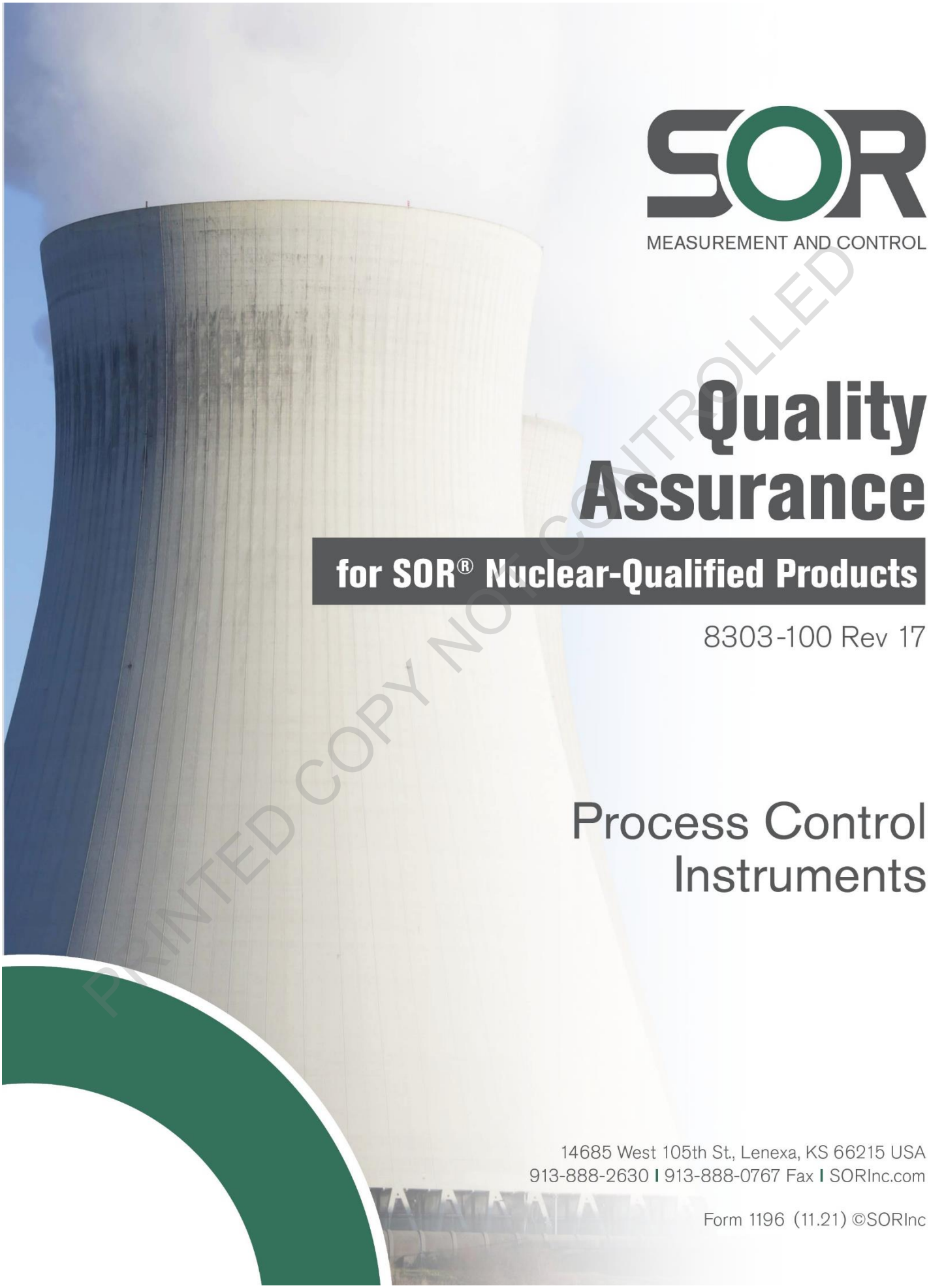

SOR
MEASUREMENT AND CONTROL

Quality Assurance

for SOR® Nuclear-Qualified Products

8303-100 Rev 17

Process Control Instruments

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Form 1196 (11.21)

NUCLEAR
QUALITY ASSURANCE MANUAL 8303-100
FOREWORD

The QA Manual sets forth requirements to ensure 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 and basic requirements of ASME NQA-1-2015 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.

