



# **ELECTRIC MOTOR & CONTRACTING CO., INC.**

## **QUALITY MANUAL**

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**Revision 15**

**September 14, 2020**

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**CONTROL NUMBER**



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## CHANGE RECORD

Rev.	Date	Responsible Person	Description of Change
1	10/27/96	QA Manager	Changed content and terminology of all sections of the quality manual to reflect policy changes and management restructuring.
2	11/4/96	QA Manager	Replaced initial issue date with revision level in the header section. Revised entire Section 11 Revised entire Section 14 Revised entire Section 18
3	8/19/97	QA Manager	Revised terminology in entire manual to reflect policy changes and management restructuring
4	3/2/98	QA Manager	Revised terminology in entire manual to reflect policy changes and management restructuring
5	12/15/98	R Pervere	Completely revised manual to structure it as one document with other changes.
6	4/19/99	R Bryant	Revise organization chart
7	8/2/99	M Raiford	Revise organization chart
8	2/8/00	R Pervere	Remove organization chart
9	10/13/00	R Pervere	Revise to parallel 10CFR50 Appendix B
10	11/22/02	N Willey	Revise to meet ISO9001:2000 requirements
11	5/26/09	N Willey	Removed statements of compliance with NQA-1. Revise Section C to incorporate the company Vision and Mission statements and reflect organizational changes. Updated to reflect current practices and meet ISO9001:2008 requirements. Added section G tables to show correspondence with ISO9001:2008.
12	5/12/14	N Willey	Updated to reflect current practices after five years of operation and growth. Although specific changes are not detailed here, revised paragraphs are marked in the left margin to facilitate review.
13	3/13/15	N Willey	Revised to show compliance with 10CFR50 requirements in this manual vs. lower level procedures. Added statements of compliance to NQA-1 2008 / 2009 Addenda and related requirements. Although specific changes are not detailed here, revised paragraphs are marked in the left margin to facilitate review.



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## CHANGE RECORD (CONTINUED)

Rev.	Date	Responsible Person	Description of Change
14	3/1/18	N Smith	Revise to meet ISO9001:2015 requirements and minor corrections to reflect current practice. Although specific changes are not detailed here, revised paragraphs are marked in the left margin to facilitate review.
15	9/21/20	J Roberts	Revise throughout to reflect safety-related pump equipment. Revise Front Cover and Section A to remove all references to the Courtland Facility. Revise Section 3 to add reference to SOP 84 (new SCADA / PLC procedure) Section 5 add clarification / link to CSA Z299 quality program compliance controls

**Note:**

The current revision of this manual can be verified on EMC website at [www.emc-co.com](http://www.emc-co.com), or by contacting the Quality Assurance Manager by phone at (757) 487-2121 or by fax at (757) 487-5983.



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## A. Introduction

Electric Motor and Contracting Co., Inc. (EMC), founded in 1960 by James L. King Sr. and Jr. is located in Chesapeake, Virginia. Long recognized as a leader in the rebuilding and rewinding of motors and generators, EMC also provides extensive mechanical, predictive maintenance, analysis, testing, precision machining, and on-site manufacturing services. Skilled, experienced, highly trained technicians and engineers are available 24 hours a day for servicing in the field or at our well-equipped facilities.

EMC has always maintained an unequalled commitment to meeting the individual requirements of our customers, across a wide range of products and services. To achieve and continuously improve the level of quality and consistency that our customers have always relied on, EMC has developed and maintains a Quality Assurance (QA) system that assures all processes are performed by trained personnel using well-maintained equipment and controlled procedures. This system has evolved over 5 decades and is designed to meet the requirements of ISO 9001 for commercial workscope and 10CFR50 Appendix B, 10CFR21 and NQA-1-2008 Edition with 2009 Addenda for safety-related workscope.

For safety-related workscope, the following requirements are applicable to the EMC QA Program:

- I. Introduction and Organization
- II. Quality Assurance Program
- III. Design Control (with specified limitations)
- IV. Procurement Document Control
- V. Instructions, Procedures, and Drawings
- VI. Document Control
- VII. Control of Purchased Material, Equipment and Services
- VIII. Identification and Control of Materials, Parts, and Components
- IX. Control of Special Processes
- X. Inspection
- XI. Test Control
- XII. Control of Measuring and Test Equipment
- XIII. Handling, Storage, and Shipping
- XIV. Inspection, Test, and Operating Status
- XV. Nonconforming Materials, Parts, or Components
- XVI. Corrective Action
- XVII. Quality Assurance Records
- XVIII. Audits

In addition, the following NQA-1-2008 Edition with 2009 Addendum Part II, Subparts are applicable:

- 2.2, Packaging, Shipping, Receiving, Storage and Handling
- 2.7, Computer Software
- 2.8, Installation, Inspection and Testing of Mechanical Equipment and Systems for Nuclear Power Plants (where invoked / applicable to support on-site services)
- 2.14, Commercial Grade Items and Services
- 2.16, Calibration and Control of M&TE used in Nuclear Facilities (where invoked / applicable to support on-site services).



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## B. Scope

This manual is EMC's top-level policy document, which identifies and defines the requirements for the Quality Assurance System. The manual demonstrates our commitment to provide the required level of quality in all areas of operation and references Quality Operating Procedures and other operating programs or documents that describe in detail how each of the activities are performed.

## C. Vision & Mission Statements

### Vision Statement:

The vision for Electric Motor and Contracting Co., Inc. is to be recognized as the nationwide leader in providing high quality, high value services to the users of rotating electrical and mechanical equipment.

### Mission Statement:

The mission for Electric Motor and Contracting Co., Inc. is to provide high quality repair services and new products to our customers, so that they can operate in a reliable manner and maximize their productivity and profitability.

### Our primary repair services include:

*Electric motor repair*

*Pump repair*

*Radiologically contaminated motor repair, including RCP motors*

*Switchgear refurbishment and calibration*

*Field service support*

### Our primary new sales products are:

*Electric motors*

*Motor controls*

*Variable frequency drives*

### Our primary customer base includes:

*Heavy industry, including Steel and Chemical*

*Nuclear Power*

*Power Generation*

*Pulp and Paper*

*U.S. Government and Ship Repair Industry*

*Waste Water Treatment*



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## Our core values are:

- *To earn the respect and loyalty of our customers through exceptional service and value.*
- *To consistently exceed customer quality, reliability and service requirements.*
- *To provide a safe, healthy, challenging and rewarding environment for all our employees.*
- *To maintain a professional workplace built around integrity, honesty, trustworthiness, reliability and dedication.*
- *To create innovative solutions for our customers through enthusiastic, energetic, customer-focused and talented people.*
- *To maintain an environment of continuous improvement in all that we do.*

## D. Quality Policy

EMC's Quality Policy is embodied in the company's Vision and Mission statements and Core Values.

## E. Quality System Requirements

The first 18 paragraphs of this manual are organized in content, and numbered, to coincide with the Quality Assurance Requirements of 10CFR50 Appendix B and NQA-1 including most of the related requirements of ISO 9001. Additional requirements, including the remaining elements of ISO 9001 are addressed starting at paragraph 19.

Each paragraph identifies the related Quality Operating Procedure (QOP).

## F. Review and Approval

This manual and the included Vision, Mission and Core Values statements incorporating the Quality Policy have been reviewed and approved by the undersigned. They will be reviewed as a minimum every two years and/or revised as necessary, to reflect changes in quality system and customer requirements.

