuring following acquisition, add requirements of ISO 9001:2000 that aren't already included; have manual apply to both SRM locations, as applicable	See DCR #244

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SECTION 0.4 CONTROLLED CIRCULATION LIST

Copy Holder	Copy Number
General Manager –Tim Hansen	1
RA/QA Manager- Chris Castleberry	2
Design Engineering Manager - Bill Zimmerman	3
Document Control Manager – Roland Massatti	4
Director of FDA/Quality Systems-Janice Brownlee	5
Director of Calibration/Customer Services-Clare Grehofsky	6
Controller-J.G. Singh	7
Director of Operations-Bruce Burns	8
Quality Manager-Zis Giatis	9
Director of Marketing and Product Development- Susan Janney	10
Human Resources	11
Facilities Engineer-Mike Goffos	12
Purchasing Manager-David Boyd	13
Regulatory Affairs/Document Control Coordinator Mary Jo Nero	14
RA/QA Engineer-Dave Smith	15
Government Sales – Ted Seifert	16
Materials Manager-Vi Angle	17
Sr.Application Engineer/Proposal Specialist- Bruce Rusnak	18
International Sales Mgr.- Sig Ditzig	19
International Sales – Mark Marlowe	20
Engineering Administrative Assistant-Angie Nutter	21
Cal Lab/Repair Manager- Rick Abbott	22
System Sales Administrator- Jeanne Zilka	23
Nuclear Associates Director- Bob Pearsall (Manual only)	24
N.A. Warehouse Mgr.- Joe Caroccio (Manual Only)	25

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Copy Holder	Copy Number
Nuclear Associates Inventory control (Manual Only)	26
Lunchroom	27
Registrar- BSI	28
Registrar -UL	29
Inside Sales – Toni Sambula	30
Customer Service- International-Linda Guy	31
Shipping Supervisor-Tom Norton	32
Customer Repair Service Mgr. - Sue Thorley	33
RSO / Cal Lab- Mark Sv ajger	34
Repair –Nuclear Associates (Manual only)	35
Customer Service Supervisor- Nuclear Associates- Peggy Cush (Manual Only)	36
Purchasing- Nuclear Associates (Manual Only)	37
Advertsiing – Nuclear Associates (Manual Only)	38

Note: Additional controlled copies will be added on an Addendum and filed with the master.

SECTION 0.5 GLOSSARY

PO – Purchase Order

MR – Management Representative

Standards/Requirements – ISO 9001: 2001, FDA Quality System Regulations for Medical Devices 21 CFR part 820, Energy Regulations 10 CFR part 50 Appendix B, ISO 13485: 1996, EN46001:1996; ISO 17025

QAM – Quality Assurance Manual

R&A – Responsibility and Authority

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Medical Device (ISO 13485/EN 46001)- Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of

- diagnosis, prevention, monitoring, treatment, or alleviation of disease
- diagnosis, monitoring, treatment alleviation of, or compensation for, an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.

Medical Device (FDA 21CFR)- An instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related articles, including any component, part or accessory, which is:

- Recognized by the National Formulary, or the United States Pharmacopoeia, or any supplement to them.
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its principal intended uses.

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4.1 MANAGEMENT RESPONSIBILITY

4.1.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 parts 5,6 and 8, 21 CFR 820.20 (a), (b), (c), 10 CFR 50 App. B part I, ISO 13485:1996 section 4.1, EN46001:1996 section 4.1 and ISO 17025 part 4.

4.1.2 RESPONSIBILITY AND AUTHORITY (R&A)

The General Manager, Directors, and Managers have the responsibility and authority for the overall administration and management of the quality system activities at Syncor Radiation Management. Only those activities conducted at the respective SRM locations are subject to these requirements. The company's personnel have the responsibility and have been given the authority and freedom to carry out activities relating to its quality policy, quality system documentation and customer requirements.

4.1.3 QUALITY SYSTEM REQUIREMENTS

Quality Policy - Syncor Radiation Management has established a quality policy that identifies quality system goals and objectives. This policy is relevant to the company's goal and the expectations and needs of its customers. This policy has been communicated to the employees and is maintained as the highest priority within the company; each associate understands their role.

Responsibility and Authority - The quality system documentation, responsibility matrix, and job descriptions define the R&A and necessary interrelations for all activities.

Resources - The resources required to complete quality system activities are defined in both the quality system documentation and job descriptions. Syncor Radiation Management has identified and provides for the resources needed to meet the ISO, EN, QSR and Nuclear System

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requirements including the assignment of trained personnel for management, performance of work and verification activities including internal quality audits.

Management Representative (MR)- The General Manager has appointed a MR for the establishment, implementation, maintenance and reporting of quality assurance system activities. The MR is the Regulatory Affairs/Quality Assurance Manager. The deputy MR is the Syncor Director for FDA/Quality Systems.

Management Review - The MR carries out scheduled Management Review meetings with the management team at defined intervals. These reviews determine the effectiveness, adequacy and suitability of the implemented quality system requirements. Minutes of these review meetings are maintained. The reviews include information on audit results, customer feedback, process performance and product conformity, status of corrective and preventive actions, follow-up actions from previous management reviews, changes that could affect the quality management system, and recommendations for improvement. Outputs from the reviews include any decision and actions related to improvement of the effectiveness of the system and its processes, product improvements related to customer requirements, and resource needs.

4.1.4 RELATED AND SUPPORT DOCUMENTATION

QSP- NN Quality system procedures
QSP-102 Responsibility and Authority Matrix
QSP-201 Procedure for Management Review of the Quality System
Appendix A Organization Chart
Job Descriptions

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4.2 QUALITY MANAGEMENT SYSTEM

4.2.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001: 2000 parts 4, 5 and 7, 21 CFR 820.5, .20(d), .20(e), 10 CFR 50 App. B part II, ISO 13485:1996 Section 4.2, and EN46001:1996 Section 4.2 and ISO 17025 part 4.2.

4.2.2 RESPONSIBILITY AND AUTHORITY (R&A)

The General Manager, Directors, and Managers have the responsibility and authority for carrying out quality system activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.2.3 ORGANIZATIONAL PROCESS REQUIREMENTS

SRM has identified the processes needed for the quality management system and their application throughout the organization. The sequence and interaction of these processes, and the criteria and methods for their operation and control have been addressed. Resources and information for the support and monitoring of these processes is available. Analysis of these processes is done, and actions to achieve planned results and continual improvement are implemented as needed.

Outsourced processes are monitored and controlled to ensure that product conformity with requirements is not adversely affected.

4.2.4 QUALITY SYSTEM REQUIREMENTS

A Quality Assurance Manual and Procedures have been created to address all requirements of the ISO 9001 and 13485 standards, the Quality System Regulations of the FDA, the Nuclear System requirements, the EN46001 Standard and ISO 17025 standard as a means of ensuring that product/service conforms to specified requirements. The Quality Manual includes or makes reference to the quality system procedures and outlines the structure of the documentation used in Syncor Radiation Management's quality system. The specified requirements, including regulatory requirements, for products, components and accessories that are medical devices are

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established and documented. The interaction of the various processes for the quality management system are described.

The Quality System Procedures are consistent with the requirements of the sited ISO and EN standards, the QSR Regulation, the Nuclear System requirements and the company's Quality Policy. The range and detail of these procedures is dependent on the complexity of the work, the methods used, and the skills and training needed by the associates involved. The procedures may make reference to other device master records/work instructions that define how an activity is performed.