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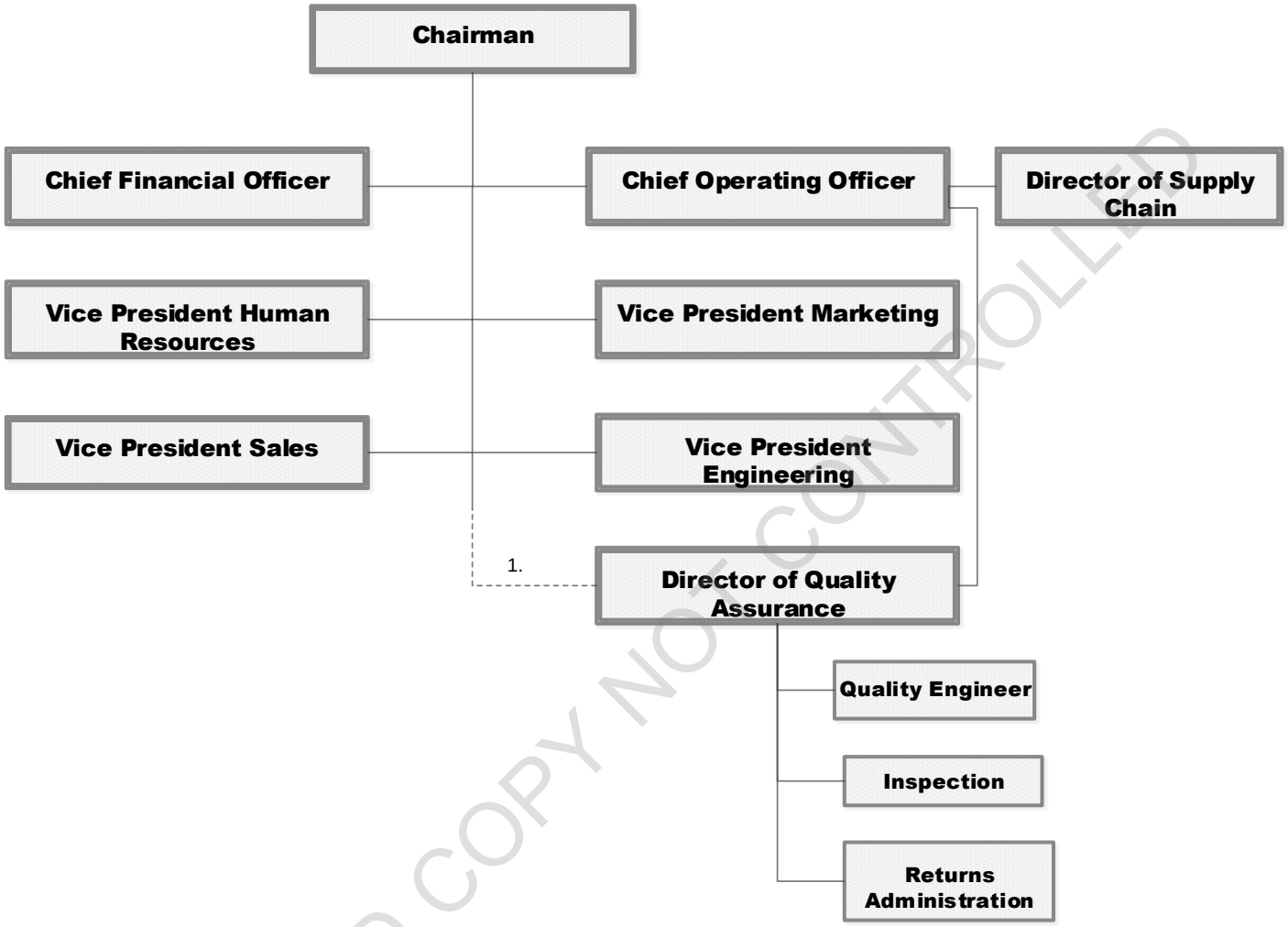
REVISIONS

