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# **Quality Management Systems (QMS) Controlled Manual QM-001**

## **Sheffield Machinery Sales Proprietary Information**

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## Quality Management System Manual Revisions

Revision	Date	Description	Originator
00	01/04/2021	Initial Release	EPIC

### APPROVING OFFICIAL (S)

Name	Title	Signature	Date
Pete Carr	President		

## Introduction

Sheffield Machinery Sales developed and implemented a Quality Management System in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and improve the overall management of the company.

The Quality Management System of Sheffield Machinery Sales meets the requirements of the international standard ISO 9001:2015. This system addresses the production of tools and dies and sales and service of machinery.

The manual is divided into ten sections that correlate to the Quality Management System sections of ISO 9001: 2015. Each section begins with a policy statement expressing Sheffield Machinery Sales's obligation to implement the basic requirements of the referenced Quality Management System section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

This manual describes the Quality Management System, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the Quality Management System to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the ISO standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instructions that create an empowered work force.

This manual is used externally to introduce our Quality Management System to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the Quality Management System is maintained and focused on customer satisfaction and continuous improvement.

President: \_\_\_\_\_

Quality Management Representative: \_\_\_\_\_

## Quality Manual Distribution

A printed and controlled QMS Manual will be at the following location:

<b>Manual Number</b>	<b>With / Location</b>
1	QMS Binder
2	Reception

Sheffield Machinery Sales maintains an electronic copy of the quality manual, procedures, forms and work instructions in the company network, which is available to all employees upon request.

Each employee at Sheffield Machinery Sales must have access to the quality manual and may refer to it as the source for procedures related to all activities at Sheffield Machinery Sales. The QMS Document Control Coordinator is responsible for distributing and maintaining current copies of the quality manual.

Customers of Sheffield Machinery Sales can be provided with authorized non-controlled copies of the quality manual for the purpose of evaluating Sheffield Machinery Sales as a supplier. Each manual is given out with the express warning that all information contained herein is proprietary and confidential and should not be disclosed to any unauthorized person or persons without the express written consent of Sheffield Machinery Sales.

A non-controlled copy of the quality manual can be provided to external Quality Management System auditors including registrars.

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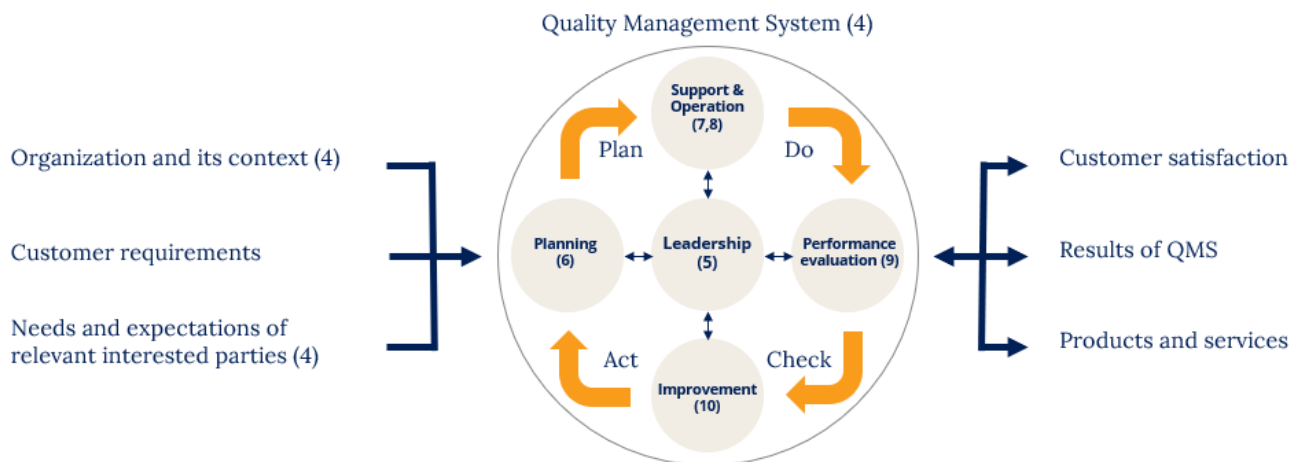
## Section 1: Scope

