QUALITY MANAGEMENT SYSTEM MANUAL

ISO 13485:2016

5370 Salem Ave.
Dayton, OH 45426
937-837-8852
Specialtymetalinc.com

TOP MANAGEMENT APPROVALS

TITLE	NAME	SIGNATURE	DATE
PRESIDENT	RICK SUESS		
VICE PRESIDENT	ERIC HOLTERMAN		
VICE PRESIDENT	ANDY SUESS		
OPERATIONS MANAGER	PATRICK PIERCE		

CHANGE CONTROL

REVISION	ISSUE DATE	DESCRIPTION OF CHANGES
1	1-3-2022	INITIAL LAUNCH OF QUALITY MANAGEMENT SYSTEM
2	1-10-2022	Revised section 8.2.4 to include newly written Internal Audit procedure.
3	6-10-2022	Updated quality policy statement, and updated exclusion list. Revised Section 7.1 to include reference to SMF.7.0.0 instead of SMF.7.1.0. Updated section 4.4 to meet new record retention description, updated process flow chart.
4	8-18-2022	Removed 8.3.4 Rework exclusion from 1.2.0, Exclusions for ISO 13485, updated Quality Policy Statement, added asterisks to define KPI's on process flow
5	8-29-2022	Removed asterisk from Customer satisfaction in 2.2.0 Process flow, added additional information to tie Process Flow Chart to Risk Assessment
6	3-29-2023	SMF.7.2.1.1, Acknowledgement added to 7.2.0 Customer Related Processes, Updated logo
7	6-9-2023	Updated SMF.7.0.0 Job Traveler to SMW7.1.1 Work Order Router
8	8-14-2023	Changed Quality Manual to Quality Management System Manual, added :2016 to manual
9	5-9-2024	Updated top management approval personnel

TABLE OF CONTENTS

1.0.0 QUALITY MANAGEMENT SYSTEM

1.1.0 PURPOSE AND SCOPE

The purpose of this Quality Manual is to define the processes performed within the scope of the Quality Management System, to assign responsibility to each process, and to detail the methods in which these processes will be documented.

The scope includes ISO 13485:2016 and any additional requirements provided by external parties such as customers or regulatory agencies. Additionally, the scope is limited to the following product lines within Specialty Metal.

This quality manual pertains to products (and their related processes) with product codes that start with SP or SF.

SP meaning Specialty Purchased, and SF meaning Specialty Finished goods.

1.2.0 EXCLUSIONS FOR ISO 13485:2016

The following sections of ISO 13485:2016 will be excluded from the quality management system. Specialty Metal is a distributor and therefore does not design, develop, produce, or service medical devices, or other products for their customers.

7.3 Design and development, 7.5.2 Cleanliness of product, 7.5.3 Installation activities, 7.5.4 Servicing activities, 7.5.5 Particular requirements for sterile medical devices, 7.5.6 Validation of processes for production and service provision, 7.5.7 Particular requirements for validation processes for sterilization and sterile barrier systems, 7.5.9.2 Particular requirements for implantable medical devices, 7.5.10 Customer Property.

