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Namco Controls  
2100 West Broad Street  
Elizabethtown, NC 28337

REVISION N

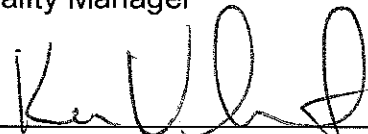
12 JANUARY 2009

QUALIFIED PRODUCTS

QUALITY MANUAL

Approved:   
Quality Manager

Date: 1-15-09

Approved:   
VP Operations Speciality Products

Date: 1-15-09

Approved:   
VP/GM Speciality Products

Date: 1/15/09

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Namco Controls  
2100 West Broad Street  
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Quality Policy – January 2009

## Quality is First Always.

Our objective is to be the leader in satisfying our customer's needs and be their first choice based on quality, delivery and value.

With a relentless pursuit of continuous improvement, developing talented people and innovative products and services, we deliver customer satisfaction and shareholder value.

Each associate is responsible for the quality of his or her work, and has the responsibility to identify any conditions or issues which could adversely affect the quality of our products.

The Quality Department has final jurisdiction in matters involving quality of workmanship, and conformance of products to design and contractual documents. The Quality Department has the authority and organizational freedom to identify quality problems and to stop work, processing, or shipment of products pending resolution of identified concerns.

Ken Gould  
Quality Manager

Ken Verhulst  
VP Operations  
Specialty Products

Tony King  
VP/GM Specialty  
Products

## TABLE OF CONTENTS

<u>Section</u>	<u>Title</u>	<u>Page</u>
	Title / Approval Signature Page	
	Quality Policy Statement	
	Table of Contents.....	i
	Revision History.....	ii
I	Organization.....	1
II	Quality Assurance Program.....	4
III	Design Control.....	6
IV	Procurement Document Control.....	7
V	Instructions, Procedures, and Drawings.....	8
VI	Document Control.....	9
VII	Control of Purchased Materials and Services.....	11
VIII	Identification and Control of Material, Parts, and Components.....	12
IX	Control of Special Processes.....	14
X	Inspection.....	15
XI	Test Control.....	17
XII	Control of Measuring and Test Equipment.....	18
XIII	Handling, Storage, and Shipping.....	19
XIV	Inspection, Test, and Operating Status.....	20
XV	Nonconforming Materials, Parts, or Components.....	21
XVI	Corrective Action.....	23
XVII	Quality Assurance Records.....	24
XVIII	Audits.....	30

## REVISION HISTORY

<u>Revision Level</u>	<u>Date</u>	<u>Description</u>
A thru H and prior	July 1997	Changes noted separately at the time of issue.
J	April 1999	Revision letter 'I' not used. First use of Revision History page. Entire manual had editorial changes and corrections, which did not affect the quality program. Changes are summarized as follows: <b>(Sect I)</b> Organization chart changed to show current reporting structures, job titles, and department names; Responsibilities adjusted accordingly; <b>(Sect II)</b> Corrected document list. Added para. 5.0 regarding documentation; <b>(Sect IV)</b> Rewritten and expanded for clarity; <b>(Sect VI)</b> Clarified para. 5.0 regarding quality manual; <b>(Sect VII)</b> Clarified verification of suppliers; <b>(Sect VIII)</b> Clarified traceability methods; <b>(Sect X)</b> Clarified use of sampling plans and updated document references; <b>(Sect XIII)</b> Clarified storage activities for shelf-life items; <b>(Sect XV)</b> Clarified conditional release process and Part 21 reporting; <b>(Sect XVI)</b> Rewritten and expanded for clarity. Added link to annual system review; <b>(Sect XVII)</b> Corrected retention period for audit reports; <b>(Sect XVIII)</b> Rewritten to clarify the scope and frequency of audits. Added link to annual system review.
K	February 2000	Manual was changed to reflect change in location from Highland Heights, OH to Lancaster, South Carolina. In addition <b>(Sect I)</b> Organization chart was changed to show current reporting structures, and job titles.
L	May 2007	Manual was changed to reflect current reporting structure and job titles.
M	June 2007	Inserted Quality Policy
N	January 2009	Changed location to Etown and change in reporting structure, Quality Policy responsables; CAR and Calibration retention

## ORGANIZATION

### 1.0 *Purpose*

The purpose of this section is to outline the organizational structure, authority, and responsibilities for implementing the quality program for NAMCO Qualified Products.

### 2.0 *Policy*

It is the policy of NAMCO Controls to provide sufficient authority and organizational freedom to the Quality Department for overseeing implementation of the quality program depicted in this manual.

