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1.0 Introduction

York Haven Fabricators developed and implemented a Quality Management System to demonstrate its ability to provide consistent product that meets customer and applicable regulatory requirements, and to address customer satisfaction through the effective application of the system, including continual improvement and the prevention of nonconformity. The quality system complies with the international standard ISO 9001.

The manual is divided into five sections modeled on the sectional organization of the ISO 9001 standard. Sections are further subdivided into several subsections representing main quality system elements or activities. Each subsection starts with a general policy statement expressing the commitment to implement the basic principles of the pertinent quality system element or activity. The general policy statement is followed by more specific procedural policies outlining how the general policy is implemented, and referencing applicable operational procedures.

The purpose of this manual is to define and describe the quality system, to define authorities and responsibilities of the management personnel involved in the operation of the system, and to provide general procedures for all activities comprising the quality system.

Another purpose of this manual is to present the quality system to our customers and other external interested parties, and to inform them what specific controls are implemented to assure quality.

2.0 Quality Manual Organization

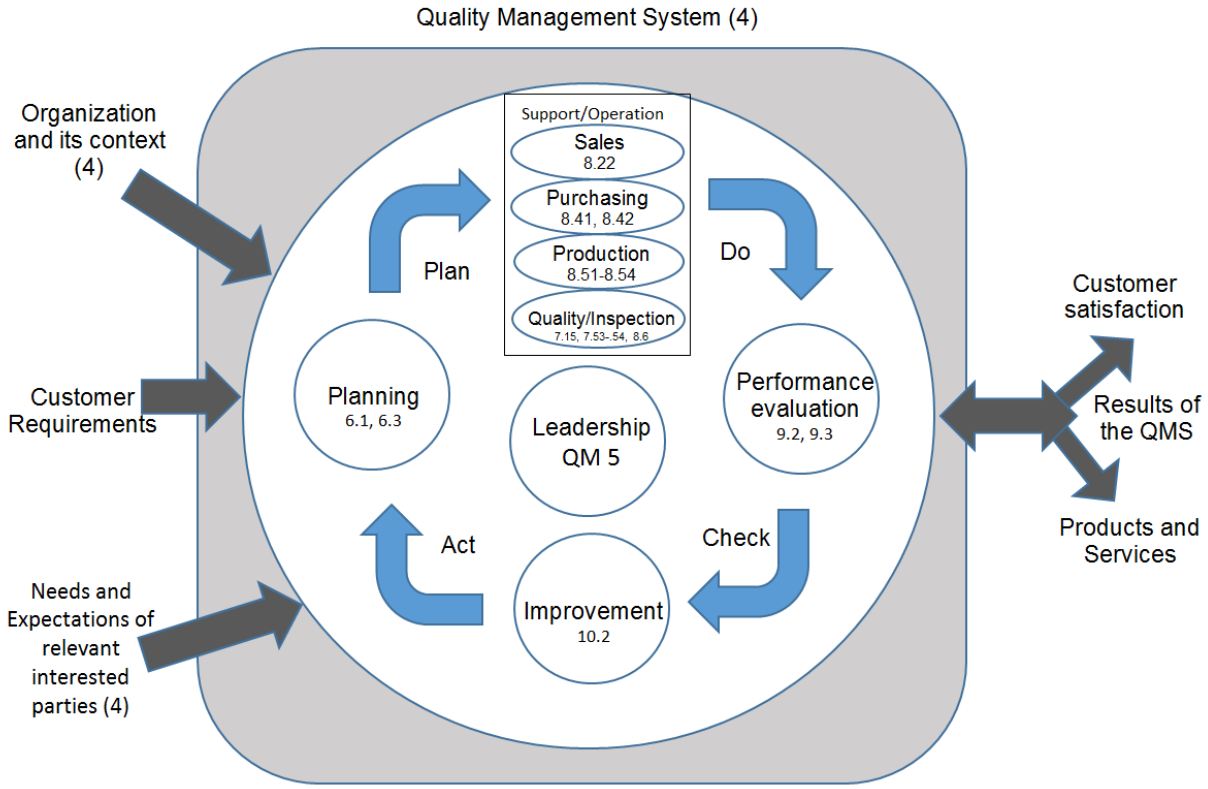
2.1 Scope of the Quality Manual

This manual is prepared for the purpose of defining the company's interpretations of the ISO 9001:2015 international standard, as well as to demonstrate how the company complies with that standard.