The Quality Management System is structured to comply with the conditions set forth in the International Standard ISO 9001:2015

This Quality Manual specifies requirement for a quality management system where Sheffield Machinery Sales :

- Demonstrates its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements.
- Aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

Process Approach:



## Section 2: Normative Reference

### 2.1 Quality Management System References

The following documents were used as reference during the preparation of the Quality Management System:

- ISO 9001:2015, Quality Management System – Requirements, Fifth Edition 2015-09-15
- ISO 9000 90:2015, Quality Management Systems – Fundamentals and Vocabulary, Fourth Edition 2015-09-15

## Section 3: Terms and definitions

### 3.1 Quality Management System Definitions

The following terms are defined based on ISO 9000:2015 QMS - Fundamentals and vocabulary.

**Quality** (3.1.1): degree to which a set of inherent **characteristics** (3.5.1) fulfils **requirements** (3.1.2)

**Product** (3.4.2): is defined as “result of a process (3.4.1)”; **process** is defined as “set of interrelated or interacting activities which transforms inputs into outputs”. If the term “process” is replaced by its definition, as follows:

**Product** then becomes “result of a set of interrelated or interacting activities which transforms inputs into outputs”

**Requirement** (3.12.1): expression in the content of a document conveying criteria to be fulfilled if compliance with the document is to be claimed and from which no deviation is permitted

**Capability** (3.1.5): ability of an organization (3.3.1), system (3.2.1) or process (3.4.1) to realize a product (3.4.2) that will fulfill the requirements (3.1.2) for that product.

**Competence** (3.1.6): demonstrated ability to apply knowledge and skills (3.2.2)

**NOTE:** The concept of competence is defined in a generic sense in this International Standard. The word usage can be more specified in other ISO documents

**System** (3.2.1): Set of interrelated or interacting elements

**Management System** (3.2.2): To establish policy and objectives and to achieve those objectives.

**NOTE:** A management system of an organization (3.3.1) can include different management systems, such as a quality management system (3.2.3), a financial management system or an environmental management system.

**Quality Management System** (3.2.2): To direct and control an organization (3.3.1) with regards to quality (3.1.1)

**Top management** (3.2.7): person or group of people who directs and controls an organization (3.3.1) at the highest level.

**Continual improvement** (3.2.13): recurring activity to increase the ability to fulfill requirements (3.1.2); extent to which planned activities are realized and planned results achieved (3.2.15) efficiency, relationship between the result achieved and the resources used.

○ Throughout the text of this International Standard, wherever the term “**product**” occurs, it can also mean “**service**”.

**Customer** (3.3.5): organization (3.3.1) or person that receives a product (3.4.2)

**EXAMPLE:** Consumer, client, end-user, retailer, beneficiary and purchaser.

**NOTE:** A customer can be internal or external.

**Traceability** (3.5.4): ability to trace the history, application or location of that which is under consideration.

**Nonconformity** (3.6.2): non-fulfillment of a requirement (3.1.2)

**Corrective action** (3.6.5): action to eliminate the cause of a detected nonconformity (3.6.2) or other undesirable situation;

**NOTE 1:** There can be more than one cause for nonconformity.

**NOTE 2:** Corrective action is taken to prevent recurrence whereas preventive action (3.6.4) is taken to prevent; occurrence;

**NOTE 3:** There is a distinction between correction (3.6.6) and corrective action.

## Section 4: Context of the organization

### 4.1 Understanding the organization and its context

Sheffield Machinery Sales has determined external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

Sheffield Machinery Sales monitors and reviews information about these external and internal issues.

### 4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, Sheffield Machinery Sales has determined:

- The interested parties that are relevant to the quality management system.
- The requirements of these interested parties that are relevant to the quality management system.

Sheffield Machinery Sales monitors and reviews information about these interested parties and their relevant requirements.

### 4.3 Determining the scope of the quality management system

Sheffield Machinery Sales has determined the boundaries and applicability of the quality management system to establish its scope.

Sheffield Machinery Sales has considered:

- The external and internal issues referred to in 4.1.
- The requirements of relevant interested parties referred to in 4.2.
- The products and services of the organization.

Sheffield Machinery Sales has applied all the requirements of this International Standard within the determined scope of its quality management system.

The scope of Sheffield Machinery Sales 's quality management system is available and maintained as documented information.