Quality Planning activities are carried out to ensure that processes are established and continually improved to enhance customer satisfaction and to meet the objectives of the SRM quality management system. The integrity of the system is maintained when changes are planned and implemented. Quality planning is also done to plan and develop the processes needed for product realization including the definition and documentation of how specified requirements have been or will be addressed and met. Quality System Documentation controls the processes and methods used to meet these requirements. Quality planning methods and practices identify and control the following:

- Acquisition of equipment, fixtures, resources and skills needed
- Ensuring design, process, installation, servicing and inspection compatibility with the applicable documentation
- Quality objectives and requirements for the products
- Updating of QC inspection and testing techniques
- Identification of measurement requirements
- Identification of suitable verification activities
- Standards of acceptability
- Identification and preparation of quality records

For each type/model of medical device, a file is established and maintained that contains or references the location of a document that defines the product specifications and quality system requirements for processing and quality assurance of the device. This technical file, or device master record, includes specifications for the complete manufacturing of each product and its installation and servicing, if appropriate.

4.2.5 RELATED AND SUPPORT DOCUMENTATION

QSP-NN Quality System Procedures

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QSP-202 Procedure for Quality Planning
Structure of Documentation- Appendix B

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4.3 CONTRACT REVIEW/CUSTOMER-RELATED PROCESSES

4.3.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 parts 5 and 7, 21CFR 820.50, 10CFR 50 App. B part IV., ISO 13485:1996 Section 4.3 , EN46001: 1996 Section 4.3 and ISO 17025 part 4.4.

4.3.2 RESPONSIBILITY AND AUTHORITY (R&A)

The Director of the Calibration Lab/Customer Services, the Systems Manager, the Customer Services Representatives and Supervisor have the responsibility and authority for carrying out contract review activities so that customer requirements are determined and met. The Engineering Manager is responsible for reviewing contract requirements when the contract requires design activities related to nonstandard specifications. The General Manager reserves the right to review contracts which involve a significant or unusual amount of revenue or resources .The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.3.3 CONTRACT REVIEW REQUIREMENTS

Contract Review - Procedures exist to control the methods and practices used to complete customer contract reviews and contract amendments. Contracts (verbal and written) are reviewed to ensure that they adequately define the specified requirements; that differences between the contract and tender are resolved; and that the company is capable of meeting the contract or order requirements in order to enhance customer satisfaction..

Amendments – The amendments to contracts are defined, documented and communicated to affected functional groups.

Records of contract reviews and amendments are maintained. Channels for communication and interfaces with the customer's organization in these contract matters are established.

4.3.4 RELATED AND SUPPORT DOCUMENTATION

QSP-203 Procedure for Contract Review

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4.4 DESIGN AND DEVELOPMENT CONTROL

4.4.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 PART 7.3, 21CFR 820.30(a) through (j), 10 CFR 50 App. B part III, ISO 13485:1996 Section 4.4, and EN46001:1996 Section 4.4.

4.4.2 RESPONSIBILITY AND AUTHORITY (R&A)

The Director of Nuclear Associates, the Design Engineering Manager and the Director of Marketing and Product Development have the responsibility and authority for carrying out design control/product development activities. The Director of Operations, the Director of the Calibration Lab/Customer Services and the Managers of RA/QA and Systems provide a supportive function for this requirement. The company associates have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.4.3 DESIGN CONTROL

Documented procedures exist to control all of the following quality system activities and requirements:

Design and Development Planning - Plans outlining design activities and their associated schedules are developed for each design project; these plans define various R&A and are used to ensure that personnel, with appropriate skills, and adequate resources, are assigned to each design project. Plans are formally documented and are modified as the design activities are evolving. Throughout the design process, the need for risk analysis is evaluated and if performed, records of the analyses are maintained.

Organizational and Technical Interfaces - The company's various functional groups are involved in reviewing and evaluating the aspects of the design through its stages; the assigned project group has the R&A for defining these interfaces, documenting and transmitting their input and seeing that the information received is regularly reviewed.

Design Input - The project group interfaces with the sales/marketing and regulatory functions in order to ensure a complete understanding of the customer(s) and other requirements (industry

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and governmental). The input takes into consideration the results of contract review activities. For medical devices, requirements that are related to the safety of the device are identified and included as design inputs.

The design inputs are then documented and reviewed for adequacy. Incomplete, ambiguous or conflicting requirements are resolved with those responsible for imposing these requirements.

Design Output – The output of the design process is documented in various forms. The design output must be expressed in terms that can be verified and, where necessary, validated against the design inputs using suitable methods. The design output must meet the specified design input requirements, and contain or make reference to the appropriate acceptance criteria. In addition, those characteristics that are crucial to the safe and proper functioning of the product such as operation, storage, handling etc. must be identified.. The results of design output activities are reviewed by objective design review committee personnel prior to release.

Design Review - At appropriate stages of the design, formal, structured and documented design reviews activities are held; these reviews are carried out to determine if all specified requirements for the phase being reviewed have been addressed. Representatives from the functional groups concerned with the design phase being reviewed, as well as other specialist personnel are asked to participate. Records of these reviews are maintained with the design history file for the project.

Design Verification –At appropriate stages of design, design verification is performed to ensure that the design stage output meets the design stage input requirements. The design verification measures are recorded and maintained with the design history file. Design verification may include tests to compare new designs to proven designs. Alternate experiments; tests and demonstrations and a review of design documents before their release are also conducted. For items subject to the requirements of 10CFR 50 Appendix B, where a test program is used to verify the adequacy of a specific design feature in place of other verifying or checking processes, it must include suitable qualification testing of the prototype unit under the most adverse conditions. The verification activities are completed and documented by individuals or groups other than those who performed the original design to ensure independent verification of design adequacy. All design verification activities for medical devices are documented and maintained, including those where clinical investigation was involved.

Design Validation- Design validation is performed to ensure that the product conforms to defined user needs and/ or requirements. This quality system activity is performed when appropriate and follows successful design verification. When conducted, it follows defined

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operating conditions, and normally is performed using product made in manufacturing which represents the proposed final product. Multiple validations may be performed if there are different intended uses. Medical devices may require clinical evaluation as part of the design validation. When performed, records of the evaluation are maintained. The clinical evaluation may include a compilation of scientific literature and historical evidence that similar designs and/or materials are clinically safe, or a clinical investigation or trial, to ensure that the device performs as intended.

Design Transfer- Procedures are in use to ensure that the device design is correctly translated into production specifications.

Design Changes - Design modifications are identified, documented, reviewed and approved by the various functional organizations affected by the associated changes. These activities are carried out prior to design change implementation. These controls apply to design changes regardless of the origin or ownership of the design. Changes to established products must be handled according to the regular change/engineering control procedures (see sections 4.5 and 4.14)

Design History/Technical File- A design history file (DHF) is maintained for each type of device. This file contains or references the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of the standards.

Software Development – As appropriate, the design procedures and requirements for software development are the same as for other designs.

Documents and records relating to product development/design control requirements are kept in the design history file.

4.4.4 RELATED AND SUPPORT DOCUMENTATION

QSP-204 Product Development/Design Control Procedure

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4.5 DOCUMENT AND DATA CONTROL

4.5.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 part 4 , 21CFR 820.40 (a) and (b), 10 CFR 50 App. B part VI, ISO13485:1996 Section 4.5, EN46001:1996 Section 4.5 and ISO 17025 part 4.3.