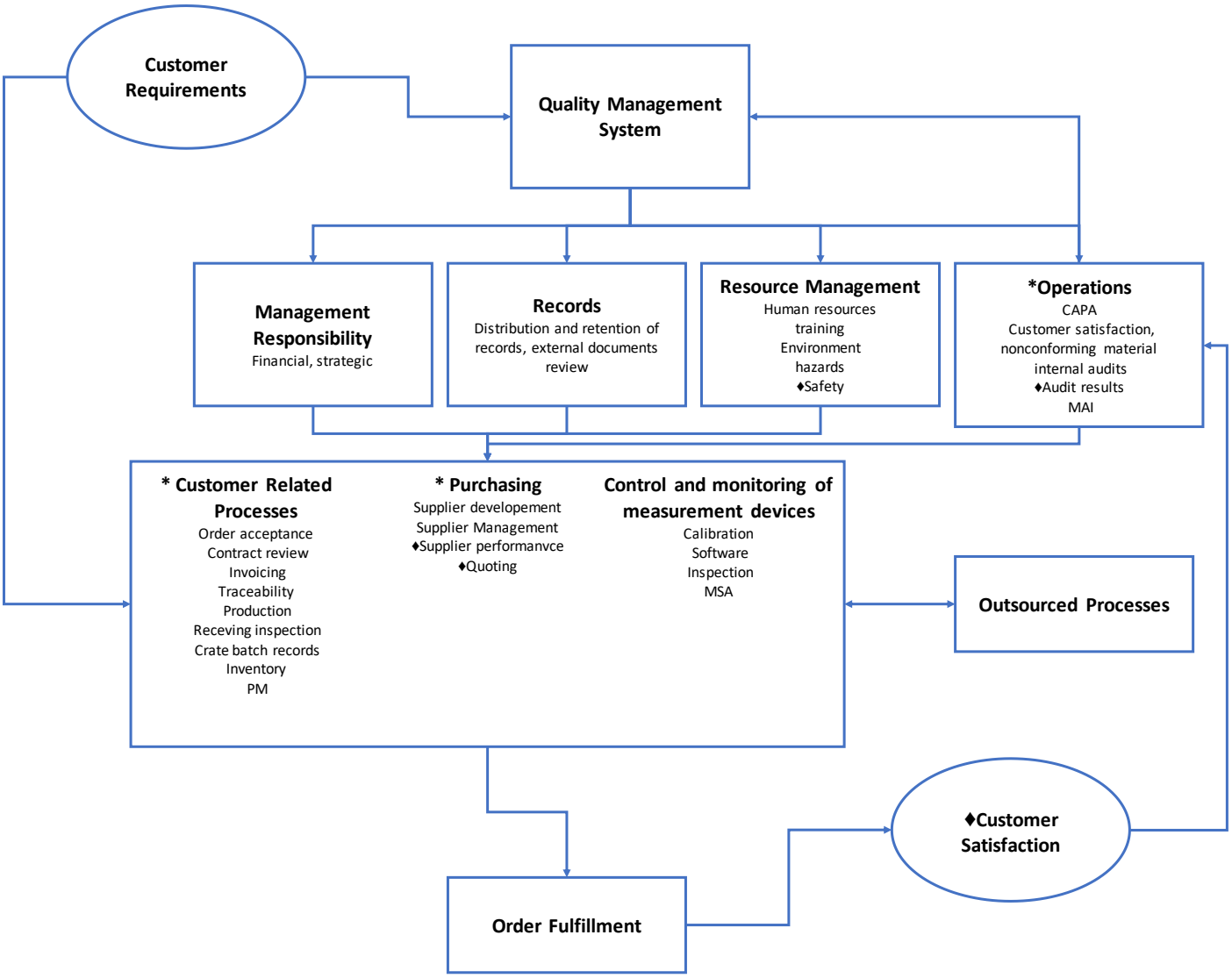
2.0.0 ORGANIZATIONAL CONTEXT

Specialty Metal is a distributor of raw materials such as titanium, stainless steels, and cobalt chrome. Specialty Metal serves various industries including but not limited to general manufacturing and medical device manufacturing.

2.1.0 INTERESTED PARTIES

Interested parties relevant to this quality management system include employees, customers, potential customers, suppliers, and regulatory agencies. All interested parties and the risks and requirements associated with them will be monitored annually by top management during management review meetings.

2.2.0 PROCESS FLOW CHART



♦ **Quality Objective**

* **Key Process**

3.0.0 QUALITY POLICY STATEMENT

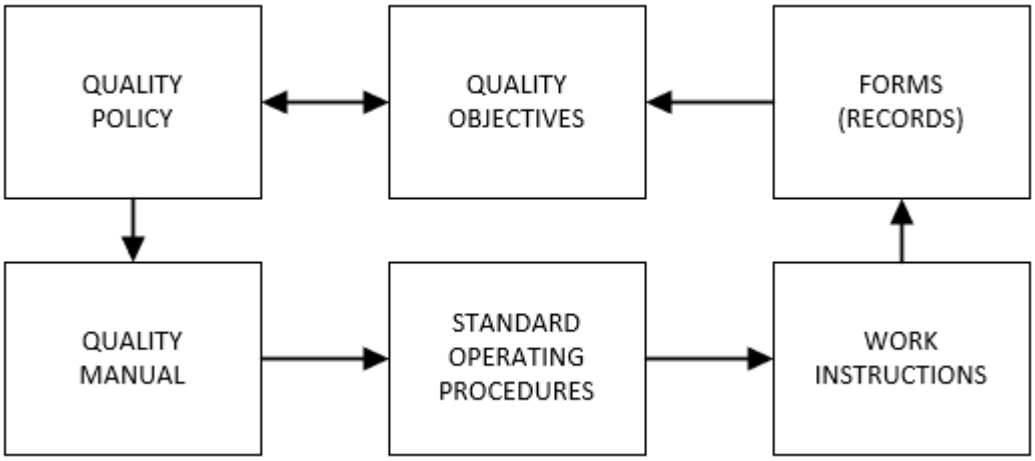
"Specialty Metal commits to provide quality products and services conforming to National and International standards for medical and general manufacturing industries. We are dedicated to meeting customer expectations by providing products conforming to requirements with on-time delivery, competitive pricing, and responsive customer service. We plan to achieve these goals through a risk-based approach and continual improvements to maintain the effectiveness of our quality management system."

