

***SHARP NUCLEAD MFG. CO.***  
***INC.***  
***QUALITY MANUAL***

**CONTROLLED COPY: STEVE MADONNA**

## **Section I**

**Policy & Organization**

**QMS 1.1**

**(Quality Manual)**

## **Section II**

**Management Control and Learning**

**QMS 1.2**

**(Procedures)**

## **Section III**

**The Primary Process**

**QMS 1.3**

**(Procedures/Forms)**

**SCOPE**

**1.1 THIS INTERNATIONAL STANDARD SPECIFIES REQUIREMENTS FOR A QUALITY MANAGEMENT SYSTEM WHERE AN ORGANIZATION**

- a) **NEEDS TO DEMONSTRATE ITS ABILITY TO CONSISTENTLY PROVIDE PRODUCT THAT MEETS CUSTOMER AND APPLICABLE STATUTORY AND REGULATORY REQUIREMENTS, AND**
- b) **AIMS TO ENHANCE CUSTOMER SATISFACTION THROUGH THE EFFECTIVE APPLICATION OF THE SYSTEM, INCLUDING PROCESSES FOR CONTINUAL IMPROVEMENT OF THE SYSTEM AND THE ASSURANCE OF CONFORMITY TO CUSTOMER AND APPLICABLE STATUTORY AND REGULATORY REQUIREMENTS.**

**NOTE 1: IN THIS INTERNATIONAL STANDARD, THE TERM “PRODUCT” APPLIES TO THE PRODUCT INTENDED FOR, OR REQUIRED BY, A CUSTOMER OR THE PRODUCT REALIZATION PROCESSES. THIS ALSO INCLUDES PURCHASED PRODUCT AND PRODUCT RESULTING FROM INTERMEDIATE STAGES OF THE REALIZATION PROCESS.**

**NOTE 2: STATUTORY AND REGULATORY REQUIREMENTS MAY BE EXPRESSED AS LEGAL REQUIREMENTS**

**QMS 1.2 APPLICATION**

- **ALL REQUIREMENTS OF THIS INTERNATIONAL STANDARD ARE GENERIC AND ARE INTENDED TO BE APPLICABLE TO ALL ORGANIZATIONS, REGARDLESS OF TYPE, SIZE AND PRODUCT PROVIDED.**
- **WHERE ANY REQUIREMENT(S) OF THIS INTERNATIONAL STANDARD CANNOT BE APPLIED DUE TO THE NATURE OF AN ORGANIZATION AND ITS PRODUCT, THIS CAN BE CONSIDERED FOR EXCLUSION.**
- **WHERE EXCLUSIONS ARE MADE, CLAIMS OF CONFORMITY TO THIS INTERNATIONAL STANDARD ARE NOT ACCEPTABLE UNLESS THESE EXCLUSIONS ARE LIMITED TO REQUIREMENTS WITHIN CLAUSE 7, AND SUCH EXCLUSIONS DO NOT AFFECT THE ORGANIZATIONS ABILITY, OR RESPONSIBILITY, TO PROVIDE PRODUCT THAT MEETS CUSTOMER AND APPLICABLE STATUTORY AND REGULATORY REQUIREMENTS**
- **FOR DATED REFERENCES, ONLY THE EDITION CITED APPLIES. FOR UNDATED REFERENCES, THE LATEST EDITION OF THE NORMATIVE DOCUMENT (INCLUDING ANY AMENDMENTS) APPLIES.**

**ISO 9000:2005 *QUALITY MANAGEMENT SYSTEMS — FUNDAMENTALS AND VOCABULARY***

**QMS 3.1**

**REV. C**

**3.1 CHANGE RECORD**

- 3.1.1 ANY CHANGES IN SYSTEMS OR ADDITIONS OF PROCESSES AND PROCEDURES REQUIRE MODIFICATIONS TO THE QUALITY MANUAL.**
- 3.1.2 THE MANUAL WILL BE REVIEWED ONCE A YEAR BY THE QUALITY CONSULTANT TO ENSURE SUCH CHANGES HAVE BEEN INCLUDED. IF CHANGES OCCUR AND MANUAL IS UPDATED A QUALITY MANUAL CHECKLIST WILL BE COMPLETED.**
- 3.1.3 THE QUALITY SYSTEM IS COMPRISED OF THREE SECTIONS:  
QMS 1.1 QUALITY MANUAL, QMS 1.2: MANAGEMENT CONTROL AND LEARNING, QMS 1.3: PRIMARY PROCESS QMS 4.22: FORMS**
- 3.1.4 FOR THE PURPOSES OF THIS INTERNATIONAL STANDARD, THE TERMS AND DEFINITIONS GIVEN IN ISO 9000 APPLY.  
THROUGHOUT THE TEXT OF THIS INTERNATIONAL STANDARD, WHEREVER THE TERM "PRODUCT" OCCURS, IT CAN ALSO MEAN "SERVICE".**
- 3.1.5 COPIES OF ALL REVISIONS WILL BE SUPPLIED PROMPTLY TO ALL INDIVIDUALS AND APPROPRIATE COMPANIES. THE RESPONSIBILITY OF DISTRIBUTING AND REMOVING OBSOLETE MANUALS AND PROCEDURES WILL BE THAT OF THE MANAGEMENT REPRESENTATIVE.**
- 3.1.6 THE FOLLOWING SPECIFICATIONS WERE UTILIZED AS THE BASIS FOR THIS MANUAL**
  - ISO-9001/2008                    QUALITY MANAGEMENT SYSTEM REQUIREMENTS**
  - ISO-10012-1 1/15/92        QUALITY ASSURANCE REQUIREMENTS FOR MEASURING EQUIPMENT**
  - ANSI/ASQC Z1.4-1993        SAMPLING PROCEDURES AND TABLES FOR INSPECTION ATTRIBUTES**

<i>DATE</i>	<i>REV. LEVEL</i>	<i>REASON</i>	<i>ISO MGT REP.</i>	<i>PRESIDENT</i>
<i>01/31/03</i>	<i>A</i>	<i>COMPLETE ISO-9002 MANUAL UPDATE</i>	<i>S. MADONNA</i>	<i>S. MADONNA</i>
<i>04/04/06</i>	<i>B</i>	<i>UPDATE NEW COMPANY</i>	<i>S. MADONNA</i>	<i>S. MADONNA</i>
<i>12/15/09</i>	<i>C</i>	<i>UPDATE TO ISO-9001:2008 STANDARD</i>	<i>S. MADONNA</i>	<i>S. MADONNA</i>

*QMS 3.2*  
*REV. B*

**TITLE: QUALITY PLANS**

**4.1 POLICY:**

**OUR GOAL IS TOTAL CUSTOMER SATISFACTION WITH ONGOING CONTINUAL IMPROVEMENT LEADING TO:**

**“QUALITY ON-TIME ALL THE TIME “**

**4.2 OBJECTIVE:**

- SHARP NUCLEAD MFG. CO. INC DEFINES CUSTOMER SATISASFACTION AS:  
CUSTOMER SATISFACTION TO BE “LESS THAN 1% RETURNS FROM CUSTOMERS”
- TO IDENTIFY, DOCUMENT EVALUTE THE MEASUREMENT OF CUSTOMER SATISFACTION AND CONTINUAL IMPROVEMENT CRITERIA. (REFERENCE QAP 4.20)
- TO ENSURE THAT THIS IS COMMUNICATED TO ALL PERSONNEL AND THAT THERE INVOLVEMENT, WHEN APPLICABLE, TO THAT CONTINUOUS AND ONGOING IMPROVEMENT IS CLEAR AND EFFECTIVE IMPLEMENTATION IS VERIFIED.

***S. MADONNA***

***PRESIDENT***

**QMS 3.3  
REV. B**

SHARP NUCLEAD MFG. CO. INC  
415 NORTH ELM ST  
WEST BRIDGEWATER, MA. 02379.

***BUSINESS PROFILE***

**BACKGROUND**

SHARP NUCLEAD MFG. CO. INC WAS FOUNDED IN 2000 AS A MANUFACTURER OF COMMERCIAL, AEROSPACE AND MEDICAL PRODUCT

**PRODUCTS / SCOPE**

SHARP NUCLEAD MFG. CO. INC IS A MANUFACTURER OF HIGH PRECISION COMMERCIAL, AEROSPACE AND MEDICAL DEVICE PRODUCT WITHIN THE UNITED STATES AND INTERNATIONALLY

**BUSINESS CLASSIFICATION**

SHARP NUCLEAD MFG. CO. INC IS A PRIVATELY HELD, SMALL BUSINESS CONCERN.

**FLOW CHART**

CUSTOMER CALLS (QAP 4.3)

SALES ORDER IMPLEMENTED

STOCK ITEM

TRAVELER PRINTS

PICKER PULLS ORDER (QAP 4.15)

TO KITING (QAP 4.15)

TO INSPECTION (QAP 4.10)

ACCEPT

TO PACKING (QAP 4.15)

TO SHIPPING (QAP 5.15)

REJECT

DMR (QAP 4.10)

TO MRB

DISPOSITION  
MATERIAL

NON STOCK ITEM

VENDOR PO GENERATED

PURCHASING BUYS PRODUCT (QAP 4.6)

PARTS RECEIVED (QAP 4.15)

TO INSPECTION (QAP 4.10)

ACCEPT

STOCK (QAP 4.15)

PACKING (QAP 4.15)

SHIPPING (QAP 4.15)

REJECT

DMR (QAP 4.10)

MRB

DISPOSITION  
MATERIAL

MFG/VALUE ADDED (QAP 4.9)

DOCUMENTATION PACKAGE IS SUBMITTED TO MFG

MFG IS PERFORMED

SUBMITTED TO INSPECTION (QAP 4.10)

LIST OF PROCEDURAL RESPONSIBILITIES AND SCOPE OF CERTIFICATION FOR ISO-9001/2000

**OVERALL RESPONSIBILITY**

ISO-9001 REGISTRATION & MAINTENANCE OF ISO-9001/2000 MANAGEMENT REPRESENTATIVE

**PROCEDURES**

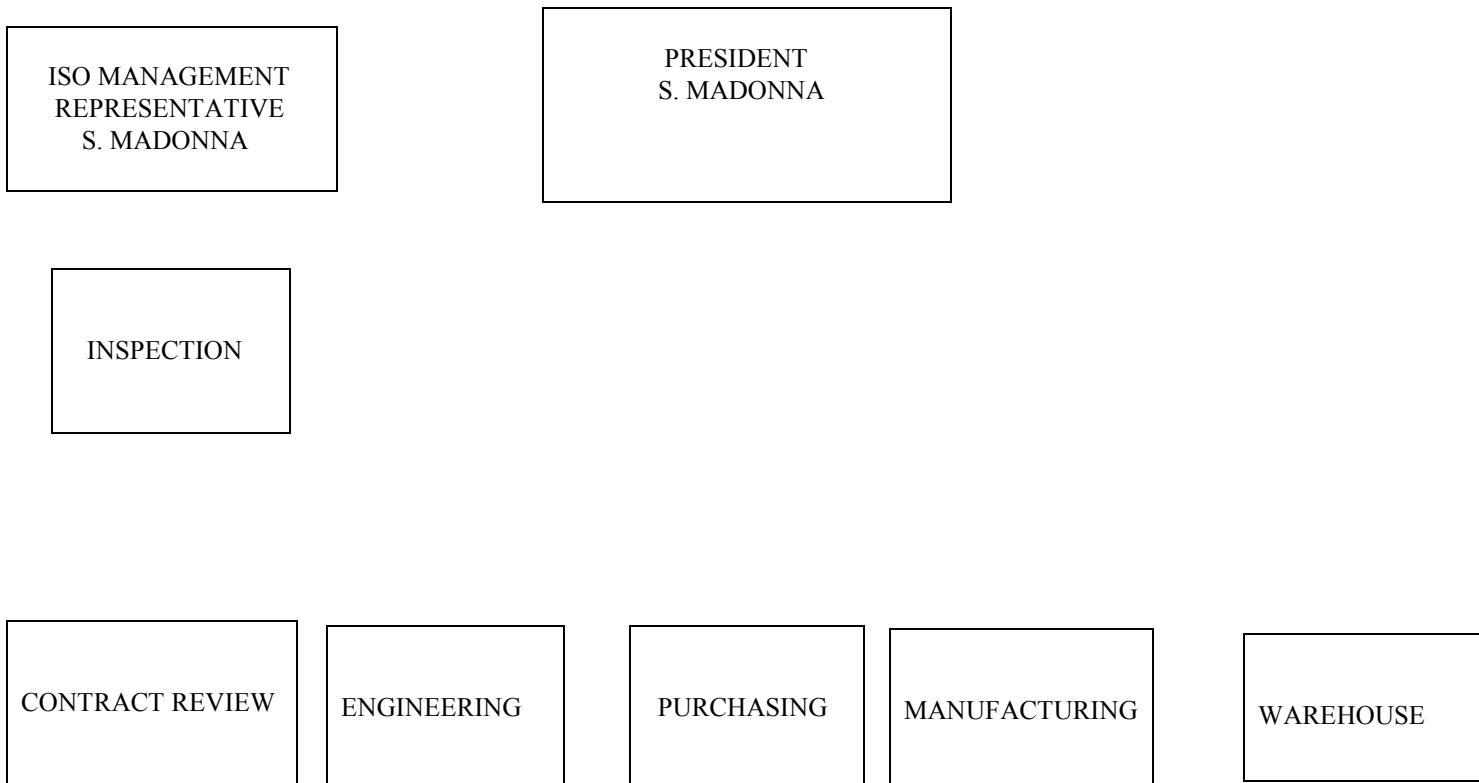
INTERNAL AUDIT  
SALES  
DESIGN CONTROL  
DOCUMENT CONTROL  
CONTROL OF CUSTOMER SUPPLIED  
MATERIALS  
PURCHASING  
VALUE ADDED  
INSPECTION & TESTING  
CALIBRATION  
NON CONFORMING MATERIAL  
CORRECTIVE ACTION  
HANDLING/STORAGE/PACKAGING,  
PRESERVATION AND DELIVERY  
STATISTICAL PROCESS CONTROL  
TRAINING  
SERVICE  
QUALITY RECORDS  
INSPECTION & TEST STATUS

**INDIVIDUAL RESPONSIBILITY**

ISO MGT REP.  
SALES MANAGER  
NOT APPLICABLE  
MANAGEMENT REPRESENTATIVE  
DEPARTMENT MANAGERS  
  
PURCHASING MANAGER  
OPERATIONS MGR  
MGT. REP.  
MGT. REP.  
MATERIAL REVIEW BOARD (PER PROCEDURE)  
MGT. REP..  
  
