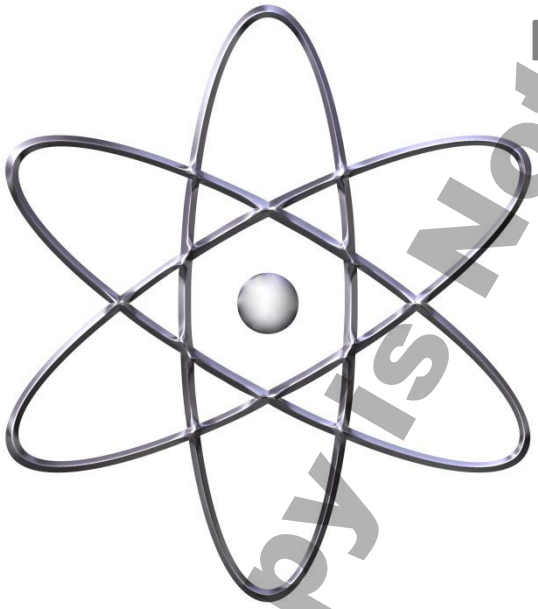
Quality Assurance

for SOR® Nuclear-Qualified Products

8303-100 Rev.15

Process Control Instruments



MEASUREMENT AND CONTROL
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MEASUREMENT AND CONTROL

NUCLEAR
QUALITY ASSURANCE MANUAL 8303-100
FOREWORD

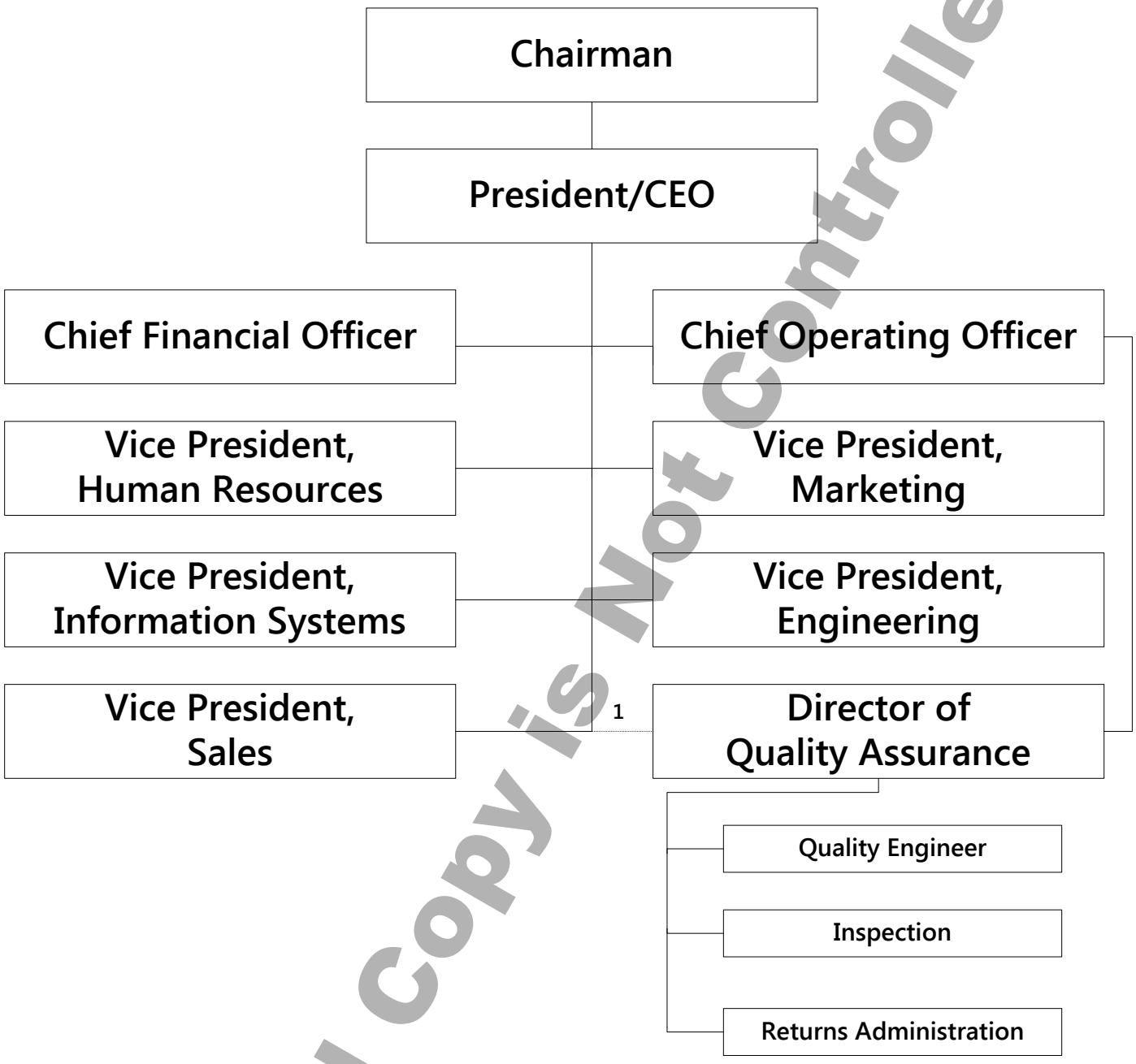
The QA Manual sets forth requirements to insure the quality of the Process Control Instruments produced by SOR®. The manual applies to nuclear safety-related work and is written to comply with the applicable elements of 10CFR50, Appendix B, ANSI N45.2 or basic requirements of ASME NQA-1, CSA N285.0 and CSA B51 Part 1. The provisions of 10CFR Part 21 apply to the products produced under this quality program. This program has been approved by all and shall be enforced by the management of SOR who retains responsibility for the program.