4.5.2 RESPONSIBILITY AND AUTHORITY (R&A)

The Document Control Manager, RA/QA Manager and the Director of Operations have the responsibility and authority for carrying out document and data control activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.5.3 DOCUMENT AND DATA CONTROL

Syncor Radiation Management adheres to documented procedures controlling aspects of the creation, review, approval, modification, issue, release, and other activities associated with document and data control. These controls apply to documents regardless of their origin, and whether they are hard copies or electronic records. Device master records and labeling masters are covered by these procedures.

Documents and data are reviewed and approved for adequacy by authorized personnel prior to issue. A listing of quality-related documentation is maintained. This listing includes current revision-level information, and is available to associates that need this information to carry out their activities, to preclude the use of invalid or obsolete documents.

Current revision levels of procedural and policy documents are maintained in the areas where the work described in the documents is being carried out. Manufacturing, testing and labeling forms, and labeling materials are issued as needed from the appropriate Document Control person or Materials Management person in order to maintain control.

Down-level (previous version) and obsolete documents are removed from points of issue and use in manufacturing to ensure that they are not used to make decisions that may affect quality. These documents are segregated and archived. Historical data is maintained for reference

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purposes. Obsolete documents may be needed in order to conduct repairs and may be used for that purpose. Retention periods for the various types of documents and records are documented. For medical devices, the retention period ensures that specifications to which the products have been manufactured are available for at least the expected lifetime of the medical device, as defined by the company. Documents that are to be retained for legal and/or knowledge preservation purposes indefinitely are identified.

Changes to documents and data are reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. Pertinent information or background is provided upon which to base their review and approval. Where practicable, the nature of the change is identified in the change request documents or attachments.

4.5.4 RELATED AND SUPPORT DOCUMENTATION

QSP-205 Document and Data Control Procedure
QSP-103 Document/Quality Record Matrix

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4.6 PURCHASING

4.6.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 part 7.4, 21CFR 820.50, 10 CFR50 App. B parts IV, VII, ISO 13485:1996 Section 4.6, EN46001:1996 Section 4.6 and ISO 17025 part 4.6.

4.6.2 RESPONSIBILITY AND AUTHORITY (R&A)

The Purchasing Manager, Purchasing personnel and the Quality Manager have the responsibility and authority for carrying out purchasing activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.6.3 PURCHASING

Documented procedures are in use to ensure that purchased product and services conform to specified requirements. The type and extent of control applied to the supplier and the purchased product or service is dependent on the effect of the product or service on subsequent product realization activities and the final product.

Vendors, contractors and consultants are evaluated on the basis of their ability to meet the requirements of the quality system and any specific quality assurance requirements. Records of acceptable vendors, contractors and consultants are maintained

The procedures also define the type and extent of control to be exercised over the vendors, contractors and consultants dependent upon the type of product or service supplied, its impact on the quality of the final products, and where applicable, the audit reports or performance record of the vendor.

Purchase order (PO) information contains adequate detail to ensure that all specified requirements have been adequately described. Reviews and approvals of all PO and related information are carried out by purchasing personnel in advance of the PO being placed with the vendor, to ensure adequacy of the specified requirements. When appropriate, the purchasing information includes requirements for approval of the product, procedures, processes and equipment, requirements for qualification of personnel, and quality management system

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requirements. Copies of relevant purchasing documents are retained as needed to the extent required by the particular requirements for traceability discussed in section 4.8 of this manual.

Activities are conducted to ensure that the purchased product or service meets specified purchase requirements. When purchased product is to be verified at the vendor's premises, the verification arrangements and the method of product release are in the purchasing documents.

When it is a condition of the contract, the customer has the right to verify that the product conforms to specified requirements on our premises or that of our vendor. Such verification is not used as evidence of effective control of the subcontractor's quality system. The verification by the customer does not absolve Syncor Radiation Management of the responsibility to provide acceptable product, nor does it preclude subsequent rejection by the customer.

4.6.4 RELATED AND SUPPORT DOCUMENTATION

QSP-206 Purchasing Procedure

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4.7 CONTROL OF CUSTOMER-SUPPLIED PRODUCT

4.7.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 part 7.5.4, 21CFR 820.60, .80(a), ISO 13485:1996 Section 4.7, EN46001:1996 Section 4.7 and ISO 17025 part 5.8.

4.7.2 RESPONSIBILITY AND AUTHORITY (R&A)

The Director of Customer Services/ Calibration Lab, the Director of Operations, the Systems Manager, the Materials Manager, the Warehouse Manager, the RA/QA Manager and Cal/Repair Manager have the responsibility and authority for carrying out control of customer-supplied product activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.7.3 CONTROL OF CUSTOMER-SUPPLIED PRODUCT

Procedures for identification, verification, protection, storage, and maintenance of customer-supplied product are in use. These products may be for incorporation into the SRM final product or for related activities or services.

Any such product that is lost, damaged or is otherwise unsuitable for use is recorded and reported to the customer.

Verification by Syncor Radiation Management does not absolve the customer of the responsibility to provide acceptable product.

4.7.4 RELATED AND SUPPORT DOCUMENTATION

QSP-207 Control of Customer-Supplied Product Procedure

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4.8 PRODUCT IDENTIFICATION AND TRACEABILITY

4.8.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 part 7.5.3, 21 CFR 820.60, .65, 10 CFR 50 App. B part VIII, ISO 13485:1996, EN46001:1996.

4.8.2 RESPONSIBILITY AND AUTHORITY (R&A)

The Directors of Calibration Lab/ Customer Services and Operations, the Managers of Materials, Warehouse, Systems, Cal/Repair and Quality have the responsibility and authority for carrying out product identification and traceability activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.8.3 PRODUCT IDENTIFICATION AND TRACEABILITY

Documented procedures exist for identifying product from receipt and during stages of production, delivery and installation. These procedures ensure that medical devices received for refurbishing or reprocessing to specified requirements are identified and distinguished at all times from normal production.

There are also documented procedures for the unique identification of individual products or batches where traceability is a requirement, as for medical devices. The identification is recorded on the applicable documents and may enable traceability to certain of the components used in the product. Traceability is maintained for the distribution of the devices and ensures that the record of the original consignee for the device is maintained to facilitate corrective or preventive action if needed.

4.8.4 RELATED AND SUPPORT DOCUMENTATION

QSP-208 Product Identification and Traceability Procedure

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4.9 PROCESS CONTROL

4.9.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 parts 6 and 7, 21CFR 820.70 (a) through (I), .75,.170, 10 CFR 50 App. B parts V, IX, X., ISO 13485:1996 Section 4.9 and EN46001:1996 Section 4.9.

4.9.2 RESPONSIBILITY AND AUTHORITY (R&A)

The Director of Operations, Manufacturing Engineering, the Director of the Calibration Lab/ Customer Service, the RA/QA Manager, the Quality Manager and the IT function have the responsibility and authority for carrying out process control activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.9.3 PROCESS CONTROL

Documented controls, plans and procedures exist to govern the methods and practices used to complete and monitor manufacturing, installation and servicing processes. These controlled conditions include the following:

- Provision and maintenance of the appropriate infrastructure including buildings, workspace and utilities
- Documented procedures defining the manner of these activities, when they affect quality
- Use of suitable process equipment, both hardware and software,
- Use of a suitable working environment if the environmental conditions are of significance in the manufacture of the products. Under such conditions, the requirements are established and documented, and if appropriate controlled and monitored.
- Personnel requirements for health, cleanliness and clothing if contact between such personnel and the product or environment could adversely affect the quality of the product. Personnel who are required to work under special environmental conditions are appropriately trained, or supervised by a trained person.
- Compliance with reference standards/codes, quality plans and/ or documented procedures
- Requirements for the cleanliness of the product if process agents are to be removed from product during manufacture.
- Monitoring and control of suitable materials, process parameters and product characteristics
- Approval and change control of processes and equipment, as appropriate

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- Criteria for workmanship, clearly defined
- Suitable maintenance, monitoring and measurement on equipment with established requirements when such activities may affect quality. Records of such maintenance are kept.
- Appropriate procedures for installation when performed, and documentation of such activities.
- Use of documented procedures for the validation of the application of computer software used for process control. The results of the validation are recorded.
- Implementation of release, delivery and post-delivery activities
- Supporting services such as transportation and communication

Where the results of processes cannot be fully verified by subsequent monitoring, inspection, measuring or testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, process validation is performed. Validation is performed to demonstrate the ability of these processes to achieve planned results. The documented validation program includes, where appropriate, installation qualification, operation qualification, performance qualification and process validation, software validation, continuous monitoring of processes, and qualification of operators. The use of specific methods and procedures is defined as applicable. Revalidation is done when needed due to a design change, new product, new application for the process or as indicated by process monitoring or feedback from customers.