This QMS is applicable to the following activities:

- Production of tools and dies
- Sales of machinery
- Repair and maintenance of machinery, tools and dies

Sheffield Machinery Sales has determined that the following requirements are not applicable to the operations at this site and are documented as exclusion:

- **Section 8.3:** Design and Development of Products or Services, including all subsections.

**Justification:** Sheffield Machinery Sales does not design parts or products.

#### 4.4 Quality Management System and its processes

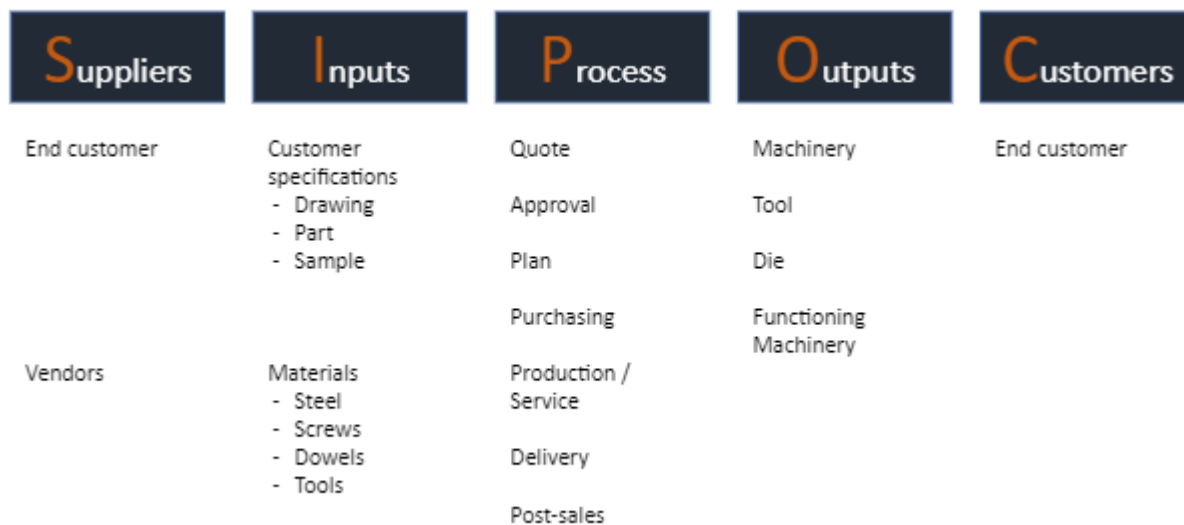
Sheffield Machinery Sales has established, implemented, maintained and continually improves a quality management system, including the processes needed and the interactions in accordance with the requirements of this International Standard.

Sheffield Machinery Sales has determined the processes needed for the quality management system and their application throughout the organization, and has:

- Determined the inputs required and the outputs expected from these processes.
- Determined the sequence and interaction of these processes.
- Determined and applied the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes.
- Determined the resources needed for these processes and ensured their availability.
- Assigned the responsibilities and authorities for these processes.
- Addressed the risks and opportunities as determined in accordance with the requirements of 6.1.

- Evaluated these processes and implemented any changes needed to ensure that these processes achieve their intended results.
- Improved the processes and the quality management system.

Sheffield Machinery Sales maintains documented information to support the operation of its processes and retains documented information to have confidence that the processes are being carried out as planned.



## Section 5: Leadership

### 5.1 Leadership and commitment

#### 5.1.1 General

Top management has demonstrated leadership and commitment with respect to the quality management system, on Procedure P-500 Leadership, by:

- Taking accountability for the effectiveness of the quality management system.
- Ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization.
- Ensuring the integration of the quality management system requirements into the organization's business processes.
- Promoting the use of the process approach and risk-based thinking.
- Ensuring that the resources needed for the quality management system are available.
- Communicating the importance of effective quality management and of conforming to the quality management system requirements.
- Ensuring that the quality management system achieves its intended results.
- Engaging, directing and supporting persons to contribute to the effectiveness of the quality management system.
- Promoting improvement.
- Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

#### 5.1.2 Customer focus

The Top management has demonstrated leadership and commitment with respect to customer focus by ensuring that:

- Customer and applicable statutory and regulatory requirements are determined, understood and consistently met.
- The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed.