TABLE OF CONTENTS

REVISIONS

Note: When a revision to the QA Manual occurs, the complete manual revision level is changed. SOR does not have pages or sections of this manual that are at different revision levels.

Rev. No.	Section	Description	Approved Date
1		Release Complete Manual	12/01/83
2		EO - 978	01/27/84
3		EO - 1168	11/29/84
4		EO - 1685	01/08/86
5		EO - 1858	06/09/86
6		EO - 2036	11/05/86
7		EO - 2512	06/30/88
8		EO - 2766	05/30/89
9	Various	See Superseded Manual Rev. 9 for details	04/12/93
10	Forward	Names changed to reflect current Management	08/01/99
10	2	Added Steps 2.7 & 2.8 and Supporting Procedures	08/01/99
10	3 - 14	Added Supporting Procedures	08/01/99
10	10	Added SPC data to 10.4	08/01/99
10	15	Added Step 15.5 and Supporting Procedures, revised 15.1 to reflect current policies.	08/01/99
10	16 – 18	Added Supporting Procedures	08/01/99
11	Various	Revise complete manual	12/10/10
12		Personnel revisions	07/17/12
13	17.4	Fire rating of records storage	12/12/12
14		Personnel revisions, minor terminology changes	01/21/14
15	Various	Added references to Order Entry, Commercial Grade Dedication, Counterfeit, Fraudulent & Suspect Items. Revised Quality Assurance Records.	08/17/15



1. Full authority & accountability directly to President/CEO for any product quality or safety consideration.

1.0 ORGANIZATION

1.1 The Director of QA has full authority and accountability directly to the President and has the authority to stop work in any area to prevent non-conforming work or components from being incorporated into the final product. The Director of QA has authority to identify quality problems and to initiate, recommend, provide solutions and verify implementation of solutions. Quality assurance personnel are independent from the Procurement, Manufacturing, Fabrication, Sales, and Marketing groups. Engineering personnel can represent QA if QA personnel are not available and if the Engineer signing the document did not sign the product releases and Engineering Test Reports.

1.2 The Director of QA is directly responsible for or oversees the following:

1.2.1 Review of the customer purchase order requirements to insure incorporation into SOR production plans and insure that the final test results meet the customer specifications.

1.2.2 All phases of incoming, in-process, final and shipping inspection.

1.2.3 Maintain and control the accuracy of inspection and test equipment by timely calibration with approved procedures.

1.2.4 Maintain QA records and forms.

1.2.5 Perform vendor quality assurance audits or surveys and corrective action follow-up where required, per approved procedure.

1.2.6 Determine necessary inspection points and establish procedures required to maintain the product quality.

1.2.7 Represent QA on Quality Review Board.

1.2.8 Train inspectors, auditors and test personnel and maintain proficiency records of these personnel.

1.2.9 Train personnel performing activities affecting the quality of products in the SOR Nuclear Program.

1.2.10 Maintain Approved Personnel List to document those personnel who are qualified to perform nuclear functions.

1.2.11 Monitor procedure(s) for Reporting of Defects per NRC 10CFR Part 21.

1.3 The QA Inspector's responsibilities are:

1.3.1 Receiving Inspection.

1.3.1.1 QA inspectors will perform inspections as necessary to ensure that material received meet the specified requirements.

1.3.2 In-Process Inspection.

1.3.2.1 QA inspectors will perform inspections as described on Work Order Traveler and drawing. Acceptance will be denoted by signature and date.