All policies, objectives, and procedures within this manual apply to operations performed by Specialty Metal employees in the facilities located in Trotwood, OH. We are committed to meeting customer requirements, needs and expectations on a continuous basis. Improvements to this quality management system will be a top priority of our management team and employees. I personally support this commitment and am leading the effort to maintain a risk-based quality management system that meets the requirements of ISO 13485:2016 and other requirements as applicable. To ensure the continued suitability and effectiveness of our quality management system, top management will review this system annually during management review meetings.

As the President of Specialty Metal, I understand that the execution of the quality management system is ultimately my responsibility and furthermore, I must ensure both my responsibilities and other delegated responsibilities are being completed as stated in the manual.

4.0.0 CONTROL OF DOCUMENTS AND RECORDS

Specialty Metal maintains the quality management system through controlled documentation such as standard operating procedures, work instructions, and forms. Standard operating procedures and work instructions define each process, while forms document the process to create batch records including evidence of conformity to requirements. The control of documents is defined within **SOP.4.2.4 Control of Documents**, while the control of records is defined within **SOP.4.2.5 Control of Records**. All controlled documents with current revisions and locations will be listed on **SMF.4.2.4.1 Master Document List**. See the general document structure below.



NOTE: Specialty Metal does not develop, manufacture, or distribute medical devices and therefore this quality management system will not include device master records, device history records, or any other records related to finished medical devices.

4.1.0 DOCUMENT CHANGE CONTROL

Changes to quality management system documents can be initiated through various outlets such as management review meetings, corrective and preventive actions, audit findings, and continual improvement practices. This process is documented on **SMF.4.2.4.2 Document Change Request** and tracked on **SMF.4.2.4.3 Document Change Log**. All document changes must be approved by Top Management or designee. Change controls will begin after the initial launch of the quality management system as of the date of the first revision of this document.

4.2.0 EXTERNAL DOCUMENTS

Specialty Metal will monitor and maintain external documentation through periodic reviews of ISO and ASTM specifications. While this activity will be performed and documented through the management review process, it is also expected to happen during purchasing activities when raw material is purchased from the mills. Specific customer requirements, specifications, and the revisions of these requirements are required to be listed on purchase orders to prompt a review of requirements before confirmation of a received order. This review process will be performed during quality planning activities as described in section 7.1 and 7.2.

External documents will be stored electronically and monitored on **SMF.4.2.4.4 External Document Log**.

4.3.0 STORAGE OF DOCUMENTS AND RECORDS

To prevent loss or deterioration of quality management system documents, all documents will be stored and backed up electronically. Where documents are kept in working areas, they shall be protected in a manner that prevents deterioration such as lamination. Records will be scanned and stored electronically on external hard drives. Physical documents will be stored within filing cabinets.

4.4.0 RECORD RETENTION

Specialty Metals provides all pertinent records to the customer during distribution. As a distributor of raw materials, the life of product is unknown, and therefore Specialty Metal will retain records indefinitely. Records will be stored as noted in section 4.3.0 of this manual.

4.5.0 ERROR CORRECTIONS

Error corrections on controlled documents or records must be made with a single line drawn through the correction area and accompanied by initial and date of the personnel performing the correction. Correction fluids or strips such as white-out are prohibited. Otherwise, the document must be revised through the change control process listed within this document.

4.6.0 CONFIDENTIAL HEALTH INFORMATION

Specialty Metal does not receive, view, or distribute confidential health information. This information is not required in the sale and distribution of raw materials. Any confidential health information accidentally received shall be returned to the sender immediately.