Quality Assurance Manager

Vice President

President

The image shows two handwritten signatures. The first signature is written over a horizontal line and appears to be 'J. R. [unclear]'. The second signature is written over another horizontal line and appears to be 'Stephen [unclear]'. The signatures are in black ink and are somewhat stylized.





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## 1 ORGANIZATION

### Quality Operating Procedure QOP 01, Organization

Top Management is ultimately responsible for establishing, implementing, maintaining, and continuously improving the quality system. Key responsibilities include:

- *taking accountability for the effectiveness of the quality system*
- *defining and documenting a quality policy*
- *establishing and reviewing measurable quality objectives consistent with the policy*
- *determining the internal and external issues that are relevant to the strategic direction and identifying interested parties*
- *assessing risk and taking appropriate action*
- *developing integrated processes that address risks and maximize opportunities to meet customer expectations*
- *defining the organizational structure*
- *assigning authorities and responsibilities*
- *communicating the importance of meeting customer, as well as statutory, regulatory, and legal requirements*
- *periodically reviewing the effectiveness of the quality system against the strategy, policy and objectives*
- *making available the resources, infrastructure, work environment, support services and trained personnel necessary to maintain the system and achieve the required product or service.*

Quality achievement is the responsibility of every employee. However, EMC's organizational structure assures:

- *personnel responsible for the effective execution of the quality assurance program have direct access to levels of management as necessary to perform their function*
- *personnel managing, performing or verifying work affecting quality have clearly defined responsibilities, authority and reporting independence*
- *verification of quality achievement is performed by personnel not directly responsible for performing the work.*

EMC organizational charts demonstrate the structure to assure that quality verification is performed by personnel with the freedom and authority to:

- *initiate action to prevent product, process, and quality system non-conformities*
- *identify and record product, process, and quality system problems*
- *initiate, recommend, or provide solutions through designated channels*





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- *verify the implementation of solutions*
- *control further processing, delivery, or installation of non-conforming product until the deficiency or unsatisfactory condition has been corrected.*

EMC has a dedicated team of Quality Control (QC) inspectors, who report to the Quality Assurance (QA) Manager. The QA Manager reports directly to the President.

Quality Operating Procedure QOP 01, Organization, describes the responsibilities of top management to establish, implement, maintain and continuously improve the quality system. It outlines the functional responsibility for key quality program elements and the specific duties for provision of training and oversight of nuclear safety-related activities in accordance with 10CFR50 Appendix B, NQA-1 and 10CFR21.

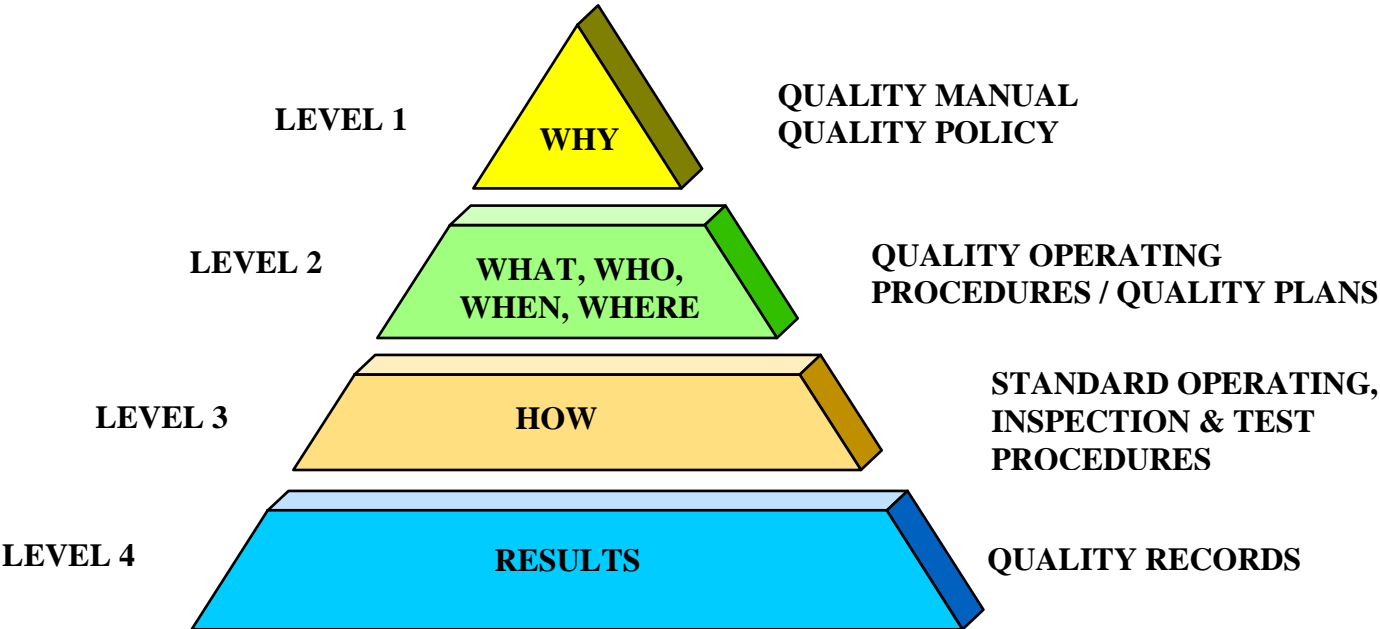
## 2 QUALITY ASSURANCE PROGRAM

Quality Operating Procedure QOP 02, Quality Assurance Program

EMC maintains a documented quality management system designed and implemented to fulfill the requirements of the latest or stated revision of 10CFR50 Appendix B, NQA-1 and ISO 9001. This system identifies required inputs and outputs for key processes and verification activities commensurate with risks, thus providing our customers assurance that products and services are processed in a planned and controlled environment.

*Note: Where a customer has unique requirements (e.g. Canadian Standards Association (CSA) N299 compliant quality program), an EMC Quality Assurance Plan (QAP) may be generated to address any gaps in the existing program. In the absence of a QAP, the Company's 10 CFR 50 Appendix B quality program may be used to provide QA oversight and assure additional quality requirements are met.*

The structure of the quality system documentation is four-tiered as shown in the following figure:





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The quality system documents collectively define a controlled quality system that:

- *provides control over activities affecting quality to an extent consistent with their risk and / or criticality*
- *assures activities affecting quality are performed under suitably controlled conditions*
- *establishes processes to detect and correct quality problems*
- *provides for indoctrination, training and qualification of personnel performing or managing quality activities, including NDE, welding, inspection, test and audit personnel*
- *defines any site or scope related clarifications and/or exceptions*
- *defines any different or additional requirements for performance of nuclear safety-related activities*
- *defines the interaction with other, separately controlled EMC programs such as Safety and Radiological Control*
- *provides records to evidence conformance with requirements and effective quality system operation.*

Top management identifies and supplies the resources needed to assure continued compliance with Quality System requirements including:

- *training at all levels of the organization*
- *suitable infrastructure and work environment, support and communication systems*
- *suitable manufacturing, test and inspection equipment*
- *on-going assessment and evaluation of product and service quality*
- *on-going monitoring and evaluation of vendors*

### **3 DESIGN CONTROL**

Quality Operating Procedure QOP 03, Design Control

EMC is only involved in the repair and refurbishment of other manufacturer's items. Design activities at EMC presently consist of redesign or product enhancement as requested by the customer. Since EMC is not the Original Equipment Manufacturer (OEM), or responsible for design changes, traditional design interfaces are not implemented. EMC customers are responsible for any design changes, thus EMC maintains close communications with customer contacts when jobs are in-process and design changes must have customer input and approval prior to implementation.