1.3.3 Final Inspection

1.3.3.1 QA inspectors will check the completed products to insure that the specified sales order requirements have been met.

1.3.3.2 QA inspectors will review data sheets and final test certificate for conformance to catalog, specification and/or customer requirements.

1.3.4 Shipping Inspection

1.3.4.1 QA inspectors will check products for correct tagging, labels and special

packaging requirements as required by sales order.

1.3.4.2 Special marking and instruction requirements located on the exterior of packages will be checked before products are shipped.

1.3.5 Gauge Control

1.3.5.1 QA inspectors will maintain and periodically calibrate inspection equipment per approved procedures.

1.3.5.2 QA inspectors will select inspection equipment as required by drawings and/or specifications.

1.3.6 Non-Destructive Testing (NDT)

1.3.6.1 QA inspectors will perform NDT as required by specification, purchase order and/or customer requirements. If the QA inspectors are not qualified to perform the inspections, the inspection will be subcontracted.

1.4 The VP of Engineering shall insure that Engineering personnel, performing activities affecting quality of SOR Nuclear Products, will follow functions described in Section 3 "Design Control" and supplemental instructions and procedures described in Customer Purchase Order, Contract Sales Order, Assembly Work Order Traveler and Part Work Order Traveler.

1.5 The Director of Supply Chain Management shall insure that Supply Chain personnel, performing activities affecting quality of SOR Nuclear Products, will follow functions described in Section 7 "Procurement Control", Section 8 " Material, Parts & Component I.D." and supplemental instructions and procedures described in Contract Sales Order, Assembly Work Order Traveler and Part Work Order Traveler.

1.6 The Pressure Products Supervisor and Machine Shop Supervisor will assure all those that perform activities affecting quality of SOR Nuclear Products, will follow functions described in Section 5 "Instructions, Procedures and Drawings", Section 8 "Material, Parts and Component I.D." and supplemental instructions and procedures described in Contract Sales Order, Assembly Work Order Traveler and Part Work Order Traveler.

1.7 The VP of Sales and the VP of Marketing shall insure that Sales, Marketing and Order Entry personnel, performing activities affecting quality of SOR Nuclear Products, will follow functions described in Section 5 "Instructions, Procedures and Drawings" and supplemental instructions and procedures described in Customer Purchase Order, Contract Sales Order, Assembly Work Order Traveler and Part Work Order Traveler.

Supporting Procedures – Section 1.0	
Procedure No.	Procedure Title
094-041	Management Review of SOR Quality System
8303-109	Qualifications of Inspection, Testing and Audit Personnel
8303-110	Reporting of Potential Deviation for Defect per NRC 10CFR Part 21

2.0 QUALITY ASSURANCE PROGRAM

2.1 Quality Control procedures and/or instructions are established and approved by Director of QA.

2.2 QA Program shall be reviewed by Management a minimum of once a year to insure adequacy of the program and compliance with latest customer specifications.

2.3 Director of QA will insure that inspectors, auditors and test personnel will receive training as required by approved procedures. Special procedures will be developed and implemented when required to meet customer specifications. Procedures for qualification of personnel shall meet intent of ANSI N45.2.6

2.4 Director of QA will issue QA Manual and maintain distribution records of original and revisions per approved procedures.

2.5 Director of QA will maintain a list of approved personnel designated to sign off certificates of conformance and/or compliance or be authorized representative for the responsible management.

2.6 Director of QA will insure that personnel performing activities affecting the quality of products in the SOR Nuclear Program will receive indoctrination and Nuclear Safety training. These training records will be documented and maintained by the Director of QA and/or Designee.

2.7 QA Program documentation consists of the SOR QA (Policy) Manual. The QA Manual is supported by Procedures. The Procedures are supported by work instructions where applicable.

2.8 Products that do not meet SOR Quality Standards or Nuclear Code Requirements will not be released for shipment to customers per Section 15 “Nonconforming Materials, Parts or Components.”

Supporting Procedures – Section 2.0	
Procedure No.	Procedure Title
094-041	Management Review of SOR Quality System
8303-109	Qualifications of Inspection, Testing and Audit Personnel
8520-896	Distribution of SOR Quality Assurance Manual
8303-117	Approved Personnel List

3.0 DESIGN CONTROL

3.1 The Engineering Department is responsible for the original design of and subsequent modifications to products which are manufactured and sold by SOR. This responsibility covers all product designs (special and standard) with adherence to applicable industry codes, standards, and regulations as well as product reliability, safety, and suitability for applications. When necessary, a procedure shall specify controls on the use of software in the design process, including needed verifications.

