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REVISION P QUALIFIED PRODUCTS 22 JULY 2019 QUALITY MANUAL

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Controlled Copy# 001



Quality Policy Statement - July 2019

# 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.

Sally Creasy

Sr. Director of Operations

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President

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22 July 2019

# **REVISION HISTORY**

| Revision              | <u>Date</u>   | Description  |
|-----------------------|---------------|--|
| A thru H<br>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: (Sect I) Organization chart changed to show current reporting structures, job titles, and department names; Responsibilities adjusted accordingly; (Sect II) Corrected document list. Added para. 5.0 regarding documentation; (Sect IV) Rewritten and expanded for clarity; (Sect VI) Clarified para. 5.0 regarding quality manual; (Sect VII) Clarified verification of suppliers; (Sect VIII) Clarified traceability methods; (Sect X) Clarified use of sampling plans and updated document references; (Sect XIII) Clarified storage activities for shelf-life items; (Sect XV) Clarified conditional release process and Part 21 reporting; (Sect XVI) Rewritten and expanded for clarity. Added link to annual system review; (Sect XVIII) 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 responsibilities; CAR and Calibration retention  |
| P                     | July 2019     | Administrative changes: text format, grammar errors, duplicate entries, consistency of terms, updated roles & titles, and added change revision bars in margin starting with this revision. Moved <i>Responsibilities</i> in Section I to Section II. Added or removed wording to clearly align with the 10CFR50, Appendix B regulation and enhance commitment to the same.  |

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## **SECTION I**

## **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 and lower tier documents. Additionally, it is the policy of NAMCO Controls to assure that this Quality Program is effectively established, which will be verified through means such as, but not limited to, checking, auditing and inspecting.

## 3.0 General

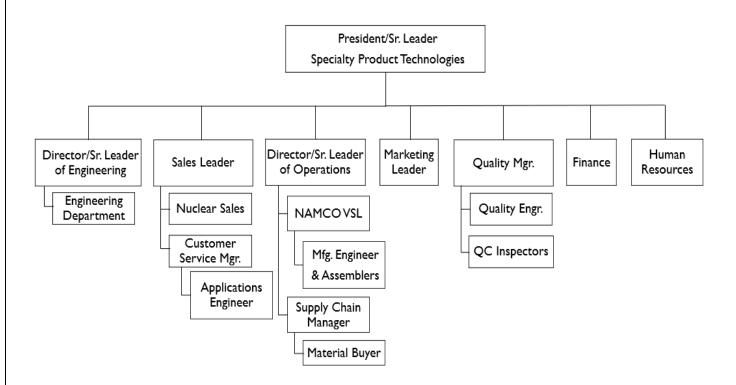
- 3.1 Each associate is responsible for the performance and quality of their work. The Quality Department has final jurisdiction in matters involving quality of workmanship and conformance of products to drawings, specifications, standards, and contractual requirements.
- 3.2 The Quality Department has 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 President / Senior Leader of Specialty Product Technologies to resolve quality issues.
- 3.4 Persons or organizations performing activities affecting quality have sufficient independence from cost and schedule 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.

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# **SECTION I**

# 4.0 *Organization Chart*



# **QUALITY ASSURANCE PROGRAM**

## 1.0 **Purpose**

The purpose of this section is to outline NAMCO's Quality Assurance 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
- 2.3 The Quality Assurance program shall provide control over activities affecting the quality of Qualified Products to an extent consistent with their importance to safety.

## 3.0 Quality Program

- 3.1 The Quality Program documentation structure consists of this Quality Manual and associated sub-tier documented procedures titled as Namco Standard Practice (NSP) documents and Quality Control Procedures (QCP).
- 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 documented 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.

#### **SECTION II**

- 3.6 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:
  - 3.6.1 Quality Manager
  - 3.6.2 Designated Quality Personnel
  - 3.6.3 Other responsible associates designated on an interim basis by the Quality Manager.

