



**STCP-1**  
**QUALITY MANAGEMENT SYSTEM MANUAL**  
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**Quality Assurance Manual Section Cross-Reference**

<b>QAM</b>	<b>AS9100D/ISO9001:2015</b>	<b>10CFR 50, Appx B</b>
Introduction	4.1, 4.2, 4.3, 4.4, 5.1, 5.2, 6.1, 6.2, 6.3, 7.1, 7.1.1, 8.1	
1 – Organization	5.3, 9.3	1 – Organization
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17 – Nonconforming Materials	8.7	15 – Nonconforming Materials
18 – Corrective & Preventive Action	9.1 (except 9.1.2), 10.2.1	16 – Corrective & Preventive Action
19 – Quality Assurance Records	7.5, 7.5.3, 8.6, 10.2.2	17 – Quality Assurance Records
20 – Audits	8.4.2(d), 9.2	18 – Audits
21 – Training	7.1.2, 7.2, 7.3	
22 – Service Provision	8.2.1, 9.1.2	
23 – Improvement	9.1.3, 10.1, 10.3	

## INTRODUCTION

### 1. SCOPE

Superior Tube Company is a manufacturer of small-diameter, cold-drawn specialty tubing produced from multiple alloys. The tubing products are produced from more than 50 alloys, including stainless steels, nickel alloys, cobalt-chrome alloys, reactive and refractory metals.

Processes used include cold reducing, heat treating, nondestructive and destructive evaluation methods, approval and control of suppliers, and certification of material testing. Superior Tube Company does not perform weld repair.

STC performs no product design/development activities. Engineering activities are limited to the development of processes intended to produce product in accordance with customer furnished designs.

### 2. COMPANY PURPOSE

We provide the specialty metal tube components that improve the quality of life around the world, with our mission being the world leader in small diameter specialty metal tubing.

Customer requirements along with legal implications, the competitive market, cultural, social, and economic environments are incorporated into our process based approach to business.

The following statements describe the principles and rationale which provide a framework for establishing and reviewing quality and adhering to the organization's goals and objectives. Principles include:

- a. Customer Focus – Understanding current and future needs while continually striving to exceed their expectations;
- b. Leadership – Creating and maintaining an internal environment where people are fully involved in achieving STC objectives;
- c. Engagement of People – Enabling and involving the abilities of all the organization's levels for the company's benefit;
- d. Process Based Approach – Identifying, understanding, and managing interrelated processes as a system;
- e. Improvement – A permanent objective of STC;
- f. Evidenced-based Approach to Decision Making – Basing decisions upon data and information analysis;
- g. Relationship Management – Strengthening mutually beneficial relationships where value is created for our customers, suppliers, and ourselves.

## INTRODUCTION

### 3. CORE VALUES

#### 3.1 Ametek Code of Ethics and Business Conduct

Ametek provides an ethics policy to help employees make the right decision. It highlights what our Stakeholders, Customers, Suppliers, Colleagues, and the Communities in which we do business expect of us. Ethical conduct has no boundaries and applies to all Ametek employees and subsidiary colleagues worldwide.

#### 3.2 Superior Tube Company Mission Statement

A global tubing supplier dedicated to the advancement of our stakeholders, we demonstrate...

**Quality and Excellence**

Touching the lives of people around the world.

**Honesty and Integrity**

Fostering trust and inspiring confidence in what we say and in what we do.

**Customer and Service Focus**

Strong external and internal relationships.

**Innovation and Improvement**

In all aspects of our business.

### 4. QUALITY POLICY

Superior Tube Company will provide products and services that completely satisfy customer and interested party requirements through leadership that strives to:

- Maintain a safe, clean, and environmentally friendly workplace,
- Lead, develop, train, and engage our workforce,
- Reduce yield loss, scrap, and rework to maximize First Time Through Quality,
- Continually improve procedures and instructions to ensure strict verbatim compliance,
- Advance our business practices to bolster on-time delivery performance,
- Invest in innovation to increase capabilities and,
- Improve the overall effectiveness of the Quality Management System through improvement initiatives.

#### 4.1 This policy will be communicated to and understood by all Superior Tube Company employees through employee meetings, emails, bulletin board notices, internal promotions, etc.

#### 4.2 This Quality Policy will be reviewed for continuing sustainability as part of Management Review.

### 5. GOALS

Leadership sets Goals that support the organization and its context. The objectives provided to each process of the Company set the standard for meeting or exceeding the Goals of the Company. These

## INTRODUCTION

are reviewed and communicated, as relevant to the process, continuously through leadership interaction with the work force. At a minimum, goals will include: Safety, Quality, Service, and Cost.

Goals will be reviewed per Section 1, Paragraph 2 of this Quality Management System Manual.

### 6. ENVIRONMENTAL STATEMENT

As a global leader in specialty metal tubing, Superior Tube Company has a longstanding commitment to responsible corporate conduct. We strive to ensure the health and safety of our fellow colleagues, benefit the communities in which they live and work, and protect the environment.

Our policy is to pursue the optimum in environmental quality, health, and safety in every aspect of our business – from the way we manufacture and deliver our products to the way our customers use them. In that spirit, Superior Tube Company's mission is to:

- Meet or surpass the requirements of environmental, health and safety laws and regulations.
- Educate, empower, and expect all of our colleagues to behave in ways that protect the environment, and make health and safety a priority.
- Strive continuously to improve the efficiency of our operations so as to minimize both the use of materials and the generation of wastes.
- Operate our facilities in a responsible and co-operative fashion in the communities where they reside.
- Improve continuously our environmental, health and safety systems.

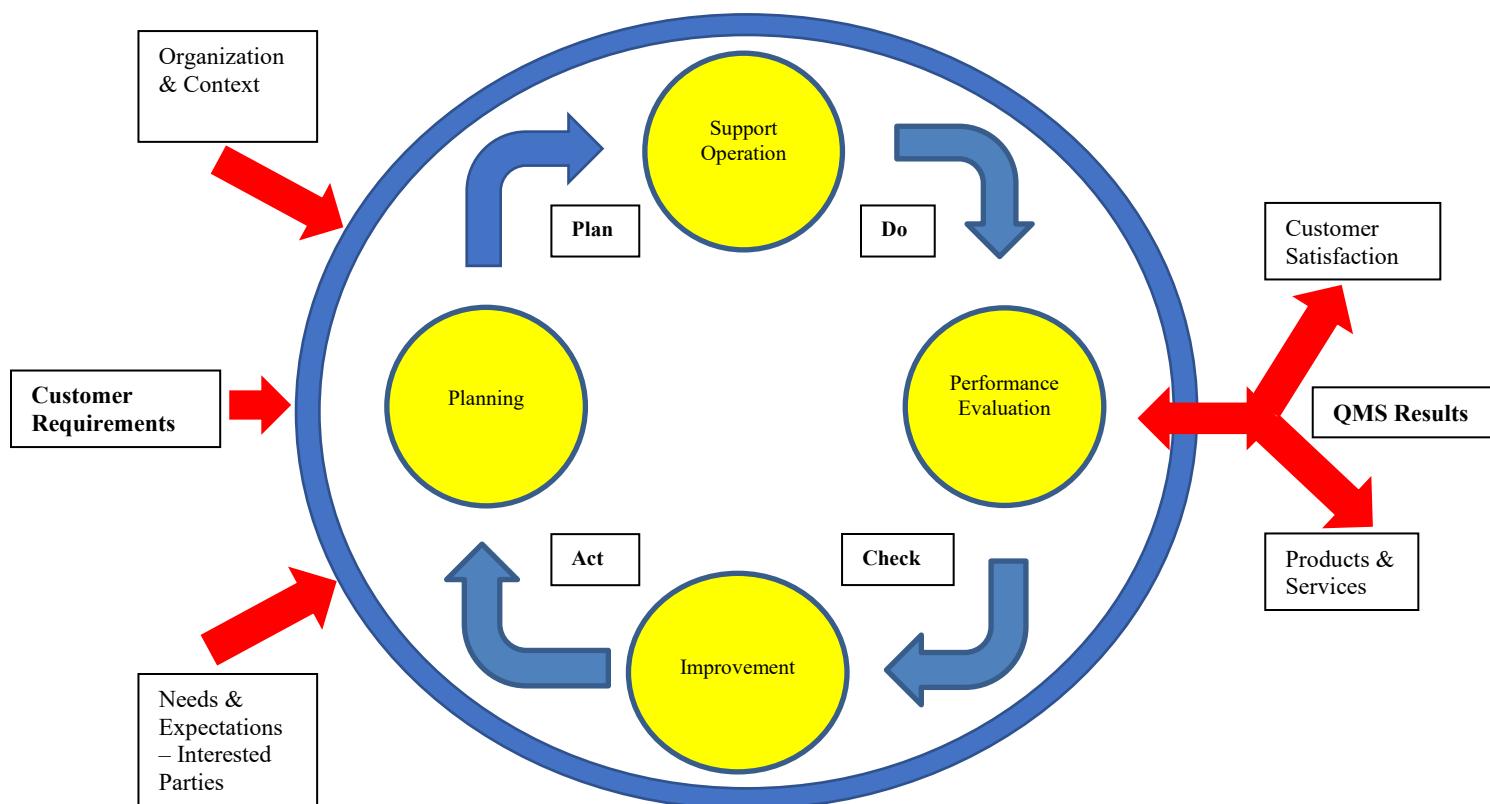
INTRODUCTION

**7. PLANNING**

The Plant Manager and Management Team ensure planning of the Quality Management System is established according to the scope, ethical principles, process approach and risk-based thinking, and strategic direction while meeting the needs and expectations of the interested parties and ensures integrity of the system is maintained when changes are planned and implemented.