WAREHOUSE MANAGER  
ISO MGT. REP.  
ALL DEPT. MANAGERS AND SUPERVISORS  
NOT APPLICABLE  
DEPARTMENT MANGERS.  
MGT. REP.

# SHARP NUCLEAD MFG. CO. INC. ORGANIZATION CHART

1/31/03



## **QMS 4.0 Quality Management System**

### **REV. B**

#### **4.1 General requirements**

- The organization has established, documented, implemented and maintained a Quality Management System and is continually improving its effectiveness in accordance with the requirements of this International Standard.
- The organization has:
- Identified the processes needed for the Quality Management System and their application throughout the organization (see 1.2 & 1.3)
- Determined the sequence and interaction of these processes
- Determined criteria and methods needed to ensure that both the operation and control of these processes are effective
- Ensured the availability of resources and information necessary to support the operation and monitoring of these processes
- Monitored, measured and analyzed these processes
- Implemented actions necessary to achieve planned results and continual improvement of these processes.
- These processes are managed by the organization in accordance with the requirements of this International Standard.
- Where an organization chooses to outsource any process that affects product conformity with requirements, the organization has ensured control over such processes. Control of such outsourced processes have been identified within the Quality Management System. Outsourced processes are currently applicable and processed as any other vendor purchase order.
- NOTE Processes needed for the Quality Management System referred to above should include processes for management activities, provision of resources, product realization and measurement.

#### **4.2 Documentation requirements**

##### **4.2.1 General**

- The Quality Management System documentation includes
- Documented statements of a Quality Policy and Quality Objectives
- A Quality Manual
- Documented procedures required by this International Standard, lower tier work instructions/procedures are not applicable.
- Documents needed by the organization to ensure the effective planning, operation and control of its processes
- Quality records required by this International Standard (see 4.2.4).
- Quality system requirements imposed by the applicable regulatory authorities (as required by contract).
- NOTE 1 where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.
- NOTE 2 The extent of the Quality Management System documentation can differ from one organization to another due to
- The size of organization and type of activities
- the complexity of processes and their interactions
- The competence of personnel.
- NOTE 3 The documentation can be in any form or type of medium.

**QMS 4.0 Quality Management System**  
**REV. B**

**4.2.2 Quality Manual**

- The organization has established and maintained a Quality Manual that Includes
- The scope of the Quality Management System, including details of and justification for any exclusion as a distributor of product, Design Control, and Servicing are not applicable to Sharp Nuclead Mfg. Co. Inc.
- The documented procedures established for the Quality Management System, or reference to them
- A description of the interaction between the processes of the Quality Management System.

**4.2.3 Control of documents**

- Documents required by the Quality Management System are controlled. Quality records are a special type of document and are controlled according to the requirements given in 4.2.4.
- A documented procedure has been established to define the controls needed
- To approve documents for adequacy prior to issue,
- To review and update as necessary and re-approve documents,
- To ensure that changes and the current revision status of documents are identified,
- To ensure that relevant versions of applicable documents are available at points of use,
- To ensure that documents remain legible and readily identifiable,
- To ensure that documents of external origin are identified and their distribution controlled, and
- To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

**4.2.4 Control of Records:**

- Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

**4.3 Configuration Management:**

- The organization shall establish, document and maintain a configuration management process appropriate to the product. (ref. QAP 4.3)

## **QMS 5.0 Management Responsibility**

### **REV. B**

#### **5.1 Management commitment**

- Top management provides evidence of its commitment to the development and implementation of the Quality Management System and continually improving its effectiveness by:
- Communicating to the organization the importance of meeting customer as well as statutory and regulatory Requirements,
- Establishing the Quality Policy
- Ensuring that Quality Objectives are established
- Conducting Management Reviews  
Ensuring the availability of resources.

#### **5.2 Customer focus**

- Top management ensures that customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction (This is conducted as part of the Management Review process, ref. QMS 5.6.3).

#### **5.3 Quality Policy**

- Top management ensures that the Quality Policy
- Is appropriate to the purpose of the organization,
- Includes a commitment to comply with requirements and continually improve the effectiveness of the Quality Management System,
- Provides a framework for establishing and reviewing Quality Objectives,
- Is communicated and understood within the organization, and
- Is reviewed for continuing suitability.

#### **5.4 Planning**

##### **5.4.1 Quality Objectives**

- Top management ensures that Quality Objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The Quality Objectives are measurable and consistent with the Quality Policy. This is conducted as part of the Management Review process (ref. QMS 5.6.3)

##### **5.4.2 Quality Management System planning**

- Top management ensures that
- The planning of the Quality Management System is carried out in order to meet the requirements given as well as the Quality Objectives
- The integrity of the Quality Management System is maintained when changes to the Quality Management system are planned and implemented.

#### **5.5 Responsibility, authority and communication**

##### **5.5.1 Responsibility and authority**

- Top management ensures that the responsibilities, authorities and their interrelation are defined and communicated within the organization.

## **QMS 5.0 Management Responsibility**

### **REV. B**

#### **5.5.2 Management representative**

- S. Madonna, President of Sharp Nuclead Mfg. Co. Inc. has appointed S. Madonna as the ISO Management Representatives, irrespective of other responsibilities, he shall have responsibility and authority that includes
- Ensuring that processes needed for the Quality Management System are established, Implemented and maintained,
- Reporting to top management on the performance of the Quality Management System and any need for
- Improvement, and
- Ensuring the promotion of awareness of customer requirements throughout the organization,
- NOTE the responsibility of a management representative can include liaison with external parties on matters relating to the Quality Management System.

#### **5.5.3 Internal communication**

- Top management ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the Quality Management System.

#### **5.6 Management review**

##### **5.6.1 General**

- Top Management reviews the organization's Quality Management System, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the Quality Management System, including the Quality Policy and Quality Objectives.
- Records from Management Reviews are maintained (see 4.2.4).

##### **5.6.2 Review Input**

- The input to management review includes information on
- Results of audits
- Customer feedback/satisfaction
- Process performance and product conformity
- Preventive and corrective actions
- Follow-up actions from previous management reviews
- Planned changes that could affect the quality management system
- Recommendations for continuous improvement

##### **5.6.3 Review output**

- The output from the management review includes any decisions and actions related to
- Improvement of the effectiveness of the Quality Management System and its processes
- Improvement of product related to customer requirements
- Resource needs.
- Note: The yearly Management Review meeting is being utilized as the tool to discuss, document, implement and verify effective implementation of any actions taken in relation to corrective, preventative, and continuous improvement of the Quality System, (Quality Manual, Procedures/processes and forms), this includes review of SPC variable data and upon review of effective implementation a review of attribute data

## **QMS 6.0 Resource Management**

### **REV. B**

#### **6.1 Provision of resources**

- The organization has determined and provided the resources needed
- To implement and maintain the Quality Management System and continually improve its effectiveness
- To enhance customer satisfaction by meeting customer requirements.

#### **6.2 Human resources**

##### **6.2.1 General**

- Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

##### **6.2.2 Competence, awareness and training**

- The organization has
- Determined the necessary competence for personnel performing work affecting product quality,
- Provided training or take other actions to satisfy these needs,
- Evaluated the effectiveness of the actions taken,
- d) Ensured that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the Quality Objectives, and
- Maintained appropriate records of education, training, skills and experience (see 4.2.4).
- Note: Periodic assessments are performed as part of the Management Review process (ref. QMS 5.6.3)

#### **6.3 Infrastructure**

- The organization has determined, provide and maintain the infrastructure needed to achieve conformity to product requirements.
- Infrastructure includes, for example:
- Current building's workspace of 2500 square feet
- Training/safety per QAP 4.18
- Equipment requirements and maintenance per QAP 4.9
- Calibration of test equipment to ensure product acceptability per QAP 4.11
- Preservation of product per QAP 4.15
- Sufficient personnel per Quality System needs
- Clean, well lit facility.

#### **6.4 Work environment**

- The organization has determined and managed the work environment needed to achieve conformity to product requirements.

## **QMS 7.0 Product Realization**

### **REV. B**

#### **7.1 Planning of product realization**

- The organization has planned and developed the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the Quality Management System (see 4.1).
- In planning product realization, the organization has determined the following, as appropriate:
  - Quality Objectives and requirements for the product.
  - The need to establish processes, documents, and provide resources specific to the product
  - Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
  - d) Records needed to provide evidence that the realization processes and resulting product fulfill requirements (see 4.2.4).
- The output of this planning is in a form suitable for the organization's method of operations.
- NOTE 1 A document specifying the processes of the Quality Management System (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.
- NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

#### **7.2 Customer-related processes**

##### **7.2.1 Determination of requirements related to the product**

- The organization has determined
- Requirements specified by the customer, including the requirements for delivery and post-delivery activities
- Requirements not stated by the customer but necessary for specified use or known and intended use
- Statutory and regulatory requirements related to the product
- Any additional requirements determined by the organization.

##### **7.2.2 Review of requirements related to the product**

- The organization has reviewed the requirements related to the product. This review will be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that
- Product requirements are defined
- Contract or order requirements differing from those previously expressed are resolved
- The organization has the ability to meet the defined requirements.
- Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).
- Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.
- Where product requirements are changed, the organization has ensured that relevant documents are amended and that relevant personnel are made aware of the changed requirements.
- NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

**QMS 7.0 Product Realization**  
**REV. B**

**7.2.3 Customer communication**

- The organization has determined and implemented effective arrangements for communicating with customers in relation to
- Product information.
- Inquiries, contracts or order handling, including amendments
- Customer feedback, including customer complaints.

**7.3 Design and development is not applicable to SHARP NUCLEAD MFG. CO. INC.**

**7.4 Purchasing**

**7.4.1 Purchasing process**

- The organization has ensured that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product
- The organization shall be responsible for the quality of all products purchased from suppliers, including customer-designated sources. (Ref. QAP 4.10)
- The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and reevaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

**7.4.2 The organization shall:**

- maintain a register of approved suppliers that includes the scope of the approval;
- periodically review supplier performance; records of these reviews shall be used as a basis for establishing the level of controls to be implemented;
- define the necessary actions to take when dealing with suppliers that do not meet requirements;
- ensure where required that both the organization and all suppliers use customer approved special process sources;
- Ensure that the function having responsibility for approving supplier quality systems has the authority to disapprove the use of sources.
- Reference QAP 4.6/4.20

## **QMS 7.0 Product Realization**

### **REV. B**

#### **7.4.2 Purchasing Information**

- Purchasing information describes the product to be purchased, including where appropriate
- Requirements for approval of product, procedures, processes and equipment
- Requirements for qualification of personnel
- Quality Management System requirements.
- the name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data,
- requirements for design, test, examination, inspection and related instructions for acceptance by the organization,
- requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing,
- requirements relative to
  - supplier notification to organization of nonconforming product and
  - arrangements for organization approval of supplier nonconforming material,
- requirements for the supplier to notify the organization of changes in product and/or process definition and, where required, obtain organization approval,
- right of access by the organization, their customer, and regulatory authorities to all facilities involved in the order and to all applicable records, and
- Requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required.
- ref. QAP 4.6
- The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

#### **7.4.3 Verification of purchased product**

- The organization has established and implemented the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.
- Verification activities may include
- obtaining objective evidence of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control),
- inspection and audit at supplier's premises,
- review of the required documentation,
- inspection of products upon receipt, and
- Delegation of verification to the supplier, or supplier certification.
- Reference QAP 4.6
- Purchased product shall not be used or processed until it has been verified as conforming to specified requirements unless it is released under positive recall procedure. (ref QAP 4.10)
- Where the organization utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. The organization shall periodically validate test reports for raw material (to be determined at time of Contract Review)
- Where the organization delegate's verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained. (ref QAP 4.6)

- Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

## **QMS 7.0 Product Realization**

### **REV. B**

#### **7.4.3 Verification of purchased product**

- Where specified in the contract, the customer or the customer's representative shall be afforded the right to verify at the supplier's premises and the organization's premises that subcontracted product conforms to specked requirements. (ref. QAP 4.6)
- Verification by the customer shall not be used by the organization as evidence of effective control of quality by the supplier and shall not absolve the organization of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

#### **7.5 Production and service provision**

##### **7.5.1 Control of Production and Service Provision:**

- Planning shall consider, as applicable,
- the establishment of process controls and development of control plans where key characteristics have been identified, N/A
- the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization N/A
- the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics N/A
- special processes (see 7.5.2)
- The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable
- the availability of information that describes the characteristics of the product,
- the availability of work instructions, as necessary,
- the use of suitable equipment,
- the availability and use of monitoring and measuring devices,
- the implementation of monitoring and measurement,
- the implementation of release, delivery and post-delivery activities,

##### **7.5.1.1 Production Documentation:**

- Production operations shall be carried out in accordance with approved data. This data shall contain as necessary
- drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards); and inspection documents (see 8.2.4.1), and a list of specific or non-specific tools and numerical control (NC) machine programs required and any specific instructions associated with their use

##### **7.5.1.2 Control of Production Process Changes:**

- Persons authorized to approve changes to production processes shall be identified.
- The organization shall identify and obtain acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements
- Changes affecting processes, production equipment, tools and programs shall be documented. Procedures shall be available to control their implementation
- The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product quality

**QMS 7.0 Product Realization**  
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**7.5.1.3 Control of Production Equipment, Tools and Numerical Control (N.C.) Machine Programs:**

- Production equipment, tools and programs shall be validated prior to use and maintained and inspected periodically according to documented procedures. Validation prior to production use shall include verification of the first article produced to the design data/specification  
Storage requirements, including periodic preservation/condition checks, shall be established for production equipment or tooling in storage

**7.5.1.4 Control of Work Transferred, on a Temporary Basis, Outside the Organization's Facilities:**

- When planning to temporarily transfer work to a location outside the organization's facilities, the organization shall define the process to control and validate the quality of the work, will be controlled on the vendor PO. Per review of customer requirements stated in QAP 4.6

**7.5.1.5 Control of Service Operations:**

- Servicing is not applicable to Sharp Nuclead Mfg. Co. Inc. due to business model.