This manual follows the numbering structure of ISO 9001 and presents "Notes" which are used to define how has tailored its management system to suit its purposes. These are intended to clarify implementation approaches and interpretations for concepts which are not otherwise clearly defined in ISO 9001:2015. *Notes appear in italics, with gray background.*

2.2 Plan-Do-Check-Act

This QMS is designed around the Plan-Do-Check-Act Cycle as defined below:



3.0 Terms and Definitions

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

4.0 Organizational Context

4.1 Determining Our Strategic Direction

York Haven Fabricators has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of the company. This involves:

Understanding our core products and services, and scope of management system (see 4.2. below).

Identifying “interested parties” (stakeholders) who receive our products or services, or who may be impacted by them, or those parties who may otherwise have a significant interest in our company. These parties are defined in the **Business Context Document**.

Understanding internal and external issues that are of concern are also identified in the **Business**

Context Document. Many such issues are identified through an analysis of risks faced internally or the interested parties. Such issues are monitored and updated as appropriate, and discussed as part of management reviews.

This information is then used by senior management to determine the company's strategic direction. This is defined in records of management review, and periodically updated as conditions and situations change.

4.2 Scope of the Management System

4.2.1 Scope Statement

Scope of Registration: **Sheet Metal Fabrication, Prototyping, and Production**

Quality Management System Scope: **The quality system applies to all processes, activities and employees internally and externally as defined in the Business Context Document.**

The facility is located at:

2850 Lewisberry Rd.
York Haven, PA 17370
Phone: 717-932-4000

4.3 Applicability

4.3.1 Permissible Non-Applicability Exceptions

The QMS shall be relevant to the nature of our organization and products, and to customer and regulatory requirements. For this purpose, those requirements of ISO 9001 that do not apply are deemed not applicable from the scope of our quality system.

PROCEDURE

1. An ISO 9001 requirement may be deemed not applicable only when it may not affect our ability, nor absolves us from the responsibility, to provide product that meets customer and applicable regulatory requirements.
2. Management is responsible for identifying those requirements of ISO 9001 that do not apply to our organization or products, and to propose exclusions of such requirements from the scope of the quality system.
3. Senior Management has the responsibility and authority for evaluating whether the proposed items are appropriately identified, and for approving them. Evaluation and approvals are conducted within the framework of management reviews of the quality system (refer to Operational Procedure SOP-9.3, Management Review).
4. Any item deemed not applicable is documented in this section of the quality manual. The excluded requirements are precisely identified with reference to specific clauses and/or statements in the standard. There is also a brief justification why the exclusion is taken and why it is appropriate.

NOT APPLICABLE

1. ISO 9001 Section 8.3, Design and development of products and services

Justification: York Haven Fabricators does not provide design services to customers.

4.4 Management System and its processes

4.4.1 Key Process Identification

York Haven Fabricators has adopted a process approach for its management system. By identifying the top-level processes within the company, and then managing each of these discretely, this reduces the potential for nonconforming instances discovered during final processes or after delivery. Instead, nonconformities and risks are identified in real time, by actions taken within each of the top-level processes.

Note: not all activities are considered "key processes" – the term "process" in this context indicates the activity has been elevated to a higher level of control and management oversight. The controls indicated herein are applicable only to the top-level processes identified.

The top-level processes have been identified for in the Business Context Document and includes:

- applicable inputs and outputs
- process owner(s)
- applicable responsibilities and authorities
- applicable risks and opportunities
- critical and supporting resources
- criteria and methods employed to ensure the effectiveness of the process
- quality objectives related to that process (Defined in Section 6.2)

The sequence of interaction of these processes is illustrated in the Business Context Document.