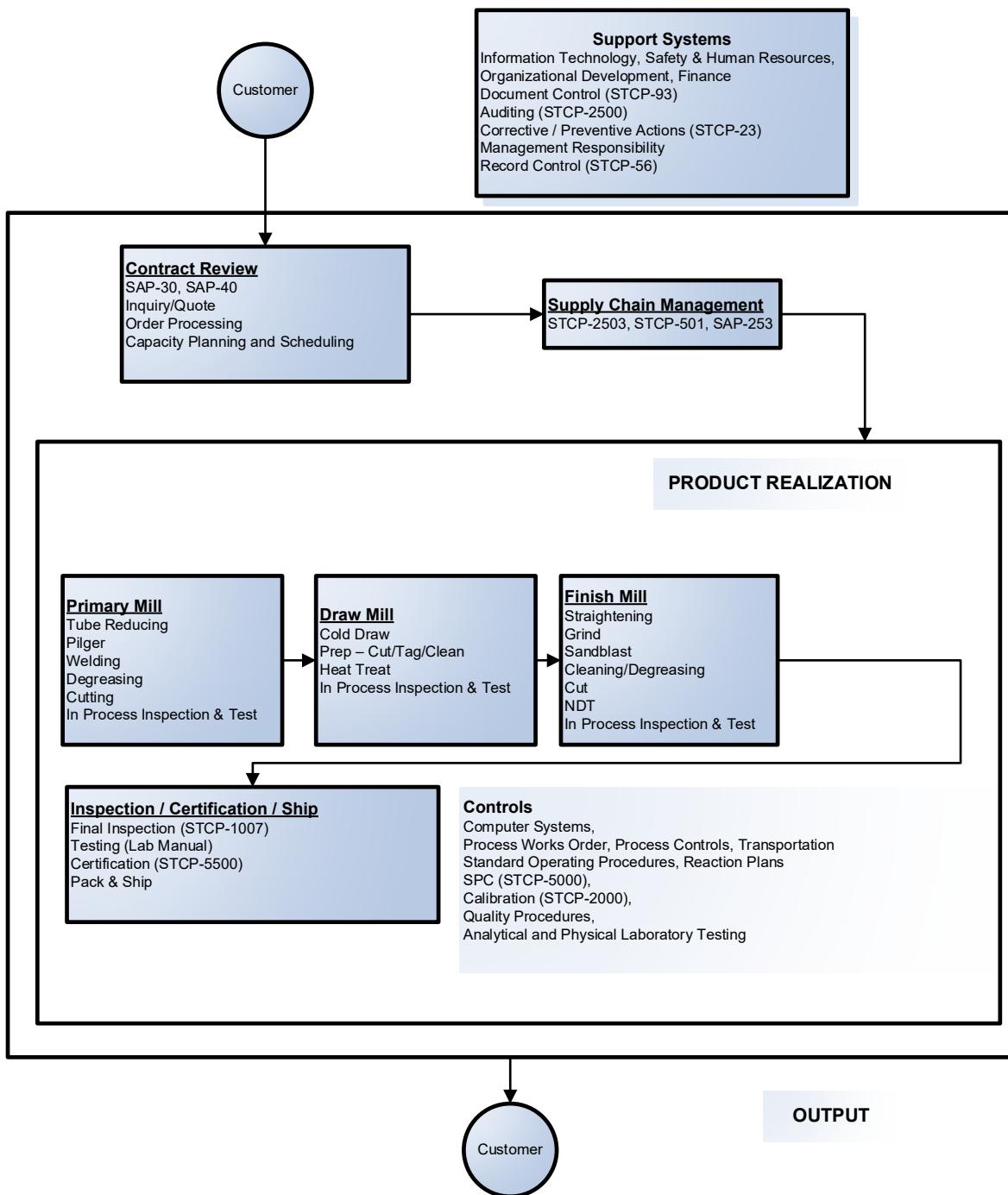
The Superior Tube Company leadership structure, the departments and processes and services of this Quality Management System Manual, are shown in STC organizational charts.

This schematic represents Superior Tube Company management's approach to planning and process improvement.



INTRODUCTION

**7.1 QUALITY PLAN AND CONFIGURATION MANAGEMENT**



## INTRODUCTION

### 7.2 Operations Management

Processes and services are planned and managed in a structured and controlled manner to meet requirements within resource and schedule constraints utilizing quality tools related to project management, risk management, obsolescence management configuration management and control of work transfers.

7.2.1 Product Management is planned appropriate to the product safety and services required to meet interested parties needs and expectations. SAP-40, “Sales Order Entry, Contract Review, and Planning Procedure” defines the guidelines and authority for project management. Planning includes assigned personnel to determine as appropriate:

- Quality objectives as well as requirements for products which include safety, reliability, availability, and recycling of product.
- Establishment of processes, documentation, and resources required specific to the product.
- Establishment of activities specific to the product including verification, validation, monitoring, measurement, inspection and test activities and the criteria for product acceptance.
- Monitor and manage direct status of orders from start to finish.
- Track and communicate on-time target completion to the customer per SAP-10, Communication of Late Orders to the Customer.
- Records that provide evidence that the product realization process and resulting product meet requirements.
- Resources required which support operation and maintenance of the product.
- Oversight of new product development items. These products are managed per requirements of STCP-29, “New Product Development Procedure.”

7.2.2 Risk is managed to achieve applicable requirements as appropriate to the processing steps and/or services. The process is documented in STCP-28, “Risk Management Procedure” which defines and addresses:

- Responsibility for identifying and managing risk,
- Definition of risk criteria,
- Identification, assessment, and the communication of risks at the appropriate intervals,
- Mitigation of risks that exceed the defined risk acceptance criteria,
- Plan the achievement of objectives more prescriptive and include the evaluation of results,
- Acceptance of risks remaining after implementing mitigating actions.
- Identifying and implementing processes and/or services to address product safety and the needs and expectations of interested parties.

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7.2.3 Configuration Management at Superior Tube Company includes route development and planning, identification and traceability of product per STCP-7515, change control, and revision control of critical documents per STCP-93.

Configuration status accounting is performed through change control per STCP-10, Request for Change Control, and review of certification requirements prior to shipment per STCP-5500, Procedure for the Preparation of Certification of Tubing.

Configuration audits are performed periodically through the Floor Surveillances process per STCP-2502 as well as during the internal auditing process.

7.2.4 Control of Work Transfers is planned and controlled to ensure material is traceable and meets product requirements and is documented in various procedures.

7.2.5 The program for Obsolescence management is documented in STCP-32. Obsolescence management includes components, processes, tooling, substances, materials, and providers that have a significant impact to STC's safety, product quality, or business continuity. Products and services used in the manufacture of small diameter specialty metal tubing will be proactively monitored to ensure product safety and services do not hinder interested party requirements or expectations.

7.2.6 Product Safety is assured by:

- Manufacturing, inspecting, and testing product to all customer requirements and specifications.
- Properly handling material to prevent damage. Instructions are included in STC PWOs as determined by customer requirements and/or STC Process/Manufacturing Engineering. Additionally, customer-specific handling and cleaning requirements are contained in the 7000 series of STCP documentation system.
- The detection and prevention of Foreign Objects & Debris (FOD). Reference QAM Section 15, paragraph 5.
- Annual training of personnel regarding Product Safety.

7.2.7 Prevention of Counterfeit Material (STCP-24) is assured by:

- Annual training of personnel in the awareness of counterfeit material.
- Implementation of the STC Supplier Approval process (STCP-2503).
- Assessment/inspection of incoming product (STCP-501/502).
- Implementation of STC Traceability/Line Clearance protocols (STCP-7515).

## 8. NORMATIVE REFERENCES

a.) ISO Q9000:2015	b.) ISO Q9001:2015	c.) AS9100D
d.) 10 CFR 50 Appx B	e.) ASME NQA-1	f.) 10 CFR Part 21

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**9. DEFINITIONS**

AOD	Argon Oxygen Decarburization
Arc	Electric Arc Melting
ASNT	American Society for Nondestructive Testing
Counterfeit Part	An unauthorized copy or modified part which is knowingly misrepresented. Counterfeit parts may include, but are not limited to, false identification, marking, documentation, certification, or performance characteristics.
Critical Items	Those items having significant effect on product realization and require specific actions to ensure they are adequately managed.
Documented Information	Information maintained and retained by STC in hard copy and/or electronic format that includes but is not limited to procedures, work instructions, manufacturing plans, inspection plans, workmanship criteria, and records.
ESR	Electro Slag Remelting
Interested Parties	People or organizations who may be affected by a situation, or who are hoping to make money out of a situation: Organization Owner, Employees, Management, Suppliers, Customers, Regulatory Agencies, Union, Certification Organizations, Stakeholder.
Key Characteristic	An attribute or feature whose variation has a significant effect on product fit, form, function, performance, service life or producibility, that requires specific actions for the purpose of controlling variation.
Lab	Metallurgical and Chemistry Laboratories
Lab Card	Metallurgical Lab Card
LTP	Laboratory Test Procedure
NDT	Nondestructive Testing
OER	Objective Evidence Report

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Product Safety	The state in which a product is able to perform to its designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.
PWO	Process Works Order
QA	Quality Assurance
Quality Record	Documentation that provides evidence of conformity with requirements.
Risk	An undesirable situation or circumstance that has both a likelihood of occurring and a potentially negative consequence.
SAP	Sales Administration Procedure
SOP	Standard Operating Procedure
SPC	Statistical Process Control
Special Requirements	Those requirements identified by the customer, or determined by the organization, which have high risks to being achieved, thus requiring their inclusion in the risk management process.
Special Process	The validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement.
Stakeholder	Interested Parties that can be affected by or perceive itself to be affected by a decision or activity.
STC	Superior Tube Company
STCP	Quality Assurance Procedure (Superior Tube Company Procedure)
VAR	Vacuum Arc Remelting
VIM	Vacuum Induction Melting

## SECTION 1

### ORGANIZATION

#### 1. SCOPE

Management at Superior Tube Company has established an organization clearly dividing responsibility among the Quality, Manufacturing, Facilities, Development and Process Engineering, Product Line Management, and Human Resources. The responsibilities for conducting the Program are delegated through Management directives issued by the Plant Manager.

The organization, as indicated by Management, is described in paragraph 3, Responsibility.

#### 2. MANAGEMENT COMMITMENT

STC Management demonstrated through leadership that understands commitment to the Quality Management System by actions including, but not limited to:

- The responsibility to meet defined Goals and to ensure the integrity of the system is maintained when changes are planned and implemented,
- Communicating the importance of meeting the quality and system requirements, and the importance of achieving the planned results,
- Engaging, directing, and supporting persons,
- Promoting improvement,
- Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.
- Management system review.
- Fraud and falsification communication and updates on documentation integrity.
- Safety, Environmental and Ethical monitoring, and training.
- Communicating the STC Company Purpose and Quality Policy.
- Ensuring appropriate resources are available for meeting goals and continually improving processes.
- Communicating the effectiveness of the Quality Management System through appropriate communication processes.
- Promoting health and wellness of employees and their families.

ORGANIZATION

SECTION 1

**3. RESPONSIBILITY**

Each function has the authority and responsibility to carry out all assignments as outlined within this document, as certified by the signature of the Plant Manager of Superior Tube Company on the approval page of this Quality Management System Manual.

Functional responsibility and reporting structure and organizational chart are detailed in STCP-1, Addendum 1, “Quality System Manual Functional Reporting Structure”.

Management shall determine, provide, and maintain the infrastructure necessary to achieve conformity to product and Customer requirements. Strategic planning and budget processes will be carried out to ensure conformance.

It is the responsibility of all personnel in each department to comply fully with the requirements of the Quality Management System.

Listed below is the Quality responsibility within the Quality Management System. The purpose of this section is to show the quality responsibilities as delegated by Management. The responsibilities shown are only those which may have an effect on the quality of the finished product.

