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Quality Manual QAM-01 REV: B 6/3/2019

415 North Elm Street, West Bridgewater, MA 02379

SHARP / NUCLEAD

ISO 9001:2015

QAM 01 QUALITY MANUAL



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Change Record

Rev	Date	Responsible Person	Description of Change
DRAFT	11/13/2017	Michael Waxman	Initial Transition to ISO 9001:2015
A	2/2/2018	Michael Waxman	Initial Release includes Pre-assessment MR Inputs
B	06/03/2019	Mike Dolan	Revise to synchronize with new QA Manual – QM-100



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1 Scope

The purpose of this quality manual is to describe the policies and company-wide control structure of the SHARP NUCLEAD Quality Management System (QMS) used to achieve the corporate quality policy and objectives. The QMS ensures the quality policy and quality objectives are established for the quality management system and are compatible with the strategic direction and the context of the organization.

The true measure of quality at SHARP NUCLEAD is customer satisfaction. Because customer satisfaction and the quality of our products are and will continue to be the keys to our competitiveness for years to come, it is increasingly vital for us at SHARP NUCLEAD to understand and use our quality management system to do the best job, the first time, every time. To ensure the quality management system continues to provide a solid foundation for success, it is essential to demonstrate continual improvement within the QMS and its processes.

Scope of the Quality Management System

SHARP NUCLEAD is a small business that develops, integrates, and manufactures product solutions consistently meeting customer as well as applicable statutory and regulatory requirements.

Mission / Strategic Direction of the Company

SHARP NUCLEAD is manufacturing company with product / processes based upon customer specifications while considering other external and internal factors supporting the strategic direction of the organization.

The quality management system described in this Quality Manual addresses the requirements of the ISO Quality Standards as defined in ISO 9001:2015.

All references made to ISO 9001 in this manual refer to the 2015 version of the Standard.

2 Normative References

The following referenced documents are vital to the success of the SHARP NUCLEAD Quality Management System:

- **ISO 9001:2015 Quality Management Systems Requirements**
- **QAP 01 Control of Documents**
- **QAP 05 Control of Nonconforming Product**
- **QAP 06 Corrective Action and Continual Improvement**
- **QAP 07 Internal Audits**

3 Terms and Definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 are applicable.

4 Context of the Organization: Template is in place

4.1 Understanding the Organization and its Context

SHARP NUCLEAD determines the external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. Issues may include positive and negative factors or conditions for consideration, and shall be monitored and reviewed.

External and Internal issues will be discussed at every management review meeting allowing for monitoring and reviewing on a scheduled basis.

External context for consideration may arise from legal, technological, competitive, market, cultural, social, and economic environments, whether international, national, regional or local.

Internal context can be facilitated by considering issues related to values, culture knowledge and performance of the organization. Performance metrics shall be measured, tracked for trends, reviewed, and reported in the *Management Review*.

4.2 Understanding the Needs and Expectations of Interested Parties

Interested parties are those considered relevant to the success of the SHARP NUCLEAD Quality Management System and providing products and services consistently meeting customer, statutory and regulatory requirement, SHARP NUCLEAD will monitor and review information concerning the interested parties and their relevant requirements.

Relevant information is determined during the contract requirement review process per the Core Process Map Order Review process. Requirements, Review are formally captured in the QA 004 Traveler Section 01.

4.3 Determining the Scope of the Quality Management System

SHARP NUCLEAD has established the boundaries of the quality management system to be, any and all sets of company sanctioned activities which are relevant for ensuring conformity to customer, statutory and regulatory requirements, and continual improvements of products (and services) ultimately leading to customer satisfaction.

The scope takes into account:

- a) The external and internal issues relating to the context of the organization (Reference 4.1).
- b) The requirements of relevant interested parties (Reference 4.2).
- c) The products and services of the organization.

4.4 Quality Management System and its Processes (QAP 01 Control of Documents)

4.4.1 SHARP NUCLEAD has established, implemented, maintained and continually improved a quality management system, including the processes needed and their interactions, in accordance with the requirements of the ISO 9001:2015 Standard.

SHARP NUCLEAD has determined the processes needed for the quality management system and their application throughout the organization as seen in the Core Process Map of QM-100.

SHARP NUCLEAD QAP 01 Control of Documents ensures the following are addressed and implemented:

- a) Inputs required and the outputs expected from these processes.
- b) Identified the sequence and interaction of these processes.
- c) Application of the criteria, methods, including measurements and related performance indicators needed to ensure the effective operation, and control of these processes
- d) Providing resources needed for these processes and ensure their availability
- e) Assigned the responsibilities and authorities for these processes-
- f) Addressed the risks and opportunities in accordance with the requirements of 6.1 of the standard, and plan and implement the appropriate actions to address them.
- g) Evaluate these processes and implement any changes needed to ensure that these processes achieve intended results.
- h) Improve the processes of the quality management system:

4.4.2 SHARP NUCLEAD maintains documented information to support the operation of processes such as customer purchase orders, customer prints, job travelers, routers, and a parts library.