### 3.0 *General*

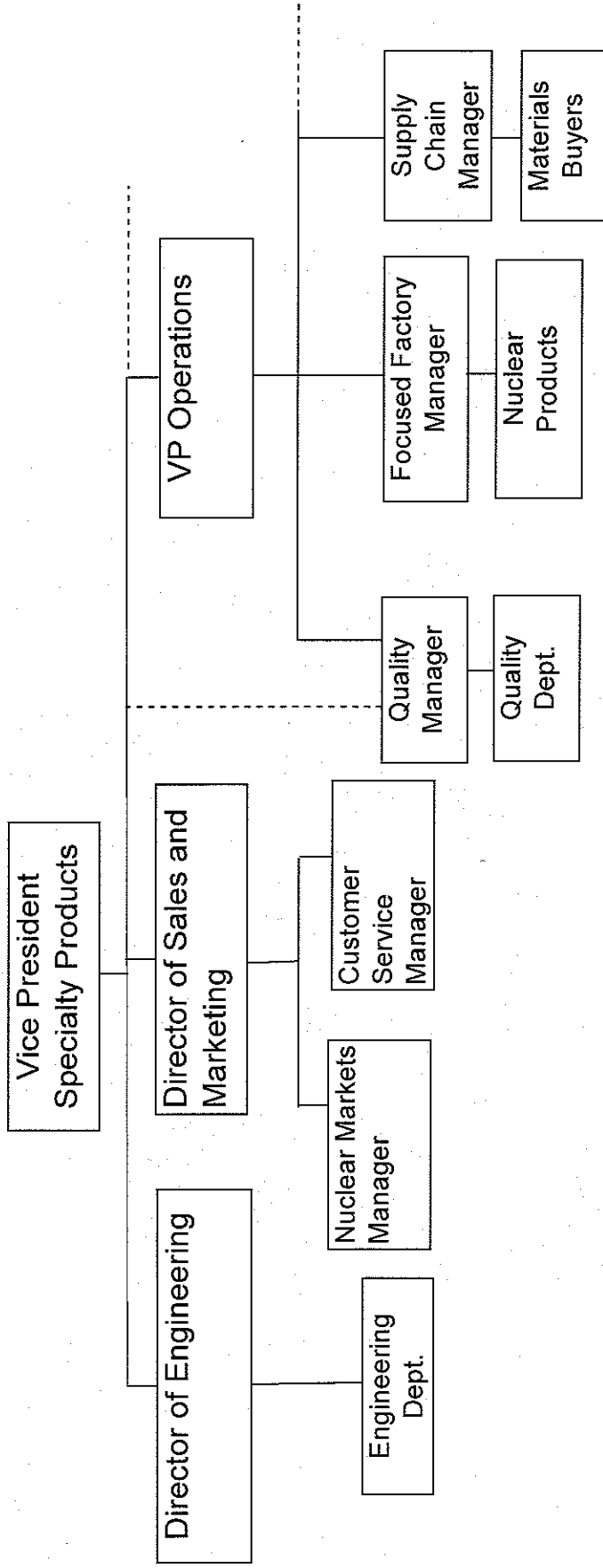
- 3.1 Each associate is responsible for the performance and quality of their work. The Quality Department has final jurisdiction in matters involving quality of workmanship and conformance of products to drawings, specifications, standards, and contractual requirements.
- 3.2 The Quality Department has the authority and organizational freedom to identify quality problems and to stop work, processing, or shipment of products pending resolution of those concerns. The Quality Department may initiate, recommend, or furnish solutions to identified problems or conditions, and shall verify implementation of corrective action.
- 3.3 The aforementioned authority and organizational freedom is established by providing the Quality Department direct access to the VP Operations to resolve quality issues.
- 3.4 Persons or organizations performing activities affecting quality have sufficient independence from production when safety or quality concerns are identified.
- 3.5 Persons performing quality functions may delegate a representative to perform their tasks during interim periods. Such delegation does not relieve the person of responsibility for the task.
- 3.6 The Quality Department shall interface with suppliers, customers, and other NAMCO departments to ensure the safety, integrity, and reliability of Qualified Products.