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9	Various	See Superseded Manual Rev. 9 for details	04/12/93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
16	Various	Remove CSA N285.0. Update VP organization chart	05/13/20
17	Various	Added Acronyms & Abbreviations page, Updated VP Organization Chart, Added general paragraph to each section, Rearranged and/or renumbered sequencing of each section, Added supporting procedures	11/09/21

Acronyms and Abbreviations

Acronym/ Abbreviation	Definition	Acronym/ Abbreviation	Definition
AB	Accredited Body	NQA-1	Nuclear Quality Assurance (ASME Industry Consensus Standard)
ACC	Accept	NRC	Nuclear Regulatory Commission
AFE	Authorization for Expenditure	NUPIC	Nuclear Utilities Procurement Issues Corporation
ANSI	American National Standards Institute	PO	Purchase Order
ASME	American Society of Mechanical Engineers	PPM	Parts Per Million
AVL	Approved Vendor List	QA	Quality Assurance
ATEX	Atmosphere Explosible	QAM	Quality Assurance Manual
CAR	Corrective Action Report	QC	Quality Control
CCR	Customer Complaint Record	QRB	Quality Review Board
CFR	Code of Federal Regulation	REP	Repair
CFSI	Counterfeit, Fraudulent, Suspect/Substandard, Item	REW	Rework
CSA	Canadian Standards Authority	RFQ	Request for Quote/Quotation
CGD	Commercial Grade Dedication	RMA	Returned Material Authorization
CGI	Commercial Grade Item	RTV	Return to Vendor
CSR	Customer Special Request	SCR	Scrap
DIT	Destroyed in Test	SO	Sales Order
DP	Differential Pressure	SOR	Static-O-Ring
EO	Engineering Order	SPC	Statistical Process Control
EOL	End of Line	UAI	Use As Is
EPRI	Electric Power Research Institute	VP	Vice President
IEC	International Electrotechnical Commission	VRMA	Vendor Return Material Authorization
IECEx	Certification of Personnel Competence for Explosive Atmospheres	WO	Work Order
ILAC	International Laboratory Accreditation Cooperation		
INS	Re-inspect or Re-test		
ISO	International Standards Organization		
JOT	Job Order Traveler		
KB	Kanban		
KPI	Key Performance Indicator		
MRO	Maintenance, Repair and Operations		
MRA	Mutual Recognition Agreement		
MRB	Material Review Board		
MRR	Material Review Report (Nonconformance Report)		
M&TE	Measuring and Test Equipment		
NCR	Nonconformance Report (Material Review Report)		
NDE	Nondestructive Evaluation		
NDT	Nondestructive Test/Testing		
NEI	Nuclear Energy Institute		
NIAC	Nuclear Industry Assessment Corporation		
NPD	New Product Development		



1. Full authority & accountability directly to Chairman for any product safety consideration.

1.0 ORGANIZATION

1.1 This section describes the organizational structure, levels of authority, and interfaces for establishing and executing SOR's QA program.

1.2 The Director of QA has full authority and accountability directly to the Chairman and has the organizational 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, or provide solutions through designated channels, 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.

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

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

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

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

1.3.4 Maintain QA records and forms.

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

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

1.3.7 Represent QA on the Quality Review Board (QRB).

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

1.3.9 Train personnel performing or managing activities affecting the quality of products in the SOR Nuclear Program.

1.3.10 Maintain Approved Personnel List to document those personnel who are authorized or qualified to perform nuclear functions.

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

1.4 The QA Inspector's responsibilities are:

1.4.1 Receiving Inspection

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

1.4.2 In-Process Inspection

1.4.2.1 QA inspectors will perform inspections as described on assembly drawings, Nuclear Calibration, Testing & Shipping forms, and x-specs. Acceptance will be denoted by signature or initials and date.

1.4.3 Final Inspection

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

1.4.3.2 QA inspectors will review data sheets and final test certificate for

conformance to catalog, specification and/or customer requirements.