**3.1 Quality Function – reports to the Plant Manager**

The Quality Assurance & Systems Manager has primary responsibility for the administration and operation of Quality Assurance and the Quality Management System. Responsibilities include the position of AS9100D management representative and the overall technical aspects of raw material inspection, final inspection, nondestructive examination, material verification, metallurgical evaluation, calibration and metrology, Quality Management System manuals, and all auditing functions. The Quality Assurance & Systems Manager monitors effectiveness of the Quality Management System and will keep Management advised of its status and adequacy. Additional responsibilities include determining that manufacturing processes meet reference codes, standards, specifications, and Customer requirements and promoting awareness of Customer requirements. Quality documentation including test reports, product certifications, document retention, SPC reports, quality improvement reports, etc., are part of this position's overall responsibilities. This position has the final decision-making responsibilities for material quality acceptance or rejection.

Although the responsibilities for conducting the Quality Management System are delegated to the various departments, the Quality Assurance & Systems Manager has been delegated primary and full authority and responsibility to implement and maintain procedure requirements and accept or reject material in any phase of production, as well as cease any operation producing nonconforming material.

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ORGANIZATION

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Those positions within the Quality Assurance and Process Engineering organizations shall have responsibility, authority, and the freedom to identify, evaluate, and resolve quality management issues, with unrestricted access to top management independent of cost and schedule considerations.

## **SECTION 2**

### **QUALITY ASSURANCE PROGRAM**

#### **1. SCOPE**

The Quality Management System Manual and the referenced procedures ensure that the Customer quality requirements are met, and that consistent and uniform control of this quality is maintained. The Program outlines how control is established and maintained by formal written procedures, competent personnel, process controls, and sufficient inspection and testing.

Superior Tube Company (STC) Program is based on the applicable requirements of various specifications, standards, and Customer requirements including Government Specifications, ASME Pressure Vessel Code NCA 3800, MIL-I-45208, 10CFR50 - Appendix B, ASME NQA-1, ANSI/NCSL-Z-540.1, ISO-10012, as well as, ISO-9001:2015 and AS9100D (Excluding Clause 8.3 Design and Development) as they relate to the manufacturing, inspection, testing and the provision for post-delivery support of small diameter tubing.

The requirements specified in this manual are complementary, not an alternative, to contractual and applicable statutory and regulatory requirements. Should there be a conflict between the requirement and applicable statutory or regulatory requirement, the latter shall take precedence.

The requirements of this Quality Management System Manual apply to all items processed and manufactured by Superior Tube Company. The processes in place to ensure compliance to quality requirements are defined in the various sections of this Quality Management System Manual. Requirements for meeting quality, at all levels, are defined in various sections of this Manual.

Other unique Customer contract requirements may be met on an individual case basis, if mutually agreed upon.

#### **2. RESOURCES**

The Plant Manager and the Management Team are responsible for identifying resource requirements and providing adequate resources required for the establishment, implementation, maintenance and continual improvement of the quality management system, capabilities, and constraints on internal resources and what needs to be obtained from external providers are evaluated and monitored.

QUALITY ASSURANCE PROGRAM

SECTION 2

2.1      People

Determine and provide the persons for the implementation of the quality management system and for the operation and control of its processes.

2.2      Infrastructure

Determine, provide, and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. Infrastructure includes:

- buildings and associated utilities,
- equipment, including hardware and software,
- transportation resources,
- information and communication technology.

2.3      Environment for the Operation of the Processes

Determine, provide, and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

- non-discriminatory and non-confrontational,
- emotionally protective – stress and burnout prevention,
- provisions for temperature, heat, humidity, light, airflow, hygiene, and noise.

2.4      Organizational Knowledge

Determine the knowledge necessary for the operation of its processes to achieve conformity of products and services and to capture changing needs and trends.

2.4.1      Development, monitoring and implementation for effective succession of intellectual transfer of knowledge or knowledge gained through experience due to but not limited to:

- leaving or retiring from the Company,
- layoff or termination,
- identification and preparation for mobility within the organization.

2.4.2      Lessons Learned

- successful as well as failed projects,
- capturing and sharing undocumented knowledge and experience,
- results of improvements in processes, products, and services

**QUALITY ASSURANCE PROGRAM**

**SECTION 2**

**2.4.3      External Sources**

Standards, Academia, Conferences, Gathering knowledge from Customers, or External Providers.

**2.4.4      Organizational knowledge is maintained at STC in several forms including but not necessarily limited to:**

- a. Job records detailing processing instructions, actual processing conditions, and inspection/test results;
- b. Non-conformance and corrective action reports;
- c. Customer generated specifications and customer communications;
- d. Third-party-generated specifications and standards;
- e. External Sources documented information:
  - Standards,
  - Academia,
  - Conferences,
  - Customers,
  - External Providers;
- f. Process Improvement documented information.

**2.5      Awareness and Communication**

All employees providing work under the organization's control shall be made aware using planned methods of communication. These will be documented in STCP-1, Addendum 2.

**3. CUSTOMER FOCUS**

Management ensures that Customer needs and expectations are determined, converted into requirements and fulfilled with the aim of achieving Customer satisfaction. Measurement of product conformity and on-time delivery performance is implemented and appropriate action taken if planned results are not, or will not be, achieved.

Management monitors information related to Customer perception to determine if requirements, both direct and implied, are met.

**4. PROGRAM REVISION**

This Program will be reviewed annually. As a minimum, the Quality Manager and the Plant Manager shall approve each revision to the Quality Management System Manual. A review of all inputs, since the last Management Review, including internal and Customer audits will be performed to ensure all updated requirements are met. Additional revisions may be required as the result of changes to specifications and standards and to new techniques in methods of management, manufacturing, testing, and inspection.

**QUALITY ASSURANCE PROGRAM**

**SECTION 2**

Access to the quality management system manual will be provided to all employees. Any relevant quality management system change will be communicated through employee's meetings, e-mail notifications, bulletin board postings, etc.

The system to document and implement Program changes is outlined in STCP-93, Guidelines Governing the Approval, Distribution and Maintenance of Procedures and Quality Related Forms.

**5. MANAGEMENT REVIEW**

The Quality Management System is reviewed throughout each year by means of various communications. Reviews are conducted annually at a minimum. The purpose of such reviews is to provide continual improvement of the Quality Management System.

Documented Reviews take into consideration the suitability, adequacy and effectiveness of the Quality Management System and corrective actions taken since the previous Management Review. Members of management participating in the review shall include, at a minimum, Quality, Operations, and Sales. Reporting responsibilities are specified in STCP-1, Addendum 3.

As a minimum, the organization shall analyze and evaluate appropriate data and information arising from monitoring and measuring to evaluate:

- Product and Service Conformity
- Customer Satisfaction
- Performance and effectiveness of the Quality Management System
- The need for improvement to the Quality Management System
- Planning Implementation Effective
- Effectiveness of actions taken to reduce risks and opportunities
- Performance of external providers

Management Review Inputs shall include:

- Follow-up Actions from Previous Management Reviews
- Changes in external and internal issues that are relevant to the QMS
- Assessment of the needs/concerns of Interested Parties (STCP-1 Addendum #4)
- Information on the performance and effectiveness of the quality management system
  - Customer Satisfaction and Feedback from Interested Parties
  - The extent of which quality objectives have been met
  - Process Performance and conformity of Products and Services
  - Nonconformities and Corrective and Preventive Action

QUALITY ASSURANCE PROGRAM

SECTION 2

- Monitoring and Measuring Results
- Audit Results
- The performance of external providers
- On time delivery performance
- Adequacy of resources
- Effectiveness of actions taken to address risks and opportunities
- Opportunities for Improvement

Management Review Outputs shall include decisions and actions related to:

- Opportunities for Improvement
- Need for changes to the Quality Management System
- Resource needs
- Risks identified

Management Review documentation is maintained by Quality. This documentation will include any proposed changes or outputs resulting from the Management Review and will be made available when requested.

**6. QUALITY MANAGEMENT SYSTEM MANUAL CONTROL**

The system to document manual control and distribution is outlined in STCP-93, Guidelines Governing the Approval, Distribution and Maintenance of Procedures and Quality Related Forms.

The Quality Management System Manual is available for review by our Customers at STC. Customers may be issued copies when required. A list of external distribution of controlled copies is maintained by the Quality Assurance Department.

Only controlled copies will be replaced as the Manual is revised or updated. Controlled copies that are distributed but not acknowledged within 90 days shall be treated as uncontrolled copies.

**7. FRAUD AND FALSIFICATION AND DELIBERATE MALPRACTICE**

It is STC policy to adhere to the requirements of Fraud and Falsification for the Naval Nuclear (Title 18 USC 1001) program and the regulations of 10CFR21 Reporting Requirements. Conditions of noncompliance to the above or deliberate malpractice will not be tolerated. Violation of the above requirements can lead to fines, imprisonment and/or discharge. Where applicable, these requirements are passed down to STC vendors.

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**QUALITY ASSURANCE PROGRAM**

**SECTION 2**

It is the responsibility of all employees to report all instances or conditions that relate to the topic to the Production Manager or the Quality Assurance and Systems Manager for research and verification. The Quality Assurance and Systems Manager will investigate, document findings, and transmit the appropriate response to applicable individuals and/or agencies. In addition, the STC internal audit program and its auditors shall make this a part of the audit process.

STC will inform all employees of these requirements through bulletin board postings and other communication means, including STCP-111, Fraud and Falsification.

**SECTION 3**  
**DESIGN CONTROL**

1. SCOPE

Superior Tube Company neither designs nor develops products therefore, design control for products is outside of the scope of the Superior Tube Company Quality Program.

## **SECTION 4**

### **CONTRACT REVIEW**

#### **1. SCOPE**

A process is in place for the review of all order inquiries and purchase orders placed with Superior Tube Company. Prior to acceptance, all contract related documentation is reviewed to ensure that Customer requirements and expectations, including delivery requirements, are defined, understood, in compliance with applicable specifications, codes and standards, and properly recorded into a process works order and associated documents. Only Sales Order Management can accept an order, after proper technical review. SAP-40, Sales Order Entry, Contract Review, and Planning Procedure, details the contract review process at STC.

#### **2. CONTRACT REVIEW AND ACCEPTANCE**

The authority for review of contracts is controlled through procedures. Management and Process Engineering shall determine the Company's capability for producing material to Customer specifications. Technical reviews and new product development ensure special customer requirements and risks that may be associated with the product are appropriately managed. Accordingly, Management, Process Engineering, and Sales shall be familiar with the appropriate specifications, inquiry, and order requirements.

Technical review is conducted by appropriate personnel. The review is concluded with the issuance of an order acknowledgement to the Customer by Sales Order Management. The order acknowledgement defines the acceptance of a contract with a Customer.