**SECTION I**

**4.0 Responsibilities**

- 4.1 The Quality Manager is responsible overall for the quality program. The Quality Manager reports to the VP Operations Speciality Products , with alternate (dotted line) reporting to the Vice President of Speciality Products.
- 4.2 Personnel reporting to the Quality Manager, or the Quality Manager, develop procedures and quality manuals; perform quality program audits; prepare forms, documents, and reports utilized by the Quality Department; and maintain quality records. Quality personnel perform other assigned tasks in support of the quality program and may issue work orders to manufacturing.
- 4.3 Qualified personnel reporting to the Quality Manager are responsible for inspecting, testing and documenting product and material to verify conformance to applicable instructions, procedures, drawings, specifications, and inspection checklists.
- 4.4 The Engineering department, reporting to the Director of Engineering is responsible for the technical adequacy of the engineering design performed within the company, or subcontracted to consultants. Qualified engineers provide guidance to designers, drafters, and technicians to assure compliance with the Quality Program.
- 4.5 The Nuclear Markets / Customer Service Manager(s) report(s) to the Director of Sales and Marketing. The Nuclear Markets Manager or customer service personnel are responsible for reviewing customer inquiries and orders to determine the ability to furnish the requested items. The Nuclear Markets Manager or Customer Service forwards copies of customer orders for Qualified Products to the Quality Department for review. The Nuclear Markets Manager or Customer Service personnel may issue work orders to manufacturing.
- 4.6 The Focused Factory Manager (Manufacturing), reporting to the VP Operations is responsible for assuring that products are fabricated by appropriately trained and qualified associates utilizing the proper tools and machinery. The Focused Factory Manager (Manufacturing) is responsible for the flow of work through the production cells.
- 4.7 The Supply Chain Manager, reporting to the VP Operations, is responsible for the overall material control and procurement functions. The Material Buyer requisitions materials and services, and generates procurement documents to obtain materials and services necessary to support the manufacturing process and may issue work orders to manufacturing.

SECTION I



## QUALITY ASSURANCE PROGRAM

### 1.0 *Purpose*

The purpose of this section is to outline NAMCO's quality program for Qualified Products.

### 2.0 *General*

2.1 Qualified Products are items, which have undergone a qualification program for use as safety related parts or components in nuclear power plants; in navy/marine applications; or any item requiring extra attention and control.

2.2 The quality program for qualified products complies with the requirements (appropriate for suppliers to operators of nuclear powerplants or fuel reprocessing plants) of the following documents (latest published version) -

- 10CFR50 Appendix B
- 10CFR Part 21

### 3.0 *Quality Program*

3.1 The quality program documentation structure consists of this Quality Manual and associated subtier-implementing procedures titled as a Namco Standard Practice documents and Quality Control Procedures. Refer to Section V.

3.2 The Quality Manager is responsible for overseeing implementation and continual maintenance of the quality program.

3.3 Quality Department associates are provided with the necessary equipment and work area to effectively perform their functions.

3.4 Quality Department associates are trained in accordance with applicable NAMCO procedures. Periodic reviews assure that required levels of proficiency are maintained.

3.5 NAMCO management reviews at least annually internal, external, and customer audit results, and summaries of corrective action and nonconforming items to determine the status and adequacy of the quality program. Appropriate actions are taken based on review results.

#### 4.0 *Certificates of Compliance/Conformance*

Certificates of Compliance/Conformance issued by NAMCO Controls shall include the signature and title of an authorized NAMCO representative responsible for the quality function. Associates authorized to sign certifications are:

- Quality Manager
- Quality Personnel
- Other responsible associates designated on an interim basis by the Quality Manager.

#### 5.0 *Control of Quality Program Documentation*

- 5.1 The Quality Manager is responsible for the control of the Quality Manual and other quality program documentation in accordance with documented procedures. Refer to Sections V and VI.
- 5.2 Quality program documentation may exist in any media type appropriate for its intended use.

## DESIGN CONTROL

### 1.0 *Purpose*

The purpose of this section is to define the methods utilized to assure that appropriate engineering and quality requirements are specified or referenced in design documents.

### 2.0 *Design Control*

- 2.1 Qualified engineers shall develop, prepare, and implement Engineering Department procedures that control the following:
  - 2.1.1 Design verification through testing, preliminary design review, qualification testing, and review of design changes.
  - 2.1.2 Final design review.
  - 2.1.3 An engineering documentation system that provides drawings, specifications, instructions, and procedures essential to the procurement, fabrication, assembly, inspection, and testing of Qualified Products.
  - 2.1.4 A system of controls for releasing documents to production; requesting and reviewing changes; and distributing released documents.
  - 2.1.5 Review of design changes by the same organization that performed the original design.
- 2.2 Qualified engineers shall assure that all applicable engineering documentation is prepared in accordance with documented procedures.
- 2.3 The Quality Manager or other quality personnel shall review design documents to verify that applicable quality requirements are specified.

## PROCUREMENT DOCUMENT CONTROL

### 1.0 *Purpose*

The purpose of this section is to outline the methods utilized to assure that appropriate regulatory, engineering, and quality requirements are specified or referenced in purchase orders to suppliers.

### 2.0 *Responsibilities*

- 2.1 Manufacturing shall issue the necessary documents for items or services to be utilized in processing Qualified Products and forward the requisitions to the appropriate department.
- 2.2 Qualified Engineers shall ensure that applicable design and regulatory requirements are specified (see Section III) and available for inclusion in purchase orders.
- 2.3 The Director of Engineering or designee shall approve requisitions for Engineering Qualification Testing and forward them to Purchasing.
- 2.4 Purchasing shall, in response to requisitions, issue purchase orders (POs) in accordance with documented procedures, assuring that the proper quality codes are referenced. Purchasing forwards the POs and any subsequent changes to the Quality Department for review prior to release.
- 2.5 The Quality Manager or designee shall develop and maintain purchase quality requirements appropriate for the type of material or service purchased. The requirements shall include, when necessary, a stipulation that the supplier develop a quality program consistent with relevant aspects of 10CFR50 Appendix B or other specified quality program.
- 2.6 The Quality Manager or designee shall review and approve POs and changes issued for items and services utilized for Qualified Products. The review shall verify that the applicable requirements for the type of purchase are specified, and that the intended supplier is on the Qualified Suppliers List.