5 Leadership

5.1 Leadership and Commitment

5.1.1 General

The SHARP NUCLEAD management team demonstrates leadership and commitment with respect to the quality management system by:

- a) Taking accountability of the effectiveness of the quality management system (QAF 018 Management Review Agenda, Summary Report, and Action Items)
- b) Ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization-
- c) Ensuring the integration of the quality management system requirements into the organization's business processes
- d) Promoting the use of the process approach and risk-based thinking:
- e) Ensuring that the resources needed for the quality management system are available
- f) Communicating the importance of effective quality management and of conforming to the quality management system requirements
- g) Ensuring that the quality management system achieves its intended results
- h) Engaging, directing and supporting persons to contribute to the effectiveness of the quality management system.
- i) Promoting improvement
- j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility

5.1.2 Customer Focus

SHARP NUCLEAD demonstrates leadership and commitment with respect to customer focus by ensuring that:

- a) Customer and applicable statutory and regulatory requirements are determined, understood and consistently met
- b) The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed
- c) The focus on enhancing customer satisfaction is maintained through customer supplied data and/or QAF 021 Customer Satisfaction Survey

5.2 Policy

5.2.1 Establishing the Quality Policy

SHARP NUCLEAD has established, implemented, and is maintaining a quality policy that:

- a) Is established, reviewed and maintained: The quality policy is established at the company by providing all employees with basic ISO 9001:2015
- b) Training and informing them that everybody in the company needs to know and understand the quality policy.
- c) Includes a commitment to continual improvement of the quality management system
- d) Provides a framework for setting quality objectives: Includes a commitment to satisfy applicable Customer requirements.

SHARP NUCLEAD QUALITY POLICY

**To Continuously Improve Providing our customers with Quality and Compliant products
“on Time All the Time”**

5.2.2 Communicating the Quality Policy

The quality policy is:

- a) Available and maintained as documented information:
- b) Communicated, understood and applied within the organization:
- c) Available to relevant interested parties, as appropriate. The quality policy and the quality manual are available to all interested parties, considering doing business with the company, upon request.

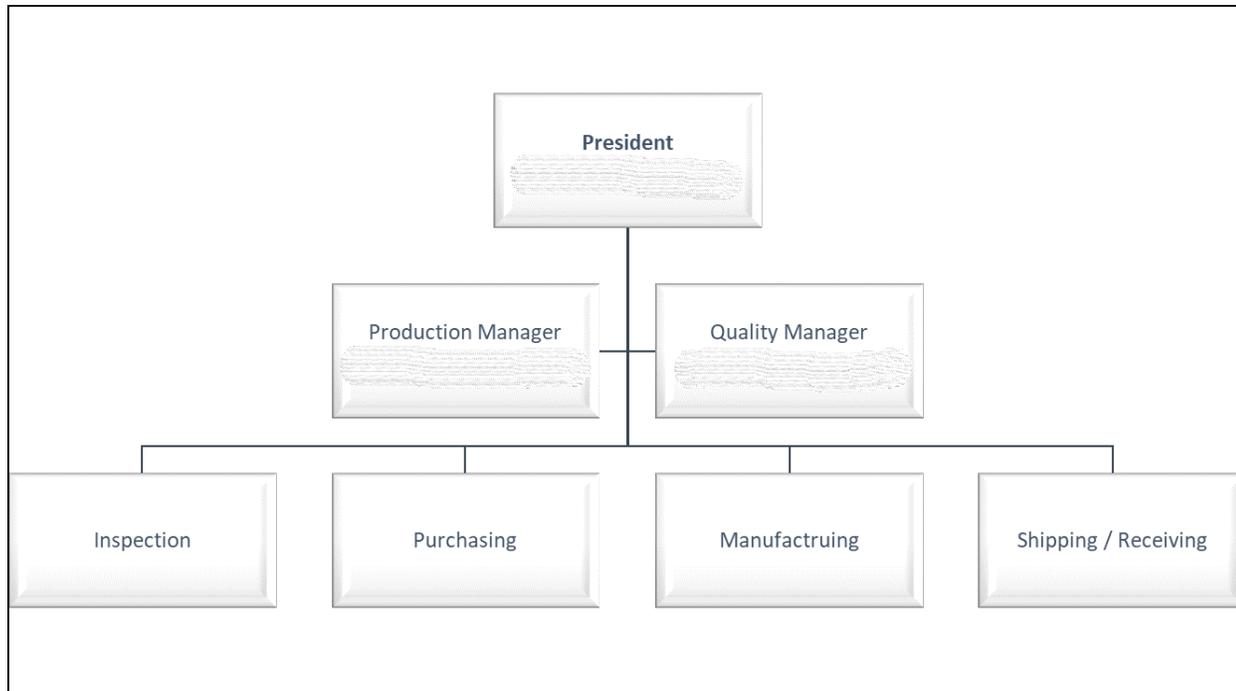
5.3 Organizational Roles, Responsibilities and Authorities (QAF 003 Organization Chart)

SHARP NUCLEAD's management team has ensured that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Top management has assigned the responsibility and authority as seen in FIGURE 5 below by:

- a) Ensuring that the quality management system conforms to the requirements of this International Standard.
- b) Ensuring that the processes are delivering their intended outputs.
- c) Reporting on the performance of the quality management system and on opportunities for improvement including top management.
- d) Ensuring the promotion of customer focus throughout the organization.
- e) Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

FIGURE 5 – ORGANIZATION CHART



6 Planning

6.1 Actions to Address Risks and Opportunities

6.1. The SHARP NUCLEAD Quality Management System considers the internal and external issues and determined the risks and opportunities that need to be addressed to:

- a) Give assurance that the quality management system can achieve its intended result(s):
- b) Enhance desirable effects
- c) Prevent, or reduce, undesired effects:
- d) Achieve continual improvement**