**7.5.2 Validation of processes for production and service provision**

- The organization has validated any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.
- NOTE These processes are frequently referred to as special processes.
- Validation shall demonstrate the ability of these processes to achieve planned results.
- The organization shall establish arrangements for these processes including, as applicable defined criteria for review and approval of the processes,
- qualification and approval of special processes prior to use,
- approval of equipment and qualification of personnel,
- use of specific methods and procedures,
- control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto,
- requirements for records (see 4.2.4), and
- Revalidation.
- Reference QAP 4.6

**7.5.3 Identification and traceability**

- Where appropriate, the organization has identified the product by suitable means throughout product realization.
- The organization shall maintain the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration (ref. QAP 4.16)
- The organization shall identify the product status with respect to monitoring and measurement requirements.
- When acceptance authority media are used (e.g., stamps, electronic signatures, passwords), the organization shall establish and document controls for the media (ref QAP 4.16)
- Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).

**QMS 7.0 Product Realization**  
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**7.5.3 Identification and traceability**

- According to the level of traceability required by contract, regulatory, or other established requirement, the organization's system shall provide for:
- identification to be maintained throughout the product life;
- all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch;
- for an assembly, the identity of its components and those of the next higher assembly to be traced;
- For a given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved.
- Reference QAP 4.16
- NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained (see 4.3).

**7.5.4 Customer Property:**

- The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).
- NOTE Customer property can include intellectual property, including customer furnished data used for design, production and/or inspection.

**7.5.5 Preservation of product**

- The organization has preserved the conformity of product during internal processing and delivery to the intended destination. This preservation shall include Identification, handling, packaging, storage and protection. Preservation applies to the constituent parts of a product.

## **QMS 7.0 Product Realization**

### **REV. B**

#### **7.6 Control of monitoring and measuring devices**

- The organization has determined the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).
- The organization shall maintain a register of these monitoring and measuring devices, and define the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria. (ref. QAP 4.11)
- NOTE Monitoring and measuring devices include, but are not limited to: test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity (ref QAP 4.11)
- The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.
- The organization shall ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out (ref. QAP 4.11)
- Where necessary to ensure valid results, measuring equipment shall:
  - Be calibrated or verified at specified intervals, or prior to use. Against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded.
  - Be adjusted or re-adjusted as necessary.
  - Be identified to enable the calibration status to be determined.
  - Be safeguarded from adjustments that would invalidate the measurement result.
  - Be protected from damage and deterioration during handling, maintenance and storage.
  - Be recalled to a defined method when requiring calibration ( ref QAP 4.11)
- In addition, the organization has assessed and recorded the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization has taken appropriate action on the equipment and any product affected. Records of the results of calibration and verification have been maintained (see 4.2.4).
- When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the Intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

## **QMS 8.0 Measurement, Analysis and Improvement**

### **REV. B**

#### **8.1 General**

The organization has planned and implemented the monitoring, measurement, analysis and improvement processes needed

- To demonstrate conformity of the product
- To ensure conformity of the Quality Management System
- To continually improve the effectiveness of the Quality Management System.
- This includes determination of applicable methods, including statistical techniques, and the extent of their use.
- Reference QAP 4.20 for those Statistical techniques currently utilized. Any additional requirements will be implemented per customer requirements.

#### **8.2 Monitoring and measurement**

##### **8.2.1 Customer satisfaction**

- As one of the measurements of the performance of the Quality Management System, the organization monitors information relating to customer perception as to whether the organization has fulfilled customer requirements. The methods for obtaining and using this Information have been determined.

## **QMS 8.0 Measurement, Analysis and Improvement**

### **REV. B**

#### **8.2.2 Internal audit**

- The organization conducts Internal audits at planned intervals to determine whether the Quality Management System
- conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the Quality Management System requirements established by the organization, and
- Is effectively implemented and maintained. (ref. QAP 4.18)
- An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.
- The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.
- The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

#### **8.2.3 Monitoring and measurement of processes**

- The organization has applied suitable methods for monitoring and, where applicable, measurement of the Quality Management System processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product.
- In the event of process nonconformity, the organization shall
- take appropriate action to correct the nonconforming process,
- evaluate whether the process nonconformity has resulted in product nonconformity, and identify and control the nonconforming product in accordance with clause Ref. 4.13

## **QMS 8.0 Measurement, Analysis and Improvement**

### **REV. B**

#### **8.2.4 Monitoring and measurement of product**

- The organization shall monitor and measure the characteristics of the product to verify that product requirements are fulfilled. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).
- When key characteristics have been identified, they shall be monitored and controlled
- (ref QAP 4.10)
- When the organization uses sampling inspection as a means of product acceptance, the plan shall be statistically valid and appropriate for use. The plan shall preclude the acceptance of lots whose samples have known nonconformities. When required, the plan shall be submitted for customer approval (ref QAP 4.10)
- Product shall not be used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities (ref QAP 4.10)
- Evidence of conformity with the acceptance criteria shall be maintained. Records indicate the person(s) authorizing release of product (see 4.2.4).
- Product release and service delivery proceeds until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

##### **8.2.4.1 Inspection Documentation:**

- Measurement requirements for product or service acceptance shall be documented. This documentation may be part of the production documentation, but shall include
- Criteria for acceptance and/or rejection,
- where in the sequence measurement and testing operations are performed,
- A record of the measurement results, and type of measurement instruments required and any specific instructions associated with their use.
- Test records shall show actual test results data when required by specification or acceptance test plan where required to demonstrate product qualification the organization shall ensure that records provide evidence that the product meets the defined requirements. (ref QAP 4.3 & 4.6)

##### **8.2.4.2 First Article Inspection:**

- The organization's system shall provide a process for the inspection, verification, and documentation of a representative item from the first production run of a new part, or following any subsequent change that invalidates the previous first article inspection result. N/A.

**QMS 8.0 Measurement, Analysis and Improvement**  
**REV. B**

**8.3 Control of nonconforming product**

- The organization ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product have been defined in a documented procedure.
- NOTE The term "nonconforming product" includes nonconforming product returned from a customer.
- The organization's documented procedure shall define the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions. (ref. QAP 4.11 & 4.13)
- The organization shall deal with nonconforming product by one or more of the following ways:
- By taking action to eliminate the detected nonconformity;
- By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- By taking action to preclude its original intended use or application.
- Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).
- When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.
- When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.
- NOTE Parties requiring notification of nonconforming product may include suppliers, internal organizations, customers, distributors, and regulatory authorities.

## **QMS 8.0 Measurement, Analysis and Improvement**

### **REV. B**

#### **8.4 Analysis of data**

- The organization has determined, collected and analyzed appropriate data to demonstrate the suitability and effectiveness of the Quality Management System and to evaluate where continual improvement of the Quality Management System can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.
- The analysis of data provides information relating to
- Customer satisfaction (see 8.2.1)
- Conformance to product requirements (see 7.2.1)
- Characteristics and trends of processes and products including opportunities for preventive action
- Suppliers.

#### **8.5 Improvement**

##### **8.5.1 Continual Improvement**

- The organization shall continually improve the effectiveness of the Quality Management System through the use of the Quality Policy, Quality Objectives, audit results, analysis of data, corrective and preventive actions and management review.

##### **8.5.2 Corrective action**

- The organization takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.
- A documented procedure has been established to define requirements for
- Reviewing nonconformities (including customer complaints)
- Determining the causes of nonconformities
- Evaluating the need for action to ensure that nonconformities do not recur
- Determining and Implementing action needed
- Records of the results of action taken (see 4.2.4)
- Reviewing corrective action taken.
- flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause, and
- Specific actions where timely and/or effective corrective actions are not achieved.

##### **8.5.3 Preventive action**

- The organization has determined actions to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.
- A documented procedure has been established to define requirements for
- Determining potential nonconformities and their causes
- Evaluating the need for action to prevent occurrence of nonconformities
- Determining and implementing action needed
- Records of results of action taken (see 4.2.4)
- Reviewing preventive action taken.

## Section II

### Management Control and Learning

<u>Procedures</u>	<u>QAP #</u>	<u>Rev</u>
Document Control	4.5	B
Corrective Action/Preventative Action	4.14	B
Quality Records	4.16	B
Internal Audit	4.17	B
Training	4.18	B

DOCUMENT NO: QAP 4.5	DESCRIPTION: DOCUMENT CONTROL
REVISION NO.: B	SHEET: 1
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

4.5.1 **PURPOSE:**

TO DEFINE A METHOD IN WHICH CUSTOMER SUPPLIED DOCUMENT CHANGES AND INTERNAL DOCUMENTS ARE CONTROLLED TO ASSURE THAT ONLY RELEASED AND CURRENT REVISIONS ARE USED FOR PROCUREMENT OF MATERIAL AND FOR VALUE ADDED PRODUCT.

4.5.2 **SCOPE:**

THIS PROCEDURE APPLIES TO ALL DOCUMENTS UTILIZED BY SHARP NUCLEAD MFG. CO. INC.

4.5.3 **PROCEDURE:**

4.5.4 THE TRAVELER IS THE CONTROLLING DOCUMENT FOR ENSURING CUSTOMER AND SHARP NUCLEAD MFG. CO. INC REQUIREMENTS ARE IDENTIFIED THROUGHOUT PROCESSING OF CUSTOMER ORDER

4.5.5 TO INSURE A PROPER REVIEW OF THE QUALITY MANUAL A QUALITY MANUAL CHECKLIST AND DISTRIBUTION LOG WILL BE COMPLETED AND FILED BY THE ISO MGT REP.

4.5.6 FORMS WHICH DO NOT INDICATE FORM NUMBER OR REVISION LEVEL ARE CONSIDERED REVISION LEVEL - (DASH). REFERENCE QMS 4.22

4.5.7 REVIEW AND APPROVAL OF ALL RECORDS WILL BE IDENTIFIED VIA INITIALS AND DATE OF PERSON REVIEWING THAT RECORD.

4.5.8 WHEN RECORDS (MANUAL, PROCEDURE, AND FORMS) ARE UPDATED IT IS THE RESPONSIBILITY OF THE MGT REP. TO DISTRIBUTE THE NEW REVISION AND DESTROY THE OLD. THE TRAINING RECORD WILL THEN BE COMPLETED INDICATING THE PROCEDURE/PROCEDURE #/PROCEDURE REVISION AND THE PERSON (S) GIVEN THE PROCEDURE. THE TRAINING RECORD WILL BE AND FILED IN THE MGT REPRESENTATIVE'S OFFICE

4.5.9 **ENGINEERING CHANGE ORDER (ECO)**

A. ANYONE CAN GENERATE AN ECO

B. AN ECO IS WRITTEN WHEN THERE IS A REQUESTED CUSTOMER OR INTERNAL CHANGE TO AN EXISTING PRODUCT

C. THE ECO WILL BE SUBMITTED TO THE ENGINEERING OR DESIGNEE AND UPON REVIEW, ENTER THE ECO INTO THE ECO LOG ASSIGNING AN ECO#

D. ONCE A WEEK, OR AS NEEDED AN ECO MEETING WILL BE HELD TO INCLUDE THE FOLLOWING REPRESENTATIVES OR DESIGNEE AS A MINIMUM:

1. ENGINEERING
2. OPERATIONS MANAGER
3. SALES MANAGER
4. PURCHASING MANAGER
5. QUALITY

E. ACTIONS WILL BE MAINTAINED IN THE ECO LOG BY THE ECO COORDINATOR

F. UPON REVIEW AND APPROVAL OF THE ECO, ALL MEMBERS WILL SIGN OFF ON THE ECO

G. ENGINEERING WILL THEN UPDATE THE ENGINEERING FILE AND SUBMIT UPDATED PACKAGE TO THE ECO COORDINATOR TO DISTRIBUTE PER DISTRIBUTION LIST AND FILE THE ECO ELECTRONICALLY OR MANUALLY, AND CLOSE OUT THE ECO LOG FOR THAT ECO.

H. ALL PERSONNEL ON DISTRIBUTION LIST FOR RECEIVING UPDATED HARD COPY DOCUMENTS ARE RESPONSIBLE FOR DESTROYING OLD REVISION AND IMPLEMENTING NEW.