Note: The sequence of interaction represents the typical sequence of processes, and may be altered depending on customer or regulatory requirements at the job or contract level, as required.

5.0 Management & Leadership

5.1.1 Management Leadership and Commitment

Senior Management provides evidence of its leadership and commitment to the development and implementation of the management system and continually improving its effectiveness by:

a) taking accountability of the effectiveness of the management system;

b) ensuring that the ***Quality Policy*** and ***Quality Objectives*** are established for the management system and are compatible with the strategic direction and the context of the organization;

c) ensuring that the quality policy is communicated, understood and applied within the organization;

d) ensuring the integration of the management system requirements into the organization's other business processes, as deemed appropriate (see note);

e) promoting awareness of the process approach;

f) ensuring that the resources needed for the management system are available;

g) communicating the importance of effective quality management and of conforming to the management system requirements;

h) ensuring that the management system achieves its intended results;

i) engaging, directing and supporting persons to contribute to the effectiveness of the management system;

j) promoting continual improvement;

k) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

Note: "business processes" such as accounting, employee benefits management and legal activities are out of scope of the QMS.

5.1.2 Customer Focus

Senior Management adopts a customer focus approach which ensures that customer needs and expectations are determined, converted into requirements and are met with the aim of enhancing customer satisfaction.

This is accomplished by assuring:

a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;

b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

c) the focus on enhancing customer satisfaction is maintained.

5.2.1 Quality Policy

Senior Management has developed the ***Quality Policy***, defined in Section 5.2.2, that governs day-to-day operations to ensure quality and is communicated and implemented throughout the organization and to relevant interested parties as appropriate.

5.2.2 Quality Policy

York Haven Fabricators is committed to customer satisfaction through performance excellence. TO achieve our vision, we must continuously improve the quality of all products and services that we provide to our customers and comply with all requirements. We are committed to doing so by using our most important resource (our employees at every level) to understand and continuously improve our processes. The management team is committed to providing the company with the best tools possible to succeed.

5.3.1 Organizational Roles Responsibilities & Authorities

Senior Management has assigned responsibilities and authorities for all relevant roles in the company. These are communicated through the Organization Chart defined in the Business Context Document. Senior Management accepts responsibility and authority for:

a) ensuring that the management system conforms to applicable standards;

b) ensuring that the processes are delivering their intended outputs;

c) reporting on the performance of the management system;

d) providing opportunities for improvement for the management system;

e) ensuring the promotion of customer focus throughout the organization;

f) ensuring that the integrity of the management system is maintained when changes are planned and implemented.

An ISO Representative has also been assigned in the Business Context Document which acts as the point of contact to reach senior management and duplicates the defined responsibilities.

6.0 Planning

6.1 Risks and Opportunities

York Haven Fabricators considers risks and opportunities when taking actions within the management system, as well as when implementing or improving the management system; likewise, these are considered relative to products and services.

Risks and opportunities are managed in accordance with the document SOP 6.1 Risk Management. When planning for the QMS, issues referred to in the Business Context Document are addressed to:

a) give assurance that the QMS can achieve its intended results;

b) enhance desired effects;

c) prevent, or reduce, undesired effects;

d) achieve improvement.

York Haven Fabricators plans for actions to address defined risks and how to integrate and implement the actions into the defined process, including evaluating the effectiveness of these actions.

Note: Formal risk management may not be utilized in all instances; instead, the level of risk assessment, analysis, treatment and record keeping will be performed to the level deemed appropriate for each circumstance or application.

6.2 Process Controls & Objectives

Quality Objectives are established at relevant functions, levels and process and are designed to:

a) be consistent with the quality policy;
b) be measurable;
c) take into account applicable requirements;
d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
e) be monitored;
f) be communicated;

Note: processes may have multiple objectives as determined by the nature of the process, it's impact on outputs and associated risks.