# 4.0 Responsibilities

- 4.1 The Quality Manager is responsible overall for the Quality Program. The Quality Manager reports to the President / Senior Leader of Specialty Product Technologies.
- 4.2 The Quality Manager or personnel reporting to 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. 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.
- 4.3 Reporting to the Director of Engineering is the Engineering department, which is responsible for the technical adequacy of the engineering design performed within the company or subcontracted to consultants. Qualified Engineer(s) provide(s) guidance to designers and technicians to assure compliance with the Quality Program.
- 4.4 Reporting to the Sales Leader is the Nuclear Sales Leader and Customer Service Manager(s). This team is responsible for reviewing customer inquiries and orders to determine the ability to furnish the requested items. Copies of customer orders for Qualified Products are forwarded to the Quality Department for review.
- 4.5 Reporting to the Senior Leader / Director of Operations, the Value Stream Leader (Manufacturing) is responsible for assuring that products are assembled by appropriately trained and qualified associates utilizing the proper tools and machinery. The VSL (Manufacturing) is responsible for the flow of work through the production cells.

## **SECTION II**

4.6 Reporting to the Senior Director of Operations, the Supply Chain Manager is responsible for the overall material control and procurement functions. The Material Buyer requisitions materials and services then generates procurement documents to obtain materials and services necessary to support the manufacturing process and may issue work orders to manufacturing.

## **DESIGN CONTROL**

# 1.0 **Purpose**

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

# 2.0 Design Control

- 2.1 Qualified Engineers shall develop, prepare, and implement Engineering Department procedures that control, as a minimum, the following:
  - 2.1.1 Verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The verifying or checking process shall be performed by individuals or groups other than those who performed the original design, but who may be from the same organization.
  - 2.1.2 Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it shall include suitable qualifications testing of a prototype unit under the most adverse design conditions.
  - 2.1.3 Commercial-grade dedication plans for the selection and review for suitability of commercially procured materials, parts, equipment and services that are essential to the safety-related functions of Quality Products.
  - 2.1.4 An engineering documentation system that provides drawings, specifications, instructions and procedures essential to the procurement, fabrication, assembly, inspection and testing of Qualified Products.
  - 2.1.5 A system of controls for releasing documents to production, requesting and reviewing changes and distributing released documents.
  - 2.1.6 Design changes shall be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design.

# **SECTION III**

- 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 as necessary 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 and available for inclusion in purchase orders.
- 2.3 The Director of Engineering or designee shall approve requisitions for the 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 revisions 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 revisions 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 (QSL).

## **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, as applicable.

#### 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.

#### **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

- 2.1 Qualified Engineers are responsible for the following actions in accordance with documented procedures:
  - 2.1.1 Assure that engineering documents, including changes, are reviewed for adequacy and approved by authorized personnel prior to release.
  - 2.1.2 Assure that obsolete documents are removed from active engineering files and cannot be inadvertently used for production.
  - 2.1.3 Issue controlled drawings for production.

# 3.0 Manufacturing Documents

- 3.1 The Manufacturing Team is responsible for the following actions in accordance with documented procedures:
  - 3.1.1 Develop and revise Work Order Routings.
  - 3.1.2 Incorporate engineering changes into Work Order Routings.
  - 3.1.3 Obtain QA approval for Work Order Routings and changes.
  - 3.1.4 Assure that obsolete drawings are not present in production areas.
  - 3.1.5 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:

## **SECTION VI**

- 3.3.1 Incorporate engineering changes into applicable inspection documents.
- 3.3.2 Obtain approval from the Quality Manager for procedures originated by the Quality Department.

#### 4.0 Customer Documents

- 4.1 The Customer Service 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 and regulatory requirements are attainable within the scope of the Quality Program.
- 4.3 An Applications Engineer reviews customer orders when technical requirements need to be evaluated or clarified.

# 5.0 Quality Manual and Quality Assurance 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.
- 5.2 The Quality Manager, Senior Leader / Director of Operations and President / Senior Leader of Specialty Product Technologies 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.
- 5.4 The Quality Manager is responsible for the control of the Quality Manual and other Quality Program documentation in accordance with documented procedures.
- 5.5 Quality Program documentation may exist in any media type appropriate for its intended use.