4.5.10 **IN PRODUCTION (WIP) CHANGES:**

A. IN ORDER TO MEET CUSTOMER DELIVERY REQUIREMENTS, IT MAY BE NECESSARY TO MAKE HANDWRITTEN CHANGES ON DOCUMENTS BEING UTILIZED, (i.e. DOCUMENTATION PACKAGE, WORK INSTRUCTION, ETC.)

1. WHEN THIS OCCURS THE FOLLOWING PROCESS WILL BE FOLLOWED:

A. ONLY ENGINEERING CAN AUTHORIZE AND APPROVE THESE CHANGES

B. WHEN A CHANGE IS REQUIRED, ENGINEERING WILL PLACE A HOLD ON CURRENT WIP, NOTIFYING THE OPERATIONS MGR IN WRITING OR E-MAIL, AND RETRIEVE THE DOCUMENTATION PACKAGE

C. THE CHANGE WILL BE REVIEWED BY ENGINEERING IN A TIMELY MANNER, AND UPON APPROVAL, THE HANDWRITTEN CHANGES WILL BE MADE ON THE APPROPRIATE DOCUMENT (S),

INITIALED/DATED BY THE APPROPRIATE ENGINEER AND RETURNED TO THE MFG MGR TO CONTINUE PROCESSING. PRIOR TO RELEASE TO MANUFACTURING, THE ENGINEER WILL COMPLETE AN ECO FORM AND SUBMIT TO THE ECO CORDINATOR TO PROCESS PER ECO PROCEDURE STATED ABOVE.

4.5.11 **RESPONSIBILITY:**

ISO MANAGEMENT REP.

DOCUMENT NO: QAP 4.14	DESCRIPTION: CORRECTIVE & PREVENTATIVE ACTION
REVISION NO.: B	SHEET: 1
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

4.14.1 **PURPOSE:**

TO ESTABLISH A SYSTEM FOR THE INITIATION OF CORRECTIVE ACTION AND TO ASSURE THAT FUTURE OCCURRENCES OF NONCONFORMANCE ARE PREVENTED.

4.14.2 **SCOPE:**

THIS PROCEDURE APPLIES TO CORRECTIVE ACTION RELATED TO SUPPLIERS OF NONCONFORMING MATERIAL. THIS PROCEDURE ALSO APPLIES TO CORRECTIVE ACTION REQUESTED BY CUSTOMERS OF SHARP NUCLEAD MFG. CO. INC.

4.14.3 **PROCEDURE:**

4.14.4 WHEN A SUPPLIER CORRECTIVE ACTION REQUEST (SCAR) IS REQUIRED PER MRB, THE ISO MGT REP. SHALL BE RESPONSIBLE FOR:

- A. ENTERING THE SCAR INTO THE DMR/SCAR LOG
- B. SENDING THE FIRST, SECOND, AND THIRD NOTICES TO THE SUPPLIER
- C. MAINTAINING A COPY IN AN "OPEN CORRECTIVE ACTION FILE".
- D. IF FIRST RESPONSE IS NOT RETURNED WITHIN 30 DAYS, A SECOND NOTICE WILL BE SENT, AND SUPPLIER IS GIVEN 30 DAYS TO RESPOND. IF SUPPLIER DOES NOT RESPOND TO SECOND NOTICE, A THIRD NOTICE IS SENT AND SUPPLIER IS GIVEN AN ADDITIONAL 30 DAYS TO RESPOND. IF NO RESPONSE TO THIRD NOTICE WITHIN THIRTY (30) DAYS, THE ISO MGT REP. WILL CONTACT SUPPLIER AND DETERMINE WHAT RECOMMENDATION TO MANAGEMENT IS APPROPRIATE.
- E. UPON THE RECEIPT OF THE COMPLETED "SUPPLIER CORRECTIVE ACTION REQUEST" FROM THE SUPPLIER, ISO MGT REP.. SHALL REVIEW, APPROVE, AND FILE IN A CLOSED SCAR FILE.

4.14.5 **CUSTOMER COMPLAINTS:**

- A. CUSTOMER COMPLAINTS ARE RECORDED ON A:
  - 1. CUSTOMER COMPLAINT FORM WILL BE GENERATED BY THE ISO MGT REP. AND COMPLETE THE CAUSE ANALYSIS AND CORRECTIVE ACTION. THE MGT REP WILL FILE IN A CUSTOMER COMPLAINT FILE TO BE REVIEWED AT THE YEARLY MANAGEMENT REVIEW MTGS.
  - 2. SUPPLIER CORRECTIVE ACTION FORM FROM THE CUSTOMER WHICH IS SUBMITTED TO THE MGT REP FOR CAUSE ANALYSIS AND CORRECTIVE ACTION. UPON COMPLETION, THE MGT REP WILL FORWARD A COPY TO CUSTOMER AND FILE A COPY IN A CUSTOMER COMPLAINT.

4.14.6 ALL CORRECTIVE ACTIONS WILL BE REVIEWED AT THE YEARLY MGT REVIEW MEETING AND ANY ACTION DOCUMENTED. EFFECTIVE IMPLEMENTATION WILL BE VERIFIED BY THE ISO MGT REPRESENTATIVE

4.14.7 **PREVENTATIVE ACTION:**

A. PREVENTATIVE ACTIONS WILL BE DISCUSSED IN A GENERAL BRAIN STORMING SESSION AT THE YEARLY MGT REVIEW MTGS.. ANY ACTION WILL DOCUMENTED AND VERIFIED FOR EFFECTIVE IMPLEMENTATION BY THE ISO MGT REPRESENTATIVE

4.14.8 **RESPONSIBILITY:**

ISO MGT REP.

DOCUMENT NO: QAP 4.16	DESCRIPTION: CONTROL OF QUALITY RECORDS
REVISION NO.: B	SHEET: 1
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

- 4.16.1 **PURPOSE:**  
TO MAINTAIN RECORDS OF INSPECTION MATERIALS, CERTIFICATIONS, TEST DATA AND ANY OTHER DOCUMENTATION AS DICTATED BY CUSTOMER REQUIREMENTS.
- 4.16.2 **SCOPE:**  
THIS PROCEDURE APPLIES TO ALL SPECIFIED DOCUMENTS UTILIZED IN THE HANDLING AND INSPECTION OF PRODUCT OF SHARP NUCLEAD MFG. CO. INC
- 4.16.3 **PROCEDURE:**
- 4.16.4 ALL QUALITY RECORDS ARE LEGIBLE AND IDENTIFIABLE TO THE RELEVANT PRODUCT.
- 4.16.5 ALL FORMS ARE IDENTIFIED IN QMS 4.22, AND IN SUCH A MANNER THAT THEY ARE READILY RETRIEVABLE AND IN A SUITABLE ENVIRONMENT TO MINIMIZE THE DETERIORATION, DAMAGE OR LOSS.
- 4.16.6 THE FILES FOR RECORD RETENTION SHALL BE BY CUSTOMER OR ALPHABETICAL AND AVAILABLE FOR QUALITY AUDITS AS WARRANTED.
- 4.16.7 DEFINITIONS OF DOCUMENTS TO BE MAINTAINED AND DATA RETENTION PERIODS WILL BE AS FOLLOWS, UNLESS SPECIFIED BY CONTRACT:
- A. QUALITY MANUAL IS CONTROLLED PER QAP 4.5.8.
  - B. THE RETENTION TIME FOR ALL DOCUMENTS STATED IN QMS 4.22 WILL BE 3 YEARS
  - C. A MASTER LIST OF QUALITY RECORDS IDENTIFIED IN QMS 4.22 IS MAINTAINED BY THE ISO MGT REP.
- 4.16.8 WHEN CONTRACT REQUIRES A CHANGE IN RETENTION TIME FRAME, THE PROCEDURE WILL BE REVISED TO REFLECT THAT EXCEPTION.
- 4.16.9 **RESPONSIBILITY:**  
VARIOUS DEPARTMENTS

DOCUMENT NO: QAP 4.17	DESCRIPTION: INTERNAL AUDIT
REVISION NO.: B	SHEET: 1
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

4.17.1 **PURPOSE:**

TO VERIFY THAT ALL ELEMENTS OF THE ISO-9001/2000 QUALITY SYSTEM ARE BEING MAINTAINED.

4.17.2 **SCOPE:**

THIS PROCEDURE APPLIES TO ALL QUALITY SYSTEMS OF SHARP NUCLEAD MFG. CO. INC.

4.17.3 **PROCEDURE:**

4.17.4 A QUALITY SYSTEMS AUDIT WILL BE PERFORMED BY THE ISO MGT. REP. ON AN ANNUAL BASIS UTILIZING THE SHARP NUCLEAD MFG. CO. INC INTERNAL AUDIT FORM 2000 REV 1 AND INTERNAL AUDIT CORRECTIVE ACTION FORM.

A. A LETTER WILL BE SENT TO MANAGEMENT STATING THE TIME AND SCHEDULE OF THE AUDIT.

B. AFTER AUDIT THE ISO MGT REP. WILL SUBMIT A FORMAL RESPONSE OF RESULTS WITH APPROPRIATE CORRECTIVE ACTIONS.

C. IACA'S WILL BE RETURNED AND REVIEWED AND APPROVED BY ISO MGT REP. UPON SUCCESSFUL COMPLETION OF ACTION ITEMS THE ISO MGT REP. WILL SEND CONFIRMATION TO THE MANAGEMENT REPRESENTATIVE.

D. PREVENTATIVE CORRECTION ACTIONS ARE ADDRESSED AND IMPLEMENTED (WHEN APPLICABLE) AT THE YEARLY MANAGEMENT REVIEW MEETING. (REF. QMS 4.1.3)

E. THE ISO MGT REP. PERFORMING THE YEARLY INTERNAL AUDIT WILL HAVE AN AUDITOR TRAINING CERTIFICATE.

4.17.5 **RESPONSIBILITY:**

ISO MGT. REP.

DOCUMENT NO: QAP 4.18	DESCRIPTION: TRAINING
REVISION NO.: B	SHEET: 1
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

4.18.1 **PURPOSE:**

TO ADEQUATELY TRAIN PERSONNEL IN THE UNDERSTANDING AND PROPER IMPLEMENTATION OF THEIR JOB FUNCTIONS AND TOO CONSTANTLY MONITOR AND AUDIT TO INSURE THE HIGHEST JOB PERFORMANCE POSSIBLE.

4.18.2 **SCOPE:**

TRAINING IS POSSIBLE FOR ALL PURCHASING, SALES, WAREHOUSE AND Q.C. INSPECTORS IN THEIR FUNCTIONAL AREAS AND IN OTHER RELEVANT AREAS (CROSS-TRAINING) WHERE APPROPRIATE.

4.18.3 **PROCEDURE:**

4.18.4 THE TRAINING OF THE WORKERS VARY IN SCOPE AND DEPTH ACCORDING TO THE COMPLEXITY OF THE TASKS AND RESPONSIBILITIES. THE SUPERVISOR SHALL IDENTIFY WHAT TRAINING IS REQUIRED FOR PERSONNEL AND INSURE THAT TRAINING IS CONDUCTED PER A REVIEW OF THE APPROPRIATE PROCEDURE (S) AND OR FORMS. THE ISO MGT. REP. IS NOTIFIED OF COMPLETION OF TRAINING AND THE TRAINING RECORD IS UPDATED AND MAINTAINED BY THE ISO MGT REP.

4.18.5 ALTHOUGH THE CONTEXT OF THE TRAINING VARIES BY FUNCTIONAL AREA, IT CAN BE CHARACTERIZED AS FOLLOWS:

- A. THE SUPERVISOR PROVIDES VERBAL INSTRUCTIONS AND A DEMONSTRATION OF THE JOB TASKS TO THE TRAINEE.
- B. THE TRAINEE REVIEWS THE PROCEDURE(S) PER LIST (MAINTAINED BY TRAINER) RELEVANT TO JOB DESCRIPTION.
- C. TRAINEE IS PAIRED WITH LEAD PERSON WHO CLOSELY MONITORS PROGRESS AND GIVES IMMEDIATE FEEDBACK TO SUPERVISOR.
- D. BASED ON PROGRESS THE TRAINEE IS LEFT ALONE TO PERFORM JOB FUNCTION.
- E. IF THE TRAINEE LEARNS AND EXECUTES THE JOB TASKS ADEQUATELY, HE/SHE WILL BE PLACED ON THE JOB AS A NEW WORKER.
- F. NEW WORKERS PERFORMANCE WILL BE MONITORED ON A DAILY BASIS AS HE/SHE INTERACTS WITH OTHER PERSONNEL AND SUPERVISOR.
- G. BASED ON NEW WORKERS PERFORMANCE OVER A PERIOD OF TIME, THE TRAINER WILL BE RESPONSIBLE FOR DETERMINING THAT NEW WORKERS PERFORMANCE IS ACCEPTABLE TO PERFORM JOB TASK. CORRECTIVE ACTION (IF REQUIRED) IS INITIATED BY SUPERVISOR/ISO MGT REP.