Note: Whereas ISO 9001 discusses process measurements and "quality objectives" as separate concepts, York Haven Fabricators combines them; i.e., quality objectives are used to control the processes. Additional objectives may be assigned, but these will also be used to measure process effectiveness.

6.2.2 Objective Planning

Each process has at least one objective established; this is a statement of the intent of the process. Each objective is then supported by at least one "metric" or key performance indicator (KPI) which is then measured to determine the process' ability to meet the quality objective.

a) Throughout the year, metrics data is measured and gathered by process owners or other assigned managers, in order to present the data to Senior Management. The data is then analyzed in order that Senior Management may set goals and make adjustments for the purposes of long-term continual improvement.
b) The specific quality objectives for each process are defined in the Business Context Document.
c) Metrics, along with current standings and goals for each objective, are recorded in records of management review.
d) When a process does not meet a goal, or an unexpected problem is encountered with a process, the corrective and preventive action process is implemented to research and resolve the issue. In addition, opportunities for improvement are sought and implemented, for the identified processes.

6.3 Change Management

When York Haven Fabricators determines the need for changes to the QMS or its processes, these changes are planned, implemented, and then verified for effectiveness; the process is defined SOP 6.3, Change Management with consideration made to:

a) the purpose of the changes and their potential consequences;
b) the integrity of the Quality Management System;
c) the availability of resources;
d) the allocation or reallocation of responsibilities and authorities.

Documents are changed in accordance with section 7.5.

7.0 Support

7.1 Provision of Resources

York Haven Fabricators determines and provides the resources needed:

a) to implement and maintain the management system and continually improve its effectiveness
b) to enhance customer satisfaction by meeting customer requirements

Resource allocation is done with consideration of the capability and constraints on existing internal resources, as well as needs related to supplier expectations.

Resources and resource allocation are assessed during management reviews.

7.1.2 People

Senior management ensures that it provides sufficient staffing for the effective operation and control of the management system, as well its identified processes, see Section 7.2 Competence and SOP 7.2 Training.

7.1.3 Infrastructure

York Haven Fabricators determines, provides and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

a) buildings, workspace and associated facilities;

b) process equipment, hardware and software;

c) supporting services such as transport;

d) information and communication technology.

Infrastructure is maintained per appropriate schedules.

Where equipment is used for critical measurement activities, such as inspection and testing, these shall be subject to control and either calibration or verification as defined in Section 7.1.5.2

Note: Calibration and measurement traceability is not employed for all measurement devices. Instead, Senior Management determines which devices will be subject to calibration based on its processes, products and services, or in order to comply with specifications or requirements. These decisions are also based on the importance of a measurement, and considerations of risk.

7.1.4 Environment for the operation of processes

York Haven Fabricators provides and maintains the environments necessary for the operation of its processes. Senior Management manages the work environment needed to achieve conformity to product requirements. Specific environmental requirements for products are determined during quality planning and are documented in subordinate procedures, work instructions, or job documentation.

Human factors are considered to the extent that they directly impact on the quality of process outputs.

Note: Social, psychological and safety aspects of the work environment are managed through activities outside of the scope of the management system. Only work environment aspects which can directly affect process efficiency or product and service quality are managed through the management system.

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

Monitoring and measuring resources are provided to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

All monitoring and measurement resources:

a) are suitable for the specific type of monitoring and measurement activities being undertaken;
b) are maintained to ensure their continuing fitness for their purpose.

Appropriate records are maintained to demonstrate fitness for use as is described in SOP 7.15, Measuring and Monitoring Resources.

7.1.5.2 Measurement Identification and Calibration

When measurement traceability is required, or is considered to be an essential part of providing confidence in the validity of measurement results, measuring equipment is:

a) 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 for calibration or verification records shall be retained;
b) identified in order to determine their status;
c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

When measuring equipment is found to be unfit for its intended purpose, the validity of previous measurements will be evaluated and appropriate actions will be taken as necessary.

SOP 7.15, Measuring and Monitoring Resources, describes the calibration process.