5.0.0 MANAGEMENT RESPONSIBILITY

The President has the ultimate responsibility for Specialty Metal products included within the scope of this manual. They have appointed a management team that will be responsible for implementing and maintaining the quality management system. The management team is identified within the QM.002 Organization Chart. The Vice President position has been designated as the Management Representative of the quality management system. These practices are further defined within **SOP.5.0.0 Management Responsibility**.

5.1.0 COMMITMENT

The top management team is committed to implementing and maintaining the quality management system through continual improvement and a risk-based approach. Top management shall evaluate risks to the business and perform mitigation activities accordingly, these practices are documented on **QPM-003 Risk Assessment**. Top management shall communicate to the organization the requirements from both customers and regulatory agencies. Additionally, management shall ensure the availability of resources for maintaining the quality management system.

5.2.0 CUSTOMER FOCUS

As a distributor, Specialty Metal will maintain the requirements of a specific batch of material originating from a larger mill run. The material will be placed into inventory marked with specific material standards such as ASTM or ISO standards. Customer requirements will be determined during the quoting process and reviewed for conformity upon release once a purchase order is received. In the event of a special customer requirement, additional requirements will be communicated to the organization through quality planning and must be documented within the material batch record.

5.3.0 QUALITY POLICY

Top management will ensure the quality policy is posted throughout working areas to communicate Specialty Metal's commitment to customer satisfaction and maintaining the quality management system. The quality policy is reviewed at Management Review. The quality policy is in Section 3.0.0 of this manual.

5.4.0 QUALITY OBJECTIVES AND PLANNING

It is the responsibility of top management to plan changes to the quality management system in a manner which ensures the integrity of the

management system is maintained. They shall communicate changes to employees when changes are made to this manual, the quality policy statement, or procedures and work instructions related to the tasks they perform. Top management is responsible for identifying and monitoring quality objectives or key process indicators as indicated within the quality policy and this manual. They will perform or delegate the responsibility for measuring and reporting the indicators of each key process during management review meetings. The objectives as defined by top management are identified within **SMF.5.3.0 Quality Objectives**.

5.5.0 RESPONSIBILITY AND AUTHORITY

Top management will define and communicate responsibility and authority with each individual employee. This practice will be documented on **SMF.5.5.0 Position Description**. Each employee listed on the organization chart shall have a signed position description within their employee file. This form will a signed declaration including the understanding of their responsibilities and authorities, and their commitment to the integrity of the quality management system and the records produced from it.

5.6.0 MANAGEMENT REVIEW

Management reviews will be performed annually by top management to review the quality management system for suitability, adequacy, and effectiveness. The Quality Policy will be reviewed at this meeting. Management reviews will include the inputs and outputs as listed in the ISO 13485 standard. This process is defined within **SOP.5.6.0 Management Review** and documented on **SMF.5.6.0 Management Review Minutes**.

6.0.0 RESOURCE MANAGEMENT

6.1.0 RESOURCES

Top management shall ensure that resources needed to maintain the quality management system are available and meet applicable regulatory and customer requirements. This includes human resources, infrastructure, work environment, and contamination controls.

6.2.0 HUMAN RESOURCES AND TRAINING

Top management is responsible for identifying resource needs, competency required for work tasks, and evaluating employee performance. This process is defined within **SOP.6.1.0 Resource Management and Training**. The minimum requirements for human resource needs are defined within **QM.002 Organization Chart**. Each position listed on the chart, and the competency requirements are documented on **SMF.5.5.0 Position Description**. Position descriptions for each employee will be kept and maintained by H.R. within the employee files. Annual evaluations for each employee are used to document progression or regression in employee competency. This practice is documented on **SMF.6.1.0 Employee Evaluation**. Employee competency ratings will be attributed by management during employee evaluation practices, these ratings will be documented on **SMF.6.1.1 Employee Competency Matrix**. All employee training sessions shall be documented on **SMF-6.1.2 Employee Training Record** including signatures from both the trainer and trainee. These records shall be kept in employee files.

6.3.0 INFRASTRUCTURE

Specialty Metal operates within the Specialty Group. Employees of Specialty Metal may also be employees of Specialty Machines and or other entities within Specialty Group. Specialty Metal is a distributor of raw materials and requires operating workspaces such as a receiving area with the use of forklifts to load and unload materials, product storage space for storing raw materials, and office space for general business activities. These workspace resources and associated utilities are provided by the Suess Enterprises at the location of business listed on the cover page of this manual. Maintenance activities performed on the building, and its core functioning utilities are the responsibility of Suess Enterprises and will not be included within this quality management system.