- The focus on enhancing customer satisfaction is maintained.

## 5.2 Policy

### 5.2.1 Quality policy

Sheffield Machinery Sales is committed to and strongly driven by the following management principles and behaviors:

- Build a mutually profitable relationship with our customers, ensuring their long-term success, through the understanding of their requirements and the needs of their customers as well.
- Achieve our commitments for quality, cost, and schedule.
- Enhance the systematic research and use of best preventive practices at all levels and ensure reliable risk management.
- Drive continual improvement and innovation of our QMS, based upon efficient business processes, well-defined measurements, best practices, and customer surveys.
- Develop staff competencies, creativity, empowerment and accountability through appropriate development programs and show strong management involvement and commitment.
- Implement ISO 9001:2015 by February 2021

Top management ensures that the quality policy is communicated to all employees. It is included in new employee training and training on the QMS. It is posted in prominent places throughout the facility to maintain high standards within our organization.

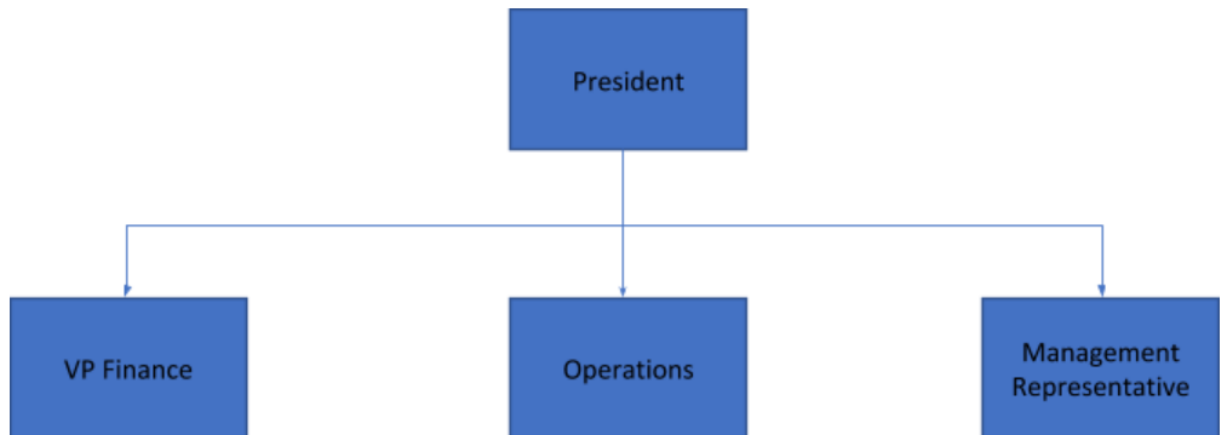
Management reviews the quality policy at each management review meeting to determine the policy's continuing suitability for our organization. The Quality Policy is documented on F-500-001, Quality Policy and Objectives.

## 5.3 Organizational roles, responsibilities and authorities

An organizational chart has been established to show the interrelation of personnel in the organization. Job descriptions define the responsibilities and authorities of each of the positions on the organizational chart below. Job descriptions and the organizational chart are reviewed and approved by top management for adequacy. These documents are available throughout the organization to help employees understand responsibilities and authorities.

Top management has assigned to the Quality Management Representative the responsibility and authority for:

- Ensuring that the quality management system conforms to the requirements of this International Standard.
- Ensuring that the processes are delivering their intended outputs.
- Reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management.
- Ensuring the promotion of customer focus throughout the organization.
- Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.



### Related Procedures:

- P-500 – Leadership

## Section 6: Planning

### 6.1 Actions to address risks and opportunities

Sheffield Machinery Sales has considered the issues referred to in 4.1 and the requirements referred to in 4.2 and determined the risks and opportunities that need to be addressed to:

- Give assurance that the quality management system can achieve its intended result(s).
- Enhance desirable effects.
- Prevent, or reduce, undesired effects.
- Achieve improvement.

Sheffield Machinery Sales has planned actions to address these risks and opportunities. Furthermore, the company has planned how to integrate and implement the actions into its quality management system processes (see 4.4) and how to evaluate the effectiveness of these actions, as per Planning procedure P-600.