7.1.5.3 Validation of Software

In-house developed inspection, test, and monitoring software is validated before it is used for product assurance or verification. Commercial software is purchased with validation certificates where available. Software is revalidated or recertified when conditions for which it was initially validated are materially changed.

7.1.6 Organizational Knowledge

York Haven Fabricators also determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This may include knowledge and information obtained from:

a) internal sources, such as lessons learned, feedback from subject matter experts, and/or intellectual property;
b) external sources such as standards, academia, conferences, and/or information gathered from customers or suppliers.

This knowledge shall be maintained, and made available to the extent necessary.

When addressing changing needs and trends, consideration is made to current knowledge and determinations on how to acquire or access the necessary additional knowledge.

7.2 Competence

Senior Management focuses training and evaluation efforts on competence by:

a) determining the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the QMS;
b) ensuring that these persons are competent on the basis of appropriate education, training, or experience;
c) where applicable, taking actions to acquire the necessary competence, and evaluating the effectiveness of the actions taken;
d) recording appropriate documented information as evidence of competence as defined in SOP 7.2, Training.

7.3 Awareness

Training and subsequent communication is defined in SOP 7.2 Training and ensure that staff are aware of:

a) the quality policy;
b) relevant quality objectives;
c) their contribution to the effectiveness of the management system, including the benefits of improved performance;
d) the implications of not conforming with the management system requirements.

Note: the management system does not include other aspects of Human Resources management, such as payroll, benefits, insurance, labor relations or disciplinary actions.

7.4 Internal Communication

Senior Management ensures internal communication takes place regarding the effectiveness of the management system. Internal communication methods may include:

a) use of corrective and preventive action processes to report nonconformities or suggestions for improvement
b) use of the results of analysis of data
c) meetings (periodic, scheduled and/or unscheduled) to discuss aspects of the QMS
d) use of the results of the internal audit process
e) regular company meetings with all employees
f) internal emails
g) memos to employees

7.5 Documentation & Records

7.5.1 General

The management system documentation includes both documents and records.

Note: the ISO 9001:2015 standard uses the term "documented information"; Instead, the terms "document" and "record" are utilized to avoid confusion. In this context the terms are defined as:

- *Document – written information used to describe how an activity is done.*
- *Record – captured evidence of an activity having been done.*

The quality system documentation comprises the following types of documents:

a) Quality manual (including a documented quality policy);
b) Documented statements of quality objectives
c) Quality procedures;
d) Work instructions;
e) Standards and other technical reference materials;
f) Engineering documents, including drawings, specifications, procedures, and other documents defining products;
g) Customer engineering documents;
h) Product realization and inspection plans;
i) QMS related forms.

Purpose, scope, and responsibility for controlling various types of documents are defined in SOP-7.53, Control of Documents.

7.5.2 General

The top level document defining the overall quality management system is the Quality Manual. It includes:

a) The scope of the quality system, including details of and justification for any sections not applicable;
b) Description of quality system processes, their sequence, and interrelation; and
c) References to documented procedures;

7.5.3 Document Control

New documents and document changes may be initiated by anyone in the organization, but may only be issued by an authorized function. The authorized functions and the rules governing the issue of documents are defined in procedures SOP 7.53 Control of Documents. All documents are reviewed and approved prior to issue.

7.5.4 Control of Quality Records

7.5.4.1 Documented Information/records are established and maintained to provide evidence that:

a) Product designs satisfy design input requirements;
b) Materials, components, and production processes meet specified requirements;
c) Finished products conform to specifications: and
d) The quality system is operated in accordance with documented procedures and that it is effective.
e) Where required, quality records also include traceability information.
f) Records shall be legible, readily identifiable, retrievable and protected from unintended alterations.
g) Retention periods for quality records are determined on the basis of the lifetime of the product or the event to which the record pertains, and on regulatory and contractual requirements.

7.5.4.2 All categories of quality records maintained by the company are listed in SOP 7.54, Control of Records.

The list identifies their storage location and retention period.