Superior Tube Company is a registered ITAR member. SAP-7, Export Compliance Policy, details the process for review and handling exporting of STC product.

#### **3. CONTRACT STIPULATIONS, EXCEPTIONS AND CHANGES**

- 3.1 Technical review determines acceptability and identifies risks when customer approved special process sources are a requirement of a contract. When necessary, an exception to the order is provided for customer approval prior to acceptance of the order.
- 3.2 STC characterizes product against customer drawing and specifications to ensure Product Safety. These are inspected on an AQL basis at final inspection. This process represents our interpretation of satisfying the requirements of first article inspection. However, when a customer specifically requests first article inspection per AS9100 requirements, an instruction will be included in the process documentation instructions. The process for first article is defined in STCP-30, First Article Inspection per Requirements of AS9102.

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- 3.3 In the event there are differences or exceptions taken, they are resolved prior to the acceptance of the purchase order.
- 3.4 Amendments or changes to purchase orders, after receipt and acceptance, and generated by the Customer are covered by SAP-50, Change Order Procedure.
- 3.5 Changes to internal documentation or instructions (process works order, standard router or laboratory instructions) are reviewed by Sales per the requirements of STCP-10, Request for Change Procedure.

**4. PRODUCT INSTRUCTIONS**

- 4.1 Instruction for the manufacturing, testing and inspection of all products produced by Superior Tube Company are generated after all contract requirements are mutually agreed upon.
- 4.2 Process Works Order and Lab Instructions are generated per SAP-40, Sales Order Entry, Contract Review, and Planning Procedure.

**5. CUSTOMER COMMUNICATIONS**

- 5.1 It is the policy of Superior Tube Company to communicate effectively with our Customers through various means, including direct contact, web site, brochures, etc. The primary contact will be Sales Order Management. Other resources will be utilized as required.
- 5.2 Any Customer concerns/complaints shall be directed to the appropriate Sales representative.
- 5.3 SAP-5, Customer Communication Procedure, details the Superior Tube Company Customer Communication Procedure.

## SECTION 5

### PROCUREMENT DOCUMENT CONTROL

#### 1. PROCUREMENT REQUIREMENTS

Procurement of raw material and subcontracted services having an effect on the quality of the final product are controlled. The control is executed through STC procedures or purchase order requirements and applies to procurement of all raw materials and services, including product or services from sources defined by the customer.

Requirements for procurement document control are detailed in STCP-2503, Procedure to Document the Requirements of Approving Vendors/Subcontractors for the Approved Vendor List (AVL).

Definition of purchasing policy and related requisitioning requirements and responsibilities for types and classes of purchased items and services is detailed in STCP-2511, Standard Requisitioning and Purchasing Procedure.

1.1 Supply Chain and Quality Assurance, with input from Process Engineering when required, ensure that purchasing documents contain information clearly describing the product or service to be purchased and are being purchased from approved suppliers. The procurement documentation will reflect, when appropriate:

- 1.1.1 Identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data.
- 1.1.2 Requirements for test inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance as applicable to the critical items including key characteristics.
- 1.1.3 Requirements for archiving test specimens for inspection/verification, investigation, or auditing.
- 1.1.4 Requirements regarding the supplier to provide per QA Form 89-03:
  - Notification of nonconforming product.
  - Request for approval of nonconforming product disposition.
  - Notification of changes in product and/or process, changes of manufacturing facility location and, where required, obtain approval.
- 1.1.5 Flow down record retention, and right of access, and applicable customer requirements per QA Form 89-03.
- 1.1.6 Applicable Quality Program requirements per QA Form 89-03.

## **SECTION 6**

### **CUSTOMER SUPPLIED PROPERTY**

#### **1. SCOPE**

When Customer supplied material, product or property is utilized, the following shall apply:

- 1.1 Upon receipt, the material shall be inspected for general condition, completeness, proper type, size, or grade. In addition, Customer special inspections shall be performed in accordance with written instructions.
- 1.2 Damaged or unacceptable material shall be placed on hold and reported to the Customer for resolution.
- 1.3 The Quality Assurance Department shall be responsible to ensure these conditions and procedures are followed.
- 1.4 If the Customer supplied material is intellectual property, such information shall be handled in confidence and governed by nondisclosure agreements, if required.
- 1.5 Customer supplied material is identified and traceable to the Customer records from the initial receipt, through manufacturing, and upon delivery.
- 1.6 Upon completion of the quality acceptance process STC assumes responsibility for conformity of product supplied by the customer.

#### **2. PROCEDURES**

- 2.1 STCP-505, Procedure for the Release of Alloy 690 Customer Furnished Material, is the procedure that governs 690 Program material.
- 2.2 STCP-506, Receipt and Release of Customer Supplied Material or any Development Alloy, is the procedure that governs Customer supplied material utilization at Superior Tube Company.
- 2.3 STCP-7514, Handling Government Furnished and Customer Furnished Equipment, details the handling of government furnished and customer furnished equipment at Superior Tube Company.
- 2.4 Other procedures and practices may be used for Customer specific requirements that go beyond the above referenced procedures.

## **SECTION 7**

### **INSTRUCTIONS, PROCEDURES, AND DRAWINGS**

#### **1. SCOPE**

Activities affecting product quality shall be designated by Quality Assurance, Process Engineering and Sales and shall be accomplished in accordance with these instructions or drawings. Definition and roles are defined in various procedures. These activities are controlled through the use of processes, procedures, instructions, specifications and/or drawings.

The available documented information, where appropriate, include:

- Work instructions,
- Flow Charts,
- Manufacturing Plans,
- Inspection Plans,
- Product specific tools,
- Use of software,
- Criteria for workmanship.

#### **2. PREPARATION AND APPROVAL**

- 2.1 The responsibility for the preparation and internal approval of the necessary documented information is detailed in this Manual. When required, certain documents can be offered to the Customer for approval.
- 2.2 All quality inspection, hold and/or witness points shall be clearly designated and scheduled on all appropriate Process Documentation and instructions.
- 2.3 The procedures, instructions, specifications, and drawings shall contain appropriate quantitative or qualitative acceptance criteria.
- 2.4 Technical review of process documentation is performed by Quality Assurance, Process Engineering, Route Engineering and Sales. The process is documented in SAP-40, Sales Order Entry, Contract Review, and Planning Procedure. Changes are controlled through a review process documented in STCP-10, Request for Change Procedure.
- 2.5 Procedure approval, review, and authority are detailed in STCP-93, Guidelines Governing the Approval, Distribution and Maintenance of Procedures and Quality Related Forms.

## **SECTION 8**

### **DOCUMENT CONTROL**

#### **1. SCOPE**

Controls have been established and documented to govern the issuance and recall of documents necessary for the control of all activities affecting quality. The control of the acceptance, approval, and distribution of the documented information is described in the paragraphs below.

#### **2. CUSTOMER DOCUMENTS**

- 2.1 Customer documents, received by Sales Order Management, shall be submitted to Engineering for technical review by Process Engineering, Quality, Route Engineering and Sales as required.
- 2.2 Customer drawings shall be used as received unless changes are required for clarification.
- 2.3 When the Customer document is used in conjunction with an STC document, it shall be so noted by referencing it in the STC document or by an addendum to the STC document. When Customer documents have been revised, the revisions will be reviewed and processed in the same manner as the original documents. Customer specifications are controlled by STCP-6, Control of Customer and Industry Specifications. Certain U.S. Government Specifications are controlled by STCP-7, Control of Specifications with Special Export or Foreign National Restrictions.
- 2.4 Customer supplied intellectual property shall be identified, verified, protected, and safeguarded. Any change in status shall be reported to the Customer.

#### **3. INDUSTRY STANDARDS**

- 3.1 It is Superior Tube Company policy to work to the latest version of the industry standards unless otherwise specified by Customer purchase orders. Industry standards, e.g., ASTM, AMS, MIL-T, ASME etc., are controlled by Quality Assurance on receipt of notification from the authority issuing those standards. These documents are procured by Quality.

DOCUMENT CONTROL

SECTION 8

3.2 On receipt of the standards, they are reviewed and approved by Quality/Engineering as required. Prompt action is to be initiated for implementation of corresponding changes in material procurement specifications and/or processing specifications, as needed. ASME specifications will be reviewed on an order by order basis. Computerized documents also will be changed immediately to reflect the latest revisions and the changes required by them. Industry specifications are controlled by STCP-6, Control of Customer and Industry Specifications.

**4. SUPERIOR TUBE COMPANY DOCUMENTED INFORMATION**

The structure of the Quality Management System is defined below. All procedures shall be readily available to the personnel who are responsible for ensuring compliance with requirements to customer and/or regulatory agency representatives.

**4.1 Superior Tube Company Procedures**

The distribution and control of these documents will be performed in accordance with STCP-93, Guidelines Governing the Approval, Distribution and Maintenance of Procedures and Quality Related Forms.

**4.1.1 Superior Tube Company Procedures – STCP**

These are the specific procedures involved in the production, inspection, or testing of the product or the STC Quality Management System.

**4.1.2 Laboratory Test Procedures – LTP**

These procedures are specific to lab techniques and procedures. The control of these documents will be performed in accordance with the Laboratory Manual.

**4.1.3 Sales and Administrative Procedures - SAP**

These procedures are specific to Management, Sales, and Supply Chain functions.

**4.2 Other Documents – Process Works Order and associated Process Documentation, Dress-Up, Laboratory Card**

4.2.1 These are specific documents designed to detail the manufacturing and laboratory instructions to produce product.

DOCUMENT CONTROL

SECTION 8

4.2.2 This documented information is revised according to procedures outlined in STCP-10, Request for Change Procedure.

**5. REVISION LEVEL VERIFICATION**

5.1 Most recent revisions of Superior Tube Company document information and procedures are available electronically and are controlled by Quality Assurance per STCP-93.

**6. DOCUMENT INTEGRITY – STCP-22**

6.1 It is STC policy that all documented information - records, forms, travelers, procedures, and various quality system documents that are a part of this quality system may not be altered without formal approval.

6.2 It is Superior Tube Company policy that all documented information shall be neat and legible.

6.3 In cases of errors or deletions and changes made during recording of information, the correct procedure is to cross out the in-correct information using one line, enter the correct information followed by the signature (first initial and last name) and clock number of the individual making the changes, and the date the changes were made. All documentation is to be made using blue or black ink. The obliteration of any information such as completely masking by inking it out or the use of liquid white-out-type product is prohibited.

## **SECTION 9**

### **CONTROL OF PURCHASED MATERIALS AND SERVICES**

#### **1. SCOPE**

The following procedures have been established and will be used to ensure that purchased materials and services conform to the procurement document and quality material requirements.