The quality records of such validated special processes identify the work instruction or procedure used, the date the special process was performed and the identity of the operator of the special process.

The requirements for any qualification of process operations, including associated equipment and personnel are specified.

Records are maintained of the process control and validation activities, and for qualified processes, equipment and personnel.

4.9.4 RELATED AND SUPPORT DOCUMENTATION

QSP-209 Process Control Procedure

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4.10 INSPECTION AND TESTING/ANALYSIS AND IMPROVEMENT

4.10.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 part 7 and 8, 21CFR 820.80 (a) through (e), 10 CFR 50 App. B parts VII, X, XI, ISO 13485:1996, Section 4.10 and EN46001:1996 Section 4.10.

4.10.2 RESPONSIBILITY AND AUTHORITY (R&A)

The Managers of RA/QA and Quality, the Director of Nuclear Associates, the Director of Operations and the Director of the Calibration Lab/ Customer Service, the Managers of Cal/Repair and Systems, and the Director of Marketing and Product Development have the responsibility and authority for carrying out inspection, testing and measuring activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.10.3 INSPECTION AND TESTING (I&T)

Documented procedures for inspection and testing activities exist in order to verify that the specified requirements for the products are met. The required inspection and testing activities are detailed in documented procedures or in quality plans.

Incoming product is not used or processed (except for products where pilot testing is specified prior to acceptance) until it has been inspected or otherwise verified as conforming to specified requirements according to documented procedures. The amount and nature of the incoming inspection is based on the nature of the material and its importance in the final product, but also on the amount of control exercised at the vendor's premises and the recorded evidence of conformance available.

Where incoming material is released for urgent production purposes prior to verification, it is positively identified and recorded in order to permit immediate recall and replacement in the event it is found to be nonconforming to specified requirements.

In-process materials and products are inspected and tested as required by documented procedures. Product is held until the required inspection and/or test has been completed or

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necessary reports and records have been received and verified, except when product is released to the next production stage under positive-recall procedures as described above. Such a conditional release does not preclude the performance of the in-process inspection and test activities.

Final inspection and testing is carried out in accordance with documented procedures to complete the evidence of conformance to the specified requirements. The procedures for the final inspection and testing require that all previously required inspections and tests have been performed and that the results meet specified requirements. No products are released for distribution until the activities specified in the documented procedures have been satisfactorily completed and the associated data and documentation have been approved and accounted for.

Records to demonstrate that the product has been inspected and/or tested are maintained. These records clearly show whether the product has passed or failed according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product are followed.

The inspection authority responsible for the release of product is identified on the records. Inspection and test activities are performed by individuals other than those who performed the activity being checked.

4.10.4 MEASUREMENT, ANALYSIS AND IMPROVEMENT

SRM has implemented monitoring, measurement, analysis and improvement processes not only to demonstrate conformity of the product, but also to ensure conformity of the quality management system and to continually improve the effectiveness of the quality management system. Information relating to customer perception and satisfaction is monitored by customer service, sales, quality and marketing and shared at the Management Review meetings. Internal audits are conducted according to part 4.17 of this manual. Processes are monitored and measured to demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective actions are taken, as appropriate, to ensure conformity of the product.

4.10.5 RELATED AND SUPPORT DOCUMENTATION

QSP-210 Inspection and Testing Procedure
Metrics from Management Review Meetings

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4.11 CONTROL OF MONITORING, INSPECTION, MEASURING, AND TEST EQUIPMENT

4.11.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 , 21CFR 820.72 (a) and (b), 10 CFR 50 App. B part XII, ISO 13485:1996, Section 4.11, EN46001:1996, Section 4.11 and ISO 17025 Section 5.5.

4.11.2 RESPONSIBILITY AND AUTHORITY (R&A)

The Director of the Calibration Lab/Customer Service, the Calibration/Repair Manager, the RA/QA Manager and the Quality Manager have the responsibility and authority for carrying out control of monitoring, inspection, measuring and test equipment activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.11.3 INSPECTION, MEASURING AND TEST EQUIPMENT (I,M,&TE)

Documented procedures to control, maintain, and calibrate monitoring, inspection, measuring and test equipment (including test software) are in use to demonstrate the conformance of product to the specified requirements. Such equipment is used in a manner, which ensures that the measurement uncertainty is known and is consistent with the required measurement capability.

Where test software or comparative references are used as suitable forms of inspection, they are checked to prove that they are capable of verifying the acceptability of product, prior to release for use during production, installation or servicing. Periodic rechecks are done according to a procedure and records of such checks are maintained. Technical data, pertaining to the inspection, measuring or test equipment, is made available to a customer when required by their contract or to verify the equipment is functionally adequate.

In order to ensure the control of the equipment, Syncor Radiation Management does the following:

- Selection of I,M&TE is based on analysis and determination of the precision required;
- Equipment affecting quality is identified and handled according to the appropriate procedures

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- Procedures are established according to equipment type, frequency of use, and nature of use, and include acceptance criteria and reference to actions for nonconforming equipment.
- I,M&TE is identified by either a controlled equipment label, calibration sticker or inscribed identifier number. The calibration status of each piece of equipment is determined by either a calibration sticker or record of calibration status, based on the equipment identification number;
- Calibration status of equipment is determined by equipment vendor documentation, actual calibration of equipment by plant maintenance personnel, calibration personnel or QC/QA personnel, or by the equipment operator when done as part of the work instructions.
- Calibration status for all I,M&TE is traceable to industry, national or international equipment standards, whenever possible;
- Methods and practices of calibration are documented and these documents are adhered to in carrying out calibration activities;
- Documented procedures detail methods and practices to be used for assessing I,M&TE found to be out of calibration and the actions related to product(s) that were inspected or tested using this equipment;
- Suitable environmental conditions are maintained to ensure the accurate operation of I,M&TE and for product that will be inspected in these environmental conditions;
- Methods of handling, preservation and storage exist to ensure that I, M&TE are used in a manner that will ensure measurement accuracy and fitness for use; and
- Measures have been taken to protect I, M&TE , including software and hardware, from unauthorized adjustment that may affect the accuracy of the equipment.