### 6.2 Quality objectives and Planning to Achieve Them

Sheffield Machinery Sales has established quality objectives at relevant functions, levels and processes needed for the quality management system.

Quality objectives are established to support our organization's efforts in achieving our quality policy and reviewed annually for suitability. Companywide objectives have been established. The Quality Policy & Objectives are documented in the attachment P-001.

#### Quality Objectives:

- Maintain a customer satisfaction level at a minimum of "Satisfied", or a 4 on a scale of 1-5 with 1 being "very unsatisfied" and 5 being "very satisfied".
- Maintain TAT at a maximum of 20% over estimated times
- Increase CNC running time to a daily average of 8 hours.
- Implement ISO 9001:2015

Sheffield Machinery Sales has determined the action, resources, responsibilities, completion time and process to evaluate the results.

### 6.3 Planning of changes

When Sheffield Machinery Sales determines the need for changes to the quality management system, the changes are carried out in a planned manner, according to Planning procedure, P-600, as established in section 4.4.

Sheffield Machinery Sales considers the following:

- The purpose of the changes and their potential consequences.
- The integrity of the quality management system.
- The availability of resources.
- The allocation or reallocation of responsibilities and authorities.

#### **Related Procedures:**

- P-600 - Planning

## Section 7: Support

### 7.1 Resources

#### 7.1.1 General

Sheffield Machinery Sales has determined and provided the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

The company considers:

- The capabilities of, and constraints on, existing internal resources.
- What needs to be obtained from external providers.

#### 7.1.2 People

Sheffield Machinery Sales determines and provides the personnel necessary for the effective implementation of its quality management system and for the operation and control of its processes.

To ensure competence of our personnel, job descriptions have been prepared identifying the qualifications required for each position that affects service quality. Qualifications include requirements for education, skills and experience. Appropriate qualifications, along with required training, provide the competence required for each position.

#### 7.1.3 Infrastructure

Sheffield Machinery Sales determines, provides and maintains the infrastructure necessary for the operation of its processes and to achieve conformity to product and service requirements through the Sheffield's Maintenance Program described on the Infrastructure Procedure (P-713). The infrastructure has been provided, and includes:

- a) Buildings and associated utilities,
- b) Process equipment (Hardware and Software) and
- c) Transportation Resources
- d) Information and communication technology

As new infrastructure requirements arise, they will be documented in quality plans. Existing infrastructure is maintained to ensure product conformity.

#### **7.1.4 Environment for the operation of processes**

Sheffield Machinery Sales has determined, provided and maintained the environment necessary for the operation of its processes and to achieve conformity of products and services. Data from the quality system is evaluated to determine if the environment is sufficient for achieving product conformance, or if -corrective action related to the work environment is required.

#### **7.1.5 Monitoring and measuring resources**

##### **7.1.5.1 General**

Sheffield Machinery Sales has determined and provided the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

The company ensures that the resources provided:

- Are suitable for the specific type of monitoring and measurement activities being undertaken.
- Are maintained to ensure their continuing fitness for their purpose.

The appropriate documented information is retained as evidence of fitness for purpose of the monitoring and measurement resources.

##### **7.1.5.2 Measurement traceability**

Sheffield Machinery Sales considers traceability to be an essential part of providing confidence in the validity of measurement results. The measuring equipment is:

- Calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;
- identified in order to determine their status;
- safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

### **7.1.6 Organizational knowledge**

Sheffield Machinery Sales has determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge is maintained and is available to the extent necessary.

When addressing changing needs and trends, Sheffield Machinery Sales considers its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

## **7.2 Competence**

Sheffield Machinery Sales :

- Determines the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system.
- Ensures that these persons are competent on the basis of appropriate education, training, or experience.
- Where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken.
- Retains appropriate documented information as evidence of competence.

Following procedure P-720 Competence, Awareness and Communication

## **7.3 Awareness**

Sheffield Machinery Sales ensures that persons doing work under the organization's control are aware of:

- The quality policy.
- Relevant quality objectives.
- Their contribution to the effectiveness of the quality management system, including the benefits of improved performance.
- The implications of not conforming with the quality management system requirements.

## **7.4 Communication**

Sheffield Machinery Sales has determined the internal and external communications relevant to the quality management system, follow procedure P-720 Competence, Awareness and Communication, including:

- On what it will communicate.
- When to communicate.
- With whom to communicate.
- How to communicate.
- Who communicates.