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*Activities are planned, executed, and verified under controlled conditions to assure that customer requirements are met, including:*

- *planning to assure the availability of adequate resources including qualified personnel*
- *frequent communication between departments involved in the redesign activity*
- *well-documented design input criteria, including data received from the customer and any associated risks identified*
- *definition and review of design output requirements prior to design release*
- *verification and validation activities that assure requirements are met, including where this can only be performed after the product is in use*
- *procedures that assure changes to the design are approved.*

For safety-related equipment repairs, the primary configuration control tool is the Disposition and Authorization Request (DAR), which captures design discrepancies noted during initial inspection and provides a resolution for customer review and authorization. DAR processes are documented in Standard Operation Procedure (SOP) 74 'Disposition and Authorization Request Guidelines'. These guidelines include responsibilities, departmental interfaces, safety classification, evaluation of replacement parts and materials and verification that the customer-authorized scope is accomplished.

The configuration control processes used to implement DAR requirements for equivalency evaluation, modifications or upgrades, or replacement of parts are documented in Engineering Standard, ES-1100 'Equivalency Evaluation and Configuration Control'. These include process inputs, outputs, interfaces, reviews, verification and validation.

Customers may also authorize standard modifications and enhancements in contract documents and related specifications. Where this is the case, EMC obtains approval of the implementing procedures, methods, drawings, parts, materials, qualified personnel and acceptance criteria as required by the contract documents.

Software design at EMC is restricted to:

- An existing Supervisory Control and Data Acquisition (SCADA) system designed and developed 15 years ago, used to control and monitor the Vacuum Pressure Impregnation (VPI) system, bake and burn out ovens. Standard Operating Procedure (SOP) 75 'Control of Non-Safety Related Computer Programs used for Safety Related Jobs', includes establishment of an initial software baseline and the change control process including review, verification and validation. This procedure also documents the process for commercial off the shelf (COTS) software utilized to support engineering activities and Nanodac stand-alone process controllers.
- Controls for integration of a replacement SCADA system IAW SOP 84 'Development and Testing of Non-Safety Related SCADA/PLC Systems used on Safety-Related Jobs'.



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## 4 PROCUREMENT DOCUMENT CONTROL

Quality Operating Procedure QOP 04, Procurement Document Control

Procurement documents are reviewed and approved prior to release to ensure that they clearly describe ordered products, including technical and quality requirements. Procurement documents, and changes, are released under controlled conditions that assure they:

- *clearly describe the product or service ordered*
- *reference appropriate drawings, specifications, codes, standards, regulations and procedures*
- *have the required information and controls to ensure that purchased products and outsourced processes meet EMC and customer requirements*
- *specify quality assurance program requirements, including flow down of relevant customer contract terms and conditions*
- *provide for access to the supplier's facility, as necessary for surveillance, inspection, or audit.*

## 5 INSTRUCTIONS, PROCEDURES AND DRAWINGS

Quality Operating Procedure QOP 05, Instructions, Procedures, and Drawings

Instructions, procedures and drawings are utilized for activities affecting quality. These documents are appropriate to the complexity of the task and proficiency and capabilities of personnel. They include appropriate acceptance criteria and evidence of satisfactory accomplishment of requirements. EMC documents include:

- *Quality Operating Procedures (QOP)*
- *Quality Assurance Plans (QAP)*
- *Standard Operating Procedures (SOP)*
- *Standard Test Procedures (STP)*
- *Standard Inspection Procedures (SIP)*
- *Standardized Job Cards for consistent data capture*
- *Job-Specific Production Plans (travelers)*
- *Pump Repair Replacement Plans (PRRP) Will be the main document in SR pump repair*
- *Controlled and / or Job-Specific drawings*



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EMC determines the knowledge necessary for the operation of its quality system processes in order to achieve product and service conformity and disseminates for effective implementation, including:

## Internal:

- *Capture of detailed task requirements in standard inspection, test and operating procedures*
- *Process to capture and implement 'Customer Special Requirements'*
- *Compilation of shop practices and knowledge (e.g. SOP 59 'Large Motor Assembly 'Lessons Learned')*

## External:

- *Electronic copies of applicable industry standards on the EMC server*
- *Electronic copies of customer specifications on the EMC server*
- *Attendance at industry conferences and training (NUPIC, NRC, EPRI, LEMUG etc.)*

The QA Public Drive on the EMC server is maintained to provide wide access to controlled documents, specifications and standards. Other drives are maintained to provide specific information (e.g. HR-Docs).

Controlled customer specifications and drawings are issued for use and where necessary Job, Customer or Safety-Related specific procedures may be generated to document differences from EMC standard processes.

A Production Plan is generated for each job defining the work scope and providing a top-level record of the work performed, also any verification, witness or hold points.

Different or additional requirements for nuclear safety-related activities are identified in the relevant procedure, or addressed in the Production Plan.

## **6 DOCUMENT CONTROL**

### Quality Operating Procedure QOP 06, Document Control

Documents generated within EMC and those received from customers are controlled by Quality Assurance to ensure that only authorized versions are used to process product. Documents are available at locations where they are needed, and obsolete documents are removed or identified as superseded.

Procedures are established and maintained to control and provide adequate protection for documents and data, including documents of external origin such as standards, customer specifications and drawings:

- *document details including title and revision are recorded in a database*
- *quality system documents, including revisions, are reviewed for adequacy and approved by authorized personnel prior to issue*
- *approved documents are made readily available on a protected 'read-only' drive and also issued for use at the location where the work or activity is being performed where required*



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- *reports are posted in central locations that clearly identify the latest revision of documents to preclude use of obsolete documents*
- *applicable documents are identified as 'Proprietary' before issue externally*
- *obsolete documents are removed from point of use and destroyed; any obsolete documents retained for legal or historical purposes are suitably identified*
- *changes to documents can be initiated by any employee in the organization but they must be authorized by the function that performed the original review*
- *review and approval of revised documents is consistent with that of newly issued documents*
- *records are maintained of external controlled copyholders (e.g. customers); controls include written notification with provision of revised documents.*

## 7 CONTROL OF PURCHASED ITEMS AND SERVICES

Quality Operating Procedure QOP 07, Control of Purchased Items and Services

EMC only purchases from those suppliers that satisfy the company's quality requirements. Supplier quality performance is an ongoing process and is monitored continuously by purchasing and quality management.

Suppliers are selected based on one or more of the following:

- *their ability to meet contract and quality requirements as determined by quality audits or surveys*
- *their certified or evaluated quality program*
- *on-site assessment of their technical and quality capability*
- *proven performance during an initial evaluation period*
- *historical performance in providing identical or similar product.*

**Note: If a calibration laboratory has current accreditation to ISO 17025 from ILAC-MRA signatories, this may be acceptable in lieu of an on-site survey utilizing the guidance of NEI 14-05A. NIST services are also exempted from on-site evaluation.**

EMC's Quality Assurance Department maintains a list of approved suppliers and re-evaluates and updates the list as needed.

EMC verifies the conformance of purchased products and services. This may be accomplished at the supplier's site, at EMC receiving inspection, through a Certificate of Conformance and/or through upper level testing. EMC also implements a Suspect / Counterfeit Item (SC/I) Prevention and Detection Program, which begins with selection of suppliers and is maintained throughout the repair process.