1.4.4 Shipping Inspection

1.4.4.1 QA inspectors will check products for correct tagging, labels and special packaging requirements as required by sales order.

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

1.4.5 Gauge Control

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

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

1.4.6 Non-Destructive Testing (NDT)

1.4.6.1 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.

1.5 The VP of Engineering shall ensure that Engineering personnel, performing activities affecting quality of SOR Nuclear Products, will follow functions described in Section 3 "Design Control", Section 4 “Procurement Document Control”, Section 11 “Test Control” and supplemental instructions and procedures described in Customer Purchase Order, Order Verification Report and Job Operation Listing Report.

1.6 The Director of Supply Chain shall ensure that Supply Chain personnel, performing activities affecting quality of SOR Nuclear Products, will follow functions described in Section 4 “Procurement Document Control”, Section 7 "Control of Purchased Material, Equipment and Services", Section 8 " Material, Parts & Component I.D." and supplemental instructions and procedures described in Order Verification Report and Job Operation Listing Report.

1.7 The Chief Operating Officer shall ensure that all Operations personnel 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.", Section 13 “Handling, Storage and Shipping” and supplemental instructions and procedures described in Order Verification Report and Job Operation Listing Report.

1.8 The VP of Sales and the VP of Marketing shall ensure that Sales, Marketing and Order Entry personnel, performing activities affecting quality of SOR Nuclear Products, will follow functions described in Section 4 “Procurement Document Control”, Section 5 "Instructions, Procedures and Drawings" and supplemental instructions and procedures described in Customer Purchase Order, Order Verification Report and Job Operations Listing Report.

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 This section outlines the establishment, execution, and maintenance of SOR's QA program. The quality program is controlled and documented by written policies, procedures, and instructions. All activities affecting quality are accomplished under suitably controlled conditions as delineated in appropriate implementing procedures and instructions. These controlled conditions include the following: appropriate equipment, suitable environmental conditions, and assurance that prerequisites for the activity have been met. Special controls, skills, processes, test equipment, and tools are also provided.

2.2 QA Program shall be reviewed by Senior Management a minimum of once a year to ensure the adequacy and effective implementation of the program and compliances.

2.3 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.

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

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

2.6 Director of QA will ensure that personnel performing or managing 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 Director of QA will ensure 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.

2.8 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.

2.9 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
094-143	Quality Manual Revisions
8303-109	Qualifications of Inspection, Testing and Audit Personnel
8303-117	Approved Personnel List
8520-896	Distribution of New and Revised Quality Manuals and Supplements

3.0 DESIGN CONTROL

3.1 This section identifies the requirements for ensuring a design control program for nuclear safety-related components.

3.2 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.

3.3 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, Supply Chain, 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.

3.4 Design inputs such as design bases, performance requirements, regulatory requirement, codes, and standards shall be identified and 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.

3.5 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.

3.6 Design output is monitored by design reviews and verified by competent personnel, other than those who performed the original design, 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.

3.7 Design modifications or changes from approved design inputs, including the reason for the change 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.

3.8 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**
001-514	Customer Special Request
001-561	Standard Tenders
001-577	Customer Contract Review
094-051	New Product Development (NPD) Process
095-022	Engineering Change Order (ECO)
095-037	Design Control
095-041	Engineering Test Reports
095-052	Software Control
8520-059	Procedure for Processing Nuclear Orders

4.0 PROCUREMENT DOCUMENT CONTROL

4.1 This section identifies the requirements and responsibilities for the preparation, review, and approval of procurement documents for nuclear safety-related items and services. The review processes apply to all phases of procurement.

4.2 Responsible department personnel along with the Director of QA or designated delegate are responsible for the preparation, review, and control of procurement documents for items and services. The review shall include the scope of work, inspection, test, and acceptance requirements, quality program requirements, document requirements, drawings, etc. Changes affecting the technical and quality assurance program requirements of procurement documents shall be controlled and subjected to the same degree of control as the original issue of procurement documents.

4.3 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.