8.0 Operation

8.1 Operational Planning and Control

8.1.1 Products and services are defined in drawings and specifications, contract documents, internal and external standards, product samples and workmanship standards, and applicable legal and regulatory requirements.

8.1.2 Quality Assurance is responsible for identifying product quality objectives and requirements. This may be integrated with the process of determining customer and product requirements (refer to SOP 8.22, Customer Communication), and/or with defining design input (refer to SOP 8.3, Design Control).

8.1.3 Product realization planning includes, as applicable:

a) Definition and evaluation of manufacturing operations and processes, including outsourced processes,
b) Development of adequate and capable processes,
c) Identification of special processes and consideration of associated risks and consequences,
d) Establishment and implementation of appropriate process control measures,
e) Development of instructions and training for process operators, and
f) Requirements for records necessary to demonstrate process conformity.

8.1.4 Product realization plans are established in collaboration between Production, Engineering, and Quality Assurance. The plans are defined in various types of production documents, production work orders, inspection plans, operator instructions, process product validation reports, etc.

8.1.5 Product verification plans determine the inspection and testing program for a product, and for materials and components incorporated into the product. This includes:

a) Identification of inspection and testing points,
b) Inspection and testing scope, frequency, and method,
c) Acceptance criteria, and
d) Requirements for records necessary to demonstrate product conformity.

8.1.6 Procedures SOP 8.42, Receiving Inspection, and SOP 8.6, Release of Products and Services, explain how outputs of product verification planning are used.

8.2 Requirements for products and services

8.2.1 Customer Communication

York Haven Fabricators has implemented effective communication with customers detailed in SOP 8.22 Customer Communication with relation to:

a) providing information relating to products and services;

b) handling enquiries, contracts or orders, including changes;

c) obtaining customer feedback relating to products and services, including customer complaints;

d) handling or controlling customer property;

e) establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the requirements for products and services

During the intake of new business York Haven Fabricators captures:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;

b) requirements not stated by the customer but necessary for specified or intended use, where known

c) statutory and regulatory requirements related to the product;

d) any additional requirements determined by Ledge.

These activities are defined in greater detail in the procedure SOP 8.22 Customer Communication.

8.2.3 Review of the requirements for products and services

Once requirements are captured, York Haven Fabricators reviews the requirements prior to its commitment. This review ensures that:

a) product requirements are defined,

b) contract or order requirements differing from those previously expressed are resolved,

c) the organization has the ability to meet the defined requirements, and/or the claims for the products and services it offers, and

d) risks have been identified and considered.

These activities are defined in greater detail in the procedure ***SOP 8.22 Customer Communication.***

8.2.4 Changes to requirements for products and services

Changes to requirements are communicated appropriately and documented information is amended as defined and required by the **SOP 8.22 Customer Communication**.

8.3 Design and development of products and services – Not Applicable

8.4 Control of externally provided processes, products and services

8.4.1 Outsourced Processes

Any process performed by a third party is considered an “outsourced process” and must be controlled, as well. The company’s outsourced processes, and the control methods implemented for each, are defined in ***SOP 84.1, Purchasing Processes***.

The type and extent of control to be applied to the outsourced process take into consideration:

e) the potential impact of the outsourced process on the company’s capability to provide product that conforms to requirements,

f) the degree to which the control for the process is shared,

g) the capability of achieving the necessary control through the purchasing contract requirements.

8.4.2 Purchasing

York Haven Fabricators ensures that purchased products or services conform to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent on the effect on subsequent product realization or the final product.

York Haven Fabricators evaluates and selects suppliers based on their ability to supply product and service in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation are established.

Purchases are made via the release of formal purchase orders and/or contracts which clearly describe what is being purchased. Received products or services are then verified against requirements to ensure satisfaction of requirements. Suppliers who provide non-conforming products or services may be requested to conduct formal corrective action.

These activities are further defined in the documents SOP 8.41 Purchasing and 8.42 Receiving Inspection.