Supplier quality performance is evaluated on an ongoing basis through review of Material Rejection Reports (MRR). Action is taken as necessary where there is evidence of lack of effective control of quality, whether a significant failure or repeated minor incidents. Safety-Related supplier quality performance is evaluated annually and records are maintained of this evaluation.



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When required by contract, our customers are provided the right to verify the product manufactured and the condition under which it is manufactured at the supplier's site. This verification does not absolve EMC of the responsibility to provide acceptable products.

## 8 IDENTIFICATION AND CONTROL OF ITEMS

Quality Operating Procedure QOP 08, Identification and Control of Items

Documented procedures are maintained to assure that product, including job-related material, and job cards or other shop travelers are identified with a unique Job Number to assure proper identification and traceability throughout the production cycle.

Procedures for identification and control of materials, parts, components and products ensure that:

- *equipment, material and documentation are identified with the unique job number*
- *related job data and job cards provide traceability to nameplate data including serial number*
- *items can be related, at all stages of processing, to the applicable order or contract*
- *only correct and acceptable items or materials are used in fulfilling customer requirements*
- *processes for traceability are utilized where required (example: 10CFR21 material traceability)*
- *methods exist to identify, segregate, and disposition non-conforming items, and to remove such items from storage or manufacture.*

## 9 CONTROL OF SPECIAL PROCESSES

Quality Operating Procedure QOP 09, Control of Special Processes

Special processes are those that control or verify quality where the resulting product cannot be verified by subsequent monitoring or measurement. These processes are controlled to ensure that specified requirements are met, including qualified personnel; a suitable work environment; the correct, properly maintained equipment and qualified procedures.

Typical special processes utilized during repair include Welding, Vacuum Pressure Impregnation (VPI), Service Level 1 (SL1) Coatings and coating inspection, and Non-Destructive Examination (NDE).

Specifically, safety-related welding, heat treatment and weld-related NDE will be controlled in accordance with EMC Nuclear Welding Program. This program may also be utilized for commercial welding.

**EMC also has a separate radiation protection program licensed by the Virginia Department of Health (VDH).**

Procedures are established and maintained to ensure:

- *all processes are identified, planned, and conducted under controlled conditions*
- *processes are designed to comply with reference standards, codes, quality plans, and/or documented procedures*





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- *suitable equipment and environmental conditions are maintained*
- *process monitoring or verification points are identified with acceptance criteria*
- *personnel are qualified and reviewed periodically*
- *appropriate records are maintained for all qualified processes, equipment and personnel.*

## 10 INSPECTION

### Quality Operating Procedure QOP 10, Inspection

Inspection and testing is conducted to verify that product conforms to quality system or contractual requirements. Inspection and testing is performed on product at preplanned points from the time it is received through designated in-process stages, and prior to release of the product to the customer.

As EMC provides equipment repair services, it is expected that customer equipment be received with potential out of tolerance conditions. During the receipt inspection, disassembly and detailed component inspection phases, results that fall outside of Acceptance Criteria are typically evaluated by the Production personnel and included in the condition report to the customer. Independent inspection and identification of discrepancies as nonconforming items are therefore applicable during the repair and acceptance phase of the process.

Controlled conditions include:

- *standard operating procedures outline the verification process used to ensure that specified requirements for products are met*
- *written inspection procedures incorporate or reference prerequisites and acceptance criteria*
- *where required by contract, specified hold points are identified, either in the production plan or in a job-specific procedure*
- *when inspection requires measuring or testing, only calibrated equipment is used for acceptance tests*
- *statistical techniques are employed when sampling product received from suppliers or during inspection and test where directed by the QA Manager*
- *verification of quality achievement is performed by personnel not directly responsible for performing the work.*
- *errors and nonconforming material are reported and processed in accordance with QOP15. Items are identified as nonconforming and segregated until proper disposition is made*
- *all required inspections and tests are completed, documented, and authorized prior to shipment of products to customer and the release authority clearly identified.*



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## 11 TEST CONTROL

Quality Operating Procedure QOP 11, Test Control

All acceptance testing of product is performed in accordance with approved test procedures with clearly defined acceptance criteria. Test results are documented and evaluated for conformance with the given criteria. Controlled conditions include:

- *standard operating procedures outline the verification process used to ensure that specified requirements for products are met*
- *written test procedures incorporate or reference prerequisites and acceptance criteria*
- *testing is performed by trained personnel only*
- *all acceptance testing is done using the calibrated test equipment prescribed in the test procedure*
- *when prerequisites and environmental conditions are a factor, they will be included in the test procedure and verified prior to testing*
- *items that fail to meet test criteria are reported and processed using the nonconforming product procedures of QOP 15. Items are identified and/or segregated until proper disposition is made.*

## 12 CONTROL OF MEASURING AND TEST EQUIPMENT

Quality Operating Procedure QOP 12, Control of Measuring and Test Equipment

Inspection, measuring and test equipment used to demonstrate conformance to specified requirements is controlled, calibrated and maintained to ensure accurate measurements of the prescribed parameters.

Controls are established to maintain the integrity of equipment used in inspection, measuring, and testing of products. EMC uses external laboratory services for the majority of calibration and requires them to:

- *calibrate to within OEM recommendations, industry standard procedures or as specified by contract*
- *calibrate against measurement standards traceable to NIST or other nationally or internationally recognized standards or intrinsic standards.*

**Note: ISO 17025 Laboratories accredited by NVLAP or ILAC-MRA signatories: The Certificate of Calibration shall be an accredited, endorsed certificate and include the Accrediting Body's logo and / or the authorized certificate number.**

Internal calibration is conducted in accordance with documented procedures and only where EMC has equipment of sufficient accuracy that has been calibrated as above.

Procedures are in place to ensure:

- *all devices used for verification of quality are the appropriate type and accuracy*
- *inspection, measuring and test equipment is recorded in a database maintained by Quality Assurance*



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- *documentation for equipment calibration includes details of equipment type, identification number, location, frequency of checks, and acceptance criteria*
- *calibration intervals are established on the basis of stability, purpose, and usage*
- *equipment is recalled for calibration*
- *indicators, such as stickers and labels, identify calibration status and any limitations to usage*
- *safeguards are in place to prevent adjustments that would invalidate the calibration settings of inspection, measurement, and test equipment*
- *records of calibration, including test data for the As Received accuracy on any equipment found out of tolerance, are maintained and are traceable to the calibration supplier*
- *equipment found damaged or out-of-calibration (e.g. previously reported as lost) is evaluated and appropriate action taken*
- *when equipment is found to be out-of-tolerance, either during use or at calibration, the validity of previous inspection and test results and impact on customer product is assessed for potential risks and documented, including the requirement to contact affected customers, if applicable*
- *computer programs utilized by Original Equipment Manufacturer (OEM) measuring and test equipment are verified as providing the required performance over the range of operations during calibration.*
- *where the above equipment is used for safety-related testing, calibration of critical equipment is performed annually by the OEM on site at EMC. Surveillance is performed during the calibration, including verifying that the software correctly processes known inputs. The software version is recorded and installation of a new version is coordinated with the next annual calibration, so that it is similarly verified. Where possible, a test performed prior to installation is repeated for consistency of results.*

**Note: If commercial devices such as rulers, tape measures, levels, etc. provide the required accuracy they are not calibrated and controlled.**

## 13 HANDLING, STORAGE AND SHIPPING

### Quality Operating Procedure QOP 13, Handling, Storage and Shipping

Procedures are established that cover the minimum requirements for handling product to prevent damage or deterioration during all phases of production, from initial receipt of material through delivery to the customer, and including periods of storage.