4.4 Procurement document provisions shall include as applicable, the following:

a. Scope of work
b. Purchased item category or classification
c. Technical requirements (see below)
d. Inspection, test, and acceptance requirements (see below)
e. Suppliers and subcontractor quality program requirements
f. Right of access by SOR, designated representative and others authorized by SOR
g. Documentation requirements to be retained/submitted
h. Provisions for reporting and disposition of a nonconformance
i. Spare and replacement parts requirements
j. Hold and/or Witness points
k. Control of subcontracting
l. 10CFR Part 21 applicability/reporting
m. Schedule and delivery provisions
n. Software controls
o. Extension of contract requirements to lower-tier suppliers
p. Prohibition of the supply or incorporation of counterfeit, fraudulent or suspect items

4.4.1 Technical requirements: drawings, specifications, codes, standards, regulations, and procedures or instructions including revisions that describe the items or services to be furnished. The procurement documents shall identify appropriate test, inspection, and acceptance criteria for determining acceptability of the item or service.

4.4.2 The Quality Assurance program requirements shall be specified in the procurement documents consistent with the importance and/or complexity of the item or service being procured.

4.5 Procurement documents for commercial grade items or services for use as Safety-Related items contain technical and quality requirements such that the procured item or service can be appropriately dedicated per Section 7.0 of the QAM.

Supporting Procedures – Section 4.0	
Procedure No.	**Procedure Title**
001-561	Standard Tenders
001-577	Customer Contract Review
002-029	Approved Vendor List
002-035	Purchase Order Preparation
8303-112	Vendor Audit/Commercial Grade Survey Procedure
8520-017	CGI Procedure

5.0 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.1 This section establishes the requirements that activities affecting quality are prescribed by and performed in accordance with implementing procedures, instructions, or drawings appropriate to the circumstance where they will be used. These documents shall be available at the locations where the work is performed.

5.2 Instructions, procedures, and drawings shall include quantitative and/or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished and prescribed results attained. These requirements must reflect the customer specifications and Purchase Order (P.O.) requirements. Parts drawings shall include acceptance criteria in the form of tolerances, material description and special notes.

5.3 Activities in instructions, procedures, and drawings shall be described to a level of detail that is based on one or more of the following: the complexity of the task, the need to ensure consistent and acceptable results, the significance of the item, work environment or worker proficiency and capability (education, training, experience).

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

5.5 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
002-300	Control of Manufacturing & Standard Work Documents
095-001	Procedure Document Control
095-022	Engineering Change Order (ECO)
095-037	Design Control

6.0 DOCUMENT CONTROL

6.1 This section establishes the requirements for the control of documents including changes that specify quality requirements or prescribe activities affecting quality.

6.2 Documents shall be controlled to ensure that the correct and applicable documents are available at point of use. Measures shall include the identification of documents to be controlled and their specified distribution; assignment of responsibility for preparing, reviewing, approving, and issuing documents; and review of documents for adequacy, completeness, and correctness prior to approval and issuance.

6.3 Changes to documents shall be reviewed and approved by the same organization that performed the original review and approval unless other organizations are specifically designated. The reviewing organizations shall have access to the pertinent background data or information on which to base their approval.

6.3.1 Minor changes to documents, such as inconsequential editorial corrections, shall not require that the revised documents receive the same review and approval as the original documents.

Supporting Procedures – Section 6.0	
Procedure No.	**Procedure Title**
001-512	Forms Control
002-300	Control of Manufacturing & Standard Work Documents
094-129	Procedure for Controlling Quality Records
095-001	Procedure Document Control

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

7.1 This section lists measures that are established to ensure that all purchased items and services meet specified requirements. These measures include as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, inspection and audit at the source, and examination of items or services upon delivery.

7.2 Vendors are evaluated and selected through the Approved Vendor List Team (AVL).

7.2.1 The AVL Team will maintain the approved vendor list. This list will be updated on at least a monthly basis.

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

7.3 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 may be precluded when safety-related items are:

a. Relatively simple and standard in design, manufacturing and testing.

b. Adaptable to standard or automated inspections or tests of the end product to verify its quality characteristics upon receipt.