## **7.5 Documented information**

### **7.5.1 General**

Sheffield Machinery Sales 's QMS documentation includes:

- A documented Quality Policy
- This Quality Manual
- Documented Procedures
- Documents identified as needed for the effective planning, operation and control of our processes, and
- Quality Records required by ISO 9001-2015

### **7.5.2 Creating and updating**

When creating and updating documentation, Sheffield Machinery Sales ensures appropriate:

- Identification and description (e.g. a title, date, author, or reference number).
- Format (e.g. language, software version, graphics) and media (e.g. paper, electronic)
- Review and approval for suitability and adequacy.

### **7.5.3 Control of documented information**

All of the QMS documents are controlled according to the Document Control Procedure (P-750), to ensure documentation is:

- Available and suitable for use, where and when it is needed.
- Adequately protected.



For the control of documented information procedure P-753, Sheffield Machinery Sales has addressed the following activities:

- Distribution, access, retrieval and use.
- Storage and preservation, including preservation of legibility.
- Control of changes.
- Retention and disposition.

**Related Procedures:**

- P-713 - Infrastructure Procedure
- P-720 - Competence, Awareness and Communication
- P-750 - Document Control Procedure
- P-753 - Control of documented information

## Section 8: Operation

### 8.1 Operational Planning and Control

Sheffield Machinery Sales plans, implements and controls the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

- Determining the requirements for the products and services.
- Establishing criteria for the processes and the acceptance of products and services.
- Determining the resources needed to achieve conformity to the product and service requirements.
- Implementing control of the processes in accordance with the criteria.
- Determining, maintaining and retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate the conformity of products and services to their requirements.

Sheffield Machinery Sales controls planned changes and reviews the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. The company ensures that outsourced processes are controlled (see 8.4).

Operational planning and control is described in procedure P-850.

### 8.2 Requirements for products and services

#### 8.2.1 Customer communication

Sheffield Machinery Sales has implemented an effective procedure, Customer Related Processes (P-820) for communicating with customers in relation to:

- Product and service Information.
- Enquiries, contracts and order handling, including amendments.
- Customer Feedback, including customer complaints.
- Handling and controlling customer property
- Requirements for contingency actions.

#### 8.2.2 Determining the requirements for products and services

Sheffield Machinery Sales determines customer requirements before acceptance of an order. Customer requirements include those:

- Requested by the customer.
- Required for delivery and post-delivery activities.
- Not stated by the customer but necessary for specified use or known and intended use.
- Statutory and regulatory requirements related to the product.
- Additional requirements determined by Sheffield Machinery Sales .

Customer requirements are determined according to the Customer Related Processes Procedure (P-820).

### **8.2.3 Review of the requirements for products and services**

Sheffield Machinery Sales reviews the requirements related to the product, based on the Customer Related Processes (P-820). The review is conducted before the order is accepted. The process ensures that:

- Requirements are defined, including the requirements for delivery and postdelivery activities.
- Requirements not state by the customer, but necessary for the specified or intended use are known.
- Requirements specified by the organization are defined.
- Statutory and regulatory requirements applicable to the products and services are defined.
- Contract or order requirements differing from those previously expressed are resolved.
- Sheffield Machinery Sales has the ability to meet the defined requirements.
- Records are maintained showing the results of the review and any actions arising from the review.
- Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance.
- When product requirements are changed, Sheffield Machinery Sales communicates changes to relevant personnel and amends relevant documents as defined in the Customer Related Processes (P-820).

The customer's requirements are confirmed by Sheffield Machinery Sales before acceptance, when the customer does not provide a documented statement of their requirements.

Sheffield Machinery Sales retains documented information, as applicable, on the results of the review and on any new requirements for the products and services.

#### **8.2.4 Changes to requirements for products and services**

Sheffield Machinery Sales ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

### **8.3 Design and development of products and services**

Sheffield Machinery Sales does not design or develop any products or services.

### **8.4 Control of externally provided processes, products and services**

#### **8.4.1 General**

Sheffield Machinery Sales ensures that externally provided processes, products and services conform to requirements.