Procedures are in place to ensure:

- *handling, storage, packaging, preservation, and delivery of all materials is controlled*
- *fork lift and crane operators are trained in the proper use of the equipment prior to handling product*
- *materials are handled in such a way as to prevent damage*



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- *materials are stored in a manner that will prevent damage, deterioration, or loss of identification*
- *any limited shelf-life materials are age-identified and discarded at the end of their useful life*
- *stock is periodically reviewed to detect any possible deterioration*
- *each shipment is checked for correct marking/labeling, and for required packing/packaging*
- *packaging is suitable for the material being shipped and the method of transportation.*
- *long-term storage of customer equipment is in an environmentally controlled custom facility and includes periodic maintenance activities as required by contract.*

**Note: EMC does not consider any items provided by suppliers as ‘property belonging to external providers’ or ‘under consignment’. All items are shown on EMC inventory and handled as EMC stock. See section 24 for specific measures for customer property.**

## 14 INSPECTION TEST AND OPERATING STATUS

Quality Operating Procedure QOP 14, Inspection, Test and Operating Status

EMC has established a documented system for identifying the inspection and test status of product through all phases of production, to ensure that only products that have passed the required inspection and testing are released to the next phase or delivered to the customer. This system includes job cards and other controlled shop travelers that clearly indicate the conformance or nonconformance of product and the authority responsible for the release of product.

EMC monitors and controls the inspection and test status of:

- *received raw materials*
- *work-in process*
- *finished products.*

The inspection and test status of a product is identified using:

- *authorized signatures or stamps*
- *tags or labels*
- *job cards, production plans and inspection records.*

Nonconforming products are segregated by distinctive markings, and by location when practical.

Test and inspection status markings and production records identify the authority responsible for the release of materials to production areas, to the next intermediate work-in-process operation, or for shipment to customers.

Items that do not meet the specified requirements cannot be released for use or shipment.



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## 15 CONTROL OF NONCONFORMING ITEMS

Quality Operating Procedure QOP 15, Control of Nonconforming Items

As EMC provides equipment repair services, it is expected that customer equipment be received with potential out of tolerance conditions. During the receipt inspection, disassembly and detailed component inspection phases, results that fall outside of Acceptance Criteria are typically evaluated by the Production personnel and included in the condition report to the customer. Nonconforming items are therefore where EMC or EMC's supplier has failed to meet acceptance criteria during the repair and acceptance phase of the process.

Product found to be nonconforming is prevented from unintended use through the process of identification, segregation (if practical), documentation, and controlled evaluation procedures. Evaluation procedures define the authority responsible for the review and disposition of the nonconforming product and possible dispositions.

Controls include:

- *nonconforming product is tagged, evaluated, segregated (if practical), and disposition made.*
- *employees are empowered to stop manufacture and/or shipment of product found not to meet specified requirements or established quality standards.*
- *responsibility for the review, method for review, authority for disposition and possible dispositions are defined, including 10 CFR21 safety-related defect reporting.*
- *repaired or reworked product is re-inspected prior to release for use or shipment in accordance with the original acceptance criteria, unless alternate criteria is part of the disposition.*
- *where the nonconformity cannot be resolved and affects the customer contract or specification, the customer is included in the disposition decision.*
- *causes of material nonconformance are investigated in a timely manner and corrective actions resulting from nonconformance are reviewed to determine their effectiveness.*

## 16 CORRECTIVE AND PREVENTIVE ACTION

Quality Operating Procedure QOP 16, Corrective and Preventive Action

Procedures are established and maintained to log and evaluate product and quality system nonconformities and potential nonconformities; to determine their cause, implement actions and verify the effectiveness of actions taken. Procedures also describe evaluation of risk and actions associated with realization of opportunities.

Clarifications are made as follows:

- *Corrective action shall be taken to eliminate the causes of existing non-conformances to prevent recurrence.*
- *Preventive action may be taken to eliminate the causes of potential non-conformances to prevent their occurrence.*



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- *A nonconformance may be identified as a **significant condition adverse to quality** that requires further investigation and corrective action.*
- *A significant condition adverse to quality is where the **risks** (consequences and / or likelihood of a repeat occurrence) are judged to be high.*
- *Risk is also associated with **opportunity**, requiring planned actions to achieve defined goals and evaluation for impact on existing processes and practices.*

The extent of investigation and action taken is to a degree appropriate to the magnitude of the problem or opportunity and the possible risks encountered.

Corrective Action: Internal Corrective Action Requests (ICAR) and Supplier Corrective Action Requests (SCAR) are generated for existing non-conformances identified as significant conditions adverse to quality. These document cause determination, extent of conditions, implementation of corrective actions, and verification of their effectiveness.

Preventive Action: Internal Preventive Action Requests (IPAR) are generated to document the cause of potential nonconformances, implementation of preventive action to minimize risk and follow up.

Quality assurance is responsible for the follow-up of corrective or preventive actions to ensure that actions were effective. When action requests are not addressed in a timely manner, the Quality Assurance Manager will take action as prescribed in the procedures.

Changes in the planned processes and documented procedures resulting from corrective and preventive action or realization of opportunities are implemented and recorded in the document control system.

Causes of significant conditions adverse to quality and corrective actions taken are included in management review of the quality program.

## 17 QUALITY ASSURANCE RECORDS

Quality Operating Procedure QOP 17, Quality Assurance Records

Quality records used to demonstrate product conformance to contract requirements and effective operation of the quality system are maintained for specified time periods in an environment that will prevent damage or deterioration. These records are readily accessible to provide objective quality evidence to customers and auditors when required.

Procedures are in place to ensure:

- *required quality records are identified in the relevant procedure or work instruction*
- *records include relevant qualifications of personnel, procedures and equipment*
- *inspection and test records items identify the inspector or data recorder, the type of observation, the results, the acceptability and action taken for identified deficiencies, as applicable to the repair phase.*
- *all records are legible and identifiable to their area of concern and are stored in a protected and retrievable manner*



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- *records will be maintained per established retention times, or as required by the customer*
- *discrepant records will be processed as a nonconformance in accordance with documented procedures*
- *electronic records are preserved by storage on a company server, with regular back-up, including storage of data copies and retrieval methods in case of equipment or software failure.*

## 18 AUDITS

Quality Operating Procedure QOP 18, Audits and QOP 18A, External Audits and Commercial Grade Surveys (CGS).

Quality audits are planned and implemented to verify compliance with established procedures and to evaluate the effectiveness of the quality system. The audits are conducted by qualified independent personnel, who record objective evidence of compliance with the planned processes, review results with responsible personnel and report audit results. Where appropriate, corrective and preventive actions are identified and processed in accordance with QOP 16, Corrective and Preventive Action.