7.3.1 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.

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

7.4.1 Incoming material, parts and components are inspected for conformance to P.O., drawing, specification or Job Operation Listing Report, 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.

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

7.4.3 Non Conformance Report (MRR) Form will be issued when incoming materials do not meet requirements.

7.4.4 Acceptance of services only vendors will include any or all the following methods: technical verification of data produced, surveillance and/or audit of the activity, review of objective evidence for conformance to the procurement document requirements.

7.5 Source Materials, components, and services that are procured as commercial grade are dedicated per SOR 8520-017.

Supporting Procedures – Section 7.0	
Procedure No.	**Procedure Title**
002-029	Approved Vendor List
094-036	Incoming Inspection Procedure
094-043	Non Conformance Report
8303-112	Vendor Audit/ Commercial Grade Survey Procedure
8520-017	Commercial Grade Dedication Procedure

8.0 IDENTIFICATION & CONTROL OF MATERIAL, PART & COMPONENTS

8.1 This section identifies measures to ensure that items (materials, parts, and components, including partially fabricated assemblies) are identified and controlled. Controls shall be established to ensure that only correct and accepted items are used, installed, or delivered to the customer.

8.2 To the extent possible, permanent marking and/or tagging will be used where described on P.O., drawings, specifications or Job Operation Listing Report to provide traceability. Where physical identification is either impractical or insufficient, physical separation, procedural control, documentation, or other appropriate means shall be employed.

8.2.1 Identification markings shall be applied using materials and methods that provide a clear and legible identifications and applied in such a manner as not to affect the function or quality of an item.

8.2.2 Material for certain switch parts as specified by the responsible Engineer will be assigned a heat code identification. This code will be marked on the ends of the bars and stamped 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.

8.3 Purchased items shall be receipt inspected and acceptable items shall be identified with Receiving Move Ticket or suitable alternate status indicator. A Non Conformance Report (MRR) Form will be issued when incoming materials do not meet requirements.

8.4 Job Operation Listing Report 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.

8.5 Approved material, parts and components shall not be removed from designated stock area, for fabrication or assembly, without the Job Operation Listing Report or sales order. The identification of these parts shall be maintained throughout entire manufacturing, assembly, testing and final calibration process.

Supporting Procedures – Section 8.0	
Procedure No.	**Procedure Title**
002-035	Purchase Order Preparation
002-269	Controlling Limited Shelf-Life Products
094-036	Incoming Inspection
094-043	Non Conformance Report
097-010	Issuing Heat Codes
8520-059	Procedure for Processing Nuclear Orders

9.0 CONTROL OF SPECIAL PROCESSES

9.1 This section establishes the requirements for the control of special processes such as those used in welding, soldering and nondestructive examination are properly controlled.

9.2 Instructions, procedures, drawings, or travelers for special manufacturing processes shall include or reference procedure, personnel, and equipment qualification requirements necessary to accomplish the process and acceptance criteria.

9.3 Personnel performing special process work will be trained and qualified per applicable procedures issued. Records are maintained as appropriate for the qualified personnel, processes and equipment, and their revalidation, for each special process.

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

9.5 If the QA personnel are not qualified to perform the necessary inspections, verification or NDE the duties will be subcontracted. The subcontracted services shall be controlled in accordance with QAM sections 4.0 and 7.0.

Supporting Procedures – Section 9.0	
Procedure No.	**Procedure Title**
8303-104	Soldering Procedure
8303-117	Approved Personnel List
8520-594	Pressure Sensor Welding Procedure

10.0 INSPECTIONS

10.1 This section describes the inspection of items and activities to verify conformance to requirements and adherence to documented instructions, procedures, and drawings.

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

10.1.2 Inspections are to be performed by qualified persons other than those who performed or directly supervised the activity being inspected.

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

10.3 Inspections are planned and 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 Parts and/or materials are inspected when received against purchase order, specification, Job Operation Listing Report or drawings.

10.5.1 Nonconforming material identified during receipt inspections will be documented on Non Conformance Report (MRR) Form. The material will be segregated and the MRR Form will accompany the nonconforming material.