4.18.6 **COMMUNICATION:**

SALES PERSONNEL ARE TRAINED TO HAVE ADEQUATE KNOWLEDGE AND COMMUNICATIONS SKILLS IN DEALING WITH CUSTOMERS BY SALES MANAGER OR DIRECT SUPERVISOR WITH THESE PROVEN SKILLS

4.18.7 THE FOLLOWING JOB SKILLS ARE REQUIRED FOR ALL POSITIONS WITHIN SHARP NUCLEAD MFG. CO. INC

- 1. HIGH SCHOOL GRADUATE
- 2. MUST READ AND SPEAK ENGLISH
- 3. ONLY THE PRESIDENT CAN WAIVE THESE REQUIREMENTS
- 4. ALL CURRENT EMPLOYEES AS OF 1/03 ARE GRANDFATHERED TO THE ABOVE REQUIREMENTS

4.18.8 **RESPONSIBILITY:**

ALL MANAGERS AND SUPERVISORS

**SECTION III**  
**THE PRIMARY PROCESS**

<b><u>PROCEDURES</u></b>	<b><u>QAP #</u></b>	<b><u>REV</u></b>
CONTRACT REVIEW	4.3	B
DESIGN CONTROL	4.4	B
PURCHASING	4.6	B
CUSTOMER SUPPLIED PRODUCT	4.7	B
PRODUCT IDENTIFICATION & TRACEABILITY	4.8	B
PROCESS CONTROL/VALUE ADDED	4.9	B
INSPECTION & TESTING	4.10	B
INSPECTION MEASURING & TEST EQUIPMENT	4.11	B
INSPECTION AND TEST STATUS	4.12	B
CONTROL OF NONCONFORMING PRODUCTS	4.13	B
HANDLING/STORAGE/PRESERVATION /PACKAGING & DELIVERY	4.15	B
SERVICING	4.19	B
STATISTICAL TECHNIQUES	4.20	B

DOCUMENT NO: QAP 4.3	DESCRIPTION: CONTRACT REVIEW
REVISION NO.: B	SHEET: 1
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

- 4.3.1 **PURPOSE**  
TO ESTABLISH A PROCEDURE FROM INCOMING CUSTOMER SALES CALLS (REQUEST FOR QUOTE) TO ACTUAL SALES ORDER, SHIPPING AND TO INSURE AN ORDERLY FLOW OF ACCOMPANYING PAPERWORK.
- 4.3.2 **SCOPE**  
PROCEDURE WILL ALLOW FOR SHARP NUCLEAD MFG. CO. INC CUSTOMER REQUESTS TO BE HANDLED EXPEDIENTLY, EFFICIENTLY AND IN A PROFESSIONAL MANNER.
- 4.3.3 **DEFINITIONS**
- 4.3.4 REQUEST FOR QUOTE (RFQ): CUSTOMER REQUESTS A QUOTATION FOR PRICE AND DELIVERY ON ONE OR MORE ITEMS.
- 4.3.5 SALES ORDER: IS AN AGREEMENT BETWEEN THE CUSTOMER AND SHARP NUCLEAD MFG. CO. INC
- 4.3.6 **PROCEDURE**
- 4.3.7 **CONTRACT REVIEW**
- 4.3.8 THE RESPONSIBILITY OF SALES IS TO DOCUMENT THE QUALITY REQUIREMENTS, INCLUDING PERFORMANCE CHARACTERISTICS, ESTHETIC CHARACTERISTICS, FORM & FIT, APPLICABLE STANDARDS, LOT TRACEABILITY AND ANY OTHER SPECIAL REQUIREMENTS SPECIFIED BY CUSTOMER CONTRACT.
- 4.3.9 **REQUEST FOR QUOTE (RFQ)**
- A. CUSTOMER CALLS/FAXES/MAILS OR E-MAILS A RFQ (REQUEST FOR QUOTE). INSIDE SALESPERSON RECORDS CUSTOMER REQUESTS FOR PRICE AND DELIVERY ON THE SALES ORDER WORKSHEET (SOW) OR UTILIZING THE CUSTOMER HARD COPY (WHEN APPLICABLE)
- B. THE RFQ IS INPUT INTO SYSTEM AND A HARD COPY QUOTE/ESTIMATE SHEET (QES) IS PRINTED AND THE CUSTOMER IS PHONED/FAXED/MAILED OR E-MAILED THE RFQ INFORMATION.
- C. THE RFQ IS THEN PLACED INTO AN OPEN QUOTE FILE.
- 4.3.10 **PLACEMENT OF CUSTOMER ORDER:**
- 4.3.11 ALL CUSTOMERS ARE REQUIRED TO SUBMIT A CONFIRMING SALES ORDER
- A. UPON RECEIPT THE CUSTOMER CONFIRMING IS REVIEWED TO THE ORIGINAL QUOTE/ESTIMATE SHEET
- B. UPON REVIEW AND APPROVAL A COPY OF QES IS SUBMITTED TO OPERATIONS MANAGER TO PREPARE FOR MANUFACTURING AND THE CUSTOMER CONFIRMING AND QES ARE ATTACHED AND FILED IN OPEN ORDER FILE
- 4.3.12 **CUSTOMER CHANGES:**
- A. CUSTOMER WILL PHONE/FAX/MAIL OR E-MAIL A REQUEST TO CHANGE AN EXISTING SALES ORDER
- B. IF REQUESTED CHANGE DOES NOT AFFECT FORM, FIT OR FUNCTION THE ORIGINAL CUSTOMER SALES ORDER IS MARKED-UP WITH CHANGE MANUALLY AND REFILED.
- C. WHEN CHANGE EFFECTS FORM, FIT OR FUNCTION THE ORIGINAL SALES ORDER IS MARKED-UP WITH REQUESTED CHANGE AND SUBMITTED TO ENGINEERING FOR REVIEW
- D. ENGINEERING WILL REVIEW CUSTOMER REQUEST FOR CHANGE AND UPON APPROVAL GENERATE AN ENGINEERING CHANGE NOTICE (ECO) (REFERENCE QAP 4.5)
- E. THE ECO WILL BE SUBMITTED TO THE OPERATIONS MANAGER:
1. IF CUSTOMER ORDER IS WORK IN PROCESS (WIP) THE PARTS AND PAPERWORK IN MFG ARE REMOVED AND THE DOC. PGK UPDATED AND THEN RESUBMITTED TO LAST OPERATION
  2. IF NOT IN WIP THE DOCUMENTATION PACKAGE IS UPDATED AND REFILED TO AWAIT SUBMITTAL TO FIRST OPERATION.

DOCUMENT NO: QAP 4.3	DESCRIPTION: CONTRACT REVIEW
REVISION NO.: B	SHEET: 2
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

4.3.13 VENDOR CHANGE:

- A. VENDOR WILL PHONE/FAX/MAIL OR E-MAIL A REQUEST TO CHANGE AND EXISTING PURCHASE ORDER.
- B. WHEN THE CHANGE DOES NOT EFFECT ANY CURRENT CUSTOMER ORDERS THE VENDOR PO IS UPDATED AND REFILED.
- C WHEN THE CHANGE EFFECTS AN EXISTING CUSTOMER ORDER THE BUYER WILL CONTACT CUSTOMER TO RESOLVE.
- D. WHEN CHANGE EFFECTS FORM, FIT OR FUNCTION THE ORIGINAL SALES ORDER IS MARKED-UP WITH REQUESTED CHANGE AND SUBMITTED TO ENGINEERING FOR REVIEW
- E. ENGINEERING WILL REVIEW CUSTOMER REQUEST FOR CHANGE AND UPON APPROVAL GENERATE AN ENGINEERING CHANGE NOTICE (ECO) (REFERENCE QAP 4.5)
- F. THE ECO WILL BE SUBMITTED TO THE OPERATIONS MANAGER:
  - 1. IF CUSTOMER ORDER IS WORK IN PROCESS (WIP) THE PARTS AND PAPERWORK IN MFG ARE REMOVED AND THE DOC. PGK UPDATED AND THEN RESUBMITTED TO LAST OPERATION
  - 2. IF NOT IN WIP THE DOCUMENTATION PACKAGE IS UPDATED AND REFILED TO AWAIT SUBMITTAL TO FIRST OPERATION
- G. UPON RESOLUTION THE BUYER WILL UPDATE VENDOR PO AND CUSTOMER CONFIRMING AND REFILE

4.3.14 RETURN AUTHORIZATIONS

- A. CUSTOMER CALLS SALES TO REQUEST RETURN OF PRODUCT(S). UPON REVIEW AND APPROVAL OF REQUEST TO RETURN, A RETURN AUTHORIZATION (RA) FORM IS COMPLETED, LOGGED INTO THE RA LOG, AN RA # ASSIGNED AND THE CUSTOMER GIVEN THE RA# AS AUTHORIZATION TO RETURN
- B. THE RA FORM IS FILED BY SALES TO AWAIT RECEIPT OF PROCDUCT

4.3.15 CUSTOMER CONFIRMING PURCHASE ORDER / CHANGE ORDER REVIEW

WHEN A CONFIRMING CUSTOMER PURCHASE OR CHANGE ORDERS IS RECEIVED, SALES REVIEWS COMPUTER RECORD OF ORDER VERIFYING THE FOLLOWING:

- 1. QUANTITY                      2. PART NUMBER                      3. PRICE                                      4. PO. NUMBER
- 5. DELIVERY DATES    6. BILL AND SHIP TO ADDRESS    7. OTHER SPECIAL REQUIREMENTS

4.3.16 IF CORRECT, CONFIRMING IS INITIALED, DATED AND FILED.

4.3.17 IF DISCREPANCIES ARE FOUND WHICH REQUIRE CUSTOMER CONTACT, SALES CALLS CUSTOMER TO RESOLVE.

4.3.18 CORRECTIVE ACTION REQUESTS FROM CUSTOMERS

IF A CUSTOMER SPECIFICALLY REQUESTS A CORRECTIVE ACTION, THE SALESPERSON WILL COMPLETE A CUSTOMER COMPLAINT FORM AND SUBMIT TO ISO MGT REP. TO PROCESS.

4.3.19 SHARP NUCLEAD MFG. CO. INC RESERVES THE RIGHT TO PERFORM ON-SITE INSPECTION OF PRODUCT IF REQUIRED BY OUR CUSTOMER CONTRACT. SHARP NUCLEAD MFG. CO. INC. CUSTOMERS ARE ALLOWED TO PERFORM ON-SITE INSPECTION OF PRODUCT PER CONTRACT REQUIREMENTS.

4.3.20 RESPONSIBILITY  
SALES MANAGER

DOCUMENT NO: QAP 4.4	DESCRIPTION: DESIGN CONTROL
REVISION NO.: B	SHEET: 1
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

4.4.1 DUE TO BUSINESS, MODEL DESIGN CONTROL IS NOT APPLICABLE TO SHARP NUCLEAD MFG. CO. INC

DOCUMENT NO: QAP 4.6	DESCRIPTION: PURCHASING
REVISION NO.: B	SHEET: 1
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

4.6.1 **PURPOSE**

TO ESTABLISH PROCEDURES FOR THE PROCUREMENT OF MATERIALS AND/OR SERVICES BY SHARP NUCLEAD MFG. CO. INC.

4.6.2 **SCOPE**

THE SCOPE OF THE PROCEDURE APPLIES TO ALL PROCURED MATERIALS, COMPONENTS AND/OR SERVICES TO BE UTILIZED BY SHARP NUCLEAD MFG. CO. INC

4.6.3 **PROCEDURE**

4.6.4 THE RESPONSIBILITY OF SALES IS TO DOCUMENT THE TYPE, CLASS, STYLE, GRADE, OR OTHER PRECISE IDENTIFICATION AS REQUIRED. IF PRODUCT IS A CATALOG ITEM THIS INFORMATION IS NOT SPECIFIED ON PURCHASE ORDER

4.6.5 **PURCHASING AUTHORITY LEVELS**

AUTHORITY LEVELS ARE NOT APPLICABLE FOR ALL PERSONNEL INVOLVED IN PURCHASING PRODUCT FOR RESALE.

4.6.6 **APPROVED VENDORS ARE DESIGNATED AS FOLLOWS:**

A. APPROVED BY CUSTOMER

B. APPROVED BY SHARP NUCLEAD MFG. CO. INC VIA ACCEPTANCE BY VENDOR OF THE SHARP NUCLEAD MFG. CO. INC VENDOR PURCHASE ORDER

4.6.7 EFFECTIVE 2/28/03 ALL SUPPLIERS HAVE BEEN GRANDFATHERED AS APPROVED. ALL FUTURE SUPPLIERS WILL BE REVIEWED AND APPROVED BY THE QUALITY MANAGER UTILIZING ONE OR ALL OF THE CRITERIA SPECIFIED IN PARAGRAPHS 4.6.6 ABOVE. NO PRODUCT MAY BE PURCHASED UNTIL SUPPLIER HAS BEEN APPROVED. ALL VENDORS APPROVED AFTER 2/28/03 WILL BE ADDED TO APPROVED VENDOR FORM. THE PRESIDENT AND GENERAL MANAGER WILL BE UPDATED AS NEEDED ON APPROVED SUPPLIERS.

4.6.8 **PRODUCT IS PROCURED FOR THE FOLLOWING:**

A. PER CUSTOMER SALES ORDER ON NON-STOCK MATERIALS

B. THE TRAVELER IS SUBMITTED TO PURCHASING WHEN MATERIALS NEED TO BE PROCURED.

C. BUYER WILL GENERATE A VENDOR PURCHASE ORDER PER TRAVELER REQUIREMENTS AND PRINT OUT A HARD COPY FROM SYSTEM

D. VENDOR IS NOTIFIED VIA PHONE/FAX/MAIL OR E-MAIL AND THE PO FILED TO AWAIT RECEIPT OF MATERIAL.

4.6.9 **CUSTOMER CHANGES:**

A. CUSTOMER WILL PHONE/FAX/MAIL OR E-MAIL A REQUEST TO CHANGE AN EXISTING SALES ORDER

B. IF REQUESTED CHANGE DOES NOT AFFECT FORM, FIT OR FUNCTION THE ORIGINAL CUSTOMER SALES ORDER IS MARKED-UP WITH CHANGE MANUALLY AND REFILED.