Controlled conditions ensure:

- *QA program elements are audited at least once each calendar year*
- *audits are scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity. Scheduled audits are supplemented by additional audits of specific subjects when necessary to provide adequate coverage.*
- *the schedule may be adjusted to give attention to potential problem areas, to be performed after significant changes in practice in an area, or where there is limited activity being performed.*
- *audits are conducted in accordance with documented procedures, by qualified personnel, independent of the activity being audited*
- *audits utilize either a checklist or the specific procedure for the activity being audited*
- *corrective and preventive actions address areas of concern discovered during an audit*
- *follow-up for implementation and effectiveness is performed in a timely manner consistent with the scope of the action to be taken*
- *internal audit results are reported to management following each audit. All audit results are reported for the Management Review process.*

## 19 TRAINING

Quality Operating Procedure QOP 19, Training

Training is provided for all employees performing activities affecting conformity to product requirements to achieve initial competency, maintain competency and adapt to changes in processes, procedures and job responsibilities. Procedures are established and maintained to ensure:





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- *employees receive appropriate indoctrination on topics such as:*
  - *safety*
  - *quality assurance indoctrination*
  - *reporting requirements of 10 CFR Part 21*
  - *quality assurance requirements of 10CFR50 Appendix B*
  - *radiological awareness*
- *initial and ongoing training needs are identified and actions taken to fulfill these needs*
- *employees are assigned specific tasks on the basis of appropriate education, training, skills and experience as required in their job description*
- *all training is recorded including tests and other evaluations of competence*
- *individual employee training reviews are conducted on an annual basis*
- *training schedules are developed and implemented.*

## 20 QUALIFICATION OF INSPECTION AND TEST PERSONNEL (SAFETY-RELATED)

Quality Operating Procedure QOP 20, Qualification of Inspection and Test Personnel (Safety-Related)

All personnel accepting the results of nuclear safety-related inspection and test will meet the education, experience, and qualification criteria described in QOP 20.

Personnel performing inspection and test on nuclear safety-related equipment will in addition have a record of Inspection & Test Personnel Qualification in accordance with the non-mandatory guidelines of NQA-1 or statement of qualification appropriate to the work being performed. Qualification will be re-evaluated annually for Level 1, 2 and 3 inspectors.

**Note: See also section 9 Control of Special Processes (SL1 Coating & NDE inspection).**

## 21 QUALIFICATION OF AUDITORS

Quality Operating Procedure QOP 21, Qualification of Auditors

Lead Auditors and Auditors will be trained, certified and evaluated. Auditors perform internal quality audits under the supervision and guidance of a lead auditor. Technical Specialists provide specific knowledge or expertise to the audit team.

Lead auditors organize and direct internal quality audits, evaluate and report on results, initiate corrective action and perform follow-up activity as needed to verify implementation. Lead auditors with appropriate qualification requirements may also survey and audit suppliers.

Prior to auditing, all auditors must demonstrate or have records that demonstrate their knowledge, comprehension and formal training on:

- *10CFR50 Appendix B, 10CFR21 and / or ISO 9001 as relevant to the scope of the audit*
- *EMC documented quality system (internal audits only)*



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- *Audit techniques and reporting.*

Auditor performance is monitored and reviewed by the Lead Auditor at regular intervals and prior to evaluation. Lead Auditor performance is reviewed annually by the President. Lead Auditors who fail to maintain their proficiency are re-qualified.

External audits or commercial grade surveys of suppliers who provide safety-related products or services may be contracted to a supplier with an audited 10CFR50 Appendix B compliant system approved for these services. Contract auditor performance is reviewed annually by the Quality Assurance Manager.

## 22 SERVICING

Quality Operating Procedure QOP 22, Servicing

In-house and field service operations offered to the EMC's customers comply with all relevant procedures of the quality system, including verification requirements.

Documented procedures to control servicing operations are established and maintained.

Services provided are:

- *product support after sale of new items*
- *service at the request of a customer*
- *technical assistance*
- *'after hours emergencies' message and service with 'on call' supervisors phone number*
- *warranty repair of previous jobs*

Conditions for servicing provided by an EMC supplier shall be defined prior to use of services.

When entering into a customer service agreement, conditions for servicing shall be defined.

## 23 CONTRACT REVIEW

Quality Operating Procedure QOP 23, Contract Review

Contracts and purchase orders are reviewed to ensure that customer requirements are adequately defined and that EMC has the resources to meet the requirements. Differences between quotes and the contract or purchase order are identified and promptly resolved prior to job commencement.

Prior to the submission of a quote or the acceptance of an order or contract, the order or contract is reviewed to ensure that:

- *customer requirements are adequately defined and documented*
- *any requirements that differ from those in the contract are resolved*
- *capabilities to meet the contractual requirements exist including:*
  - *quality resource requirements*



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- 
- *work instructions*
  - *inspection/test procedures*
  - *drawings/specifications*
  - *unique resources or processes*
  - *statutory & regulatory requirements*
  - *any other requirements necessary for intended use, where this is known.*

Differences between customer requirements tendered and company specifications are understood before acceptance and any resolutions and agreements are documented. Any limitations to or exclusions from EMC's normal scope of processes and activities are established with the customer and defined in the Production Plan.

Each order is assigned to a Production or Project Manager who is responsible for communication with the customer regarding progress, technical questions, nonconformance disposition and recording customer feedback. Customer feedback may also be received from any other employee in communication with the customer (e.g. sales, site personnel and management).

Order or contract amendments are made by revision to the existing order and communicated to the departments concerned within the organization in the same manner as contract review.

## 24 CUSTOMER PROPERTY

### Quality Operating Procedure QOP 24, Customer Property

Procedures for the verification, storage and maintenance of material or equipment supplied by the customer for use in a repair or service are maintained. When specified in the contract or job order these procedures will include customer required special handling instructions. Any loss or damage to customer property is promptly reported to the customer.

Customer property is:

- *inspected upon receipt*
- *identified as customer supplied and logged*
- *stored or handled to prevent damage or deterioration.*
- *customer property received in a non-conforming or damaged condition is:*
  - *tagged as nonconforming*
  - *segregated to prevent its use*
  - *reported to the customer.*

In the event of loss, damage, deterioration or unsuitability of customer property, the customer is immediately notified.

**Note: See section 6 Document Control for customer-supplied documents.**



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## **25 MEASUREMENT, ANALYSIS AND IMPROVEMENT**

Quality Operating Procedure QOP 25, Measurement, Analysis and Improvement

In order to measure the performance of the quality management system and drive continual improvement, EMC monitors and collects data on customer satisfaction, audit results, nonconformance and rework, supplier performance, causes of significant conditions adverse to quality and corrective actions taken and other relevant information.

Management meets annually to review the collected data for the prior calendar year and identify problems, trends, risks and opportunities, and areas for continual improvement. Possible solutions proposed during the meeting are assigned as actions to appropriate managers and handled as an IPAR in accordance with QOP 16. Completion of actions and effectiveness is reported and evaluated at the next meeting.

In addition, management meets on a scheduled basis to review interim progress towards existing goals and objectives and discuss any emergent risks and opportunities. Actions are documented and assigned to relevant managers for resolution and status of actions evaluated at the next meeting.

Management defines priorities and measurable objectives to achieve the company's Vision and Mission goals, including continuous improvement. Objectives are published and flowed down to staff. Progress and effectiveness are reviewed and further actions assigned during management meetings and results of objectives published.



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## 26 TECHNICAL EVALUATION & DEDICATION OF COMMERCIAL GRADE ITEMS OR SERVICES

Quality Operating Procedure QOP 26, Technical Evaluation & Dedication of Commercial Grade Items or Services.

EMC carefully controls the process for accepting a commercial grade item for nuclear safety-related use. These controls include:

- *affirmation that the item or service is commercial grade*
- *identification of any 'bounds' or limitations to the dedication*
- *technical evaluation of the item's failure modes and effects*
- *determination of appropriate identification attributes, critical characteristics and acceptance methods*
- *testing and inspection by qualified personnel or approved suppliers*
- *measures to detect potential counterfeit / fraudulent items*
- *controlled storage and usage.*

Dedication may be contracted to a supplier with an audited 10CFR50 Appendix B compliant system approved for dedication services.