## INSTRUCTIONS, PROCEDURES, and DRAWINGS

### 1.0 *Purpose*

The purpose of this section is to outline the NAMCO Controls' system of instructions, procedures, drawings, and other documents controlling activities that affect quality.

### 2.0 *Drawings*

- 2.1 The primary documents establishing qualitative and quantitative acceptance criteria for Qualified Products are the drawings and specifications produced and controlled by Engineering.
- 2.2 Pertinent information defining product quality is distributed in the form of controlled drawings and specifications, assembly/lubrication procedures, maintenance instructions, and baseline control documents.

### 3.0 *Instructions*

- 3.1 Products manufactured, assembled, inspected, and tested at NAMCO Controls are accompanied by a Work Order Routing, or a Floor Job Instruction (FJI), as applicable. The processing package also contains a Production Order, Assembly Inspection Record (AIR), and a current Bill of Material.
- 3.2 The Work Order Routing and AIR are the primary documents used to provide instructions and indicate verification and completion of applicable manufacturing operations, inspections, and tests.

### 4.0 *Procedures*

- 4.1 The procedures that control departmental activities affecting quality are designated as NAMCO Standard Practice (NSP) documents.
- 4.2 Additionally, the Quality Department operates with Quality Control Procedures (QCPs) and Calibration Procedures.
- 4.3 Assembly and Lubrication Procedures are utilized at the manufacturing level to control specific operations in the assembly process.

## DOCUMENT CONTROL

### 1.0 *Purpose*

The purpose of this section is to outline NAMCO Controls' system for the control of documents prescribing activities that affect quality.

### 2.0 *Engineering Documents*

Qualified engineers are responsible for the following actions in accordance with documented procedures:

- Assure that engineering documents, including changes, are reviewed for adequacy and approved by authorized personnel prior to release.
- Assure that obsolete documents are removed from active engineering files and cannot be inadvertently used for production.
- Update Assembly and Lubrication Procedure Manuals.
- Issue controlled drawings for production.

### 3.0 *Manufacturing Documents*

3.1 The Focused Factory Manager (Manufacturing) is responsible for the following actions in accordance with documented procedures:

- Develop and revise Work Order Routings.
- Incorporate engineering changes into Work Order Routings.
- Obtain QA approval for Work Order Routings and changes.
- Assure that obsolete drawings are not present in production areas.
- Issue Production Order packages in accordance with documented procedures.

3.2 Purchasing is responsible for notifying suppliers of items or services affected by engineering changes and providing current drawings and specifications.

3.3 The Quality Department is responsible for the following actions in accordance with documented procedures:

- Incorporate engineering changes into applicable inspection documents.
- Review and approve Purchase Orders for material, parts, and services utilized in Qualified Products.
- Obtain approval from the Quality Manager for procedures originated by the Quality Dept.

#### 4.0 *Customer Documents*

4.1 The Customer Service Manager, Product Manager or designee is responsible for the order entry process in accordance with documented procedures. This includes the review of customer orders to verify that items are correctly specified per applicable Qualification Test Reports; regulatory and quality requirements; and NAMCO conditions of sale.

4.2 The Quality Manager or designee reviews customer orders to determine whether specified quality requirements are attainable within the scope of the quality program.

4.3 A qualified engineer reviews customer orders when technical requirements need to be evaluated or clarified.

#### 5.0 *Quality Manual and Quality Program Documentation*

5.1 The Quality Manager is responsible for the revision; coordination of review by affected functional areas, distribution, and control of quality program documentation, including the Quality Manual, in accordance with documented procedures. Refer to Sections II and V.

5.2 The Quality Manager, VP Operations and VP/GM Speciality Products shall approve the Quality Manual prior to revision implementation. The Quality Manager is also responsible for obtaining customer review / approval of the Quality Manual in accordance with contractual requirements and documented procedures.

5.3 The Quality Manager maintains a *controlled copy* list of the quality program documentation issued internally and externally.

## CONTROL OF PURCHASED MATERIAL and SERVICES

### 1.0 *Purpose*

The purpose of this section is to outline measures to assure that purchased material and services conform to Purchase Orders.