A software system is used to track jobs as they progress through processing. This software is called Global Shop Solutions and is utilized by both Specialty Metal and the other entities within Specialty Group. Specific codes differentiate products for each entity. Codes SP and SF will

be used for Specialty Metal products within the scope of this quality management system.

Documented maintenance within Specialty Metal is limited to activities relating to the forklifts used in receiving inspection. Maintenance on the forklifts is performed by a third-party at pre-determined intervals. This is documented with forms provided by the third-party vendor. Records of this process are scanned and stored within the quality management system. Employee training on forklifts is done internally, and records for forklift operation are within their employee files. Employees are re-tested every 3 years. Each qualified employee will have a certificate of completion within their employee file.

6.4.0 WORK ENVIRONMENT AND CONTAMINATION CONTROLS

Top management, or designee is responsible for identifying requirements for the work environment needed to achieve conformity to product requirements including regulatory and customer requirements. Ambient conditions such as temperature and humidity do not affect the storage and distribution of raw materials, however these conditions will be monitored to ensure an adequate work environment for all employees. Work safety rules and clothing requirements for personnel are discussed within the employee handbook. The last page of the employee manual includes a signed acknowledgement from the employee stating they are familiar with all guidelines within.

Safety requirements to cleanliness and clothing for specific workspaces, if applicable, shall be present within **SOP.6.3 Infrastructure and Work Environment** or related process work instructions. No other special work environment conditions are applicable and contamination controls are limited to ensuring storage controls are in place to prevent mix-ups or deterioration of product. As Specialty Metal is not a manufacturer of medical devices, other contamination controls and special requirements related to sterile medical devices are not applicable to Specialty Metal or this quality management system.

7.0.0 PRODUCT REALIZATION

7.1.0 PLANNING OF PRODUCT REALIZATION

All processing steps at Specialty Metal are developed, implemented, and maintained in a planned way to include mitigation of potential risks. This is defined within **SOP.7.1.0 Planning of Product Realization**. Potential risks are identified on **QPM-003 Risk Assessment**. Processes are defined within procedures and additional requirements are communicated through work instructions. When material is received, a receiving inspection process will occur to capture the verification of purchase orders as defined within **SOP.7.5.0 Receiving Inspection**. If additional processing is required, **SMF.7.1.1 Work Order Router** will be issued to document all additional activities. Once processing is completed the raw material is stored in finished goods inventory until it is purchased and shipped.

7.2.0 CUSTOMER RELATED PROCESSES

The determination and review of customer requirements is performed at various stages of the distribution process. It is expected that customer requirements will be communicated through material requirements listed on their purchase orders. These requirements are identified as ASTM standards, or other material requirements such as tensile strength or hardness requirements. When material is secured (from stock or from source) form **SMF.7.2.2.2 Acknowledgement**, is used to document par and delivery information and sent to the customer.

7.3.0 DESIGN AND DEVELOPMENT

Specialty Metal does not distribute, design, or develop medical devices and therefore has deemed this section not applicable.

7.4.0 PURCHASING

Specialty Metal relies on industry leaders to provide quality product. This process is documented and controlled by guidelines within **SOP.7.4.0 Purchasing**. A list of all suppliers utilized by Special Metal is documented on **SMF.7.4.0 Approved Suppliers**. Supplier evaluation activities are performed on key suppliers at set intervals. This task is set to ensure suppliers are maintaining a respectable level of quality.

This process is documented on **SMF.7.4.2 Supplier Evaluation**. Once a supplier has been properly vetted and approved for use, purchase orders may be issued. The purchased goods process is completed through the GSS software system and documented on **SMF.7.4.1 Purchase Order**. Verification of purchase products occurs within the receiving inspection procedure listed in section 7.5.0 of this manual.

7.5.0 PRODUCTION AND SERVICE PROVISION

As a distributor of raw materials, Specialty Metal does not manufacture the product. Once the raw materials or "bar stock" is received, receipt and distribution data will be used to document traceability from the certifying mill and the customer. Raw materials are inspected upon receipt both dimensionally and through verification of conformance to requirements. This process is documented on **SMF.7.5.0 Receiving Inspection**. All materials received are identified with **SMF.7.5.8 Raw Material Tag** and recorded on **SMF.7.5.4 Receiving Log**. If a product requires additional processing such as centerless grinding, **SMF.7.1.0 Work Order** is created to document the additional processing steps. Once the product reaches inventory and can be sold, the sale and distribution process are documented by forms **SMF.7.5.1 Packing List** and **SMF.7.5.2 Certificate of Compliance**. Records of each individual batch and its sales are maintained to ensure both traceability and accountability for the quality of the products provided to our customers.