8.5 Production and service provision

8.5.1 Control of Provision of Products or Services

To control its products or services, York Haven Fabricators considers, as applicable, the following:

a) the availability of documents or records that define specific characteristics as well as the results to be achieved;

b) the availability and use of suitable monitoring and measuring resources;

c) the implementation of monitoring and measurement activities;

d) the use of suitable infrastructure and environment;

e) the appointment of competent persons, including any required qualifications;

f) the implementation of actions to prevent human error;

g) the implementation of release, delivery and post-delivery activities.

“Special processes” where the result of the process cannot be verified by subsequent monitoring or measuring may be utilized. When an internal “Special Process” is utilized the methods for validation are defined in the Business Context Document. See SOP 8.51 Control of Provision of Products or Services.

8.5.2 Identification and Traceability

Where appropriate, York Haven Fabricators identifies products or other critical process outputs by suitable means. Such identification includes the status with respect to monitoring and measurement requirements. Unless otherwise indicated as nonconforming, pending inspection or disposition, or some other similar identifier, all products shall be considered conforming and suitable for use.

If unique traceability is required by contract, regulatory, or other established requirement, York Haven Fabricators controls and records the unique identification.

The documented procedure ***SOP 8.52 Identification and Traceability*** defines these methods in detail.

8.5.3 Property Belonging to Third Parties

York Haven Fabricators exercises care with customer property while it is under the organization's control or being used by the organization. Upon receipt, such property is identified, verified, protected and safeguarded. If any such property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records maintained.

For customer intellectual property, including customer furnished data used for design, production and / or inspection, this is identified by customer and maintained and preserved to prevent accidental loss, damage or inappropriate use.

This activity is defined in greater detail in the documents **SOP 8.53 Customer Supplied Product**.

8.5.4 Preservation

York Haven Fabricators preserves conformity of product or other process outputs during internal processing and delivery. This preservation includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product.

The documented procedure ***8.54 Preservation of Product*** defines the methods for preservation of product.

8.5.5 Post-Delivery Activities

Not currently applicable. In the event that York Haven Fabricators would conduct activities which are considered "post-delivery activities", they would be considered in conjunction with:

a) statutory and regulatory requirements;
b) the potential undesired consequences associated with its products and services;
c) the nature, use and intended lifetime of its products and services;
d) customer requirements;
e) customer feedback.

Post-delivery activities would be conducted in compliance with the management system defined herein.

8.5.6 Control of changes

York Haven Fabricators reviews and controls both planned and unplanned changes to processes to the extent necessary to ensure continuing conformity with all requirements and retain appropriate documentation.

Change management is defined in the document ***SOP 6.3 Change Management and SOP 7.53 Control of Documents.***

8.6 Release of products and services

Acceptance criteria for products and services are defined in appropriate subordinate documentation. Reviews, inspections and tests are conducted at appropriate stages to verify that the product and service requirements have been met prior to release. Traceability is maintained as required.

Each process utilizes different methods for measuring and releasing products or services. SOP 8.6, Release of Products and Services defines the release of products and services.

8.7 Control of Nonconforming Products

York Haven Fabricators ensures that products, services or other process outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

8.7.1 Identification and documentation

All product nonconformities are identified and documented, regardless of how insignificant they seem to be or how easily they can be repaired or reworked. Product nonconformity records are invaluable for tracking performance and trends, and for identifying areas where corrective or preventive actions should be implemented.

Nonconforming products are documented using a nonconformity report. It describes the nonconformity, documents the disposition decision, and records close-out of follow-up activities (re-inspection, concessions, corrective actions, etc.). To prevent nonconforming products from being used or shipped, the products are identified and segregated. The use of nonconformity report and its processing are explained in Procedure **SOP 8.7, Control of Nonconforming Product**.

8.7.2 Nonconformity review and disposition

The disposition decision may be: Rework, Return to Vendor, Accept As-Is, Regrade, or Scrap.

Detailed rules for nonconformity review, for making the disposition decision, and for recording these activities are provided in Procedure **SOP 8.7, Control of Nonconforming Product**.