3.2 The Engineering Department establishes design specifications and project plans for performing design activities such that design outputs are verified at scheduled milestones. These plans assign qualified personnel to major design tasks and identify the necessary resources to adequately accomplish the development activity. Both internal (manufacturing, Materials Management, etc.) and external (consultants, special services, etc.) organizational and technical interfaces are to be delineated to allow for regular reviews and feedback on project direction and status.

3.3 Design inputs are documented and in turn reviewed by the Engineering Department for adequacy and feasibility. Design input requirements for new products and modification to existing products that affect the original specifications are controlled by a documented approval process.

3.4 Functional specifications, agency requirements, performance criteria, and identified safety related requirements are translated into design documents and product (design output). All design documents and activities relevant to the final design are authenticated and retained.

3.5 Design output is monitored by design reviews and verified by competent personnel to ensure that design requirements are met. Final design is reviewed to verify that design specifications are met and, at a minimum, is approved by assigned personnel from Quality Assurance and Engineering.

3.6 Design modifications or changes are identified, documented, reviewed, and approved. In carrying out design control, the Engineering Department ensures that during the design cycle and throughout the product life, the product meets company standards, customer standards, and any applicable regulatory standards.

3.7 It is the responsibility of Manufacturing Engineering, Supply Chain, Quality Assurance, Sales, and Marketing to provide supporting procedures that ensure that all design revisions are correctly implemented. The SOR design control system extends to the customer and supplier. When a customer's procurement document is received, the document shall be processed to ensure that contract requirements and customer expectations are satisfied and contract requirements are correctly translated into drawings, specifications, instructions, and project documents. Inside Sales is accountable for "closing the loop" with the customer, and Supply Chain is accountable for "closing the loop" with the supplier.

Supporting Procedures – Section 3.0	
Procedure No.	Procedure Title
001-513	Product Design Proposal
001-514	Customer Special Request
001-561	Standard Tenders

095-001	Documentation Control
095-022	Engineering Change Order
095-037	Design Control
094-052	Software Control
8520-059	Procedure for Processing Nuclear Orders

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 Director of QA or designated delegate will review purchase documents to ensure quality assurance requirements are included. A copy of the required drawing is furnished with the purchase order, which provides the technical requirements. These drawings have been formally reviewed and approved by Engineering. The review shall include verification that customer purchase order requirements are specified on SOR purchase order. Statement may be added to purchase order for applicable specific regulations. Purchase order is to be re-checked after completion of all processing i.e. typing, to ensure required QA information has been included. Revisions to purchase orders will be reviewed in the same manner as original issue.

4.2 Director of QA or designated delegate will review subcontractor QA program, to verify that the subcontractor can meet requirements of procurement documents. The results of review and acceptance of QA program shall be documented and the records will be maintained by QA. Acceptance of the subcontractor's QA program shall be by Director of Quality Assurance.

4.3 Procurement document provisions shall include as applicable, the following:
Scope of work
- 4.3.1 Purchased item category or classification
- 4.3.2 Technical requirements
- 4.3.4 Inspection, test and acceptance requirements
- 4.3.5 Suppliers and subcontractor quality program requirements
- 4.3.6 Right of access by SOR
- 4.3.7 Documentation requirements to be retained/submitted
- 4.3.8 Provisions for reporting and disposition of a nonconformance
- 4.3.9 Spare and replacement parts requirements
- 4.3.10 Hold and/or Witness points
- 4.3.11 Control of subcontracting
- 4.3.12 10 CFR Part 21 applicability/reporting
- 4.3.13 Schedule and delivery provisions
- 4.3.14 Software controls
- 4.3.15 Extension of contract requirements to lower-tier suppliers
- 4.3.16 Prohibition of the supply or incorporation of counterfeit, fraudulent or suspect items.

Supporting Procedures – Section 4.0	
Procedure No.	Procedure Title
002-035	Purchase Order Preparation
002-029	Approved Vendor List
8520-017	CGI Procedure

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 Instructions, procedures and drawings shall include inspection requirements. These requirements must reflect the customer specifications and Purchase Order (P.O.) requirements. Parts drawings shall include inspection requirements in the form of tolerances, material description and special notes.

5.2 The instructions, procedures and drawings must include acceptance criteria to insure compliance with customer quality requirements.

5.3 All instructions, procedures and drawings must be reviewed, checked and approved per approved procedures.

5.4 Catalogs, General Instructions and Technical Bulletins must be reviewed, checked and approved per procedures.

Supporting Procedures – Section 5.0	
Procedure No.	Procedure Title
001-512	Forms Control - Marketing Department
095-001	Documentation Control
095-022	Engineering Change Order
095-037	Design Control

6.0 DOCUMENT CONTROL

6.1 Quality-related documents require a "closed-loop" procedure to control their handling.

6.1.1 There is a single responsible function for issuance of each document, as well as any changes to the specific issuance. Each occurrence of an issue or a change is approved by the appropriate manager.