The company has determined the controls to be applied to externally provided processes, when:

- Products and services from external providers are intended for incorporation into the organization's own products and services.
- Products and services are provided directly to the customer(s) by external providers on behalf of the organization.
- A process, or part of a process, is provided by an external provider as a result of a decision by the organization.

in procedure P-840-Control of External Processes.

Sheffield Machinery Sales determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.

The company retains documented information of these activities and any necessary actions arising from the evaluations.

## 8.4.2 Type and extent of control

Sheffield Machinery Sales ensures that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers. The company:

- a) Ensures that externally provided processes remain within the control of its quality management system.
- b) Defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output.
- c) Takes into consideration the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements, and the effectiveness of the controls applied by the external provider.
- d) Determines the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

## 8.4.3 Information for external providers

Sheffield Machinery Sales ensures the adequacy of requirements prior to their communication to the external provider. The company communicates to external providers its requirements for:

- The processes, products and services to be provided
- The approval of products and services, methods, processes and equipment, and the release of products and services.
- Competence, including any required qualification of persons.
- The external providers' interactions with the company.
- Control and monitoring of the external providers' performance to be applied by the organization.
- Verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

## 8.5 Production and service provision

### 8.5.1 Control of production and service provision

Sheffield Machinery Sales plans and carries out production and service provision under controlled conditions. Controlled conditions include, as applicable:

- The availability of information that describes the characteristics of the product and service.

- The availability of work instructions.
- The use of suitable equipment.
- The availability and use of monitoring and measuring devices.
- The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met.
- The implementation of release, delivery and postdelivery activities.
- the appointment of competent persons, including any required qualification.
- 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.
- the implementation of actions to prevent human error.

### **8.5.2 Identification and traceability**

Sheffield Machinery Sales identifies outputs throughout the processes to ensure the conformity of products and services. The status of outputs is identified with respect to monitoring and measurement requirements.

Sheffield Machinery Sales controls the unique identification of the outputs when traceability is a requirement, and retains the documented information necessary to enable traceability.

### **8.5.3 Property belonging to customers or external providers**

Sheffield Machinery Sales applies full control to property belonging to customers while it is under the organization's control or being used by the organization. All parts and equipment are identified, traced and care for according to procedure P-853 Customer Property.

### **8.5.5 Post-delivery activities**

Sheffield Machinery Sales meets requirements for post-delivery activities associated with the products and services. The company has considered as post-delivery activities:

- Statutory and regulatory requirements.
- The potential undesired consequences associated with its products and services.
- The nature, use and intended lifetime of its products and services;
- Customer requirements.

- Customer feedback.

### **8.5.6 Control of changes**

Sheffield Machinery Sales reviews and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. The company retains documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

Production and service provision is described in procedure P-850.

### **8.6 Release of products and services**

Sheffield Machinery Sales implements planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The release of products and services to the customer proceeds after the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and by the customer.

Sheffield Machinery Sales retains documented information on the release of products and services. This documentation includes evidence of conformity with the acceptance criteria, and traceability to the person(s) authorizing the release.

### **8.7 Control of nonconforming outputs**

Sheffield Machinery Sales ensures that outputs which does not conform to their requirements are identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in the Control of Nonconforming Product procedure (P-870). This also apply to nonconforming products and services detected after delivery of products.

Where applicable, Sheffield Machinery Sales will deal with nonconforming product by one or more of the following ways:

- By taking action to eliminate the detected nonconformity.
- By segregation, containment, return or suspension of provision of products.
- By informing the customer.
- By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer.

When nonconforming product is corrected it is subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained.

**Related Procedures:**

- P-820 - Customer Related Processes
- P-840 - Control of External Processes
- P-850 – Production and Service Provision
- P-853 - Control of External Property
- P-870 - Control of Nonconforming Product



## Section 9: Performance Evaluation

### 9.1 Monitoring, measurement, analysis and evaluation

#### 9.1.1 General

Sheffield Machinery Sales plans and implements the monitoring, measurement, analysis and improvement processes as needed, and determines:

- What needs to be monitored and measured.
- The methods for monitoring, measurement, analysis and evaluation needed to ensure valid results.
- When the monitoring and measuring shall be performed.
- When the results from monitoring and measurement shall be analyzed and evaluated.