### 2.0 *Program Controls*

- 2.1 Records providing documented evidence that material and services conform to Purchase Order requirements shall be compiled and available prior to installation or use of the items.
- 2.2 Records shall identify the specific codes, standards, specifications, or other requirements satisfied by the items or services.
- 2.3 All purchased material and services are subject to receiving inspection utilizing the Dimensional Inspection Record (DIR), relevant specifications, and drawings. Results are recorded on the DIR. Alternate documentation methods may be used at the discretion of the Quality Manager.
- 2.4 Items or services that are adaptable to standard inspection techniques may be verified by inspection and test or through material analysis in accordance with documented procedures.
- 2.5 The effectiveness of supplier quality shall be assessed at intervals consistent with the quantity, importance, and complexity of the items or services provided in accordance with documented procedures. The maximum interval period shall be three years. Methods include, as appropriate, but are not limited to review of supplier performance records, on-site quality system audit (see Section XVIII), or material analysis.

### 3.0 *Qualified Suppliers List*

- 3.1 Suppliers are chosen on the basis of their ability to satisfy the applicable requirements. Only those suppliers approved by the Quality Department and appearing on the QSL may furnish material, parts, or services for Qualified Products.
- 3.2 Quality personnel are responsible for maintaining and controlling the Qualified Suppliers List (QSL) in accordance with documented procedures.

## IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

### 1.0 *Purpose*

The purpose of this section is to outline measures for the identification of materials, parts, and components to assure that correct and traceable items are used for manufacturing.

### 2.0 *General*

2.1 NAMCO Controls assigns unique part numbers to material, parts, and components. Work order numbers are used internally as lot numbers for processing items. Purchase order numbers are used as lot numbers for items purchased complete.

2.2 Traceability of materials, parts, and components utilized in Qualified Products shall be maintained by using lot numbers in accordance with documented procedures.

### 3.0 *Receiving Inspection*

3.1 Items purchased for use in Qualified Products shall undergo receiving inspection as specified in the applicable procedures.

3.2 Accepted items shall be identified with Traceable Material Tags indicating the lot number, inspection date, and as applicable, the cure date, and expiration date. Nonconforming items shall be processed per Section XV of this manual.

### 4.0 *Stocked Items*

4.1 Only items accepted during receiving or in-process inspection and identified with Traceable Material Tags shall be placed into the nuclear storage areas.

4.2 Parts in the nuclear storage areas are identified with the NAMCO part number and other required information noted on the Traceable Material Tag.

5.0 *Assembly and Subassembly*

- 5.1 Materials, parts, or components required for an assembly or subassembly are identified on the Production Order and Bill of Material by part number, revision level, and required quantity.
- 5.2 Traceability information is recorded on the Production Order for each item as it is pulled from the nuclear storage areas, and remains with the parts throughout processing.

## **CONTROL OF SPECIAL PROCESSES**

### **1.0 Purpose**

The purpose of this section is to outline measures for controlling special processes.

### **2.0 General**

- 2.1 Special processes shall be performed by qualified suppliers in accordance with applicable codes, standards, or specifications indicated on controlled drawings or supplemental process documents.
- 2.2 Painting shall be performed in-house by qualified personnel or subcontracted to a qualified supplier. Other special processes shall be subcontracted to qualified suppliers.
- 2.3 The Quality Department is responsible for assuring that all special processes have been completed (see Section VII).

**INSPECTION**

1.0 ***Purpose***

The purpose of this section is to outline measures for inspection of activities affecting quality.

2.0 ***General***

- 2.1 Inspection personnel are qualified and periodically reviewed to ensure that acceptable proficiency is achieved and maintained. Qualification and subsequent reviews are documented.
- 2.2 Inspections are performed by individuals other than those performing the activity or process being inspected.
- 2.3 Appropriate manufacturing operations are inspected or witnessed to assure the quality, safety, and reliability of Qualified Products.
- 2.4 Mandatory inspection and/or witness points are specified in appropriate processing documents. Work shall not proceed beyond such hold or witness point until the inspection or witness activity is complete.
- 2.5 Where inspection is not possible or advantageous, indirect control through monitoring process methods, equipment, personnel, or vendors is provided.

3.0 ***Inspection Activities***

- 3.1 Receiving, in-process, and final inspections are performed in accordance with documented procedures, drawings, specifications, and instructions.
- 3.2 Assembly inspection and test is performed in accordance with documented procedures and the applicable Assembly Inspection Record (AIR).
  - 3.2.1 The Inspector or other qualified person witnesses each inspection and test operation on the AIR document. Acceptance of each operation is indicated by initialing (or stamping) and dating the AIR.
  - 3.2.2 Qualified Products are considered dedicated as basic components for Nuclear Safety-Related applications after successful completion of the inspections and tests specified on the AIR.

3.0 *Inspection Activities (continued)*

3.3 The inspection status of items shall be documented throughout the process in accordance with documented procedures (see Section XIV).