6.1.2 There are procedures that route and control the intra- and interdepartmental flow of documents.

6.1.3 The result of the routing of each occurrence is fed back to the issuing function to ensure the response to the document issuance is accurate.

6.2 Responsibility for document control lies with the department that issues the document. It is each department manager's responsibility to assure that all quality- related documents issued by his/her department meet the following procedural guidelines, by establishing:

6.2.1 How documents are approved.

6.2.2 Who (position, title) approves documents.

6.2.3 Where documents are located so that they are available to employees needing access to them.

6.2.4 How obsolete documents are identified and recorded.

6.2.5 How changes to documents are identified and recorded.

6.2.6 How many changes are allowed before a revision is issued.

6.2.7 A "loop system," or route, that newly issued documents travel for approvals and issues, making sure that both new issues and changes to issue follow the same route.

6.2.8 That the document procedure requires the document title be added or subtracted, as needed, to the Master List of Quality Documents.

Supporting Procedures – Section 6.0	
Procedure No.	Procedure Title
001-512	Forms Control - Marketing Department
095-001	Documentation Control
094-129	Procedure For Controlling Quality Records

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

7.1 Vendors are approved by the Approved Vendor List Team (AVL) either by historical quality performance data, or source survey, audit, verification of material or parts by inspection or review of test reports.

7.2 Check lists approved by QA shall be used for audits or surveys of vendors. These check lists shall be originated and approved by the Director of QA.

7.3 The AVL Team will maintain an approved vendor list. This list will be updated on at least a quarterly basis.

7.4 Re-evaluation will occur on or before due dates specified on approved vendor list.

7.5 Purchased materials, parts and equipment shall be inspected for compliance with procurement documents.

7.6 Certified Material test reports shall be reviewed and approved by authorized QA personnel.

7.7 Raw Materials and components that are procured as commercial grade items are dedicated per SOR 8520-017.

7.8 Incoming material, parts and components are inspected for conformance to P.O., drawing, specification or Work Order Traveler, i.e. color codes, inspection identifying marks, tags/labels and material certification. Receiving inspection shall verify by objective evidence such features as configuration, identification, dimensional, physical, and other characteristics, freedom from shipping damage, freedom from CFSI indicators, cleanliness, and supplier documentation, as applicable. Additional testing may be performed as required to identify material.

7.9 Nonconformance Report (NCR) Form will be issued when incoming materials do not meet requirements.

7.10 Suppliers of safety-related or commercial grade (dedicated) items or services are evaluated and approved by the QA Department prior to placement of the purchase order. Active qualified suppliers are evaluated monthly and audited at least every 3 years. Supplier audits or surveys may be precluded when safety-related items are:

a. Relatively simple and standard in design, manufacturing and testing, and
b. Adaptable to standard or automated inspections or tests of the end product to verify its quality characteristics upon receipt.

Supporting Procedures – Section 7.0	
Procedure No.	Procedure Title
002-029	Approved Vendor List
094-036	Incoming Inspection Procedure
094-043	Nonconformance Report (NCR)
8303-112	Vendor Audit/ Commercial Grade Survey Procedure
8520-017	CGI Procedure

8.0 IDENTIFICATION & CONTROL OF MATERIAL, PART & COMPONENTS

8.1 Permanent marking and/or tagging will be used where described on P.O., drawings, specifications or Work Order Traveler to provide traceability.

8.2 Nonconformance Report (NCR) Form will be issued when incoming materials do not meet requirements.

8.3 Work Order Traveler or P.O., complete with date, order number, part number, description, quantity and routing, must be approved by inspection before movement of accepted material to designated stock or assembly area.

8.4 Approved material, parts and components shall not be removed from designated stock area, for fabrication or assembly, without Work Order Traveler or sales order. The identification of these parts shall be maintained throughout entire manufacturing, assembly, testing and final calibration process.

8.5 Metal for certain switch parts as specified by the responsible Engineer will be assigned a heat code identification from the heat code log. This code will be stamped on the ends of the bars and on castings. Heat code traceability is maintained as follows: the heat code is transferred to individual pieces as they are removed from the main heat coded bar, during the manufacturing process, if part size or configuration allows or the individual pieces are placed in a container marked with heat code.