C. WHEN CHANGE EFFECTS FORM, FIT OR FUNCTION THE ORIGINAL SALES ORDER IS MARKED-UP WITH REQUESTED CHANGE AND SUBMITTED TO ENGINEERING FOR REVIEW

D. ENGINEERING WILL REVIEW CUSTOMER REQUEST FOR CHANGE AND UPON APPROVAL GENERATE AN ENGINEERING CHANGE NOTICE (ECO) (REFERENCE QAP 4.5)

E. THE ECO WILL BE SUBMITTED TO THE OPERATIONS MANAGER:

1. IF CUSTOMER ORDER IS WORK IN PROCESS (WIP) THE PARTS AND PAPERWORK IN MFG ARE REMOVED AND THE DOC. PGK UPDATED AND THEN RESUBMITTED TO LAST OPERATION

2. IF NOT IN WIP THE DOCUMENTATION PACKAGE IS UPDATED AND REFILED TO AWAIT SUBMITTAL TO FIRST OPERATION

DOCUMENT NO: QAP 4.6	DESCRIPTION: PURCHASING
REVISION NO.: B	SHEET: 2
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

4.6.10 VENDOR CHANGE:

- A. VENDOR WILL PHONE/FAX/MAIL OR E-MAIL A REQUEST TO CHANGE AND EXISTING PURCHASE ORDER.
- B. WHEN THE CHANGE DOES NOT EFFECT ANY CURRENT CUSTOMER ORDERS THE VENDOR PO IS UPDATED AND REFILED.
- C WHEN THE CHANGE EFFECTS AN EXISTING CUSTOMER ORDER THE BUYER WILL CONTACT CUSTOMER TO RESOLVE.
- D. WHEN CHANGE EFFECTS FORM, FIT OR FUNCTION THE ORIGINAL SALES ORDER IS MARKED-UP WITH REQUESTED CHANGE AND SUBMITTED TO ENGINEERING FOR REVIEW
- E. ENGINEERING WILL REVIEW CUSTOMER REQUEST FOR CHANGE AND UPON APPROVAL GENERATE AN ENGINEERING CHANGE NOTICE (ECO) (REFERENCE QAP 4.5)
- F. THE ECO WILL BE SUBMITTED TO THE OPERATIONS MANAGER:
  - 1. IF CUSTOMER ORDER IS WORK IN PROCESS (WIP) THE PARTS AND PAPERWORK IN MFG ARE REMOVED AND THE DOC. PGK UPDATED AND THEN RESUBMITTED TO LAST OPERATION
  - 2. IF NOT IN WIP THE DOCUMENTATION PACKAGE IS UPDATED AND REFILED TO AWAIT SUBMITTAL TO FIRST OPERATION
- G. UPON RESOLUTION THE BUYER WILL UPDATE VENDOR PO AND CUSTOMER CONFIRMING AND REFILE

4.6.11 RESPONSIBILITY  
PURCHASING MANAGER

DOCUMENT NO: QAP 4.7	DESCRIPTION: CONTROL OF CUSTOMER SUPPLIED MATERIAL
REVISION NO.: B	SHEET: 1
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

4.7.1 CUSTOMER SUPPLIED PRODUCT IS APPLICABLE AND PROCESSED AS ALL OTHER MATERIALS

DOCUMENT NO: QAP 4.8	DESCRIPTION: PRODUCT IDENTIFICATION & TRACEABILITY
REVISION NO.: B	SHEET: 1
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

- 4.8.1 **PURPOSE:**  
TO INSURE PROPER MATERIAL IDENTIFICATION AND TRACEABILITY PER CUSTOMER REQUIREMENTS
- 4.8.2 **SCOPE:**  
ENCOMPASSES IDENTIFICATION AND TRACEABILITY OF ALL MATERIALS PROCESSED PER SHARP NUCLEAD MFG. CO. INC
- 4.8.3 **PROCEDURE:**
- 4.8.4 **PRODUCT IDENTIFICATION AND TRACEABILITY:**
- 4.8.5 PRODUCT IDENTIFICATION IS REQUIRED AND IS MAINTAINED VIA PART NUMBERS, LOT NUMBERS OR AS REQUIRED BY CONTRACT ON ALL MATERIALS PROCURED AND PROCESSED
- 4.8.6 **RESPONSIBILITY**  
ALL DEPT MGRS

DOCUMENT NO: QAP 4.9	DESCRIPTION: VALUE ADDED/MFG
REVISION NO.: B	SHEET: 1
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

- 4.9.1 **PURPOSE:**  
TO FABRICATE MODIFICATIONS ON PRODUCT PER CUSTOMER SPECIFIED REQUIREMENTS
- 4.9.2 **SCOPE:**  
THIS PROCEDURE ENCOMPASSES ALL VALUE ADDED/MFG FUNCTIONS OF SHARP NUCLEAD MFG. CO. INC
- 4.9.3 **PROCEDURE:**
- A. A QUOTE/ESTIMATE SHEET IS SUBMITTED TO OPERATIONS MANAGER
  - B. THE OPERATIONS MANAGER (OPS MGR) WILL COMPLETE A DOCUMENTATION PACKAGE (DP) CONSISTING OF TRAVELER/DRAWING OR ANY OTHER REQUIRED SPECIFICATIONS
  - C. THE DOCUMENTATION PACKAGE IS THEN SUBMITTED TO FIRST OPERATION
- 4.9.4 THE INDIVIDUAL PERFORMING EACH OPERATION IS RESPONSIBLE FOR THE FOLLOWING:
- A. REVIEW DP TO ENSURE ALL DOCUMENTS ARE AVAILABLE
  - B. ENSURE ALL PREVIOUS OPERATIONS HAVE BEEN COMPLETED
  - C. UPON FINISHING CURRENT OPERATION THE TRAVELER IS COMPLETED AND PARTS AND PAPERWORK ARE SUBMITTED TO NEXT STAGE
  - D. UPON COMPLETION THE DOCUMENTATION PACKAGE IS FILED BY CUSTOMER
- 4.9.4 MAINTENANCE OF EQUIPMENT IS PERFORMED AND DOCUMENTED IN THE MAINTENANCE LOG
- 4.9.5 **RESPONSIBILITY:**  
OPERATIONS MANAGER

DOCUMENT NO: QAP 4.10	DESCRIPTION: INSPECTION & TESTING
REVISION NO.: B	SHEET: 1
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

4.10.1 **PURPOSE:**

TO CONTROL THE ISSUE AND MAINTENANCE OF QUALITY ASSURANCE OPERATIONS

4.10.2 **SCOPE:**

THIS PROCEDURE APPLIES TO INSPECTION OF ALL MATERIALS PROCESSED THROUGHOUT SHARP NUCLEAD MFG. CO. INC.

4.10.3 **PROCEDURE:**

4.10.4 THE INSPECTION DEPARTMENT WILL PERFORM A VISUAL AND MECHANICAL INSPECTION AS REQUIRED BY APPLICABLE SPECIFICATIONS UTILIZING ANSI/ASQC Z1.4-1993 OR SPECIFIC CUSTOMER REQUIREMENTS. CURRENTLY ALL SUPPLIERS ARE DOCK TO STOCK AND INSPECTION IS PERFORMED PER CUSTOMER REQUEST.

4.10.5 ALL MATERIALS WILL BE INSPECTED TO ENSURE CONFORMANCE TO THE FOLLOWING:

DOCUMENTS:

PURCHASE ORDER

SUPPLIER CONTROL DOCUMENT

MILITARY SPECIFICATIONS

SHARP NUCLEAD MFG. CO. INC REQUIREMENTS (AS REQUIRED IN QUALITY MANUAL)

4.10.6 RECEIVING INSPECTION:

4.10.7 ACCEPTED MATERIAL

- A. THE INSPECTOR WILL MATCH PARTS, TO VENDOR PACKING SLIP AND SHARP NUCLEAD MFG. CO. INC VENDOR PO. TO ENSURE COMPLIANCE
- B. UPON REVIEW AND APPROVAL THE SHARP NUCLEAD MFG. CO. INC VENDOR PO IS INITIALED AND DATED BY INSPECTOR
- C. THE SHARP NUCLEAD MFG. CO. INC VENDOR PO IS THEN SUBMITTED ACCOUNTING AND THE VENDOR PACKING SLIP DISCARDED
- D. ANY CERTIFICATES OF COMPLIANCE ARE LOGGED INTO THE MATERIAL CERT REFERENCE LOG AND C OF C FILED BY CERT. # ASSIGNED
- E. THE PRODUCT IS TAGGED OR MARKED WITH THE CERT # AND SUBMITTED TO WAREHOUSE TO PROCESS.

4.10.8 NONCONFORMING MATERIAL

- A. MATERIAL AND PAPERWORK WILL BE SUBMITTED TO ISO MGT REP
- B. THE QREP. WILL BE NOTIFIED AND A DISCREPANT MATERIAL REPORT DMR IS GENERATED.
- C. PARTS AND PAPERWORK WILL BE SEGREGATED UNTIL DISPOSITION BY THE MRB HAS BEEN COMPLETED AND APPROPRIATE DISPOSITION AND SIGNATURES OBTAINED. TO INSURE PRODUCT IS NOT PROCESSED UNTIL IT HAS BEEN INSPECTED AND COMPLIES WITH ISO-9001 REQUIREMENTS REF. QAP 4.13

4.10.9 IN-PROCESS INSPECTION:

- A. IN-PROCESS INSPECTION IS PERFORMED PER TRAVELER REQUIREMENTS AND DOCUMENTED ON THE IN/PROCESS-FINAL INSPECTION RECORD (IPFIR) FORM

4.10.10 NONCONFORMING MATERIAL

- A. MATERIAL AND PAPERWORK WILL BE SUBMITTED TO ISO MGT REP
- B. THE QREP. WILL BE NOTIFIED AND A DMR GENERATED.
- C. PARTS AND PAPERWORK WILL BE SEGREGATED UNTIL DISPOSITION BY THE MRB HAS BEEN COMPLETED AND APPROPRIATE DISPOSITION AND SIGNATURES OBTAINED. TO INSURE PRODUCT IS NOT PROCESSED UNTIL IT HAS BEEN INSPECTED AND COMPLIES WITH ISO-9001 REQUIREMENTS REF. QAP 4.13

4.10.11 FINAL INSPECTION:

4.10.12 ACCEPTED MATERIAL

- A. COMPLETE INSPECTION PER TRAVELER REQUIREMENTS AND COMPLETE THE IPFIR
- B. SUBMIT PARTS AND PAPERWORK TO NEXT OPERATION

DOCUMENT NO: QAP 4.10	DESCRIPTION: INSPECTION & TESTING
REVISION NO.: B	SHEET: 2
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

4.10.13 NONCONFORMING MATERIAL

A. MATERIAL AND PAPERWORK WILL BE SUBMITTED TO ISO MGT REP

B. THE QREP. WILL BE NOTIFIED AND A DMR GENERATED.

C. PARTS AND PAPERWORK WILL BE SEGREGATED UNTIL DISPOSITION BY THE MRB HAS BEEN COMPLETED AND APPROPRIATE DISPOSITION AND SIGNATURES OBTAINED. TO INSURE PRODUCT IS NOT PROCESSED UNTIL IT HAS BEEN INSPECTED AND COMPLIES WITH ISO-9001 REQUIREMENTS 4.13

4.10.14 RETURNED MATERIAL:

4.10.15 INSPECT PRODUCT TO VERIFY DISCREPANCY. AND SUBMIT PRODUCT, PAPERWORK TO ISO MGT REP. TO PROCESS.

4.10.16 PRODUCT IS THEN MAINTAINED IN THE INSPECTION AREA WHICH IS CONSIDERED SECURE DURING MRB PROCESSING.

4.10.17 UPON DISPOSITION BY MRB PRODUCT AND PAPERWORK ARE SUBMITTED TO APPROPRIATE DEPARTMENT MGR FOR PROCESSING. INCOMING PRODUCT IS NOT UTILIZED OR RELEASED FOR URGENT PURPOSES UNTIL IT HAS BEEN INSPECTED.

4.10.18 IF CORRECTIVE ACTION BY VENDOR IS NECESSARY A SUPPLIER CORRECTIVE ACTION REQUEST WILL BE GENERATED AND ISSUED TO THE SUPPLIER.

4.10.19 RESPONSIBILITIES:

ISO MANAGEMENT REPRESENTATIVE.

DOCUMENT NO: QAP 4.11	DESCRIPTION: INSPECTION, MEASURING & TEST EQUIPMENT
REVISION NO.: B	SHEET: 1
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

4.11.1 **PURPOSE:**

TO ESTABLISH A MANDATORY RECALL SYSTEM OUTLINING PROCEDURES FOR THE CALIBRATION AND CONTROL OF ALL MEASURING AND INSPECTION TEST EQUIPMENT.

4.11.2 **SCOPE:**

SUBJECT TO CALIBRATION ARE ALL MEASURING AND TEST EQUIPMENT USED TO ASSURE THAT MATERIALS, SUPPLIES AND PRODUCTS PRESENTED TO THE CUSTOMER ARE IN CONFORMANCE WITH SPECIFICATION REQUIREMENTS.

4.11.3 **PROCEDURE:**

4.11.4 ALL NEWLY PURCHASED EQUIPMENT SHALL BE ROUTED DIRECTLY TO THE CALIBRATION DEPARTMENT FOR CLASSIFICATION AS FOLLOWS:

4.11.5 VISUAL INSPECTION TO INSURE NO DAMAGE HAS OCCURRED DURING TRANSIT.

4.11.6 CALIBRATION OF EQUIPMENT AS REQUIRED. IDENTIFICATION OF EACH UNIT SHALL BE A TOOL NUMBER AFFIXED VIA ELECTRIC PENCIL OR LABEL.