Traceability is maintained for reporting of defects in accordance with 10CFR21 requirements.



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## **G Correspondence between ISO 9001: 2015 and EMC Quality System**

<b>ISO 9001: 2015</b>		<b>EMC Quality System Reference</b>	
<b>Clause #.</b>	<b>Title</b>	<b>Document #.</b>	<b>Title</b>
<b>4.</b>	<b>Context of Organization</b>		
4.1	Understanding the organization and its context	QAM QOP 01	Quality Manual Organization
4.2	Understanding the needs and expectations of interested parties	QOP 01 QOP 25	Organization Measurement, Analysis and Improvement
4.3	Determining the scope of the quality management system	QAM	Quality Manual
4.4	Quality management system and its processes	QOP 01 QOP 02	Organization Quality Assurance Program
<b>5.</b>	<b>Leadership</b>		
5.1.1	Leadership and commitment / General	QAM QOP 01	Quality Manual Organization
5.1.2	Leadership and commitment / Customer Focus	QAM QOP 01	Quality Manual Organization
5.2.1	Policy / Establishing the quality policy	QAM	Quality Manual
5.2.2	Policy / Communicating the quality policy		
5.3	Organizational roles, responsibilities and authorities	QOP 01	Organization
<b>6.</b>	<b>Planning</b>		
6.1	Actions to address risk and opportunities	QOP 01 QOP 16	Organization Corrective & Preventive Action
6.2	Quality objectives and planning to achieve		
6.3	Planning of changes		
<b>7.</b>	<b>Support</b>		
7.1.1	Resources / General	QOP 01	Organization
7.1.2	Resources / People		
7.1.3	Resources / Infrastructure		
7.1.4	Resources / Environment for the operation processes		



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ISO 9001: 2015		EMC Quality System Reference	
Clause #.	Title	Document #.	Title
7.1.5	Monitoring and measuring resources	QOP12	Control of Measuring and Test Equipment
7.1.5.1	Monitoring and measuring resources / General		
7.1.5.2	Monitoring and measuring resources / Measurement traceability		
7.1.6	Organizational knowledge	QAM QOP 06	Quality Manual Document Control
7.2	Competence	QOP 19 QOP 20 QOP 21	Training Qualification of Inspection and Test Personnel (Safety-Related) Auditor Qualification
7.3	Awareness	QOP 19 QC-021	Training Quality System Information Booklet
7.4	Communication	QOP 01	Organization
7.5.1	Documented information / General	QAM QOP 02	Quality Manual Quality Assurance Program
7.5.2	Documented information / Creating and updating	QOP 06	Document Control
7.5.3	Documented information / Control of documented information	QOP 06 QOP 17	Document Control Quality Assurance Records
<b>8.</b>	<b>Operation</b>		
8.1	Operational planning and control	QOP 02 QOP 05 QOP 17	Quality Assurance Program Instructions, Procedures and Drawings Quality Assurance Records
8.2.1	Requirements for products and services / Customer communications	QOP 16 QOP 23 QOP 24	Corrective & Preventive Action Contract Review Customer Property





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ISO 9001: 2015		EMC Quality System Reference	
Clause #.	Title	Document #.	Title
8.2.2	Requirements for products and services / Determining the requirements for products and services	QOP 23	Contract Review
8.2.3	Requirements for products and services / Review of the requirements for product and services		
8.2.4	Requirements for products and services / Changes to the requirements for product and services		
8.3.1	Design and development of product and services / General	QOP 03	Design Control
8.3.2	Design and development of product and services / Design and development planning		
8.3.3	Design and development of product and services / Design and development inputs		
8.3.4	Design and development of product and services / Design and development controls		
8.3.5	Design and development of product and services / Design and development outputs		
8.3.6	Design and development of product and services / Design and development changes		
8.4.1	Control of externally provided processes, products and services / General	QOP 04	Procurement Document Control
8.4.2	Control of externally provided processes, products and services / Type and extent of controls	QOP 07 QOP 10	Control of Purchased Items and Services Inspection
8.4.3	Control of externally provided processes, products and services / Information for external providers	QOP 18A	External Audits & Commercial Grade Surveys
8.5.1	Production and service provision / Control of production and service provision	QOP 02 QOP 09 QOP 12 QOP 18 QOP 22 SIP/SOP/STP	Quality Assurance Program Control of Special Processes Control of Measuring and Test Equipment Training Servicing Standard Inspection, Operating and Test Procedures



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ISO 9001: 2015		EMC Quality System Reference	
Clause #.	Title	Document #.	Title
8.5.2	Production and service provision / Identification and traceability	QOP 08	Identification and Control of Items
8.5.3	Production and service provision / Property belonging to customers or external providers	QOP 06 QOP 13 QOP 24	Document Control Handling, Storage and Shipping Customer Property
8.5.4	Production and service provision / Preservation	QOP 13	Handling, Storage and Shipping
8.5.5	Production and service provision / Post-delivery activities	QOP 16 QOP 22	Corrective & Preventive Action Servicing
8.5.6	Production and service provision / Control of changes	QOP 01 QOP 06	Organization Document Control
8.6	Release of products and services	QOP 10 QOP 11 QOP 14 SIP/SOP/STP	Inspection Test Control Inspection, Test and Operating Status Standard Inspection, Operating and Test Procedures
8.7	Control of nonconforming outputs	QOP 15	Control of Nonconforming Items
9.	Performance Evaluation		
9.1.1	Monitoring, measurement, analysis and evaluation / General	QOP 08	Identification and Control of Items
9.1.2	Monitoring, measurement, analysis and evaluation / Customer Satisfaction	QOP 10 QOP 11 QOP 16 QOP 25	Inspection Test Control Corrective & Preventive Action Measurement, Analysis and Improvement
9.1.3	Monitoring, measurement, analysis and evaluation / Analysis and Evaluation	QOP 25	Measurement, Analysis and Improvement
9.2	Internal audits	QOP 16 QOP 18 QOP	Corrective & Preventive Action Audits
9.3.1	Management review / General	QOP 25	Measurement, Analysis and Improvement
9.3.2	Management review / Management review inputs		
9.3.3	Management review / Management review outputs		



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ISO 9001: 2015		EMC Quality System Reference	
Clause #.	Title	Document #.	Title
10.	Improvement		
10.1	General	QOP 16 QOP 25	Corrective and Preventive Action Measurement, Analysis and Improvement
10.2	Nonconformity and corrective action	QOP 16	Corrective & Preventive Action
10.3	Continual improvement	QAM QOP 25	Quality Manual Measurement, Analysis and Improvement



## H Definitions

The following definitions are provided to assure a uniform understanding of select terms as they are used in the EMC QA Program. These definitions apply unless alternative definition is made within the specific procedure (example: ASME definitions used in the welding program).

**Acceptance criteria:** specified limits placed on the performance, results, or other characteristics of an item, process or service defined in codes, standards or other requirement documents.

**Audit:** a planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

**Audit, external:** an audit of those portions of another organization's quality assurance program not under the direct control or within the organizational structure of the auditing organization.

**Audit, internal:** an audit of those portions of an organization's quality assurance program retained under its direct control and within its organizational structure.

**Audit, findings:** results of the evaluation of the collected audit evidence against audit criteria.

**Certificate of conformance:** a document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

**Certification:** the act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

**Characteristic:** any property or attribute of an item, process, or service that is distinct, desirable, and measurable.