#### 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.
  - 2.5.1 For suppliers with nuclear quality assurance programs in accordance with 10CFR50 Appendix B, the assessment shall utilize a Nuclear Industry Assessment Committee (NIAC) audit checklist with results of similar scope, (or) an on-site quality system audit, or a combination of the two methods.
  - 2.5.2 For commercial suppliers, the assessment shall utilize an on-site evaluation of their Quality Assurance Program.

## **SECTION VII**

2.5.3 For commercial-grade calibration and / or testing services from domestic and / or international calibration and / or testing laboratories accredited by an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory, the ILAC accreditation process may be used as an alternative to performing a commercial-grade survey as part of the commercial-grade dedication process. Requirements for the use of this alternative are included in the specific commercial-grade dedication procedure.

# 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 Qualified Suppliers List (QSL) may furnish material, parts, or services for Qualified Products.
- 3.2 Quality personnel are responsible for maintaining and controlling the 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 or other appropriate means 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 documented 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.
- 3.3 Nonconforming items shall be processed per documented procedures.

#### 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.

## **SECTION VIII**

# 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.

## **SECTION IX**

## 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, such as but not limited to, include welding, heat treating, coating and non-destructive testing.
- 2.2 Special processes shall be performed by qualified personnel using qualified procedures in accordance with applicable codes, standards or specifications indicated on controlled drawings or supplemental process documents.
- 2.3 Special processes may be performed in-house or subcontracted to an approved supplier.
- 2.4 The Quality Department is responsible for assuring that all special processes have been appropriately completed.

## **SECTION X**

## **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 practicable, indirect control through monitoring process methods, equipment, personnel or approved suppliers 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.
- 3.3 The inspection status of items shall be documented throughout the process in accordance with documented procedures.

#### 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 (QTP) and documented procedures. Test results shall be documented and evaluated to assure that test requirements have been satisfied.
- 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 production 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 and the test requirements have been satisfied.
- 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 standards. Use of the International Laboratory Accreditation Cooperation (ILAC) and/or American Association of Laboratory Accreditation (A2LA) accreditation (in lieu of commercial grade survey) to ISO 17025 satisfies this requirement for laboratories and calibration services. Where no such standard exists, the basis used for calibration shall be documented and approved by the Quality Manager, or designee.
- 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 and processed in accordance with documented procedures. 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 used in activities affecting quality.

## 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 documented procedures.

## 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 and/or NQA-1 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.

# 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. Non-conformance documentation requirements are identified per documented procedures.
  - 3.1.1 The non-conformance document is tracked to provide status and help assure that disposition and resolution occurs in a timely manner.
  - 3.1.2 A copy of the non-conformance 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 VSL 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 Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures. 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 or designee. The required traceability information shall be maintained as required by documented procedures.

# 4.0 10CFR Part 21 Reporting

- 4.1 Engineering and Quality Manager shall, in accordance with documented procedures, contractual requirements, and 10CFR Part 21, evaluate non-conformity conditions *potentially* reportable to regulatory bodies and customers.
- 4.2 The President / Senior Leader of Specialty Product Technologies or (Senior) Director of Operations shall, in accordance with documented procedures and 10CFR Part 21, notify the required regulatory bodies and customers whenever nonconforming conditions have been *determined* reportable as a result of the evaluation conducted per documented procedure.