4.11.7 CALIBRATION HISTORY LOG SHALL BE FILLED OUT AND PUT ON FILE. THE LOG SHALL DOCUMENT THE FOLLOWING (WHEN APPLICABLE):

1. TOOL/GAGE NAME AND TYPE
2. MODEL NUMBER
3. SERIAL NUMBER
4. IDENTIFICATION CONTROL NUMBER
5. RANGE
6. LOCATION/DEPT. USED
7. CALIBRATION RESULTS
8. LAST DATE OF CALIBRATION
9. DATE OF NEXT DUE CALIBRATION
10. SIGNATURE OF PERSON RESPONSIBLE FOR ENTRY
11. DATE OF ENTRY

4.11.8 A CALIBRATION STICKER WILL BE APPLIED TO EQUIPMENT INDICATING DATE OF CALIBRATION, DATE OF NEXT CALIBRATION AND INITIALS OR STAMP OF INDIVIDUAL WHO PERFORMED THE CALIBRATION.

4.11.9 MGT. REP. OR DESIGNEE WILL REVIEW HISTORY LOGS ON A MONTHLY BASIS TO IDENTIFY WHAT EQUIPMENT IS DUE FOR CALIBRATION.

4.11.10 TWO WEEKS PRIOR TO DUE DATE OF NEXT CALIBRATION THE CALIBRATION DEPARTMENT WILL NOTIFY THE APPROPRIATE DEPARTMENT TO INSURE PROPER PLANNING SO PRODUCT FLOW IS NOT EFFECTED.

4.11.11 EQUIPMENT CALIBRATION BY OUTSIDE INDEPENDENT LABS SHALL SUPPLY THE APPROPRIATE CERTIFICATE OF COMPLIANCE TO ISO-10012-1 AND TRACEABLE TO NIST STANDARDS. THAT CERTIFICATE SHALL BE KEPT ON FILE BY THE CALIBRATION DEPARTMENT.

4.11.12 EQUIPMENT FOUND DEFECTIVE SHALL HAVE A RED REPAIR TAG ATTACHED, BE REPAIRED AND APPROPRIATE REPAIR RECORDS MAINTAINED.

4.11.13 **EQUIPMENT NOT IN USE:**

4.11.14 WHEN CONTRACT REQUIREMENTS INDICATE AN INSTRUMENT IS NO LONGER NEEDED IT WILL BE TAKEN FROM AREA; PLACED IN A DESIGNATED STORAGE AREA AND THE CALIBRATION HISTORY CARD WILL BE MARKED, "NOT IN USE".

4.11.15 **CALIBRATION DEPARTMENT STANDARDS:**

4.11.16 CERTIFIED MEASUREMENT STANDARDS, WHICH HAVE KNOWN VALID RELATIONSHIPS TO NATIONAL STANDARDS ARE MAINTAINED BY THE CALIBRATION DEPARTMENT. CERTIFICATION TRACEABLE TO NIST IS REQUIRED.

4.11.17 **DISPOSITION:**

ALL EQUIPMENT, TO INCLUDE EMPLOYEE OWNED GAGES, SHALL BEAR TOOL ID NUMBERS TO IDENTIFY IT FROM ANY OTHER EQUIPMENT THAT MAY LOOK AND PERFORM THAT SAME FUNCTION IN THE EVENT OF AN "OUT OF CALIBRATION" CONDITION.

DOCUMENT NO: QAP 4.11	DESCRIPTION: INSPECTION, MEASURING & TEST EQUIPMENT
REVISION NO.: B	SHEET: 2
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

4.11.18 IN THE EVENT THAT A SIGNIFICANTLY OUT OF TOLERANCE CONDITION IS DISCOVERED ON A PIECE OF EQUIPMENT A DISCREPANT MATERIAL REPORT IS GENERATED. AN INVESTIGATION TO DETERMINE THE EXTENT TO WHICH THE OUT OF TOLERANCE CONDITION HAS EFFECTED PRODUCTS DELIVERED TO CUSTOMERS AND PRODUCTS STILL IN STOCK; SHALL BE GENERATED. THOSE PRODUCTS THAT ARE IN STOCK SHALL BE RESCREENED USING EQUIPMENT THAT IS KNOWN TO BE IN CALIBRATION. FOR THOSE PRODUCTS THAT HAVE BEEN DELIVERED TO CUSTOMERS; THE ISO MGT REP. WILL GENERATE A CUSTOMER SCAR (CUSTOMER DISCREPANT MATERIAL NOTIFICATION FORM) TO NOTIFY THE CUSTOMER(S) ABOUT THE NATURE OF THE CONDITIONS SO THAT THEY MAY PERFORM TESTING AT THEIR FACILITY TO CORRECT NONCONFORMING PRODUCTS OR RETURN THE PRODUCT. TO INSURE PRODUCT OR EQUIPMENT IS NOT USED OR PROCESSED, IT MUST COMPLY WITH ISO-9002 REQUIREMENTS REF. QAP 4.13

4.11.19 CALIBRATION SCHEDULE:

THREAD PLUG GAGES	20 USES	MICROMETERS	2 YEARS
THREAD RING GAGES	20 USES	DIAL INDICATORS	2 YEARS
PROFILOMETER(MASTER)	50 USES	VERNIER CALIPERS	2 YEARS
DELTRONIC PIN GAGES	50 USES	GAGE BLOCKS	3 YEARS
SURFACE PLATE	3 YEARS	COMPARATOR	3 YEARS
CMM	2 YEARS		

4.11.20 REFERENCE ONLY EQUIPMENT:

A. ALL INSPECTION MEASURING AND TEST EQUIPMENT NOT LISTED IN CALIBRATION LOG BOOK IS CONSIDERED REFERENCE ONLY.

4.11.21 IN- HOUSE CALIBRATION OF EQUIPMENT:

- A. VISUALLY INSPECT FOR DAMAGE
- B. CLEAN EQUIPMENT BEFORE CALIBRATING
- C. COMPLETE GAGE CALIBRATION CERTIFICATE

4.11.22 MICROMETERS:

- 1. UTILIZE IN-HOUSE CALIBRATION CERTIFICATE
- 2. TAKE ZERO READING AND RECORD
- 3. RECORD BEFORE READINGS PER DIMENSIONS LISTED ON GAGE CALIBRATION CERTIFICATE
- 4. CALIBRATE TO DIMENSIONS LISTED ON GAGE CALIBRATION CERTIFICATE AND LIST AFTER READINGS
- 5. IF ACCEPTABLE PLACE INTO SERVICE AND PLACE CALIBRATION STICKER ON TOOL
- 6. IF OUT OF CALIBRATION ADJUST OR SCRAP GAGE AND RECORD ON GAGE CALIBRATION CERTIFICATE.

4.11.23 VERNIERS:

- 1. UTILIZE IN-HOUSE CALIBRATION CERTIFICATE
- 2. TAKE ZERO READING AND RECORD
- 3. RECORD BEFORE READINGS PER DIMENSIONS LISTED ON GAGE CALIBRATION CERTIFICATE
- 4. CALIBRATE TO DIMENSIONS LISTED ON GAGE CALIBRATION CERTIFICATE AND LIST AFTER READINGS
- 5. IF ACCEPTABLE PLACE INTO SERVICE AND PLACE CALIBRATION STICKER ON TOOL
- 6. IF OUT OF CALIBRATION ADJUST OR SCRAP GAGE AND RECORD ON GAGE CALIBRATION CERTIFICATE

4.11.24 HEIGHT GAGES

- 1. UTILIZE IN-HOUSE CALIBRATION CERTIFICATE
- 2. TAKE ZERO READING AND RECORD
- 3. RECORD BEFORE READINGS PER DIMENSIONS LISTED ON GAGE CALIBRATION CERTIFICATE
- 4. CALIBRATE TO DIMENSIONS LISTED ON GAGE CALIBRATION CERTIFICATE AND LIST AFTER READINGS
- 5. IF ACCEPTABLE PLACE INTO SERVICE AND PLACE CALIBRATION STICKER ON TOOL
- 6. IF OUT OF CALIBRATION ADJUST OR SCRAP GAGE AND RECORD ON GAGE CALIBRATION CERTIFICATE

4.11.25 DIAL INDICATORS:

- 1. UTILIZE IN-HOUSE CALIBRATION CERTIFICATE
- 2. TAKE ZERO READING AND RECORD
- 3. RECORD BEFORE READINGS PER DIMENSIONS LISTED ON GAGE CALIBRATION CERTIFICATE
- 4. CALIBRATE TO DIMENSIONS LISTED ON GAGE CALIBRATION CERTIFICATE AND LIST AFTER READINGS
- 5. IF ACCEPTABLE PLACE INTO SERVICE AND PLACE CALIBRATION STICKER ON TOOL
- 6. IF OUT OF CALIBRATION ADJUST OR SCRAP GAGE AND RECORD ON GAGE CALIBRATION CERTIFICATE

DOCUMENT NO: QAP 4.11	DESCRIPTION: INSPECTION, MEASURING & TEST EQUIPMENT
REVISION NO.: B	SHEET: 3
PREPARED BY: TERRY SMALL	APPROVED BY: ISO MGT REP.

4.11.26 COMPARATOR INDICATORS

1. UTILIZE IN-HOUSE CALIBRATION CERTIFICATE
2. TAKE ZERO READING AND RECORD
3. RECORD BEFORE READINGS PER DIMENSIONS LISTED ON GAGE CALIBRATION CERTIFICATE
4. CALIBRATE TO DIMENSIONS LISTED ON GAGE CALIBRATION CERTIFICATE AND LIST AFTER READINGS
5. IF ACCEPTABLE PLACE INTO SERVICE AND PLACE CALIBRATION STICKER ON TOOL
6. IF OUT OF CALIBRATION ADJUST OR SCRAP GAGE AND RECORD ON GAGE CALIBRATION CERTIFICATE

4.11.27 ENVIRONMENTAL CONDITIONS;

TEMPERATURE 68 DEGREES +/- 1.8 DEGREES

HUMIDITY IS 35 TO 55 RELATIVE HUMIDITY

4.11.28 WHEN NOT IN USE ALL THE INSPECTION EQUIPMENT IS MAINTAINED EITHER IN PROTECTIVE CASES OR PROTECTIVE AREAS TO MINIMIZE DAMAGE.

4.11.29 TEST HARDWARE (E.G. JIGS, FIXTURES, TEMPLATES, PATTERNS) DOES NOT APPLY TO SHARP NUCLEAD MFG. CO. INC.

WHEN CUSTOMER CONTRACT REQUIRES THE AVAILABILITY OF TECHNICAL DATA PERTAINING TO THE INSPECTION MEASURING AND TEST EQUIPMENT, SUCH DATA WILL BE MADE AVAILABLE FOR CUSTOMER REVIEW.

SAFEGUARD INSPECTION, MEASURING AND TEST FACILITIES INCLUDING BOTH TEST HARDWARE AND TEST SOFTWARE FROM ADJUSTMENTS WHICH WOULD INVALIDATE THE CALIBRATION SETTING IS NOT APPLICABLE TO SHARP NUCLEAD MFG. CO. INC

4.11.30 RESPONSIBILITY:

ISO MGT REP.

DOCUMENT NO: QAP 4.12	DESCRIPTION: INSPECTION & TEST STATUS
REVISION NO.: B	SHEET: 1
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

- 4.12.1 **PURPOSE:**  
TO IDENTIFY AND CONTROL INSPECTION & TEST STATUS OF SHARP NUCLEAD MFG. CO. INC.
- 4.12.2 **SCOPE:**  
THIS PROCEDURE IDENTIFIES PERSONNEL AUTHORIZED TO DOCUMENT AND PERFORM INSPECTION AND TEST OF SHARP NUCLEAD MFG. CO. INC
- 4.12.3 **PROCEDURE:**  
ONLY DESIGNATED INSPECTORS ARE AUTHORIZED TO PERFORM INSPECTION & TEST OF PRODUCT AND THAT INSPECTION & TEST IS SO DOCUMENTED VIA THE INITIALS OR SIGNATURE OF THE INDIVIDUAL AND SO IDENTIFIED ON THE INITIAL INSPECTION LOG
- 4.12.4 **RESPONSIBILITY:**  
ISO MGT REP.

DOCUMENT NO: QAP 4.13	DESCRIPTION: NONCONFORMING MATERIAL
REVISION NO.: B	SHEET: 1
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

4.13.1 **PURPOSE:**

THIS PROCEDURE OUTLINES THE REVIEW AND DISPOSITION OF ALL MATERIALS, VENDOR ITEMS, SUB-CONTRACTED ITEMS, SUB-UNITS AND UNITS OF FINAL PRODUCT WHICH DEVIATE FROM ESTABLISHED STANDARDS AND SPECIFICATIONS. NON-CONFORMING MATERIAL FOUND IN THIS CATEGORY SHALL BE REMOVED FROM NORMAL CHANNELS TO PREVENT UNAUTHORIZED USE, SHIPMENT OR INTERMINGLING WITH CONFORMING MATERIAL.

4.13.2 **SCOPE:**

THIS PROCEDURE APPLIES TO THE INSPECTION OF THE MATERIALS PROCESSED BY DIAMONF FASTENERS

4.13.3 **PROCEDURE:**

4.13.4 A. MATERIAL REVIEW BOARD (MRB) IS COMPRISED OF TWO MEMBERS OF SHARP NUCLEAD MFG. CO. INC, A PURCHASING REP. AND ISO MGT REP.

B. A REP. OF EITHER THE GOVERNMENT OR THE CUSTOMER IF SO INVOLVED BY CONTRACT.

4.13.5 OTHER RESPONSIBLE PERSONNEL MAY BE CALLED TO ACT IN AN ADVISORY OR CONSULTANT CAPACITY. SUCH PERSONNEL WILL HAVE NO VOTE IN THE DECISION MADE BY THE BOARD.