Sections 7.5.2, 7.5.3, 7.5.4, 7.5.5, 7.5.6, and 7.5.7 of the ISO 13485:2016 standard are considered non applicable to Specialty Metal.

7.5.8 IDENTIFICATION

All raw material is identified and traced by the material heat lot number provided by the certifying mill. Each individual batch received by Specialty Metal is labeled with **SMF.7.5.8 Raw Material Tag**. The tag includes batch information such as material heat lot numbers, material type, material size, etc. The tag is fixated to a color coordinated label card relative to specific material types. The material types and colors are listed in the table below. These are also identified on **SMF.7.5.8.1 Raw Material Identification**.

Material Type	Color
Titanium	Yellow
Cobalt	Blue
17-4 SS	Pink
17-4 SS P70+	Pink w/black dot
455 SS	Orange
465 SS	Green

Raw material that is nonconforming will be identified with a red nonconforming tag. (ULINE S-17553)

7.5.9 TRACEABILITY

As a distributor, Specialty Metal documents the receipt and sale of raw materials. The raw material heat number provided on the mill cert is used to identify each batch of raw material. This number is present on all records created during receiving and distributing processes defined within section 7.5.0 of this manual. This number will also be present on the Raw material tag which will accompany material throughout all processes including receipt of material, storage, and shipping to customer.

7.5.10 CUSTOMER PROPERTY

Specialty Metal does not receive or use customer property during the distribution of raw materials. Goods are sold and shipped from inventory, and once they have been shipped, they are controlled by the bill of lading.

7.5.11 PRESERVATION OF PRODUCT

The warehouse is organized to prevent both deterioration of product and product mix-up. Raw materials are bundled and stored in racks, off the floor, accompanied by a raw material tag as described in section 7.5.8 of this manual. The bar stock in inventory does not require specific conditions to prevent deterioration and does not have a shelf life. Specific controls related to those conditions are not applicable. For shipping, materials are packaged per customer requirements. If not defined, material is bundled and placed in shipping container with filler as needed to minimize potential damage during the shipping process.

7.6.0 CONTROL OF MONITORING AND MEASURING EQUIPMENT

A determination of measurements and measurement devices is developed during the quality planning stage as defined in section 7.1.0 of this manual. Specialty Metal measures the bar stock when raw materials are received from the mill to ensure they are conforming to the purchase order issued per section 7.4.0 of this manual. The control of monitoring and measurement equipment is defined within **SOP.7.6.0 Control of Monitoring and Measuring Equipment**. All measuring devices used at Specialty Metal are listed on **SMF.7.6.0 List of Measuring Equipment**. Inspection results, including the equipment used are documented on **SMF.7.5.0 Receiving Inspection** and are maintained within the material batch record as described in section 7.5.0 of this manual.

8.0.0 MEASUREMENT, ANALYSIS, AND IMPROVEMENT

8.2.1 CUSTOMER FEEDBACK

Top Management is responsible for monitoring and measuring customer satisfaction through receipt of customer feedback. Top Management and Quality shall receive customer feedback through avenues such as communication by email, phone, or letter. Additional feedback such as scorecards or evaluations performed by customers which are related to Specialty Metal will be reviewed by Top Management during management review meetings. Customer feedback in the form of complaints will be handled as described in section 8.2.2 of this manual.

8.2.2 COMPLAINT HANDLING

Specialty Metal investigates all formal complaints received. This includes but is not limited to receipt of nonconforming reports and product returns, emails and phone conversations received by sales or customer service teams. Negative customer feedback and customer complaints related to Specialty Metal processes or product will be evaluated and documented as described in **SOP.8.2.2 Complaint Handling**. The number of complaints received will be reviewed annually during management review meetings during analysis of data and trending exercises. Complaints will be documented on **SMF.8.2.2-1 Complaint Evaluation** and compiled on **SMF.8.2.2-2 Complaint Log**.