10.5.2 When parts and/or materials have passed inspection or been released from MRR hold, sign or initial and date purchase order, Job Operation Listing Report and record inspection results.

10.6 Some commercial parts and/or materials may be dedicated for nuclear usage by re-inspection per Job Operation Listing Report. Inspections for dedicated items may include pre, in-process and post inspection examinations.

10.7 The accepted parts and/or materials are routed to Nuclear Stores per purchase order or Job Operation Listing Report. The parts and/or materials then reside under control per Nuclear QA Program 8303-100 when placed in Nuclear Stores.

10.8 In-process inspections are performed at various intervals to detect nonconformance. Records of inspection will be identified on Job Operation Listing Report, assembly drawings, Nuclear Calibration, Testing & Shipping forms, or x-specs.

10.9 Final inspections shall include a records review of the results and resolution of nonconformances identified by prior inspections. 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.

10.9.1 Modifications, repairs or replacement of items performed after final inspection shall require reinspection or retest, as appropriate to verify acceptability.

Supporting Procedures – Section 10.0	
Procedure No.	**Procedure Title**
094-036	Incoming Inspection
094-042	In-Process Inspection Procedure
094-043	Non Conformance Report
8303-109	Qualifications of Inspection, Testing and Audit Personnel
8520-017	Commercial Grade Dedication Procedure
8520-059	Procedure for Processing Nuclear Orders

11.0 TEST CONTROL

11.1 This section establishes the requirements for the control of testing required to verify conformance or to demonstrate satisfactory performance for service. Characteristics to be tested and test methods to be employed are specified. Test results are documented and their conformance with the test requirements and the acceptance criteria are evaluated.

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

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

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

11.5 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.

11.6 Documented test results shall be evaluated and approved by Engineering and QA to ensure that the test requirements have been satisfied. 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
094-155	Control of Software Quality
095-037	Design Control
095-041	Engineering Test Reports
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 This section establishes the requirements for the control of measuring and test equipment (M&TE) used for activities affecting quality.

12.2 Procedure for control of measuring and test equipment used for activities affecting quality shall list location, custodian, manufacturer's serial number and SOR equipment numbers.

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

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

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 Measure and test equipment shall be suitably marked, tagged, labeled or otherwise identified to indicate calibration status and establish traceability to calibration records.

12.7 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.

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 This section outlines the requirements for the control of the handling, storage, packaging, cleaning, shipping, and preservation of items. These activities shall be conducted in accordance with established procedures, work instructions, drawings, specifications, or other pertinent documents to prevent damage, loss and to minimize deterioration.

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

13.3 Approved material will not be removed from controlled designated stock area without Job Operation Listing Report or sales order. Material identification will be maintained throughout the entire manufacturing, assembly and testing process to provide traceability.

13.4 Approved material will not be processed, stored, or shipped without required sales order, Job Operation Listing Report or shipping paper accompanying the material.

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

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

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

Supporting Procedures – Section 13.0	
Procedure No.	**Procedure Title**
002-035	Purchase Order Preparation
002-269	Controlling Limited Shelf-Life Products
8215-636	Cleaning of Nuclear Safety-Related Products
8303-101	Packaging, Shipping and Documentation for Nuclear Safety Related products
8520-059	Procedure for Processing Nuclear Orders

14.0 INSPECTION, TEST & OPERATING STAUS

14.1 This section identifies the requirements to ensure that the inspection, test, and operating status of the items is known and prevents inadvertent installation, use, or operation.

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

14.3 Inspection status of raw materials, vendor parts and/or assemblies, SOR manufactured parts and/or assemblies are recorded on Job Operation Listing Report or purchase order and inspection record.

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

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

14.5 Non Conformance Report (MRR) Form will be issued as required for nonconformance to design drawing, customer specification and/or purchase order.