4.0 *Sampling Plans*

4.1 NAMCO Controls utilizes sampling plans for inspection activities as needed. Sampling plans are used in accordance with documented procedures and are based on one or more of the following external standards (currently published version):

- MIL-STD-105
- ANSI/ASQC Z1.4

4.2 Other plans appropriate for the circumstance may be used. The Quality Manager will approve such plans prior to use.

## TEST CONTROL

### 1.0 *Purpose*

The purpose of this section is to outline measures for a test program to assure that design and application requirements are satisfied.

### 2.0 *Qualification Testing*

- 2.1 The Engineering Department is responsible for performing qualification tests in accordance with the applicable Qualification Test Plan and documented procedures.
- 2.2 A representative of the Quality Department shall witness qualification testing to verify that it is performed in accordance with the approved QTP.
- 2.3 Records of qualification tests shall be produced and maintained in accordance with documented procedures.

### 3.0 *Functional Testing*

- 3.1 Functional (production) testing is the responsibility of the Manufacturing Department, and is performed during the assembly of qualified switches in accordance with the applicable Assembly Inspection Record (AIR).
- 3.2 The Inspector or other qualified person shall witness functional testing to verify that it is performed in accordance with the AIR.
- 3.3 Acceptance of production testing is documented by the Inspector or other qualified person on the AIR by initials (or stamp) and date.

## CONTROL OF MEASURING AND TEST EQUIPMENT

### 1.0 *Purpose*

The purpose of this section is to outline methods for assuring those tools, gages, instruments, and other measuring or test devices utilized for product acceptance are identified, calibrated, and controlled.

### 2.0 *Program*

- 2.1 The Quality Manager is responsible for establishing and administering the calibration program, which includes calibration procedures and records.
- 2.2 The Quality Department is responsible for the operation of the calibration program as defined in documented procedures.
- 2.3 Only calibrated and controlled measuring and test equipment shall be used to determine product acceptance.
- 2.4 Measuring and test equipment shall be calibrated at established intervals in accordance with documented procedures, utilizing standards traceable to the National Institute of Standards and Technology (NIST) or other recognized national standard. Where no such standards exist, the basis used for calibration shall be documented and approved by the Quality Department.
- 2.5 Measuring and test equipment shall be identified by a unique recall number and the calibration status indicated on a label affixed to the item or its dedicated case, box, or container. Where labeling is not possible or is impractical, the status of the equipment shall be verified using the recall number prior to use of the equipment.
- 2.6 Instruments found to be outside the specified calibration range shall be removed from service. An evaluation of the impact on products previously inspected or tested with the instrument shall be performed and documented.
- 2.7 Calibration records shall be maintained on all equipment.

## HANDLING, STORAGE, and SHIPPING

### 1.0 *Purpose*

The purpose of this section is to outline measures for handling, storing, and shipping material, parts, and components to prevent damage or deterioration.

### 2.0 *Handling and Storage*

- 2.1 Appropriate preservation, storage, and handling practices are detailed in documented procedures.
- 2.2 Shelf life and cure date data for elastomers or other nonmetallic items are recorded on the Traceable Material Tags attached to material and parts after inspection to assure that outdated materials are not used for Qualified Products. Limited-life items are periodically reviewed for continued storage. Expired items are processed in accordance with Section XV.

### 3.0 *Packaging and Shipping*

- 3.1 The Shipping Order shall reference any special packaging required by the customer's order or specification.
- 3.2 Qualified Products requiring packaging to ANSI N45.2.2 Level B requirements shall be packaged in accordance with documented procedures.
- 3.3 Orders not requiring special packaging shall be packaged in accordance with other documented procedures.

## INSPECTION, TEST, AND OPERATING STATUS

### 1.0 *Purpose*

The purpose of this section is to outline measures for identifying the status of inspections and tests of material, parts, and components.

### 2.0 *General Requirements*

- 2.1 Inspection and test criteria for receiving inspection and some in-process inspections shall be documented. Completion of the inspections and tests is recorded. The appropriate records shall be identified in the procedures.
- 2.2 Manufacturing operations, inspections, tests and witness points associated with production shall be identified on production documents. Completion of inspections and tests associated with production shall be indicated by the initials (or stamp) of the Inspector or other qualified person and date on the production documents. The appropriate documents shall be identified in the procedures.
- 2.3 Traceable Material Tags shall be applied to acceptable material or parts released to stock and indicate the Inspector initials (or stamp) and date.
- 2.4 Nonconforming items shall be identified, segregated, and processed in accordance with documented procedures (see Section XV).

### 3.0 *Inspection Stamps*

- 3.1 Inspection stamps may be issued to Inspectors or other qualified persons at the option of the Quality Manager or designee.
- 3.2 The Quality Manager or designee shall maintain a log of assigned inspection stamps.

## NONCONFORMING MATERIALS, PARTS or COMPONENTS

### 1.0 *Purpose*

The purpose of this section is to outline measures to identify, document, control, and disposition nonconforming items.