4.11.4 RELATED AND SUPPORT DOCUMENTATION

QSP-211 Control of Inspection, Measuring and Test Equipment Procedure

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4.12 INSPECTION , TEST and OPERATING STATUS

4.12.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s):ISO 9001:2000 part 7.5.3, 21CFR 820.86, 10 CFR 50 App. B part XIV, ISO 13485:1996, Section 4.12, EN46001:1996, Section 4.12 and ISO 17025 section 5.8

4.12.2 RESPONSIBILITY AND AUTHORITY (R&A)

The RA/QA Manager, Quality Manager, Director of Operations, Materials Manager, Warehouse Manager, Systems Manager, Cal/Repair Manager and the Directors of the Calibration Lab/ Customer Services, have the responsibility and authority for carrying out inspection and test status activities. The Regulatory Affairs/Quality Engineers and the Facilities Engineer have a supportive role for this function. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.12.3 INSPECTION AND TEST STATUS

Documented procedures are in use to control the methods for identifying accepted or released (conforming) product and product on hold (which may be nonconforming product) based on their inspection and test results.

The identification of inspection and test status is maintained, as defined in the documented procedures, throughout the production, packaging, labeling, installation and servicing of the product. Only product that has passed the required inspections and tests and is released, is distributed, used or installed.

To meet safety or other requirements, measures are taken for indicating the operating status of equipment , such as by tagging valves and switches, to prevent inadvertent operation.

4.12.4 RELATED AND SUPPORT DOCUMENTATION

QSP-212 Inspection and Test Status Procedure

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4.13 CONTROL OF NONCONFORMING PRODUCT

4.13.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 part 8.3 , 21CFR 820.90, 10 CFR 50 App. B part XV, ISO 13485:1996, Section 4.13 , EN46001:1996, Section 4.13 and ISO 17025 section 4.9.

4.13.2 RESPONSIBILITY AND AUTHORITY (R&A)

The Directors of the Calibration Lab/Customer Services and Operations, the Materials Manager, Warehouse Manager, and Purchasing Manager, Manufacturing Engineering, Systems Manager, RA/QA Manager, and the Quality Manager have the responsibility and authority for carrying out control of nonconforming product activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.13.3 CONTROL OF NONCONFORMING PRODUCT

Documented procedures are in use to ensure that materials, parts, components or finished product that does not conform to specified requirements is prevented from unintended use or installation. These procedures specify the methods for the identification, documentation, evaluation, segregation (when practical), and disposition of such nonconforming product, and the notification to the functions or departments concerned.

Responsibility for review and the authority for the disposition are defined. Nonconforming product is reviewed in accordance with documented procedures to determine the appropriate action to take, which may include:

- rework or repair to specifications
- reinspection or retest if there is reason to believe the initial results may be due to operator or equipment error
- scrapping or recycling,
- acceptance through customer concession (not an option for FDA-regulated product)
- rejection/return to vendor

Rework and repair are carried out in accordance with documented instructions and product is retested according to the documented procedures. Rework for medical devices is documented in

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a work instruction that has undergone the same authorization and approval procedure as the original work instruction.

For product not regulated by the FDA and where contractually required, Syncor Radiation Management reports the proposed use of nonconforming product to the customer for concession. Descriptions of the accepted nonconformity are recorded to denote the actual condition. Nonconforming product is accepted for concession only if regulatory requirements are met. The identity of the person authorizing concession is recorded.

4.13.4 RELATED AND SUPPORT DOCUMENTATION

QSP-213 Control of Nonconforming Product Procedure

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4.14 CORRECTIVE AND PREVENTIVE ACTION

4.14.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 part 8.5, 21CFR 820.100, .198, 10 CFR 50 App. B part XVI, ISO 13485:1996, Section 4.14, EN46001:1996, Section 4.14 and ISO 17025 sections 4.8, 4.10 and 4.11..

4.14.2 RESPONSIBILITY AND AUTHORITY (R&A)

The General Manager, Directors, Managers, Manufacturing Engineering and Regulatory/Quality personnel have the responsibility and authority for carrying out continual improvement activities including corrective and preventive actions. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.14.3 CORRECTIVE AND PREVENTIVE ACTION

A documented feedback system is established to provide early warning of quality problems and for input into the corrective and/ or preventive action system. Experience gained from post-production, or postmarketing surveillance, is reviewed as part of this feedback system when required.

Documented procedures for implementing corrective and preventive action are in use. The determination of action to be taken to eliminate the causes of actual or potential nonconformities is appropriate to the magnitude of the problem and the risks. Changes made to the device master records as a result of corrective and preventive action are handled through established change control procedures for review, implementation and recording.

The procedures for corrective action include methods for documenting and handling customer complaints, returned product, deviations in production, and reports of product nonconformities. An investigation of the cause and the associated risk of the nonconformities, relating to the product, process or quality system is done and the results recorded. The feedback information is investigated, interpreted, collated, and communicated in accordance with defined procedures by designated personnel.

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A record is kept of all customer complaint investigations. When the investigation determines that the activities at remote premises contributed to the customer complaint, a copy of the report is sent from SRM to the remote premises. The corrective action needed is then determined and followed up to ensure the action is implemented and effective. If any customer complaint is not followed by corrective and/or preventive action, the reason is recorded.

The procedures for preventive action include the use of information from various sources including internal operation reports, audit results, quality records, service reports and customer complaints to detect, analyze and eliminate potential causes of nonconformities. These procedures include steps to deal with problems requiring preventive action, the initiation of such actions and instructions for follow-up to ensure implementation and effectiveness. Again, such proposed actions are handled according to the established change control procedures, which include management review.

If a customer alleges that one of our medical device products has caused or contributed to a serious injury or death, or that it has malfunctioned, and if that malfunction were to recur it could cause or contribute to a serious injury or death, the Medical Device Reporting regulations are followed as described in 21CFR 803, and the requirements of Regulatory Authorities in other countries as applicable. Procedures for the notification of such regulatory authorities are established to meet the reporting criteria.

If a correction or removal of distributed medical devices is needed, then the requirements of the FDA's 21CFR 806, and those of applicable foreign Regulatory Authorities are followed. Procedures are established for the issue of such advisory notices or recalls, which can be implemented at any time.

For items subject to regulation by the Nuclear Regulatory Commission or the Atomic Energy Act of 1954, a defect or nonconformance is deemed to exist if anyone obtains information reasonably indicating that a basic component, licensed activity or a portion of the facility has a defect or failure that could be associated with a substantial safety hazard. A notification of failure to comply or existence of a defect must be made according to 10 CFR part 21.21.

4.14.4 RELATED AND SUPPORT DOCUMENTATION

QSP-214 Corrective and Preventive Action Procedure

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4.15 HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY

4.15.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 part 7.5, 21CFR 820.120, .130,.140,.150, .160, 10 CFR 50 App. B part XIII, ISO 13485:1996, Section 4.15, EN46001:1996, Section 4.15 and ISO 17025 section 5.8.

4.15.2 RESPONSIBILITY AND AUTHORITY (R&A)

The Materials Manager, Director of Operations, Warehouse Manager and the Radiation Safety Officer have the responsibility and authority for carrying out handling, storage, packaging, preservation and delivery activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.15.3 HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY

Documented procedures are in use for the handling, storage, packaging, preservation and delivery of product, as well as for returned product. These procedures control the following activities:

Handling - Handling methods and practices are intended to prevent damage and deterioration of material and products throughout the receiving, manufacturing, packaging, preservation and shipping, and return process.

Storage - Receiving, in-process and pre-shipment areas have been identified and are used; these areas have the intended purpose of preventing damage and deterioration to product(s) and or material(s) and for segregating materials released from those that are to be held. Clearly defined methods and practices are in use for the receipt and dispatching of items from these areas. The condition of product in stock is assessed at appropriate intervals.

Packaging and Labeling- Methods of packing, packaging, labeling and marking of packaging materials are controlled to ensure that all specified requirements have been met.