Sheffield Machinery Sales evaluates the performance and the effectiveness of the quality management system, and retains appropriate documented information as evidence of the results

#### 9.1.2 Customer satisfaction

As one of the measurements of the performance of the quality management system, Sheffield Machinery Sales monitors information relating to customer perception as to whether the organization has fulfilled customer requirements. The method for obtaining and using this information is identified in the Customer Related Processes (P-820).

#### 9.1.3 Analysis and evaluation

Sheffield Machinery Sales analyses and evaluates the appropriate data and information arising from monitoring and measurement, to demonstrate the suitability and effectiveness of the quality management system.

The process for analyzing this data is defined in the Management Review procedure (P-930).

The result of the analysis is used to evaluate:

- Conformity of products and services.

- Customer satisfaction.
- Performance and effectiveness of the quality management system.
- If planning has been implemented effectively.
- The performance of external providers.
- Effectiveness of planning.
- The effectiveness of actions taken to address risks and opportunities.
- The need for improvements to the quality management system.

## 9.2 Internal audit

Sheffield Machinery Sales conducts internal audits at planned intervals to determine whether the quality management system conforms to the planned arrangements to the requirements of ISO 9001:2015 and to the quality management system requirements established by Sheffield Machinery Sales, and is effectively implemented and maintained.

An audit program has been designed and implemented and identifies an audit schedule, based on the importance of the areas to be audited, changes affecting the organization and the results of previous audits. The audit criteria, scope, frequency, methods, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining results, are defined and documented in the Internal Audit procedure (P-920).

## 9.3 Management review

### 9.3.1 General

Top management reviews the QMS a minimum of once a year at management review meetings. This review assesses the continuing QMS suitability, adequacy, effectiveness and alignment with the strategic direction of the company, identifying opportunities for improvement and needed changes. Records are maintained for each management review meeting.

### 9.3.2 Management review inputs

The management review is planned and carried out taking into consideration:

- The status of actions from previous management reviews.
- Changes in external and internal issues that are relevant to the quality management system.
- Information on the performance and effectiveness of the quality management system, including:

- Customer satisfaction and feedback from relevant interested parties.
- The extent to which quality objectives have been met.
- Process performance and conformity of products and services.
- Nonconformities and corrective actions.
- Monitoring and measurement results.
- Audit results.
- The performance of external providers;
- The adequacy of resources;
- The effectiveness of actions taken to address risks and opportunities (see 6.1)
- Opportunities for improvement.

### 9.3.3 Management review outputs

During these review meetings, management will identify appropriate actions to be taken regarding the following issues:

- Improvement of the effectiveness of the quality management system and its processes.
- Improvement of product related to customer requirements.
- Resource needs.

Responsibilities for required actions are assigned to members of the management review team. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the minutes of management review.

### Related Procedures:

- P-820 - Customer Related Processes
- P-500 - Leadership procedures
- P-920 - Internal Audit
- P-930 – Management Review

## Section 10: Improvement

### 10.1 General

Sheffield Machinery Sales determines and selects opportunities for improvement, and implements any necessary actions to meet customer requirements and enhance customer satisfaction. These includes:

- Improving products and services to meet requirements as well as to address future needs and expectations.
- Correcting, preventing or reducing undesired effects.
- Improving the performance and effectiveness of the quality management system.

### 10.2 Nonconformity and corrective action

When a nonconformity occurs, including any arising from complaints, Sheffield Machinery Sales takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure, Corrective and Preventive Action (P-1020), defines requirements for:

- React to the nonconformity and, as applicable:
  - a. Take action to control and correct it;
  - b. Deal with the consequences
- Evaluate the need to action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
  - a. Reviewing and analyzing the nonconformity;
  - b. Determining the causes of the nonconformity;
  - c. Determining if similar nonconformities exist, or could potentially occur;
- Implement any action needed
- Review the effectiveness of any corrective action taken
- Update risks and opportunities determined during planning, if necessary;
- Make changes to the quality management system, if necessary.

Sheffield Machinery Sales retains documented information as evidence of the nature of the nonconformities and any subsequent actions taken, and the results of any corrective action.

### 10.3 Continual improvement

Sheffield Machinery Sales continually improves the suitability, adequacy and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

**Related Procedures:**

- P-1020 - Corrective and Preventive Action