Supporting Procedures – Section 8.0	
Procedure No.	Procedure Title
Form 1097	Heat Code Log
002-035	Purchase Order Preparation
094-036	Incoming Inspection Procedure
094-043	Nonconformance Report (NCR)
8520-059	Procedure for Processing Nuclear Orders

9.0 CONTROL OF SPECIAL PROCESSES

9.1 Instructions or procedures for special manufacturing processes will be issued and approved by the Director of QA as required by customer requirements. Instructions or procedures must include complete description of equipment required, special conditions, methods and personnel qualifications.

9.2 Personnel performing special process work will be trained and qualified per procedure issued and approved by Director of QA.

9.3 Personnel performing quality inspection, verification or NDE will be approved by Director of QA.

9.4 If the QA personnel are not qualified to perform the necessary inspections, verification or NDE the duties will be subcontracted.

Supporting Procedures – Section 9.0	
Procedure No.	Procedure Title
8303-104	Soldering Procedure
8303-117	Approved Personnel List

10.0 INSPECTIONS

10.1 The Director of QA shall establish and implement procedures to qualify inspection personnel. Only approved, qualified personnel are permitted to perform inspections.

10.2 Inspections are to be performed by other than those who performed the activity being inspected.

10.3 Inspections are performed in accordance with written procedures or inspection plans. These may include checklists, forms, steps integrated into other process control documents and work instructions.

10.4 Unless otherwise noted, “inspect” shall be defined as sample the received lot, per sampling plan procedure and check specified dimensions.

10.5 Mandatory inspection or hold points as required by customer or Director of QA shall be incorporated in sales, assembly or part fabrication work order.

10.6 Parts and/or materials are inspected when received against purchase order, specification, Work Order Traveler or drawings.

10.7 Some commercial parts and/or materials may be dedicated for nuclear usage by re-inspection per Work Order Traveler. Inspections for dedicated items may include pre, in-process and post inspection examinations.

10.8 Nonconforming material identified during receipt inspections will be documented on Nonconformance Report (NCR) Form. The material will be segregated and the NCR Form will accompany the nonconforming material.

10.9 When parts and/or materials have passed inspection or been released from NCR hold, sign and date purchase order, Work Order Traveler and record inspection results in log book.

10.10 The accepted parts and/or materials are routed to Nuclear Stores per purchase order or Work Order Traveler. They come under control per Nuclear QA Program 8303-100 when placed in Nuclear Stores.

10.11 In-process inspections are performed at various intervals to detect nonconformance. Records of inspection are attached to Work Order Traveler.

10.12 Final calibration, test data sheets and certificate of conformance are reviewed for conformance to sales order requirements. Completed items shall be inspected for completeness, markings, calibrations, adjustments, protection from damage, or other characteristics as required to verify the quality and conformance of the item to specified requirements.

Supporting Procedures – Section 10.0	
Procedure No.	Procedure Title
001-561	Standard Tenders
094-036	Incoming Inspection Procedure
094-042	In-Process Inspection Procedure
094-043	Nonconformance Report (NCR)
8303-109	Qualifications of Inspection, Testing and Audit Personnel
8520-059	Procedure for Processing Nuclear Orders
8520-017	CGI Procedure

11.0 TEST CONTROL

11.1 The VP of Engineering or designated delegate shall develop written test procedures to meet customer requirements. Engineering Order or Document Control procedures shall be used to control issue or revision of test procedures as applicable.

11.2 Only Inspection or test personnel approved by the Director of QA will be permitted to perform approved tests.

11.3 When necessary, a procedure shall specify the controls on software (and related computer equipment) used to operate test equipment or test processes.

11.4 Software that is used to design products, manufacture products and/or test products must have measures established and implemented to control software quality. This requirement applies to software purchased from an outside vendor or software developed in-house. Procedures shall be established to assure the life cycle activities proceed in a traceable, planned and orderly manner.

11.5 Test results shall be evaluated and approved by Engineering and QA to insure conformance with customer's requirements. The manufacturing routing shall specify check points during tests and final approval before shipping.

Supporting Procedures – Section 11.0	
Procedure No.	Procedure Title
002-143	Manufacturing Software Control
095-037	Design Control
095-041	Engineering Test Reports
095-155	Control of Software Quality
8303-109	Qualifications of Inspection, Testing and Audit Personnel
8520-059	Procedure for Processing Nuclear Orders

12.0 CONTROL OF MEASURING & TEST EQUIPMENT

12.1 Procedure for control of measuring and test equipment shall list location, custodian, manufacturer's serial number and SOR equipment numbers.