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Preservation - Measures are taken to preserve materials and products to prevent damage and deterioration, and to segregate materials released for distribution from those to be held.

Delivery - Practices and procedures are in use that provide for the protection of products after final inspection and testing; as required, this protection applies to the delivery of the product to the customer.

Procedures are established and maintained for the control of product with a limited shelf- life or requiring special storage conditions. Such special storage conditions for medical devices are controlled and recorded as applicable.

If appropriate, special arrangements are established and maintained for the handling and control of used product in order to prevent the contamination of other product, the manufacturing environment or personnel.

4.15.4 RELATED AND SUPPORT DOCUMENTATION

QSP-215 Handling, Storage, Packaging, Preservation and Delivery Procedure

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4.16 CONTROL OF QUALITY RECORDS

4.16.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 part 4.2.4, 21CFR 820.180, .181, .184, .186, 10 CFR 50 App. B part XVII, ISO 13485:1996, Section 4.16, EN46001:1996, Section 4.16 and ISO 17025 section 4.12.

4.16.2 RESPONSIBILITY AND AUTHORITY (R&A)

The Directors, Managers, Supervisors and the RA/QA Engineer and Document Control/Regulatory Coordinator have the responsibility and authority for carrying out control of quality record activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.16.3 CONTROL OF QUALITY RECORDS

Procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records, including device history records and design history files, are in use. The quality records are maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Applicable records from vendors are also considered and handled as quality records.

The quality records are legible and maintained in a retrievable manner. The records are kept in a storage environment that prevents damage, deterioration and loss. Electronic records are backed-up, via electronic means, and stored to prevent loss or damage. Record retention periods are specified and conform to regulatory and contract requirements. For medical devices, the quality records are retained for a period of time at least equivalent to the lifetime of the device as defined by the supplier, but not less than 2 years from the date of dispatch.

A record for each batch, unit or run of medical devices is maintained that provides traceability to the extent required by section 4.8 and identifies the quantity manufactured and the quantity released for distribution. The record is verified and authorized.

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4.17 QUALITY AUDITS

4.17.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 part 8.2.2 and 8.2.3, 21CFR 820.22, 10 CFR 50 App. B parts VII, XVIII, ISO 13485:1996, Section 4.17, EN 46001:1996, Section 4.17 and ISO 17025 section 4.13.

4.17.2 RESPONSIBILITY AND AUTHORITY (R&A)

The RA/QA Manager, the Quality Manager, the Regulatory/Quality Engineers, Document Control/Regulatory Coordinator and other trained and designated auditors have the responsibility and authority for carrying out quality audit activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.17.3 QUALITY AUDITS

Documented procedures for planning and implementing internal and external quality audits are in use. Quality audits are carried out to verify that planned and documented procedures, quality and control plans, and other quality system documentation are in conformance, and to assess their effectiveness. The internal audits are scheduled based on the department's or regulatory element's impact on quality and quality performance, and are carried out against the requirements of the standard(s) that apply to the operation being audited. External audits are done at intervals consistent with the importance, complexity, performance history and quantity of the product or services obtained from the vendor. Trained and qualified personnel who understand the standard(s), auditing requirements, and basic communication skills, and who are independent of the functional area being assessed, conduct the audits.

The results are documented and are communicated to the personnel having responsibility for the area audited. The management of the audited area must determine and implement timely corrective action. Follow-up activities are carried out to verify the implementation and effectiveness of corrective action. Records of quality audits are maintained.

4.17.4 RELATED AND SUPPORT DOCUMENTATION

QSP-217 Quality Audit Procedure

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4.19 SERVICING

4.19.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 part 7.5.1, 21CFR 820.200, ISO 13485:1996 Section 4.19 and EN46001:1996., Section 4.19.

4.19.2 RESPONSIBILITY AND AUTHORITY (R&A)

The Directors of the Calibration Lab/ Customer Services, the Calibration/Repair Manager and the Repair coordinator at Nuclear Associates have the responsibility and authority for carrying out servicing activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.19.3 SERVICING

Where servicing is a specified requirement, documented procedures for scheduling, performing, verifying and reporting the servicing are in use. These procedures ensure that the servicing activities are done under controlled conditions, meet the specified requirements for the product and that the servicing activities are documented. Servicing, like production, is done using correct information for the product, work instructions (as necessary), suitable equipment, monitoring and measuring devices, measuring and monitoring of the service itself, and proper release, delivery and post-delivery activities.

4.19.4 RELATED AND SUPPORT DOCUMENTATION

QSP-219 Servicing Procedure
QSP-101 Quality Manual for Calibration Services

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4.16 CONTROL OF QUALITY RECORDS

4.16.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 part 4.2.4, 21CFR 820.180, .181, .184, .186, 10 CFR 50 App. B part XVII, ISO 13485:1996, Section 4.16, EN46001:1996, Section 4.16 and ISO 17025 section 4.12.

4.16.2 RESPONSIBILITY AND AUTHORITY (R&A)

The Directors, Managers, Supervisors and the RA/QA Engineer and Document Control/Regulatory Coordinator have the responsibility and authority for carrying out control of quality record activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.16.3 CONTROL OF QUALITY RECORDS

Procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records, including device history records and design history files, are in use. The quality records are maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Applicable records from vendors are also considered and handled as quality records.

The quality records are legible and maintained in a retrievable manner. The records are kept in a storage environment that prevents damage, deterioration and loss. Electronic records are backed-up, via electronic means, and stored to prevent loss or damage. Record retention periods are specified and conform to regulatory and contract requirements. For medical devices, the quality records are retained for a period of time at least equivalent to the lifetime of the device as defined by the supplier, but not less than 2 years from the date of dispatch.

A record for each batch, unit or run of medical devices is maintained that provides traceability to the extent required by section 4.8 and identifies the quantity manufactured and the quantity released for distribution. The record is verified and authorized.

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Records are available for review by regulatory authorities, quality system auditors, company personnel, and by a customer when specified as part of their contract. Management review and internal or external audit records are not to be provided to FDA inspectors for review.

4.16.4 RELATED AND SUPPORT DOCUMENTATION

QSP-216 Control of Quality Records Procedure
QSP-103 Document/Quality Record Matrix

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4.17 QUALITY AUDITS

4.17.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 part 8.2.2 and 8.2.3, 21CFR 820.22, 10 CFR 50 App. B parts VII, XVIII, ISO 13485:1996, Section 4.17, EN 46001:1996, Section 4.17 and ISO 17025 section 4.13.

4.17.2 RESPONSIBILITY AND AUTHORITY (R&A)

The RA/QA Manager, the Quality Manager, the Regulatory/Quality Engineers, Document Control/Regulatory Coordinator and other trained and designated auditors have the responsibility and authority for carrying out quality audit activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.17.3 QUALITY AUDITS

Documented procedures for planning and implementing internal and external quality audits are in use. Quality audits are carried out to verify that planned and documented procedures, quality and control plans, and other quality system documentation are in conformance, and to assess their effectiveness. The internal audits are scheduled based on the department's or regulatory element's impact on quality and quality performance, and are carried out against the requirements of the standard(s) that apply to the operation being audited. External audits are done at intervals consistent with the importance, complexity, performance history and quantity of the product or services obtained from the vendor. Trained and qualified personnel who understand the standard(s), auditing requirements, and basic communication skills, and who are independent of the functional area being assessed, conduct the audits.