#### **2. VENDOR SELECTION**

2.1 The selection of sources for the procurement of materials and services shall be based on one or more of the following:

- Approved source lists supplied by the Customer.
- Approved source lists established by STC. These sources are listed in Superior Tube Company's Approved Vendor List (AVL), which is evaluated and updated continually. The AVL documents the product(s) or service(s) for which each organization is approved. This list is maintained and distributed by the Quality Assurance Department.
- Through the evaluation of potential suppliers.
- Determination and management of risk when selecting the supplier.

#### **3. INITIAL VENDOR EVALUATION**

##### **3.1 Raw Material**

3.1.1 Various checklists and evaluation tools are used to evaluate vendors, depending upon the scope and extent of the product or service provided.

3.1.2 Vendors supplying raw material to meet ASME, NQA-1 and/or 10CFR50 Appendix B requirements will be audited or be processed through a commercial grade dedication.

3.1.3 Vendors supplying raw material to the other requirements shall be approved by one or more of the following methods:

- ISO9001, AS9100, ASME Accreditation
- Audit or Survey.
- Commercial Grade Dedication.
- Incoming inspection.
- Review of Superior final product manufactured from the vendor's material.

CONTROL OF PURCHASED MATERIALS AND SERVICES

SECTION 9

3.2 Services

3.2.1 Approval of vendors of services will be accomplished by one or more of the following methods:

- ISO9001 and/or AS9100 accreditation.
- STC personnel visit the vendor's facility to perform the evaluation.
- Evaluation of the service at STC as it is being performed.
- Calibration service accreditations by NVLAP, A2LA, PJLA or other accreditation bodies recognized by NVLAP through the ILAC Mutual Recognition Arrangement (MRA), provided the following criteria are met:
  - The laboratory is accredited to ANSI/ISO/IEC 17025.
  - The published scope of accreditation for the calibration laboratory covers the needed measurement parameters, ranges and uncertainties.
  - The procurement documentation shall specify that the calibration certificate/report shall identify the laboratory equipment/standards used and shall include the as-found and as-left data.
  - QA shall review objective evidence for compliance with the procurement documents.

4. ON-GOING MATERIAL AND SERVICE EVALUATION

4.1 The evaluation of the quality of purchased materials or services will be achieved in one or more of the following methods:

- By conducting source inspection at the vendor's facility prior to shipment.
- By reviewing the vendor's certification or obtaining objective evidence to verify conformance to the purchase order requirements.
- By performing a receiving inspection on the incoming raw materials.
- By evaluating quality performance over time, on an as needed basis.
- On time delivery performance.
- By audit of quality system and/or process controls.

5. VENDOR AUDITING

5.1 Raw Material Vendors

Auditing of raw material vendors shall be per STCP-2503, Procedure to Document the Requirements of Approving Vendor/Subcontractors for the Approved Vendor List (AVL).

STC periodically samples material from raw material suppliers for an analysis against the controlling material specification.

CONTROL OF PURCHASED MATERIALS AND SERVICES

SECTION 9

5.2 Service Vendors

Auditing of service vendors shall be per STCP-2503, Procedure to Document the Requirements of Approving Vendor/Subcontractors for the Approved Vendor List (AVL).

5.3 Approved Vendor List (AVL)

Requirements for Superior Tube Company AVL are detailed in STCP-2503, Procedure to Document the Requirements of Approving Vendor/Subcontractors for the Approved Vendor List (AVL). The AVL is maintained and controlled by Quality Assurance.

5.4 Audit Reports

All vendor audit reports will be maintained by the Quality Assurance Department. Audits will not be closed-out until all findings are resolved and signed-off by Quality Assurance.

**6. RAW MATERIAL APPROVAL AND RELEASE**

6.1 Raw material inspections are detailed in STCP-501, Raw Material Release Process. Upon acceptance of material, STC is responsible for the conformity of product purchased from suppliers, including sources defined by the customer.

6.1.1 Quality/Process Engineering evaluates risk on the release of material prior to the acceptance of all required inspections or tests. Quality Assurance records and monitors these limited releases, as trial lots, for possible rejection per STCP-502.

6.2 Nonconforming raw material will be handled in accordance with STCP-502, Raw Material Nonconformance Process. The procedure defines requirements for:

6.2.1 Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the nonconformity.

6.2.2 Specific actions where timely and/or effective corrective actions are not achieved.

6.2.3 Determining if additional nonconforming product exists based on the cause(s) of the nonconformities and taking further action when required.

CONTROL OF PURCHASED MATERIALS AND SERVICES

SECTION 9

7. APPROVED MATERIALS LIST

7.1 STC maintains a program and a list of approved materials that may physically contact tubing or tubing products, as follows.

STCP-7501, Program for Control of Detrimental Materials Requirements at Superior Tube Company details the program.

## **SECTION 10**

### **IDENTIFICATION AND CONTROL OF MATERIALS**

#### **1. SCOPE**

The identification of material throughout receipt, storage, manufacture, inspection, testing, and the identification of the finished acceptable parts shall be indicated as follows.

#### **2. RECEIPT, STORAGE AND IDENTIFICATION**

2.1 From the time raw material is received from the supplier or Customer and stored prior to the release for production, it is identified by one or more of the following methods.

- Tags affixed to bundle, skids, or boxes of material.
- Continuous ink marking of each piece.
- Electro etching of each piece.

**Note:** Due to the metallurgical nature of raw materials at STC, environmental storage or aging issues are not a concern with raw materials. However, the raw material is to be stored in a manner to preserve all as received conditions.

2.2 The identification on the raw material will be checked against the supplier's or Customer's raw material certification. The check will be made for heat number, size, material type, and quantity received and will then be subjected to raw material inspection. All tags identifying raw material will be legible and appropriate for the environment in which they are stored. See STCP-501, Raw Material Release Process.

2.3 For heats processed by single melts (Arc, Arc+AOD, VIM, etc.): STC defines the heat number to be the original melt identification as supplied by the melter. This heat number shall be maintained for traceability and resulting individual ingot identity need not be maintained.

2.4 For heats processed by multiple melts, primary melt followed by a remelt, (Arc+AOD+VAR, VIM+VAR, VIM+ESR, etc.): STC defines the heat number to be the identification applied to each remelted ingot since the remelting operation results in a unique melt or heat chemistry. The remelt heat number, including ingot number, shall be maintained for traceability.

2.5 Any materials affecting product quality with shelf life requirements shall be controlled by the relevant STCP. For example, LPT materials are controlled via STCP-3003, Dye Penetrant Inspection Materials.

IDENTIFICATION AND CONTROL OF MATERIALS

SECTION 10

**3. MANUFACTURE, INSPECTION, AND TESTING**

The process for traceability and accountability of tubing manufactured by STC is detailed in STCP-7515, Requirements for Line Clearance, Traceability and Accountability of Tubing.

Unique identification of product is maintained from heat melt to product shipping. Heat identification is established by the raw material supplier during the initial melt and maintained through delivery to STC along with country of origin and manufacturer. The heat is assigned to a Process Works Order (PWO) and material as well as inspection records are identified throughout the tube manufacturing process. Traceability of the heat / PWO is kept on record in the IBS system as well.

Each lot of tubing being processed will be identified in the following manner:

3.1 Traveler - Each lot of material being processed on an order will have a Traveler affixed to it or within close proximity to the lot, to ensure lot identification integrity. The following information appears on the Traveler: process works order number, lot number, and material type.

3.2 Process Documentation – Each lot of tubing being processed through the mill will have a Process Works Order (PWO) accompanying the material. The PWO will reference a standard part number that maintains the identity of the product configuration. Changing the configuration of the PWO requires authorization of the change per the requirements of STCP-10, “Request for Change Procedure.”

The PWO and associated process documentation will be identified by an order and lot number that must coincide with the number on the Traveler affixed to the lot of material. In the event of a processing problem which could result in nonconforming material or the presence of an actual nonconforming condition, the PWO along with associated process documentation and material will be segregated to stop further processing of this material until the problem or nonconformance is resolved.

3.3 Test Pieces - When test pieces are removed from the lot of material they will be tied together and have a tag affixed to them. The tag shall identify the material being tested. At a minimum, the tag shall state the PWO number which can be traced to the material type, size and heat number.

3.4 Inspection and Test Plan - For those Customers requiring an Inspection and Test Plan, Superior will develop the plan and obtain applicable approvals.

IDENTIFICATION AND CONTROL OF MATERIALS

SECTION 10

- 3.5 Metallurgical Lab Card - Each order has a Lab Card and carries identity of the Process Works Order. The Lab Card lists the metallurgical requirements of the contract. The detailed instructions for tests and inspections performed by the Metallurgical Lab will be referenced on the card. These tests can include chemistry, when specified.
- 3.6 Return to Stock Tag – All excess material that is NOT being scrapped but is returned to stock shall have a Return to Stock tag affixed to the bundle. This includes breakdown inventory stock. Use of this tag is covered in STCP-7524, Disposition of Excess, Rejected and Short Length Material and Return to Stock Procedure.

**4. NONCONFORMING MATERIAL**

- 4.1 Nonconforming material will be tagged appropriately and kept separate from acceptable material by segregating in designated HOLD areas. Details are contained in Section 16 and 17 of this Manual. Such nonconforming material may be kept with conforming material provided the nonconforming material is segregated and that the nonconformance is removed at the next operation. For example, NDT rejects being cut out at the next operation.

## **SECTION 11**

### **PROCESS CONTROL**

#### **1. SCOPE**

The tube manufacturing processes which affect quality at Superior Tube Company are carried out under controlled conditions. Controlled conditions shall include the following:

- Availability of work instructions and product characteristic information.
- Use of suitable production equipment and a suitable working environment.
- Compliance with reference standards/codes, manufacturing plans and/or documented procedures.
- Monitoring, measuring and controlling suitable process parameters and product characteristics, including suitable measuring equipment.
- The approval/qualification of processes and equipment, as appropriate.
- Criteria for workmanship.
- Suitable maintenance of equipment to ensure continuing process capability.
- Design and control of tooling to ensure process capability.
- Safe working practices for all employees.
- Operate the business in an environmentally sound manner to protect the environment, our employees, and the public.
- Accountability for all product during production.
- Provision for the prevention, detection, and removal of foreign object debris (FOD).

#### **2. CONTROL**

- 2.1 Control is accomplished through the use of the Superior Tube Company Manufacturing Plans – Process Works Orders and Lab Cards. As the listed operations on these documents are completed, operators are required to sign-off the appropriate operation on the PWO and enter the appropriate information into ShopVue. See STCP-22, Document Integrity, for sign-off details.
- 2.2 When appropriate to the product, project management shall be planned and managed using a structured and controlled process taking into consideration acceptable risk within resource and schedule constraints.
- 2.3 Risk and Project management, when appropriate, will be used to identify, assess and mitigate risks throughout the manufacturing process and ensure the product is adequately controlled.