4.13.6 ALL DISCREPANCIES WILL BE RECORDED ON A DISCREPANT MATERIAL REPORT FORM (DMR), LOGGED INTO THE DMR/SCAR COVER SHEET AND NONCONFORMING MATERIAL WILL IMMEDIATELY BE SEGREGATED IN A SECURED AREA.

4.13.7 APPROPRIATE PAPERWORK IS STAMPED REJECTED AND WILL BE UPDATED UPON COMPLETION OF MRB DECISION.

4.13.8 THE ISO MGT REP. WILL THEN CONTACT THE WAREHOUSE MANAGER TO VERIFY IF ANY ADDITIONAL PARTS ARE IN STOCK.

4.13.9 "QUANTITY IN STOCK" SECTION WILL BE COMPLETED ON DISCREPANT MATERIAL REPORT.

4.13.10 WAREHOUSE MANAGER WILL HAVE UNITS TAKEN FROM STOCK AND ROUTED TO INSPECTION AREA.

4.13.11 UNITS WILL BE INSPECTED TO VERIFY IF ACCEPTED OR REJECTED.

4.13.12 IF IN STOCK MATERIAL IS ACCEPTABLE, IT WILL BE ROUTED TO WHSE MGR SO IT MAY BE PUT BACK INTO STOCK.

4.13.13 IF MATERIAL IS REJECTED IT WILL REMAIN IN THE INSPECTION AREA AND BECOME PART OF ORIGINAL DMR.

4.13.14 ALL REJECTED MATERIAL WILL THEN BE SEGREGATED IN A SPECIFIC SECURED AREA FOR MRB REVIEW.

4.13.15 MRB UPON REVIEW OF DISCREPANT MATERIAL WILL BE AUTHORIZED TO MAKE THE FOLLOWING DECISIONS UTILIZING DISCREPANT MATERIAL REPORT. IF CUSTOMER APPROVAL IS REQUIRED BY CONTRACT, THE CUSTOMER WILL BE REQUIRED TO RESPOND IN WRITING BY THE ISO MGT REP. AND THAT INPUT WILL BE UTILIZED IN THE MRB DECISION.

4.13.16 ACCEPT AS IS -- IF THE DISCREPANCY IS OF SIMILAR TYPE OR NATURE TO THAT WHICH MRB HAS PREVIOUSLY DETERMINED TO HAVE NO EFFECT ON SAFETY, PERFORMANCE INTERCHANGEABILITY OR SPECIFIC RELIABILITY.

4.13.17 **REWORK**

4.13.18 UNDER ONE OF THE FOLLOWING SITUATIONS:

A MATERIAL DISCREPANCY WHICH CAN BE CORRECTED BY NORMAL OPERATIONAL METHODS SO AS TO COMPLY WITH APPLICABLE SPECIFICATIONS AND/OR DRAWING REQUIREMENTS. THE REWORK WILL BE DOCUMENTED ON THE WORK ORDER TRAVELER AND REINSPECTED BEFORE PROCESSING CONTINUES.

4.13.19 **REPAIR:**

A MATERIAL DISCREPANCY WHICH CANNOT BE CORRECTED BY NORMAL OPERATIONAL METHODS AS TO COMPLY WITH APPLICABLE SPECIFICATIONS AND/OR DRAWING REQUIREMENTS, BUT CAN BE REPAIRED SO AS TO PROVIDE AN ACCEPTABLE ITEM. CUSTOMER APPROVAL IS REQUIRED. THE

REPAIR WILL BE DOCUMENTED ON THE WORK ORDER TRAVELER AND REINSPECTED BEFORE PROCESSING CONTINUES.

DOCUMENT NO: QAP 4.13	DESCRIPTION: NONCONFORMING MATERIAL
REVISION NO.: B	SHEET: 2
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

- 4.13.20 SCRAP MATERIAL  
WILL BE SCRAPPED WHEN MATERIAL OR PRODUCT CANNOT MEET REQUIREMENTS.
- 4.13.21 RETURN TO VENDOR:  
MATERIAL AND SCRAP WILL BE RETURNED TO SUPPLIER WHEN MRB DECIDES IT TO BE BEST COURSE OF ACTION.
- 4.13.22 INITIATE SUPPLIER CORRECTIVE ACTION WHEN DISCREPANCY AFFECTS FORM, FIT, FUNCTION OR RELIABILITY OF PRODUCT.
- 4.13.23 THE BOARD CONSIDERS THE MATERIAL PRESENTED, RESULTS OF INVESTIGATION AND BACKGROUND INFORMATION AND DETERMINES DISPOSITION OF MATERIALS. DECISIONS TO ACCEPT MUST BE UNANIMOUS. DECISIONS TO REJECT MUST BE IN THE MAJORITY.
- 4.13.24 **RESPONSIBILITY:**  
MATERIAL REVIEW BOARD

DOCUMENT NO: QAP 4.15	DESCRIPTION: HANDLING/STORAGE/PACKAGE/PRESERVATION/ DELIVERY
REVISION NO.: B	SHEET: 1
PREPARED BY: S. MADONNA	APPROVED BY: ISO MGT REP.

- 4.15.1 **PURPOSE:**  
TO IMPLEMENT PROCEDURES FOR THE RECEIVING, STOCKING, PRESERVATION, PULLING, PACKAGING, AND SHIPPING OF MATERIALS.
- 4.15.2 **SCOPE:**  
TO ENCOMPASS ALL MATERIALS RECEIVED, PROCESSED, AND SHIPPED BY SHARP NUCLEAD MFG. CO. INC.
- 4.15.3 **PROCEDURE:**  
**SAFETY:**  
DO NOT LEAVE PACKAGES ON DOCK. DO NOT LIFT ANYTHING OVER FIFTY (50) POUNDS ALONE, BEND KNEES WHEN LIFTING. ASK FOR ASSISTANCE IF NEEDED EXERCISE CAUTION AT ALL TIMES.  
**PRESERVATION:**  
PRESERVATION OF PRODUCT SHALL ALSO INCLUDE, WHERE APPLICABLE IN ACCORDANCE WITH PRODUCT SPECIFICATIONS AND/OR APPLICABLE REGULATIONS.
- 4.15.4 **RECEIVING/INSPECTION**  
A. VISUALLY INSPECT PACKAGES FOR PHYSICAL DAMAGE, IF CARTONS ARE DAMAGED, THEY ARE REFUSED AND THE OPERATIONS MANAGER NOTIFIED  
B. VERIFY THAT PARTS AND PAPERWORK MATCH. UPON ACCEPTANCE INITIAL PAPERWORK AND THEN FORWARD TO STOCKING. IF UNACCEPTABLE SUBMIT PARTS AND PAPERWORK TO QUALITY REP. FOR MRB/DMR PROCESSING  
C. ALL CUSTOMER RETURNS MUST HAVE A RETURN AUTHORIZATION NUMBER.  
D. TAKE CARE OF CUSTOMER PICK-UPS WHEN NEEDED.
- 4.15.5 **STOCKING**  
A. MATERIAL/PARTS ARE PLACED INTO STOCK BY PART NUMBER OR MATERIAL TYPE
- 4.15.6 **PICKING**  
A. STOCK CLERK TAKES PRODUCT FROM PICKING HOLDING TABLE AND PLACES INTO STOCK.  
B. ALL PRODUCT IS LABELED PRIOR TO STOCKING
- 4.15.7 **ORDER PICKING**  
A. ALL PRODUCT IS PULLED FROM STOCK PER TRAVELER REQUIREMENTS
- 4.15.8 **PACKING**  
A. SPECIAL PACKAGING INSTRUCTIONS WILL BE LOCATED ON THE TRAVELER  
B. UNLESS SPECIFIED BY CUSTOMER, THE METHOD OF PACKING IS AT THE DISCRETION OF THE PACKER SO AS TO INSURE SAFE TRANSPORT OF PRODUCT.
- 4.15.9 **SHIPPING**  
A. SHIPPING OF ALL PRODUCT WILL BE PER TRAVELER REQTS  
B. IF NO SPECIAL REQUIREMENTS SHIPPING OF PRODUCT WILL BE PER MOST ECONIMICAL MANNER
- 4.15.10 AN INVENTORY IS CONDUCTED YEARLY
- 4.15.11 **RESPONSIBILITY**  
WAREHOUSE MANAGER

DOCUMENT NO: QAP 4.19	DESCRIPTION: SERVICING
REVISION NO.: B	SHEET: 1
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

4.19.1 DUE TO BUSINESS MODEL THIS REQUIREMENT IS NOT APPLICABLE TO SHARP NUCLEAD MFG. CO. INC.

DOCUMENT NO: QAP 4.20	DESCRIPTION: STATISTICAL PROCESS CONTROL
REVISION NO.: B	SHEET: 1
PREPARED BY: STEVE MADONNA	APPROVED BY: ISO MGT REP.

4.20.1 **PURPOSE:**

TO ACCUMULATE DATA AT PRE-DESIGNATED FUNCTIONS AND EVALUATE STATISTICAL TRENDS FROM THAT DATA SO AS TO IMPROVE PROCESSES.

4.20.2 **SCOPE:**

THIS PROCEDURE APPLIES TO VENDOR RATING, RETURN MATERIALS ANALYSIS AND CUSTOMER SATISFACTION

4.20.3 **PROCEDURE:**

4.20.4 **VENDOR RATING ANALYSIS:**

QUARTERLY, THE ISO MGT REP WILL REVIEW ALL DMR'S WRITTEN FOR VENDOR DISCREPANCIES (IE ERROR CODE 30) AND GENERATE A REPORT HIGHLIGHTING VENDOR PERFORMANCE AND DISTRIBUTE TO MANAGEMENT

4.20.5 **ANALYSIS CRITERIA:**

- A. THE QUANTITY OF PARTS DELIVERED FOR THAT QUARTER WILL BE TOTALED AND EVALUATED TO THE QTY REJECTED.
- B. IF THE % ACCEPT IS BELOW 95% THE VENDOR WILL BE PLACED ON PROBATION FOR 90 DAYS AND A SCAR SUBMITTED TO VENDOR REQUESTING CAUSE AND CORRECTIVE ACTION.
- C. IF WITHIN THAT PROBATIONARY TIME THE VENDOR MEETS OR EXCEEDS THE 95% ACCEPTANCE NO FURTHER ACTION SHALL BE TAKEN; IF THEY FALL BELOW THE 95% ACCEPT THE ISO MGT. REP. WILL SUBMIT FORMAL RECOMMENDATION, AS TO WHAT ACTION SHOULD BE TAKEN, TO PRESIDENT AND PURCHASING MANAGER.

4.20.6 **CUSTOMER SATISFACTION:**

- A. SHARP NUCLEAD MFG. CO. INC. DEFINES CUSTOMER SATISFACTION AS:  
"LESS THAN 1% RETURNS FROM CUSTOMERS"
- B. QUARTERLY THE ISO MGT REP WILL IDENTIFY AND DOCUMENT THE PERCENT OF RETURNS FROM PRODUCT DELIVERED TO CUSTOMERS
  - A. A REPORT WILL BE GENERATED TO SALES, PURCHASING AND EXECUTIVE MANAGEMENT
  - B. IF THE PERCENT OF RETURNS IS GREATER THAN 1% THE ISO MGT REP. WILL GENERATE AN IACA TO THE APPROPRIATE DEPT MGR FOR CAUSE AND CORRECTIVE ACTION.
  - C. UPON REVIEW AND APPROVAL BY THE ISO MGT REP. THE IACA WILL BE FILED AND REVIEWED AT THE YEARLY MGT REVIEW MEETING S AND EFFECTIVE IMPLEMENTATION DETERMINED.

4.20.7 **RESPONSIBILITY:**

ISO MGT REP.

QMS 4.22  
 REVISION B

<u>SHARP NUCLEAD MFG. CO. INC.</u>	<u>FORM #</u>	<u>REVISION</u>
TRAVELER	-	-
QUALITY MANUAL CHECKLIST	-	-
DISTRIBUTION LOG	-	-
TRAINING RECORD	-	-
SUPPLIER CORRECTIVE ACTION REQUEST	-	-
CUSTOMER COMPLAINT	-	-
SHARP NUCLEAD MFG. CO. INC		
INTERNAL AUDIT	2000	1
SALES ORDER WORKSHEET	-	-
QUOTE/ESTIMATE SHEET	7/10/02	A
CUSTOMER CONFIRMING SALES ORDER	-	-
ECO LOG	-	-
ENGINEERING CHANGE NOTICE	-	-
VENDOR PURCHASE ORDER	7/11/02	A
RETURN AUTHORIZATION	-	-
RETURN AUTHORIZATION LOG	-	-
APPROVED VENDOR LOG	-	-
IN-HOUSE CALIBRATION CERT.	-	-
CALIBRATION USAGE	-	-
VENDOR PACKING SLIP	-	-
CERTIFICATE OF CONFORMANCE	-	-
MATERIAL CERTIFICATE LOG	-	-
DISCREPANT MATERIAL REPORT	-	-
DMR/SCAR COVER SHEET	-	-
IN-PROCESS FINAL INSPECTION	7/11/02	A
CUSTOMER SATISFACTION REPORT	-	-
VENDOR RATING REPORT	-	-
MANAGEMENT REVIEW	-	-
INTERNAL AUDIT CORRECTIVE ACTION	-	-
DMR ERROR CODES	-	-

Note: Unless otherwise specified all forms/documents listed above will be maintained for 3 years. One master list exists and is maintained by the ISO Mgt Rep.