The results are documented and are communicated to the personnel having responsibility for the area audited. The management of the audited area must determine and implement timely corrective action. Follow-up activities are carried out to verify the implementation and effectiveness of corrective action. Records of quality audits are maintained.

4.17.4 RELATED AND SUPPORT DOCUMENTATION

QSP-217 Quality Audit Procedure

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4.18 TRAINING

4.18.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 6.2.2, 21CFR 820.25, ISO 13485:1996, Section 4.18 , EN46001:1996, Section 4.18 and ISO 17025 section 5.2.

4.18.2 RESPONSIBILITY AND AUTHORITY (R&A)

The Directors, Managers, Supervisors and the Facilities Engineer have the responsibility and authority for carrying out training activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.18.3 TRAINING

The necessary competence for personnel performing work affecting product quality has been determined through the job descriptions. Documented procedures for identifying training needs are in use. Training, including Quality System requirements, is provided for personnel performing activities affecting quality. Personnel who perform specific assigned tasks are qualified on the basis of appropriate education, training and/or experience, as required. Records of training and qualifications are maintained.

Personnel are made aware of the relevance and importance of their activities and how they contribute to the achievement of the SRM quality objectives.

Personnel who are required to work under special environmental conditions or who perform special processes or functions are appropriately trained or supervised by a trained person.

4.18.4 RELATED AND SUPPORT DOCUMENTATION

QSP-218 Training Procedure

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4.19 SERVICING

4.19.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 part 7.5.1, 21CFR 820.200, ISO 13485:1996 Section 4.19 and EN46001:1996., Section 4.19.

4.19.2 RESPONSIBILITY AND AUTHORITY (R&A)

The Directors of the Calibration Lab/ Customer Services, the Calibration/Repair Manager and the Repair coordinator at Nuclear Associates have the responsibility and authority for carrying out servicing activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.19.3 SERVICING

Where servicing is a specified requirement, documented procedures for scheduling, performing, verifying and reporting the servicing are in use. These procedures ensure that the servicing activities are done under controlled conditions, meet the specified requirements for the product and that the servicing activities are documented. Servicing, like production, is done using correct information for the product, work instructions (as necessary), suitable equipment, monitoring and measuring devices, measuring and monitoring of the service itself, and proper release, delivery and post-delivery activities.

4.19.4 RELATED AND SUPPORT DOCUMENTATION

QSP-219 Servicing Procedure
QSP-101 Quality Manual for Calibration Services

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4.20 STATISTICAL TECHNIQUES

4.20.1 SCOPE AND PURPOSE

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2000 parts 8.1, 8.2 and 8.4, 21CFR 820.250, ISO 13485:1996, Section 4.20 and EN46001:1996, Section 4.20.

4.20.2 RESPONSIBILITY AND AUTHORITY (R&A)

The Directors and Managers have the responsibility and authority for carrying out statistical technique activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

4.20.3 STATISTICAL TECHNIQUES

SRM has implemented monitoring, measurement, analysis, and improvement processes needed to demonstrate conformity of the product, and the quality management system, and to continually improve the effectiveness of the quality management system.

Where appropriate, procedures are in use to identify the need for valid statistical techniques required for establishing, controlling and verifying process capability, product characteristics and the ability of the processes to achieve planned results. Where such needs have been identified, procedures or practices are in use to control the application of the statistical techniques and to define the appropriate sampling methods and plans. The sampling methods chosen are adequate for their intended use and are reviewed when there are changes in a product or process. Sampling methods are reviewed in light of the occurrence of nonconforming product, quality audit reports, feedback information and other appropriate considerations. Activities related to these requirements for statistical techniques are documented.

Data analysis provides information relating to customer satisfaction, conformity to product requirements, characteristics and trends of processes and products, and suppliers. This data is typically reviewed as part of the Management Review meetings.

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4.20.4 RELATED AND SUPPORT DOCUMENTATION

QSP-220 Statistical Techniques Procedure

QSP-201 Management Review

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T. B. Hansen - GM
P. Barnwell - Executive Asst.

**Director
Sales**
T. E. Price

- 7 Sales Associates
R. Fergus
K. Hill
B. Hughes
M. Loftus
J. Yasenak
NE (Hold)
Mid-Atlantic (Hold)
- 2 Inside Sales
Open
- Key Accounts Mgr.
T. Krivan
- + Gov/Ser Specialist
T. Seifert
- + Proposal Specialist
B. Ruanak
- International Sales Mgr.
S. Ditzig
- + 2 Specialists
M. Marlowe
A. Mathews
- + Admin
L. Guy

**Director
Mktg. & Prod.
Development**
S. Janney

- 5 Advertising, Sales
Promo, Marketing
Communications
E. Covino*
K. Gobbo*
M. Hughes
N. Moreno*
A. Swayhoever*
- Tech Support
M. Kuhar
- Eng. Manager
B. Zimmerman
- + 8 Engineers
D. Donaghue
J. Francescangeli
B. Jones
C. McFarren
A. Nutter
W. Tidwell
R. White
H. Xu
- Therapy PLM
Open
- Systems PLM
J. Hale
- + 5 Associates
G. Buck
R. Horvath
A. Lasko
D. Warner
J. Zilka

**RSO/Director
Global Cal
Lab**
C. E. Grehofsky

- Cal Services Mgr.
R. Abbott
- + 12 Associates
K. Barnes
R. Brunat
P. Hartman
L. Hines
T. Hradek
J. James
R. Kay
J. Kulonwka
B. Mahood
L. Sincich
R. Sweetman
D. Thomas
- ADCL
B. Hurlace
- Alt. RSO
- M. Sveiger
- Cust. Service Mgr.
S. Thorley
- + 4 Associates
D. Crispino
B. Hradek
G. Marlock
K. Wills

**Director
Nuclear
Associates**
B. J. Pearsall*

- Nuclear Med. PLM
F. Talbot*
- Diagnostic PLM (Hold)*
- CPb PSM
S. Ignatz*
- Sec*
J. Axel*
- NA Cust. Service Supervisor*
P. Cusack*
- + 3* Associates
C. Egger*
L. Marzejewski*
S. Sherman*
- SRM Cust. Service Supervisor
D. Gorman
- + Associate
J. Giargiana
- + Receptionist
J. Lewis

**Director
Operations**
B. E. Burns

- Sec
R. Lebadie
- Mfg Mgr. (Open)
+ 18 Direct
C. Bevelacqua
S. Black
M. Blackley
B. Hall
R. Hoyasak
M. Iacovetta
J. Johnson
S. Simons
T. Stewarding
R. Vales
S. Word
E. Chanowith
T. Hughes
J. Koehler
T. McCoy
R. Moore
R. Radwa
D. Ramerk
- Facilities Hazmat
M. Goffka
- Mfg. Eng.
J. Hildebran
- + 3 Associates
L. Laurel
J. Spos
L. Winters
- Purchasing
D. Boyd
- + 5 Associates
C. Gordon
B. Ornell*
S. Orlace
V. Trelech
M. Zywicki
- Materials
V. Angle
- + 7 Associates
P. Dubose
B. Kordal
T. Norton
D. Pleaka
S. Smith
T. Tale
E. Wilson
- Warehouse Mgr.*
J. Caroccolo*
- + 5 Associates
W. Foster*
J. Guleo*
B. Hemphill*
B. Kir*
R. Merdian*
- Documentation Control
R. Masswell
- + 3 Associates
M. Holt
C. Maciejowski
M. Nero
- Regulatory/QA Mgr*
C. Castleberry*
- + 7 Associates
K. Davis
Z. Glafie
C. Gbur
B. Sheffield
D. Smith
A. Sutamo*
C. Wells