#### CORRECTIVE ACTION

# 1.0 **Purpose**

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

#### 2.0 Corrective Action

- 2.1 Conditions adverse to quality identified on internal product, Quality Program nonconformances or supplier product shall be promptly identified and corrected in a Corrective Action system.
  - 2.1.1 Resolution of the nonconformance shall document the corrective action to be taken and verification that the corrective action has been implemented.
  - 2.1.2 Implementation of corrective action should be followed-up as necessary to determine the effectiveness of the actions in eliminating the identified cause.
- 2.2 Conditions significantly adverse to quality shall be documented in a Corrective Action system and processed in accordance with documented procedures. Significant adverse conditions are those determined by the Quality Department and/or Engineering, based on judgment and experience, to adversely affect safe operation or performance of the product and/or usability of the product for its intended purpose. Resolution of a nonconformance shall include:
  - 2.2.1 Determining the cause of the condition;
  - 2.2.2 Corrective action(s) to be taken;
  - 2.2.3 Preventative action(s) taken to preclude repetition;
  - 2.2.4 Verification that the corrective action has been implemented;
  - 2.2.5 Reported to the appropriate levels of management.
- 2.3 The Quality Department shall maintain a log of nonconformances 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.

# 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 the following sections.
- 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.
- 2.5 The Director of Engineering or designee is responsible for the records listed in the Engineering Records Index.
- 2.6 Records shall be complete, legible, reproducible, identifiable and retrievable.
- 2.7 Individuals removing records for review are accountable for their return. Whenever possible, duplicate copies shall be issued for review.
- 2.8 Storage locations and methods are subject to change, provided that records are adequately protected for the specified retention period.

# **SECTION XVII**

# 3.0 Quality Records Index

| Audit Reports (6 years)   |
|---|
| Corrective Action Requests (Lifetime)   |
| Personnel Qualification Records (3 years after being superseded or invalidated) |
| Receipt Inspection Records (Lifetime)   |
| Calibration Records (3 years)   |
| Purchase Orders to Suppliers (10 years)   |
| Quality Manual and NSP Manual Masters (3 years after being superseded or in-    |
| validated)  |
| Supplier furnished certificates of compliance / conformance (Lifetime)          |
| Qualified Suppliers List – master (1 year after being superseded)               |
| Inspection Reports for nonconforming items (Lifetime)                           |
| Inspection Report Log (3 years after being superseded)                          |
| Inspection Stamp Log (3 years after being superseded)                           |
| Qualified Products Production Order (Lifetime)                                  |
| Qualified Products Work Order Routings (Lifetime)                               |
| NAMCO certificates of compliance / conformance (10 years)                       |
| Customer purchase orders / contracts (10 years from product delivery)           |
| FJIs / Repair Tickets (Lifetime)  |
| Microfilm (Lifetime)  |

# 4.0 Engineering Records Index

| Bills of Material – active and obsolete (Lifetime)               |
|--|
| Drawing files – active and obsolete (Lifetime)                   |
| Engineering Change files (Lifetime)                              |
| LP files (Lifetime)  |
| P files (Lifetime)   |
| QTP files (Lifetime)   |
| QTR files (Lifetime)   |
| TR Files (Lifetime)  |
| Design Review (Nuclear M) files (3 years after being superseded) |
| Microfilm (Lifetime)   |

## **SECTION XVIII**

#### **AUDITS**

# 1.0 **Purpose**

The purpose of this section is to outline a system of audits, surveys and evaluations to verify the implementation and effectiveness of Quality Program requirements at NAMCO and suppliers.

# 2.0 Basis for Audits, Surveys and Evaluations

- 2.1 Internal and external quality system audits, surveys and evaluations shall be planned and scheduled periodically as noted below:
  - 2.1.1 Internal audit of all applicable elements of the NAMCO quality system shall be completed at least once each year or at least once during the life of the activity, whichever is shorter.
  - 2.1.2 External audit / survey / evaluation by NAMCO of suppliers (at least once every three years as part of an on-going approval process for certain suppliers).
- 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 / surveys / evaluations utilizing checklists as guidelines. Such personnel shall not have direct responsibility in the area audited.
- 3.2 Audit / survey / evaluation results shall be documented and provide objective evidence of the implementation and effectiveness of Quality Program requirements.
- 3.3 Identified nonconformances shall be documented and require corrective action in accordance with documented procedure.
- 3.4 Audit results shall be provided to management of the area. Supplier audit / survey / evaluation results shall be summarized and provided to NAMCO management for consideration as part of the annual management review.

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