12.2 Procedure shall indicate primary standard, calibration period, and record of calibration for all equipment.

12.3 Test equipment shall be marked to indicate calibration status.

12.4 Calibration record will list equipment status, including removal from service for nonconformance, damaged or obsolete condition. The record shall be maintained by QA, and controlled by approved procedure.

12.5 Traceability is required to National Institute of Standards and Technology (NIST), other nationally accepted standards, or intrinsic standards. Where standards do not exist, or are deviated from, the basis for the calibration shall be documented.

12.6 Where calibration suppliers are used, SOR will perform a triennial auditor survey, will witness the calibration of the equipment or will follow SOR procedure for accepting commercial grade suppliers with accreditation recognized by the ILAC MRA.

Supporting Procedures – Section 12.0	
Procedure No.	Procedure Title
7418-100	Calibration Procedure For Measuring And Test Equipment
8303-112	Vendor Audit/Commercial Grade Survey Procedure

13.0 HANDLING, STORAGE AND SHIPPING

13.1 Approved materials are located in a controlled designated stock area. These materials are identified by tags, color codes and/or identifying marks.

13.2 Approved material will not be removed from controlled designated stock area without Work Order Traveler or sales order. Material identification will be maintained throughout the entire manufacturing, assembly and testing process to provide traceability.

13.3 When required for critical, sensitive, perishable, or high value items, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.

13.4 Approved material will be protected from damage and deterioration per supplier, vendor or customer requirements.

13.5 Approved material will be packaged, marked and shipped per customer requirements and/or SOR specifications.

13.6 Approved material will not be processed, stored or shipped without required sales order, Work Order Traveler or shipping paper accompanying the material.

Supporting Procedures – Section 13.0	
Procedure No.	Procedure Title
002-035	Purchase Order Preparation
002-269	Controlling Limited Shelf-Life Products
8303-101	Packaging, Shipping and Documentation for Nuclear Safety Related products
8520-059	Procedure for Processing Nuclear Orders

14.0 INSPECTION, TEST & OPERATING STATUS

14.1 Inspection, test, and operating status of items shall be accomplished by physical location, status indicators such as stamps, tags, labels, or routing cards or by inspection records.

14.2 Inspection status of raw materials, vendor parts and/or assemblies, SOR manufactured parts and/or assemblies are recorded on Work Order Traveler or purchase order and inspection log.

14.3 Final inspection testing status of units is recorded on final test certificate accompanying product and/or sales order.

14.4 Nonconformance Report (NCR) Form will be issued as required for nonconformance to design drawing, customer specification and/or purchase order.

14.5 Director of QA will maintain a list of approved personnel designated to approve final test certificate.

Supporting Procedures – Section 14.0	
Procedure No.	Procedure Title
094-036	Incoming Inspection Procedure
094-042	In-Process Inspection Procedure
094-043	Nonconformance Report (NCR)
8303-117	Approved Personnel List
8520-059	Procedure for Processing Nuclear Orders

15.0 NONCONFORMING MATERIALS, PARTS OR COMPONENTS

15.1 Material and/or parts that do not conform to design drawings, specifications and/or purchase orders are documented per SOR 094-043 Nonconformance Report (NCR). Nonconforming material and/or parts are identified, segregated, and held from production until disposition per SOR 094-043 NCR procedure.

15.2 Disposition is recorded on the Nonconformance Form. Materials, parts and components are routed to areas per disposition recorded on Nonconformance Form. Designated scrap materials area is isolated from special hold area, stocking area and production area.

15.3 If disposition requires additional inspection or inspection after repair/rework, the additional inspection is recorded.

15.4 Products that do not conform to the Nuclear Code(s) specified on the sales order will not be released for shipment. Any SOR Employee can stop nonconforming products by initiating an NCR per SOR 094-043. The product will not be released for further processing until the NCR authorizes release.

15.5 Nonconformance Reports that apply to nuclear parts are reviewed for a potential NCR 10CFR Part 21 reportable condition.

15.6 Customer complaints are recorded and reviewed by Engineering, Quality and Inside Sales. The review will include consideration for potential NCR 10CFR Part 21 reportable conditions.

15.7 The RMA process evaluates any material that is returned. The evaluation results will be reviewed and consideration will be given to determine if a NCR 10CFR Part 21 report should be issued.

Supporting Procedures – Section 15.0	
Procedure No.	Procedure Title
001-568	Returned Products
001-570	Customer Complaints
094-043	Nonconformance Report (NCR)
8303-110	Reporting of Potential Deviation for Defect per NRC 10CFR Part 21

16.0 CORRECTIVE ACTION

16.1 When inspection of materials, parts and components reveals conditions that are adverse to quality or possible nonconformance to design drawing, customer specifications, and/or purchase order, management in affected area are notified immediately. These items will be identified and placed in a designated hold area.