### 2.0 *Responsibilities*

The Quality Manager or designee shall assure that nonconforming items are identified, documented, segregated, and dispositioned in accordance with documented procedures.

### 3.0 *Program Controls*

3.1 Nonconforming parts and sub-assemblies are identified, documented and segregated pending disposition. The documents are identified in the procedure.

3.1.1 The documents are tracked to provide status and help assure that disposition and resolution occurs in a timely manner.

3.1.2 A copy of the document is kept with the segregated item.

3.2 The Material Review Board (MRB) provides disposition of nonconforming items in accordance with documented procedures.

3.2.1 The MRB consists of the Quality Manager or designee, Qualified Engineer, and the Focused Factory Manager or designee. Alternate members may be designated.

3.2.2 The MRB does not have the authority to deviate from customer requirements without the written consent of the customer.

3.3 Rework or repair instructions shall be documented. The documents are identified in the procedure(s). Reworked or repaired items are re-inspected to the original requirements.

**SECTION XV**

3.4 Conditional release of material or parts is permitted prior to acceptance by the Quality Department if approved in writing by the Quality Manager. The required traceability information shall be maintained as required by documented procedures.

4.0 ***10CFR Part 21 Reporting***

4.1 Engineering and quality management shall, in accordance with documented procedures, contractual requirements, and 10CFR Part 21, evaluate nonconformity conditions *potentially* reportable to regulatory bodies and customers.

4.2 The VP/GM of Speciality Products or VP Operations shall, in accordance with documented procedures and 10CFR Part 21, notify the required regulatory bodies and customers whenever nonconformity conditions have been *determined* reportable as a result of the evaluation conducted per paragraph 4.1 above.

## CORRECTIVE ACTION

### 1.0 *Purpose*

The purpose of this section is to outline measures to identify and correct causes of nonconformities.

### 2.0 *Corrective Action*

2.1 Conditions adverse to quality, such as supplier product or system nonconformities, and internal product or system nonconformities, shall be promptly identified and corrected. Conditions significantly adverse to quality shall be documented on a Corrective Action Request (CAR) and processed in accordance with documented procedures.

2.1.1 Resolution of CARs shall include determining the cause of the condition; the corrective action to be taken; steps to prevent recurrence; and verification that the corrective action has been implemented.

2.1.2 Implementation of corrective action shall be followed-up as necessary to determine the effectiveness of the actions in eliminating the identified cause

2.2 Significant conditions are those determined by the Quality Department and/or Engineering, based on judgment and experience, to adversely affect one or more of the following –

2.2.1 Safe operation or performance of the product;

2.2.2 Usability of the product for its intended purpose;

2.2.3 Internal or external costs;

2.3 The Quality Department shall maintain a log of CARs and their current status for tracking to assure timely closure.

2.4 Data from analysis of corrective actions shall be summarized and provided to management for consideration as part of the quality system review (see Section II).

## QUALITY ASSURANCE RECORDS

### 1.0 *Purpose*

The purpose of this section is to outline a system for the identification, collection, storage, and retention of certain Quality and Engineering records that provide evidence of activities affecting quality.

### 2.0 *General*

- 2.1 Quality and Engineering records are stored in specific areas with reasonable control to prevent damage or loss.
- 2.2 The record types and retention periods are specified in Paragraphs 3.0 and 4.0 of this section.
- 2.3 Prior to the disposal of any contractually required Quality or Engineering records, the affected customer shall be notified and offered the opportunity to take possession of the records.
- 2.4 The Quality Manager or designee is responsible for the records listed in the Quality Records Index (Paragraph 3.0).
- 2.5 The Director of Engineering or designee is responsible for the records listed in the Engineering Records Index (Paragraph 4.0).
- 2.6 Records shall be complete, legible, and reproducible.
- 2.7 Records shall be identifiable and retrievable.
- 2.8 Individuals removing records for review are accountable for their return. Whenever possible, duplicate copies shall be issued for review.
- 2.9 Storage locations and methods are subject to change, provided that records are adequately protected for the specified retention period.

### 3.0 *Quality Records Index*

#### 3.1 Audit Reports

Retention: 6 years after completion of report

Location: Records storage room

Storage: Steel file cabinet

SECTION XVII

3.2 Corrective Action Requests

Retention: Lifetime  
Location: Server  
Storage: Electronic

3.3 Personnel qualification records

Retention: 3 years after being superseded or invalidated  
Location: Records storage room  
Storage: Steel file cabinet

3.4 Inspection records

Retention: Lifetime  
Location: Inspection area (recent records)  
Records storage room (archived records)  
Storage: Fire resistant file cabinet (recent records)  
Steel file cabinet (archived records)

3.5 Calibration records

Retention: 3 years  
Location: Inspection area  
Storage: Fire resistant file cabinet