Supporting Procedures – Section 14.0	
Procedure No.	**Procedure Title**
094-036	Incoming Inspection
094-042	In-Process Inspection Procedure
094-043	Non Conformance Report
8303-117	Approved Personnel List
8520-017	Commercial Grade Dedication Procedure
8520-059	Procedure for Processing Nuclear Orders

15.0 NONCONFORMING MATERIALS, PARTS OR COMPONENTS

15.1 This section identifies the measures for control of items that do not conform to specified requirements to prevent inadvertent installation or use.

15.2 Material and/or parts that do not conform to design drawings, specifications and/or purchase orders are documented per SOR 094-043 Non Conformance Report. Nonconforming material and/or parts are identified, segregated, when practical, and held from production until disposition per SOR 094-043 Non Conformance Report procedure.

15.3 The responsibility and authority for the evaluation and disposition of nonconforming items is defined in implementing procedures.

15.4 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.

15.5 If disposition requires repair/rework, an additional inspection will be performed and documented in accordance with applicable procedures.

15.6 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 MRR per SOR 094-043. The product will not be released for further processing until the MRR authorizes release.

15.7 Non Conformance Reports that apply to nuclear parts are reviewed for a potential Nuclear Regulatory Commission (NRC) 10CFR Part 21 reportable condition.

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

15.9 The RMA process evaluates any material that is returned. The evaluation results will be reviewed, and consideration will be given to determine if a NRC 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	Non Conformance Report
8303-110	Reporting of Potential Deviation for Defect per NRC 10CFR Part 21

16.0 CORRECTIVE ACTION

16.1 This section addresses those aspects of the QA program concerned with the identification, reporting and correction of conditions adverse to quality. In the case of a significant condition adverse to quality, the cause of the condition shall be determined, and corrective action taken to preclude recurrence.

16.2 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 segregated when practical.

16.3 A Nonconformance Report (MRR) with documented reasons for hold and disposition, shall be issued. The condition will be reviewed by qualified personnel to determine if a potential 10CFR Part 21 reportable condition exists and/or corrective or preventative action is warranted.

16.3.1 Corrective and preventive actions shall be recorded on Form 621, Corrective/Preventive Action Report.

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

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

16.5 Corrective action reports that apply to nuclear parts and products are reviewed for potential 10CFR Part 21 reportable conditions.

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

17.0 QUALITY ASSURANCE RECORDS

17.1 This section identifies measures necessary for the collection, storage, and maintenance of QA records. Records which document evidence that items/activities meet specified requirements shall be legible and traceable.

17.2 Records to be generated, supplied, or maintained shall be specified in applicable documents, such as design specifications, procurement documents, test procedures, and operational procedures.

17.3 Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.

17.4 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:

17.4.1 Records that would be significant value in demonstrating capability for safe operation.

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

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

17.4.4 Records that provide required baseline data for in-service inspections.

17.5 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.

17.6 SOR will maintain completed sales order QA records in a single storage consisting of a vault room or container designed to comply with a minimum two-hour fire rating or duplicate records will be kept off premises.

17.7 When temporary storage of records (such as processing, review, or use) is required, the storage facility or container shall provide a one-hour fire rating, unless dual storage requirements are met.

17.8 QA records are maintained per SOR procedure 094-129 Procedure for Controlling Quality Records.

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 The section establishes requirements for verifying compliance to quality assurance program requirements, to verify that performance criteria are met, and to determine the effectiveness of the program.

18.2 Audits are planned and performed in accordance with written procedures or checklists by qualified personnel who do not have direct responsibility for performing the activities being audited.

18.3 Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

18.4 Objective evidence shall be examined to the depth necessary to determine if the elements are effectively implemented.

18.5 Audit results shall be documented and reported to and reviewed by responsible management.

18.6 SOR management or the audited organization or activity shall investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality and notify the appropriate organization in writing of action taken or planned.

18.7 QRB will perform a status report of deficient areas until corrective action is accomplished.

Supporting Procedures – Section 18.0	
Procedure No.	**Procedure Title**
7701-128	Internal Audit Work Instructions
8303-109	Qualifications of Inspection, Testing, and Audit Personnel
8303-112	Vendor Audit/Commercial Grade Survey Procedure
8303-117	Approved Personnel List

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