PROCESS CONTROL

SECTION 11

Risk mitigation authority is detailed in STCP-3, Authority, Disposition, Recording and Corrective Action of Nonconforming Product.

Product release is not complete until vetted through the Quality certification release process. Controls are detailed in STCP-5500, Procedure for the Preparation of Certification of Tubing.

- 2.4 Control of process operations is documented through various means. Where appropriate, STC Procedures (STCPs), Standard Operating Procedures (SOP's), reaction plans, and job aids are available. When a conflict exists between PWO instructions and a procedure instruction, the former shall take precedence.
- 2.5 Methods for monitoring and measuring quality of processes are in place. These methods are in place to ensure desired results are achieved. If not, appropriate corrective actions are taken including determining the extent of product that may be affected. Product that is nonconforming is identified and segregated.

**3. SPECIAL PROCESS QUALIFICATION**

The control of Special Processes shall be accomplished through the use of various procedures, instructions, specifications, plans and other documents. The applicable document for controlling the process will be referenced in the Process Works Order, Inspection and Test Plan, or Lab Card.

Special processes utilized by STC are welding, heat treating and nondestructive testing.

- 3.1 Procedures – When required, the procedures shall be submitted for approval to the Customer.
  - 3.1.1 NDT procedures are in the 3000 series of the STCP documentation system.
  - 3.1.2 Heat Treat Standards are in the 8000 series of the STCP documentation system.
  - 3.1.3 STCP-7024 through 7027 are the control procedures for the welding process. STC does not perform weld repair.

PROCESS CONTROL

SECTION 11

3.2 Personnel – Qualification of personnel will be achieved as outlined in Section 21. Only qualified personnel shall be used to perform special processes, except as noted below:

3.2.1 In-process nondestructive inspections that are not part of final product certification may be performed by personnel who are not certified in that method. Examples include liquid penetrant of raw stock material and of development material.

3.3 STC maintains NADCAP accreditation for special processes. Audits are performed per the NADCAP criteria.

**4. PREVENTIVE MAINTENANCE**

4.1 All equipment which directly affects quality, is subject to preventive maintenance to ensure continuing process capability.

4.2 The Preventive Maintenance program is administered by Facility Maintenance per requirements of STCP-7525, Preventive Maintenance Program.

**5. TOOLING CONTROL**

5.1 Control of tooling is documented in TOOL.007, Tool Room Process Flow and other related job aids.

5.2 Tooling inventory, identification and storage, maintenance, and replenishment is controlled per various standard operating procedures, job aids and customer specific procedures.

5.2.1 Tool requirements include verification of condition when returned to storage and prior to use.

5.2 Dedicated tooling is controlled by procedure or PWO text and used only if appropriate controls are invoked.

**6. PROCESS QUALIFICATION & VALIDATION**

6.1 Superior Tube Company performs process/equipment validations per STCP-8500. This system applies to equipment and processes that form, heat treat, clean, or test product intended for shipment to a customer.

6.2 Equipment installed prior to the implementation of the program stated in STCP-8500 has been considered validated based upon the inspection and approval of product.

6.3 Validations will be coordinated by the Process Engineering Group with support from Quality Assurance, Facilities, and Operations Management.

## **SECTION 12**

### **INSPECTION**

#### **1. SCOPE**

The inspections required by the contract for the certification of the product and any necessary in-process inspections required to maintain control of the product quality will be listed in their proper sequence in the Process Works Order or Lab Card. If specific procedures or instructions are necessary for the performance of a particular inspection, they will be referenced.

Requirements for product acceptance include, where applicable:

- Criteria for acceptance and/or rejection,
- Process step where the measurement is to be performed,
- The method of measurement to be used,
- Specific measurement instruments and/or instructions associated with their use,
- Required records of the measurement results.

STCP-1007, “General Visual and Mechanical Inspection Tubing” provides general inspection guidelines. This procedure includes recognized sampling plans, and inspection technique usage and instructions (including measurement identification usage for later recall, if required).

#### **2. INSPECTION**

##### **2.1 In-Process**

The inspections required to maintain control of the product and its quality throughout processing is the responsibility of the department where the processing is taking place, unless that inspection is to be used as part of the final certification of the product. In the later case, the requirements for the performance of the inspection shall be listed on the Process Works Order or in procedures. All data for certification purposes shall be reviewed by Quality Assurance for conformance to the requirements.

INSPECTION

SECTION 12

2.2 Final Inspection

The inspection to be performed on the finished product for the purpose of obtaining data for the certification of the product will be outlined in the Process Works Order or Lab Card. All final inspections will be performed by individuals not directly responsible to those providing the work and are performed in an appropriate environment to ensure consistent measurement results. The requirements for the performance of the inspection shall be listed on the Process Works Order or in procedures. All data for certification purposes shall be reviewed for conformance to the requirements, approved, and released by a signature by a Quality Assurance representative.

2.3 Process Control

Process Control techniques, including statistical techniques (SPC) where applicable, are used during various mill process steps to control key characteristics.

## **SECTION 13**

### **TEST CONTROL**

#### **1. SCOPE**

This section deals with tests performed in the Laboratory (Lab) at Superior Tube Company. The tests required by the contract for the certification of the product and any necessary tests required to maintain control of the product quality will be listed in their proper sequence in the Process Works Order or Lab Card. If specific procedures or instructions are necessary for the performance of a particular test, they will be referenced.

#### **2. TESTING**

##### **2.1 In-Process**

The testing required to maintain control of the product and its quality throughout processing shall be performed in the Lab. The testing criteria will be listed on the Process Works Order or laboratory procedures. All data for certification purposes shall be reviewed by Quality Assurance for conformance to the requirements.

##### **2.2 Final Testing**

The tests to be performed on the finished product for the purpose of obtaining data for the certification of the product will be outlined in the Process Works Order or Lab Card. All testing is performed as required on the Process Works Order per STC detailed Laboratory Test Procedures (LTP) unless otherwise specified by the customer and documented on the Lab Card as part of the Specification Review Process.

## **SECTION 14**

### **CONTROL OF MEASURING AND TEST EQUIPMENT**

#### **1. SCOPE**

Measuring and test equipment used in determining material conformance to internal and to Customer requirements is governed by STCP-2000, Calibration and Metrology Process Procedure. All such equipment is subject to periodic calibration and verification that is traceable to NIST. Superior Tube Company performs in-house calibrations and subcontracts calibrations of measuring and test equipment according to the Calibration Schedule in STCP-2000, Calibration and Metrology Process Procedure. In the case of measuring and test equipment that deviates from individual Customer requirements, such differences will be reviewed with the Customer prior to use of such equipment.

#### **2. MEASURING AND TEST EQUIPMENT (STCP-2000)**

##### **2.1 Equipment Evaluation**

All purchased measuring and test equipment under the control of the Calibration Program shall be inspected by personnel of the Gage Lab to evaluate the accuracy and tolerances and to determine its compliance to the requirements set forth in the purchase order. Each gage shall be uniquely identified. Superior Tube Company reviews all new measuring and test equipment and determines if it has the appropriate facilities, standards, and resources to perform calibration. If the in-house calibration laboratory cannot perform the calibration, it is subcontracted to an approved calibration laboratory.

- 2.1.1 As required, specific types of gages are selected to have Gage R & R studies performed. Results will be used to evaluate appropriate gage selection and utilization, based upon gage and measurement uncertainty.
- 2.1.2 Computer aided measurement and test equipment will be periodically evaluated in accordance with STCP-2040, Verification of Computer Aided Inspection and Test Systems.
- 2.1.3 The protocol for validation or verification of software used in the Universal Testing Machines used at Superior Tube Company is documented in LTP-48. The comparative tests are performed to determine if the derived data acquired with a computerized universal testing machine agrees with the results acquired on the same machine from graphical records.

CONTROL OF MEASURING AND TEST EQUIPMENT

SECTION 14

**2.2 Control of In-Process and Final Inspection Measuring and Test Equipment**

The procedures for the control of measuring and test equipment, including identification, handling, maintenance, recall, and storage, are outlined in STCP-2000, Calibration and Metrology Process Procedure.

A register/list of Measuring & Test Equipment is maintained in accordance with STCP-2000, Calibration and Metrology Process Procedure.

Well defined, approved, and controlled calibration and verification procedures are used to train technicians who perform in house calibrations. No departures from procedures are allowed unless documented and approved by the Superior Tube Company Quality Management.

To ensure the validity and accuracy of calibrations, Superior Tube Company participates in Critical Task Assessments and independent Proficiency Tests. Results are evaluated by the Quality Department.

Calibration frequencies are established for all measuring and test equipment and may be adjusted according to STCP-2000, Calibration and Metrology Process Procedure.

Superior Tube requires that the collective uncertainty of calibration standards used for measuring and test equipment meets a 4 to 1 accuracy ratio for calibrations performed in house. When required, measurement uncertainty is calculated for in house calibrations according to STCP-2046, Calculating Measurement Uncertainty Procedure. Subcontracted calibrations must have the measurement uncertainty documented on the calibration certificate and must meet the requirements outlined in STCP-2001.

**2.3 Calibration Standards and Reference Materials (where applicable)**

Procedures for the use and maintenance of calibration standards are outlined in STCP-2000, Calibration and Metrology Process Procedure. Calibration standards and materials (when applicable) must be traceable to NIST. Qualified technical personnel review and sign-off outside measurement and test equipment calibration certificates to ensure that ANSI/NCSL Z540.1 and ISO 10012 requirements are met. NDT equipment standards are controlled by procedures outlined in the NDT procedures and STCP-3008, Procedure for Calibration of Electronic Equipment Used for Nondestructive Testing. STCP-3077, Procedure for Control of Nondestructive Testing Calibration Standards, details the inventory and physical control of such standards.

CONTROL OF MEASURING AND TEST EQUIPMENT

SECTION 14

2.4 Discrepant Equipment

Procedures for controlling equipment in which discrepancies are found are outlined in STCP-2000, Calibration and Metrology Process Procedure. This document includes corrective action taken for materials examined with gages later found discrepant.

3. RESPONSIBILITY

The responsibility for the control and calibration of measuring and test equipment is described in STCP-2000, Calibration and Metrology Process Procedure.

## **SECTION 15**

### **HANDLING, STORAGE, AND SHIPPING**

#### **1. SCOPE**

The practices and procedures established by STC for the preservation, handling, storage, and shipping of materials vary because of the range of alloys processed and broad variation in Customer requirements.

Manufacturing route operation instructions are developed to ensure:

- Cleanliness
- Prevention and Detection of Foreign Objects,
- Special Handling Requirements (i.e. light wall, long lengths)
- Marking and Labeling,
- Storage and Identification.