3.6 Purchase Orders to vendors

Retention: 10 years after being superseded  
Location: Inspection area (recent orders)  
Records storage room (archived orders)  
Storage: Fire resistant file cabinet (recent orders)  
Steel file cabinet (archived orders)

3.7 Quality Manual and NSP Manual masters

Retention: 3 years after being superseded or invalidated  
Location: Records storage room  
Storage: Steel file cabinet

**SECTION XVII**

3.8 Vendor furnished certificates of compliance/conformance

Retention: Lifetime  
Location: Inspection area (recent orders)  
Records storage room (archived orders)  
Storage: Fire resistant file cabinet (recent orders)  
Steel file cabinet (archived orders)

3.9 Qualified Suppliers List (master)

Retention: 1 year after being superseded  
Location: Records storage room  
Storage: Steel file cabinet

3.10 Inspection Reports for nonconforming items

Retention: Lifetime  
Location: Inspection area (recent)  
Records storage room (archived)  
Storage: Fire resistant file cabinet (recent)  
Steel file cabinet (archived)

3.11 Inspection Report Log

Retention: 3 years after being superseded  
Location: Inspection area  
Storage: Fire resistant file cabinet

3.12 Inspection Stamp Log

Retention: 3 years after being superseded  
Location: Records storage room  
Storage: Steel file cabinet

3.13 Qualified Products Production Order

Retention: Lifetime  
Location: Production Control  
Storage: Fire resistant file cabinet

3.14 Qualified Products Work Order Routings

Retention: Lifetime  
Location: Production Control  
Storage: Fire resistant file cabinet

3.15 NAMCO certificates of compliance/conformance

Retention: 10 years  
Location: Records storage room  
Storage: Steel file cabinet

3.16 Copies of customer purchase orders/contracts

Retention: 10 years after being superseded  
Location: Records storage room  
Storage: Steel file cabinet

3.17 FJIs/Repair Tickets

Retention: Lifetime  
Location: Records storage room  
Storage: Fire resistant file cabinet

3.18 Microfilm

Retention: Lifetime  
Location: Records storage room  
Storage: Steel file cabinet

4.0 ***Engineering Records Index***

4.1 Audit reports

Retention: 6 years after being superseded  
Location: Records storage room  
Storage: Steel file cabinet

4.2 Bills of Material (active and obsolete)

Retention: Lifetime  
Location: Records storage room  
Storage: Steel file cabinet

4.3 Drawing files (active and obsolete)

Retention: Lifetime  
Location: Records storage room  
Storage: Steel file cabinet

4.4 Engineering Change files

Retention: Lifetime  
Location: Records storage room  
Storage: Steel file cabinet

4.5 LP files

Retention: Lifetime  
Location: Records storage room  
Storage: Fire resistant file cabinet

4.6 P files

Retention: Lifetime  
Location: Records storage room  
Storage: Fire resistant file cabinet

4.7 Personnel qualification records

Retention: While employed by NAMCO Controls; 3 years  
after being superseded or invalidated  
Location: Records storage room  
Storage: Steel file cabinet

4.8 QTP files

Retention: Lifetime  
Location: Records storage room

Storage: Fire resistant file cabinet

**SECTION XVII**

4.9 QTR files

Retention: Lifetime

Location: Records storage room

Storage: Fire resistant file cabinet

4.10 T.R. files

Retention: Lifetime

Location: Records storage room

Storage: Fire resistant file cabinet

4.11 Design review (Nuclear M) files

Retention: 3 years after being superseded

Location: Records storage room

Storage: Fire resistant file cabinet

4.12 Microfilm

Retention: Lifetime

Location: Records storage room

Storage: Steel file cabinet

## AUDITS

### 1.0 *Purpose*

The purpose of this section is to outline a system of audits and surveys to verify the implementation and effectiveness of quality program requirements at NAMCO and suppliers.

### 2.0 *Basis for Audits and Surveys*

2.1 Internal and external quality system audits and surveys shall be planned and scheduled periodically as noted below -

2.1.1 Internal audit of the NAMCO quality system (at least annually or more frequently depending upon the status and importance of the activity).

2.1.2 External audit by NAMCO of suppliers (at least once every three years as part of an on-going approval process for certain suppliers). See Section VII.

2.2 The Quality Manager shall be responsible for administering the audit program and approving the audit schedule (both internal and external).

### 3.0 *Program Controls*

3.1 Trained personnel, in accordance with documented procedures, shall perform audits utilizing checklists as guidelines. Such personnel shall not have direct responsibility in the area audited.

3.2 Audit results shall be documented and provide objective evidence of the implementation and effectiveness of quality program requirements.

3.3 Identified nonconformities shall be documented and require corrective action in accordance with Section XVI.

3.4 Audit results shall be provided to management of the area or supplier audited and summary results shall be provided to NAMCO management for consideration as part of the system review (see Section II).