8.2.3 REPORTING TO REGULATORY AUTHORITIES

Medical Device Reporting and Medical Device Recalls as required by ISO 13485 and 21 CFR 803 are not the responsibility of Specialty Metal. Specialty Metal does not design, manufacture, or distribute medical devices. However, in the event of a medical device reporting or recall initiated by a customer of Specialty Metal, support services such as providing batch records and test inspection results will be provided to aid investigations, as necessary.

8.2.4 INTERNAL AUDIT

Internal audits may be completed by Internal employees or outsourced to a third party to ensure proper auditing of the quality management system, and to prevent potential conflicts of interest by using employees of Specialty Metal. The credentials of the internal auditor must be present within a supplier file or employee file as required by **SOP.7.4.0 Purchasing** and other related controls. Auditor credentials must include at a minimum a certificate of training from a reputable and accredited source. Requirements of Internal Auditing are defined within **SOP.8.2.4 Internal Audit**. If the internal audit is performed by an internal source, the auditor must not have work functions relative to the process being performed. **SMF.8.2.4 Internal Audit Worksheet** will be used to document any internal audits performed by Specialty Metal employees. Third party internal audits will be documented on records provided by the external auditor.

8.2.5 MONITORING AND MEASUREMENT OF PROCESSES

Monitoring and measuring of processes at Specialty Metal is performed through the quality objective studies performed as described within section 5.4, 5.6, and 8.4 of this manual. Top management is responsible for ensuring this process drives continual improvements to the quality management system and internal processes at Specialty Metal.

8.2.6 MONITORING AND MEASUREMENT OF PRODUCT

Product realization activities are performed at various stages of product procurement. These activities are performed and monitored as described within section 7.1 of this manual. Top management shall ensure that product realization activities are performed and completed before release and distribution of raw materials.

8.3.0 CONTROL OF NONCONFORMING PRODUCT

A nonconformance system has been created to identify, investigate, and document internal findings related to the effectiveness of processes and the quality of products. In the event of a detection, activities to be performed are described in **SOP.8.3.0 Nonconforming Products**. Inputs to this system include internally detected nonconformances or process related nonconformities. Oversight of this system will be performed by Quality and Top Management. Investigations including remedial actions, rework activities, and reverification inspection results will be documented using **SMF.8.3.0-1 Nonconformance Report** and entered **SMF.8.3.0-2 Nonconformance Log** for trending purposes.

8.4.0 ANALYSIS OF DATA

As mentioned in section 5.4.0 of this quality manual, data is collected on core processes performed within Specialty Metal. Monitoring of these key process indicators is documented on **SMF.5.3.0 Quality Objectives** and is reviewed by top management annually at management review meetings. Analysis of data activities are defined within **SOP.8.4.0 Analysis of Data**.

8.5.0 IMPROVEMENT

Improvement activities within Specialty Metal will be documented through the CAPA (Corrective and Preventive Action) system. The system and its activities are defined within **SOP.8.5.0 Improvement and CAPA**. Additionally, top management shall maintain the continued suitability, adequacy, and effectiveness of the quality management system through annual reviews performed at management review meetings.

Medical device safety and performance, while important, is not relevant or applicable to Specialty Metal as they do not design, manufacture, or distribute medical devices and are not responsible for monitoring their performance.

8.5.2 CORRECTIVE ACTION

Corrective Actions will be taken to prevent recurrence or eliminate nonconformities related to both products and processes. This includes identifying the root cause of the issue, identifying responsible parties, and documenting all actions taken including immediate, corrective, and preventive actions to address the nonconformance, or nonconforming trend that has occurred. Corrective Actions may be raised at any time by Top Management or Quality if an event, or series of events has led to the identification of a product or process failure, or potential failure. More information on this system is identified within **SOP.8.5.0 Improvement and CAPA**. This process is documented using **SMF.8.5.2-1 Corrective Action** and entered **SMF.8.5.2-2 Corrective Action Log**.

8.5.3 PREVENTIVE ACTION

The preventive action system has been included within the Corrective Action system documentation. Inputs to preventive actions include trending exercises related to nonconformance Logs, supplier evaluations, and complaint logs. Outputs of management review meetings, and quality objective studies may also provide opportunities for improvement that may be addressed with preventive actions. Additionally, preventive actions may be raised when any new risks are identified to either products or processes. More information on this system is provided within **SOP.8.5.0 Improvement and CAPA**.