### **Commercial grade item:**

1) a structure, component, or part thereof that affects its safety function that was not designed and manufactured as a basic component.

Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e. one or more critical characteristics of the item cannot be verified).

2) an item satisfying the following:

(a) not subject to design or specification requirements that are unique to nuclear facilities;

(b) used in applications other than nuclear facilities;

(c) is to be ordered from the manufacturer / supplier on the basis of the specifications set forth in the manufacturer's published product description (for example, a catalog).

**Commercial grade service:** As commercial grade item, but as relates to services such as calibration.<sup>1</sup>

**Computer program:** a combination of computer instructions and data definitions that enables hardware to perform computational or control functions.

Note: Computer programs covered by NQA-1 are those used for:

(a) design analysis

(b) operations or process controls

(c) data base or document control registers when used as the controlled source of quality information (a) or (b) above.

**Condition adverse to quality:** an all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one that, if uncorrected, could have a serious effect on safety or operability.

**Configuration:** the physical, functional, and operational characteristics of the structures, systems, components, or parts of the existing facility.



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**Configuration item (software):** a collection of hardware or software elements treated as a unit for the purpose of configuration control.

**Configuration management:** the process that controls the activities, and interfaces, among design, construction, procurement, training, licensing, operations, and maintenance to ensure that the configuration of the facility is established, approved, and maintained.

**Corrective action:**

1) measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

2) measures taken to eliminate the causes of existing non-conformances to prevent recurrence.<sup>1</sup>

**Continuous improvement:** recurring activity to increase the ability to fulfil requirements.<sup>1</sup>

**Critical characteristic:** important design, material, and performance characteristics of a commercial grade item or service that, once verified, will provide reasonable assurance that the item or service will perform its intended safety function.

**Design, final:** approved design output documents and approved changes thereto.

**Design authority:** the organization having the responsibility and authority for approving the design bases, the configuration, and changes thereto.

**Design bases:** that information which identifies the specific functions to be performed by a structure, system, or component of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. These values may be:

- (a) restraints derived from generally accepted "state-of-the-art" for achieving functional goals; or
- (b) requirements derived from analysis (based on calculations and/ or experiments) of the effects of a postulated accident for which a structure, system, or component must meet its functional goals.

**Design Change:** any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

**Design input:** those criteria, performance requirements, codes and standards, design bases, regulatory requirements, or other design requirements upon which detailed final design is based.

**Design output:** drawings, specifications, and other documents used to define technical requirements of structures, systems, components, and computer programs.

**Design process:** technical and management processes that commence with identification of design input and that lead to, and include the issuance of, design output documents.

**Design review:** a critical review to provide assurance that the final design is correct and satisfactory.

**Deviation:** a departure from specified requirements before performance of the related activity.<sup>1</sup>

**Document:** any written, pictorial, or electronic information describing, defining, specifying, reporting or certifying activities, requirements, procedures, or results. A document is not considered to be a quality assurance record until it satisfies the definition of a quality assurance record.

**Document control:** the act of assuring that documents are reviewed for adequacy, approved for release by authorized personnel, and distributed to and used at the location where the prescribed activity is performed.

**Electronic document:** a document stored in a form (i.e. magnetic or optical media) that is typically accessible only by a computer.

**Guidance:** a suggested practice that is not mandatory. The word *should* denotes guidance; the word *shall* denotes a requirement.

**Inspection:** examination or measurement to verify whether an item or activity conforms to specified requirements.

**Inspector:** a person who performs inspections activities to verify conformance to specific requirements

**Item:** an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system or unit.



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**Management / Top Management:** Person or group of people who directs and controls an organization / at the highest level.<sup>1</sup>

**Measuring and test equipment (M&TE):** devices or systems used to calibrate, measure, gage, test or inspect in order to control or acquire data to verify conformance to specified requirements.

**Nonconformance:** a deficiency in characteristic, documentation or procedure that renders the quality of an item or activity unacceptable or indeterminate.

**Objective evidence:** any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

**Owner:** the organization legally responsible for the construction and/ or operation of a nuclear facility including but not limited to one who has applied for, or who has been granted, a construction permit or operating license by the regulatory authority having lawful jurisdiction.

**Preventive action:** measures taken to eliminate the causes of potential non-conformances to prevent their occurrence.<sup>1</sup>

**Procedure:** a document that specifies or describes how an activity is to be performed.

**Procurement document:** purchase requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchase.

**Process:** set of interrelated or interacting activities which transforms inputs into outputs.<sup>1</sup>

**Purchaser:** the organization responsible for establishment of procurement requirements and for issuance or administration, or both, of procurement documents.

**Qualification, personnel:** the characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests that qualify an individual to perform a required function.

**Qualified automated means:** automated methods of controlling or monitoring processes that have been demonstrated to produce required quality within controlled limits.

**Qualified procedure:** an approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.

**Quality assurance (QA):** All those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

**Quality assurance record:** a completed document that furnishes evidence of the quality of items and / or activities affecting quality. Types of record media may include paper, electronic (magnetic or optical), or specially processed media such as radiographs, photographs, negatives, and microforms. The term *record*, as used throughout, is to be interpreted as a quality assurance record.

**Quality control (QC):** part of quality management focused on fulfilling quality requirements.

**Quality management:** coordinated activities to direct and control an organization with regard to quality.

**Quality Manual:** document specifying the quality management system of an organization.<sup>1</sup>

**Quality Objective:** something sought, or aimed for, related to quality<sup>1</sup>

**Quality Plan:** document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract.<sup>1</sup>

**Quality standard:** a code or standard that provides design inputs, acceptance criteria, or other criteria necessary to assure the quality of the designated item.

**Receiving:** taking delivery of an item at a designated location

**Repair:** the process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement.

**Rework:** the process by which an item is made to conform to original requirements by completion or correction.

**Right of access:** the right of a Purchase or designated representative to enter the premises of a Supplier for the purpose of inspection, surveillance, or quality assurance audit.





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**Safety function:** the performance of an item or service necessary to achieve safe, reliable, and effective utilization of nuclear energy and nuclear material processing.

**Scrap:** action on a nonconforming product to preclude its originally intended use.<sup>1</sup>

**Service:** the performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation.

**Shall:** see *Guidance*.

**Should:** see *Guidance*.

**Software:** computer programs and associated documentation and data pertaining to the operation of a computer system.

**Special process:** a process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

**Specification:** document stating requirements.<sup>1</sup>

**Supplier:** any individual or organization who furnishes items or services in accordance with a procurement document. An all-inclusive terms used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their sub-tier levels.

**Surveillance:** the act of monitoring or observing to verify whether an item or activity conforms to specified requirements.

**Technical specialist:** person who provides specific knowledge or expertise to the audit team. Note: A technical specialist does not act as an *auditor* in the audit team.<sup>1</sup>

**Testing:** an element of verification for the determination of the capability of an item to meet specified requirements, by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

**Traceability:** the ability to trace the history, application or location of an item and like items or activities by means of recorded identification.

**Use-as-is:** a disposition permitted for a nonconforming item when it has been established that the item is satisfactory for its intended use.

**Verification:** the act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

**Validation:** confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.<sup>1</sup>

**Waiver:** documented authorization to depart from specified requirements after performance of the related activity.<sup>1</sup>

<sup>1</sup> Non NQA-1 definition (e.g. ISO 9000), or definition modified as applicable to EMC program or workscope.