**Plant
Controller**
J. G. Singh

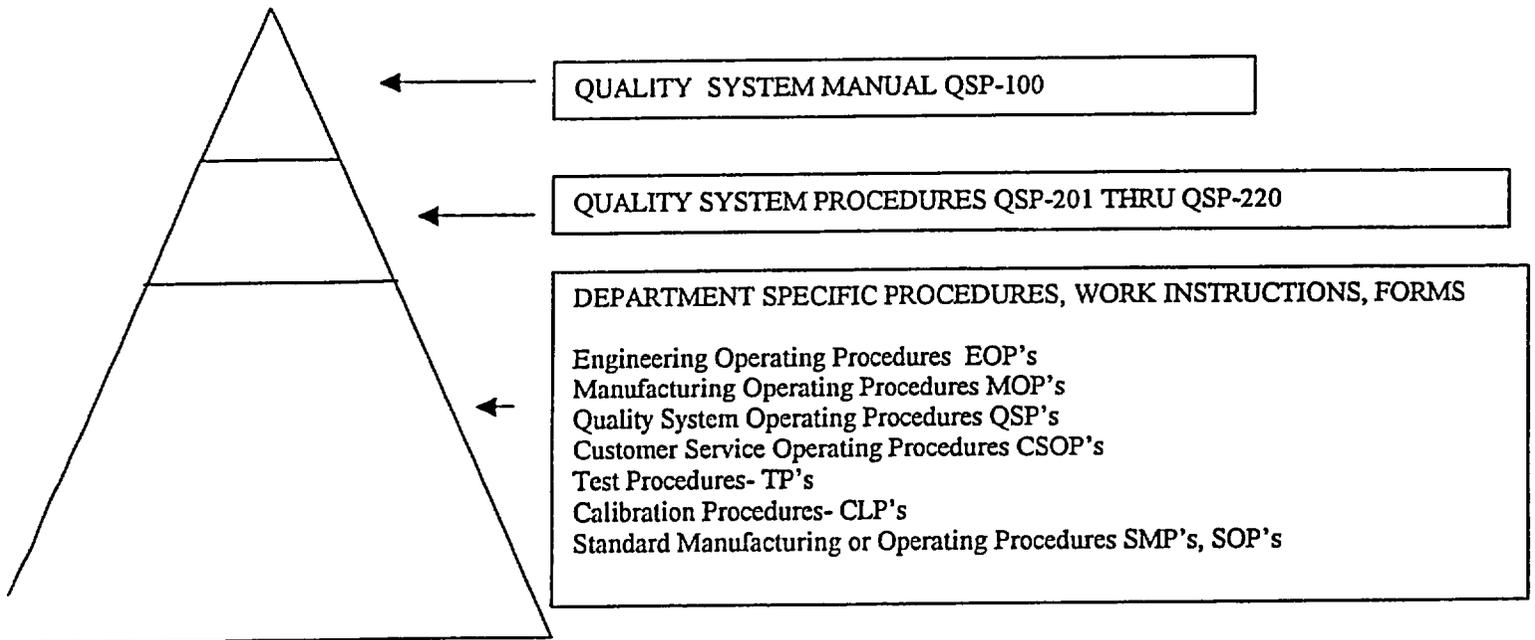
- Accounting (Open)
- 3 AR
L. Adams
B. Luecht
C. Quinn
- 3 AP
S. Brownell*
C. Sladky
P. Rupp
- Payroll/HR
L. McDonald
- 4 IT
J. Facck*
R. Rodriguez
P. Stalger (c)
M. Tirbaniesingh*

* Located in NY

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COMPANY CONFIDENTIAL

SYNCOR RADIATION MANAGEMENT DOCUMENTATION STRUCTURE



Annex B (informative)

Correspondence between ISO 9001:2000 and ISO 9001:1994

Table B.1 — Correspondence between ISO 9001:1994 and ISO 9001:2000

ISO 9001:1994	ISO 9001:2000
1 Scope	1
2 Normative reference	2
3 Definitions	3
4 Quality system requirements [title only]	
4.1 Management responsibility [title only]	
4.1.1 Quality policy	5.1 + 5.3 + 5.4.1
4.1.2 Organization [title only]	
4.1.2.1 Responsibility and authority	5.5.1
4.1.2.2 Resources	6.1 + 6.2.1
4.1.2.3 Management representative	5.5.2
4.1.3 Management review	5.6.1 + 8.5.1
4.2 Quality system [title only]	
4.2.1 General	4.1 + 4.2.2
4.2.2 Quality system procedures	4.2.1
4.2.3 Quality planning	5.4.2 + 7.1
4.3 Contract review [title only]	
4.3.1 General	
4.3.2 Review	5.2 + 7.2.1 + 7.2.2 + 7.2.3
4.3.3 Amendment to a contract	7.2.2
4.3.4 Records	7.2.2
4.4 Design control [title only]	
4.4.1 General	
4.4.2 Design and development planning	7.3.1
4.4.3 Organizational and technical interfaces	7.3.1
4.4.4 Design input	7.2.1 + 7.3.2
4.4.5 Design output	7.3.3
4.4.6 Design review	7.3.4
4.4.7 Design verification	7.3.5
4.4.8 Design validation	7.3.6
4.4.9 Design changes	7.3.7
4.5 Document and data control [title only]	
4.5.1 General	4.2.3
4.5.2 Document and data approval and issue	4.2.3
4.5.3 Document and data changes	4.2.3
4.6 Purchasing [title only]	
4.6.1 General	
4.6.2 Evaluation of subcontractors	7.4.1
4.6.3 Purchasing data	7.4.2
4.6.4 Verification of purchased product	7.4.3

Table B.1 — Correspondence between ISO 9001:1994 and ISO 9001:2000 (continued)

ISO 9001:1994	ISO 9001:2000
4.7 Control of customer-supplied product	7.5.4
4.8 Product identification and traceability	7.5.3
4.9 Process control	6.3 + 6.4 + 7.5.1 + 7.5.2
4.10 Inspection and testing [title only]	
4.10.1 General	7.1 + 8.1
4.10.2 Receiving inspection and testing	7.4.3 + 8.2.4
4.10.3 In-process inspection and testing	8.2.4
4.10.4 Final inspection and testing	8.2.4
4.10.5 Inspection and test records	7.5.3 + 8.2.4
4.11 Control of inspection, measuring and test equipment [title only]	
4.11.1 General	7.6
4.11.2 Control procedure	7.6
4.12 Inspection and test status	7.5.3
4.13 Control of nonconforming product [title only]	
4.13.1 General	8.3
4.13.2 Review and disposition of nonconforming product	8.3
4.14 Corrective and preventive action [title only]	
4.14.1 General	8.5.2 + 8.5.3
4.14.2 Corrective action	8.5.2
4.14.3 Preventive action	8.5.3
4.15 Handling, storage, packaging, preservation & delivery [title only]	
4.15.1 General	
4.15.2 Handling	7.5.5
4.15.3 Storage	7.5.5
4.15.4 Packaging	7.5.5
4.15.5 Preservation	7.5.5
4.15.6 Delivery	7.5.1
4.16 Control of quality records	4.2.4
4.17 Internal quality audits	8.2.2 + 8.2.3
4.18 Training	6.2.2
4.19 Servicing	7.5.1
4.20 Statistical techniques [title only]	
4.20.1 Identification of need	8.1 + 8.2.3 + 8.2.4 + 8.4
4.20.2 Procedures	8.1 + 8.2.3 + 8.2.4 + 8.4