#### **2. HANDLING**

- 2.1 The precautions to be taken regarding the handling of material will be outlined in the Process Works Order as specified by the Customer and/or by Process Engineering to meet the quality requirements. Cranes are subject to periodic inspections per STCP-9501, Operation and Maintenance of Bridge and Gantry Cranes and Slings. Metal-to-Metal contact is prevented whenever possible.
- 2.2 Customer-specific handling and cleaning requirements are contained in the 7000 series of STCP documentation system or in PWO text.
- 2.3 Naval Nuclear tubing, when processed or stored, shall rest in stainless steel pans, in wood lined racks or on unpainted surfaces of an approved material. Surfaces not listed must be covered with kraft paper or plastic sheeting before placing tubing on them.

#### **3. PACKAGING AND SHIPPING**

- 3.1 Instructions for carrying out these functions are included in the Process Works Order per the applicable procedure. Included with packaging instructions may be the final cleaning instructions, as required by Customer specifications. These are detailed in various Customer-specific STCP documentation system procedures.

HANDLING, STORAGE, AND SHIPPING

SECTION 15

**4. PRESERVATION AND STORAGE**

- 4.1 In-Process and finished material will be stored in a fashion to preserve all quality characteristics in their as-stored conditions. Unacceptable conditions are evaluated and dispositioned.
- 4.2 Materials utilized in processing or testing shall be controlled for storage shelf-life in accordance with manufacturer's recommendations.
- 4.3 Storage areas will be audited for potential damage and product deterioration, as part of the internal audit system.

**5. FOREIGN OBJECT DEBRIS (FOD) DETECTION**

5.1 STC program for FOD detection is promoted utilizing various methods:

- 5S posters and visual aids
- 5S blitz endeavor
- Daily cleaning and work routines
- Company policy outlining the consumption of food or beverages in work or prohibited areas.
- Employee expectation posting
- Employee awareness notifications and training

5.2 Manufacturing routes include proactive instructions for the removal of debris from the surfaces of tubing such as final cleaning procedures, blowing compressed air through the inside diameter, wiping of the outside diameter surface, and various inspection / verification techniques, etc.

5.3 Prior to boxing, all material is subject to final inspection to verify the visual appearance conforms to requirements.

5.4 STC document 5S.001, General 5S Requirements for Housekeeping, provides general housekeeping guidance in support of STC's FOD prevention program.

## **SECTION 16**

### **INSPECTION, TEST, AND OPERATING STATUS**

#### **1. SCOPE**

This section defines the methods employed to indicate the performance of inspection or testing and the status of the material following an inspection or test.

#### **2. PERFORMANCE**

The completion of a test or inspection shall be indicated on the Process Works Order and indicated electronically in ShopVue. Additionally, the inspection report form or stamp used shall contain the inspector's name and/or clock number and date. Technicians and Management personnel may use signatures or initials, along with the date, at that particular step of the Process Works Order or Lab Card.

#### **3. STATUS**

- 3.1 Use of status tags is detailed in STCP-27, Inspection, Test and Operating Status.
- 3.2 Product dispositioned for scrap is controlled per the requirements of GEN.004, Scrap Disposal Instructions. The provisions in this process ensure scrapped product cannot be used in a fraudulent scheme or counterfeit application.

## **SECTION 17**

### **NONCONFORMING MATERIAL**

#### **1. SCOPE**

Superior Tube Company has established and documented procedures for the control and disposition of in-house nonconforming material. These procedures include the identification, disposition, documentation, evaluation, and segregation of nonconforming material.

#### **2. MATERIAL NONCONFORMANCE**

- 2.1 Throughout processing and inspection, any nonconforming material is identified to prevent its use until a satisfactory disposition is made. The identification process is defined in Section 16.
  - 2.1.1 Product dispositioned for scrap shall be conspicuously and permanently marked until physically rendered unusable. The process addressing counterfeit material is contained in STCP-24.
- 2.2 STC documents and reports in a timely manner to affected customers and interested parties nonconformances regarding delivered products including, as appropriate to their impacts, corrective actions per STCP-23.
- 2.3 STCP-3, Authority, Disposition, Recording and Corrective Action of Nonconforming Product, is used to handle the classification, review, and disposition of nonconforming material.
- 2.4 STCP-33, Authorized Authority for PWO Sign-Off, Change Control and Rework further documents authority for review, and the personnel approval process.

## **SECTION 18**

### **CORRECTIVE AND PREVENTIVE ACTION**

#### **1. SCOPE**

The Corrective and Preventive Action System is detailed in STCP-23, Corrective and Preventive Action System. This procedure covers material complaints, audits findings, raw material and other corrective and preventative action methods.

- 1.1 Responsibility for the Corrective and Preventive Action program is a function of Quality Assurance.
- 1.2 Changes to appropriate documents will be implemented and recorded when resulting from any corrective or preventive action.
- 1.3 Nonconformance trends identified by analysis of quality data are captured in the Corrective and Preventive database.
- 1.4 STC Management will assess corrective and preventive actions to ensure that the identified actions are commensurate with the risk and magnitude of each problem or deficiency, in order that the condition does not recur or occur elsewhere, by:
  - Reviewing and analyzing trends and data,
  - Determine cause, including as applicable, human factors,
  - Similar conditions, or potential similar conditions,
  - The effectiveness of corrective actions
  - Update risks and opportunities during planning,
  - Implement changes to the Quality Management System,
  - Flow down corrective actions to suppliers,
  - Ensure timely and effective corrective actions are achieved.

#### **2. CORRECTIVE ACTION**

- 2.1 Corrective Action procedures are in place to identify, document, evaluate and eliminate the cause of nonconformances and prevent recurrence in products and systems. A periodic review is performed to verify the effectiveness of the actions taken per STCP-23.

CORRECTIVE AND PREVENTIVE ACTIONS

SECTION 18

2.2 Preventive practices and processes are in place to use sources of information (business indicators, quality and productivity trends, scrap and yield loss, rework data, nonconforming product analysis, human factors, etc.) to define and direct actions to detect, analyze and eliminate root causes and drive continual improvement. Reviews will be performed to ensure actions taken are effective at eliminating the root cause for the defined problem as well as similar problems.

## **SECTION 19**

### **QUALITY ASSURANCE RECORDS**

#### **1. SCOPE**

This procedure is established to outline the methods for the control, preparation, and retention of quality-related records.

#### **2. PREPARATION OF CERTIFICATE OF TEST**

- 2.1 Certificates of Test are prepared in accordance with STCP-5500, Procedure for the Preparation of Certification of Tubing.
- 2.2 Each activity shall generate the required records needed for certification of the product being offered for acceptance. Where appropriate, a record of Accept or Reject will be noted on quality records.
- 2.3 The Certificate of Test shall report actual results, heat treatments (including time and temperature), attestation to accuracy, forwarding of approved subtier certificates, conformance to dimensional requirements, compliance with applicable specifications and codes, traceability of products to certification, and documenting of Manual Revision and date, as required by Customer purchase order requirements.
- 2.4 Electronic signature may be used on product certificates provided they are controlled by Quality Assurance and allowed by the Customer. When required, an original signature will be used on certificates. STCP-5502, Approved Electronic Signatures, details the controls used at STC.

#### **3. RETENTION**

##### **3.1 Quality Record Files**

Data protection processes for documented information monitored electronically includes server back-ups daily and electronic storage off site.

STCP-56, Retention of Quality Records details the retention activities at Superior Tube Company.

QUALITY ASSURANCE RECORDS

SECTION 19

4. GENERAL

- 4.1 Archive samples required to be kept by the contract will be gathered by Quality Assurance and retained for the length of time specified and agreed to between the Customer and STC.
- 4.2 Quality records shall be legible, stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to minimize deterioration or damage and to prevent loss.
- 4.3 The records are available to authorized representatives of the Customer, Management, or other authorized personnel.
- 4.4 The control of the material storage as dictated by customers. The scope of this process is documented in STCP-93.

## **SECTION 20**

### **AUDITS**

#### **1. SCOPE**

1.1 The scope of the audit program is to assess the STC activities affecting the quality of product shipped. The purpose of audits is to:

- Verify the conformance of the Quality Management System with applicable customer, statutory, regulatory, and third-party standards and requirements;
- Verify the effectiveness of QMS implementation;
- Verify appropriate controls are effectively implemented by suppliers.

1.1.1 Periodic and systematic audits are planned, scheduled, and supervised by the designated Audit Manager. These audits are performed every calendar year.

1.1.2 Additional, unplanned audits may be conducted if the need is indicated through nonconformance trends, Management reviews, etc.

1.1.3 To assess process control during manufacturing, STC performs surveillances of work centers on a monthly basis per STCP-2502.

#### **2. QUALIFICATION OF PERSONNEL**

2.1 Personnel performing internal and vendor audits will be trained per STCP-2500, Quality System Audit Program.

2.2 Personnel who lead audits are qualified on the basis of education, experience, training, audit participation and examination.

2.3 Audits are performed by individuals who are not directly responsible for the area to be audited.

2.4 The use of third party auditors/lead auditors is allowed, provided that they meet the applicable qualification criteria.

**AUDITS**

**SECTION 20**

**3. PROCEDURE**

3.1 The process for auditing and evaluating the Program is detailed in STCP-2500, Quality System Audit Program.

**4. REPORTING AND RECORDS**

4.1 At the end of each internal audit, a closing meeting is held with Management. The results of the internal audit will be reviewed at that meeting.

4.2 The Audit Manager shall prepare a Quality System Audit Report to management, which becomes a part of the Management Review.

4.3 Records of internal audits are maintained by Quality Assurance.

## **SECTION 21**

### **TRAINING**

#### **1. SCOPE**

All employees receive appropriate training in order to properly perform their jobs and to meet internal and external Customer requirements.

#### **2. GENERAL**

2.1 STC's training programs ensure that personnel performing work affecting quality conform to product requirements by addressing the following:

- competence,
- training to achieve the necessary competence,
- evaluation of training effectiveness,
- awareness and relevance of training activities, and
- maintenance of records of education, training, skills, and experience.

#### **3. TRAINING REQUIREMENTS**

3.1 General training requirements are documented in STCP-9500 which details the Guidelines Governing Superior Tube Company Training Requirements.

3.2 Special qualification training is defined in STCP-9500.

#### **4. RECORDS**

4.1 Records of training are maintained by the appropriate cognizant trainer, or by the Human Resources Department.

## **SECTION 22**

### **SERVICE PROVISION**

#### **1. SCOPE**

Superior Tube Company continually strives to improve our products and services to our customers through product and process developments aimed at providing improved material performance and delivery service.

Information is monitored to ensure Customer satisfaction includes, but is not limited to, on-time delivery performance, customer complaints, corrective actions, product conformity and post-delivery support. STC addresses deficiencies and assesses the effectiveness with resulting actions to improve customer satisfaction.