16.2 The NCR Form, with documented reasons for hold and disposition, shall be reviewed by qualified personnel to determine if corrective action or preventative action is warranted.

16.3 The corrective action shall be recorded on the Corrective Action Report Form 621. Preventive action shall be recorded on the Preventive Action Report, Form 621.

16.4 Request for Engineering Change Order (ECO) to implement the corrective action shall be issued, when applicable.

16.5 ECO discussion, evaluation and disposition meetings are held as required, to meet customer delivery requirements or other special requirements.

16.6 Corrective action reports that apply to nuclear parts and products are reviewed for potential 10CRF21 reportable conditions.

Supporting Procedures – Section 16.0	
Procedure No.	Procedure Title
095-022	Engineering Change Order
094-152	Corrective Action Report Procedure
094-138	Preventive Action
8301-117	Quality Review Board
8303-110	Reporting of Potential Deviation for Defect per NRC 10CFR Part 21
094-043	Non Conformance Report

17.0 QUALITY ASSURANCE RECORDS

17.1 QA records are maintained per procedure 094-129 Procedure for Controlling Quality Records

17.2 QA records for SOR nuclear safety-related products are limited to "non-permanent" category. These records will be maintained by SOR for a minimum of ten (10) years at which time SOR will notify customers before disposal of QA records. “Non- permanent” records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records. Non- permanent records shall be maintained for the identified retention period.

17.3 QA records considered by the customer to be in the "lifetime" category are the customer's responsibility to maintain. “Lifetime” records are those that meet one or more of the following criteria:

17.3.1 records that would be of significant value in demonstrating capability for safe operation

17.3.2 records that would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item.

17.3.3 records that would be of significant value in determining the cause of an accident or malfunction of an item.

17.3.4 records that provide required baseline data for in-service inspections.

Lifetime records are required to be maintained by or for the Owner for the life of the particular item while it is installed in the plant or stored for use.

17.4 SOR will maintain QA records during processing of sales order. These records will be filed in facility designed to comply with 2 hour fire rating, or duplicate records will be kept off premises.

Supporting Procedures – Section 17.0	
Procedure No.	Procedure Title
094-129	Procedure for Controlling Quality Records
8520-059	Procedure for Processing Nuclear Orders

18.0 AUDITS

18.1 Qualified personnel will perform evaluations and periodic audits or surveys of vendors using approved check lists.

18.2 Qualified personnel will perform periodic internal audits for compliance to QA program using approved check list.

18.3 QA will maintain record of all vendor and internal surveys or audits.

18.4 Procedures for internal audits shall be followed with final results submitted for management review. Management shall review QA program and internal audits a minimum of once a year. Corrective action will be taken on conditions adverse to quality.

18.5 QA will perform quarterly status report of deficient areas until corrective action is accomplished.

18.6 Audit procedures to be established and implemented using ASME NQA-1 for guidance.

18.7 Procedure for qualification of audit personnel, to be established and implemented using NQA-1 Appendix 2A-3.1 for guidance.

Supporting Procedures – Section 18.0	
Procedure No.	Procedure Title
7701-128	Internal Audit Work Instructions
8303-112	Vendor Audit/Commercial Grade Survey
8303-117	Approved Personnel List

MEASUREMENT AND CONTROL

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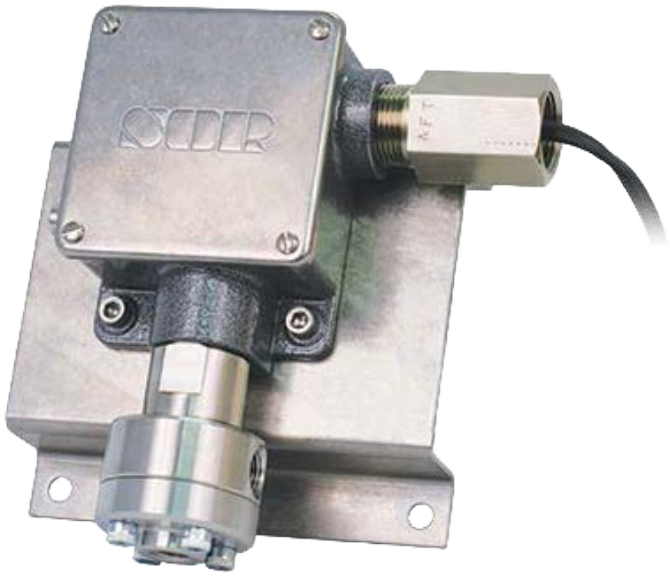

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