#### **2. CUSTOMER COMMUNICATION**

- 2.1 SAP-5, Customer Communication, details the means by which STC will communicate with our customers.
- 2.2 STC will work with individual Customers to solicit ideas for improvement in product and processes. Ideas for improvement may be generated by the Customer or by STC personnel. Outputs are generally oriented at improved material and delivery performance, reduced cost and increased profitability. Records of such improvements are proprietary when specific Customer requirements are invoked.
- 2.3 STCP-11, Industry Change Management, defines the change notification process as it applies to industrial change requirements.
- 2.4 SAP-6, Customer Satisfaction Procedure, details intent, methods, resources, and frequency that Superior Tube Company will use to measure customer satisfaction. These techniques will be used to identify new market opportunities.
- 2.5 Post Delivery Support is provided to customers to address material concerns or discrepancies. Sales is responsible for communication to the customer, either proactively, or when a concern is presented by the customer.
  - 2.5.1 Sales proactively track and communicate on-time target completion per SAP-10, Communication of Late Orders to the Customer.
  - 2.5.2 Product discrepancies are addressed by Sales from the time information received by the customer, through disposition, rework or remake operations, and final disposition and resolution. SAP-70, Customer Return Procedure provides the process of internal communication. Material discrepancies requiring corrective actions will be handled per the requirements of STCP-23, Corrective and Preventive Action System.

## **SECTION 23**

### **IMPROVEMENT**

#### **1. SCOPE**

Superior Tube Company is committed to the philosophy of continual improvement through the use of process controls, including statistical methods, in order to reduce scrap, rework, and variability, and to improve Customer satisfaction. Management is committed to provide resources and support necessary to make this program a success. Measures may include process capabilities, business indicators, nonconformance trending, etc.

#### **2. IMPROVEMENT INITIATIVES**

2.1 The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These shall include:

- 2.1.1 Improving products to meet requirements as well as address future needs and expectations,
- 2.1.2 Correcting, preventing, or reducing undesired effects,
- 2.1.3 Improving the performance and effectiveness of the Quality Management System.

2.2 Areas of improvement include but are not limited to:

- Safety - Utilize a proactive approach by identifying and eliminating hazards before they cause incidents and accidents.
- Environmental – Minimize environmental risks to the community by employing safe and environmentally sound technologies and operating procedures sound environmental controls.
- Quality Improvement Projects
- Facility and Machinery Improvement Plans
- 5S initiatives and clean-as-you-go standard work practices
- Support of FOD program
- Incorporation of Lessons Learned
- Utilization of Best Practices
- Information Technology Initiatives
- Organizational Development / Employee Empowerment
- Health and Wellness of employees through efforts such as biometric screenings
- Mentoring Programs

2.3 Implementation of improvement initiative activities are monitored and evaluated by organizational managers for the effectiveness of the results.

IMPROVEMENT

SECTION 23

**3. STATISTICAL PROCESS CONTROL**

- 3.1 The Statistical Process Control process is guided by STCP-5000, Statistical Process Control (SPC).
- 3.2 According to the nature of the product and depending on the specified requirements, statistical techniques are used to support:
  - Verification (e.g., reliability, maintainability, safety),
  - Process Control,
  - Inspection,
  - Failure mode, effect, and criticality analysis.
- 3.3 Quality tools that may be employed to evaluate controls:
  - Yield, Scrap and Rework Summaries
  - Run Charts
  - Histograms
  - Cause and Effect Diagrams
  - Pareto Diagrams
  - Graph and Control Charts
  - Check Sheets
  - Stratifications
  - Scatter Diagrams
  - X Bar/R Charts
  - Electronic Data Collection
  - Gage R+R Studies
  - Capability Studies, Cp and CpK

**4. ANALYSIS OF DATA**

- 4.1 Superior Tube Company Management periodically reviews certain statistical data to determine the effectiveness of the Quality Management System.
- 4.2 Data reviewed includes Customer satisfaction, Supplier performance, nonconformances, Cost of Poor Quality (layout scrap, rework, yield loss, customer returns), and others as deemed appropriate by management.
- 4.3 The data analysis is used to identify continuous improvement and preventative action opportunities.

**5. CONTINUAL IMPROVEMENT**

- 5.1 The organization shall continually improve the suitability, adequacy, and effectiveness of the Quality Management System.

IMPROVEMENT

SECTION 23

5.2 The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

5.3 The organization shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.

5.3.1. This can include lessons learned, problem resolutions, and benchmarking of best practices.

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**Revision History:**

REVISION NUMBER	DATE	COMMENTS
1	10/02/73	STCP-31
2	02/03/75	STCP-31
3	01/30/76	STCP-31
4	05/02/77	STCP-31
5	05/25/78	STCP-31
6	05/25/79	STCP-31
7	06/04/80	STCP-31
8	05/01/82	STCP-31
9	05/08/83	STCP-31
10	10/23/87	STCP-31
11	10/25/89	STCP-31
		Last of the 31 Series
0	07/01/94	STCP-1

*Note: STCP-1 was removed from the STC procedure system and converted into a stand-alone document, the Quality Manual. As of February 2006 it has now been identified again as STCP-1, Rev. 0*

QA Manual, Rev. 0	07/01/95	
QA Manual, Rev. 1	11/24/97	
QA Manual, Rev. 2	11/16/98	
QA Manual, Rev. 3	01/24/00	
QMS Manual, Rev. 4	08/10/02	Internally audited, not issued.
QMS Manual, Rev. 5	10/11/02	
QMS Manual, Rev. 6	06/06/03	ISO Audit Responses
QMS Manual, Rev. 7	06/04/04	Various Audit Responses
STCP-1, Rev. 0,	03/14/06	Numerous updates to reflect correct procedures. No substantial change to philosophy or commitment to quality.
STCP-1, Rev. 1,	04/10/07	
STCP-1, Rev. 2,	03/14/08	
STCP-1, Rev. 3,	08/31/09	
STCP-1, Rev. 4,	02/01/11	
STCP-1, Rev. 5	05/01/12	This revision was not issued.
STCP-1, Rev. 6	08/01/12	
STCP-1, Rev. 7	12/01/13	
STCP-1, Rev. 8	04/15/14	
STCP-1, Rev. 9	05/15/14	
STCP-1, Rev. 10	07/15/14	
STCP-1, Rev. 11	06/30/16	
STCP-1, Rev. 12	07/30/17	
STCP-1, Rev. 13	07/31/20	
STCP-1, Rev. 14	01/17/22	

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**Revision History Table**

Revision	Date	Description	Reason
13	7/31/2020	<p>1.) <b>Revision</b> History: Moved to the back of the QAM.</p> <p>2.) <b>Introduction:</b> Modified first sentence of Scope to match AS9100D accreditation certificate.</p> <p>3.) <b>Introduction:</b> Added 7.2.6 and 7.2.7.</p> <p>4.) <b>Process Control (Sec 11):</b> Added the following to 2.4: <i>When a conflict exists between PWO instructions and a procedure instruction, the former shall take precedence.</i></p> <p>5.) <b>Section 23, 3.2:</b> Replaced quality loss with Cost of Poor Quality.</p>	<b>Audit #2020-5</b> <b>CAPA #A-C1224</b> <b>Clarification</b> <b>Clarification</b>
14	1/17/2022	<p><b>Introduction:</b> Re-organized scope and company purpose sections.</p> <p><b>Introduction (7.1):</b> Deleted reference to SAP-42 (obsolete document).</p> <p><b>Section 2:</b> Added <i>“Assessment of the needs/concerns of Interested Parties (STCP-1 Addendum #4)”</i> to Management Review paragraph.</p> <p><b>Section 2:</b> Responsibility to maintain MR records changed from Operations to Quality.</p> <p><b>Section 3:</b> Updated Scope for clarity. STC does not perform product design activities.</p> <p><b>Section 9:</b> In para 5.3, assigned Procurement the responsibility to keep supplier dates current.</p> <p><b>Section 11:</b> Added 6.1-6.3</p> <p><b>Section 15:</b> Added 4.2</p> <p><b>Section 20:</b> Removed reference to PEARs and OERs. Added 1.1.3.</p>	<b>Audit #2021-6</b> <b>A-C1250</b>
15	4/4/2023	<p>Removed “Inc.” throughout document</p> <p>Updated Quality Assurance Manual Section Cross-Reference</p> <p><b>Introduction:</b> Updated quality policy based on MR output</p> <p><b>Introduction (7.2.1):</b> changed reference of SAP-42 to SAP-40 (SAP-42 is obsolete)</p> <p><b>Introduction (7.2.3):</b> added references to STCP-7515 and STCP-93. Changed “Objective Evidence Reporting” to “Floor Surveillances process per STCP-2502”. <b>Introduction (7.2.6):</b> added “Annual training of personnel regarding Product Safety.”</p> <p><b>Introduction (7.2.7):</b> Added procedure STCP-24</p> <p><b>Section 1:</b> 1. changed “Director, Operations” to “Plant Manager”</p> <p>3.1 Updated “Quality Manager” to “Quality Assurance and Systems Manager”</p> <p>Changed “Product Development” to “Process Engineering”</p>	N/A

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	<p><b>Section 2:</b> 7. Changed “Director Quality &amp; New Product Development” to “Quality Assurance and Systems Manager” in two instances</p> <p><b>Section 5:</b> added “per QA Form 89-03” to 1.1.4, 1.1.5 &amp; 1.1.6</p> <p><b>Section 6:</b> removed 1.3 to match current practices</p> <p><b>Section 8:</b> 2.1 removed “process” and added “as required” 3.2 removed “process”, added “and approved”, added “as required”, removed second sentence 5.1 updated to match current practices</p> <p><b>Section 9:</b> 5.3 removed “as a separate document” and added “and”. Removed last sentence</p> <p><b>Section 11:</b> 5.1 changed “STCP-8500, Qualification and Validation Procedure” to “TOOL.007, Tool Room Process Flow and other related job aids.”</p> <p><b>Section 14:</b> 2.2 added “and must meet the requirements outlined in STCP-2001” to last sentence</p> <p><b>Section 15:</b> 2.2 added “or in PWO text” 4.1 removed “Periodic monitoring to ensure traceability is performed.”</p> <p><b>Section 17:</b> 2.1.1 changed GEN.004 to STCP-24 2.2 added “per STCP-23”</p> <p><b>Section 18:</b> 2.1 added “periodic” and “per STCP-23”</p> <p><b>Section 19:</b> Changed STCP-5 to STCP-93 (STCP-5 is obsolete)</p> <p><b>Section 20:</b> Reworded 1.1.3 and added “per STCP-2502”</p> <p><b>Section 23:</b> Changed header to “Improvement” from “Statistical Techniques”. Added sections regarding improvement and continual improvement from AS9100</p>	
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