8.7.3 Re-verification of repaired or reworked product

Repaired or reworked products are reinspected in accordance with applicable procedures and instructions.

8.7.4 Product returns and recalls

When product nonconformity is detected by the customer after delivery or use has started, the customer is instructed to return the product, or a part, on a return authorization.

When product nonconformity is detected internally after delivery or use has started, customers are informed and instructed what to do with the product. In situations when the nonconformity may create a safety or other hazard, the product may be recalled. Only the Senior Management of the company is authorized to make recall decisions.

9.0 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

York Haven Fabricators uses the Quality Management System to improve its processes, products and services by determining appropriate measurements based on the following criteria:

a) what needs to be monitored and measured;
b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
c) when the monitoring and measuring shall be performed;
d) when the results from monitoring and measurement shall be analyzed and evaluated.

Quality Objectives, defined in the Business Context Document, define the measurements which evaluate the performance and effectiveness of the quality management system. Appropriate documentation is maintained as evidence of the results in conjunction with SOP 7.54 Control of Records.

9.1.2 Customer satisfaction

As one of the measurements of the performance of the management system, York Haven Fabricators monitors information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information may include:

a) product rejections or returns (RMAs)
b) repeat orders for product
c) changing volume of orders for product
d) trends in on-time delivery
e) obtain customer scorecards from certain customers

The corrective and preventive action system shall be used to develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.

9.1.3 Analysis and evaluation

York Haven Fabricators uses the management system to improve its processes, products and services. Such improvements aim to address the needs and expectations of customers as well as other interested parties, to the extent possible at the Management Review Meeting, see Section 9.3.

The results of analysis shall be used to evaluate:

a) conformity of products and services;
b) the degree of customer satisfaction;
c) the performance and effectiveness of the management system;
d) the effectiveness of planning;
e) the effectiveness of actions taken to address risks and opportunities;
f) the performance of external providers;

g) other improvements to the management system.

9.2 Internal Audit

York Haven Fabricators conducts internal audits at planned intervals to determine whether the management system conforms to contractual and regulatory requirements, to the requirements of ISO 9001, and to management system requirements. Audits also seek to ensure that the management system has been effectively implemented and is maintained.

These activities are defined in the document ***SOP 9.2 Internal Audits.***

9.3 Management Review

9.3.1 General

The purpose of management reviews is to:

a) Evaluate the suitability, adequacy and effectiveness of the quality system;
b) Consider changes to the quality management system and to the quality policy and quality objectives; and
c) Identify opportunities for improvement of the quality system, processes and products.

Management reviews are chaired by the Senior Management Team and are attended by managers representing the key processes. Management reviews are conducted at least once a year. More frequent reviews are scheduled in periods when organizational or product changes, or other circumstances require increased attention and input from the top management. The details of the Management Review, including agenda/inputs and records/outputs are covered in SOP 9.3 Management Review.

10.0 Improvement

10.1 General

10.1.1 Opportunities for improvement

Opportunities and priorities for improvement are identified by comparing present quality performance to objectives defined in the quality policy and quality objectives.

Quality performance is determined by analyzing information about customer satisfaction, records of product and process nonconformity, results of internal audits, and other data and information relevant to quality performance. Section 9.1.3, Analysis and evaluation, defines the scope and system for collecting and analyzing such information.

Quality performance is evaluated by management reviews of the quality system. Where quality performance falls short of a defined objective, the management review identifies specific improvement actions to reach the objective. When a quality objective is reached, the management review may set a new, higher objective in this area and specify new improvement actions for reaching it.

In addition to management reviews, departmental managers identify improvement opportunities continually, based on daily feedback from their operations and other activities. Employees are also encouraged to come forward with ideas for improving products, processes, systems, productivity, and working environment. These improvement opportunities are evaluated and prioritized by Management and are implemented though a system of corrective, preventive actions.

10.1.2 Implementation of improvement projects

Improvement projects are usually implemented through management review actions and through corrective and preventive actions. Where appropriate, improvement projects may also be initiated by management directives, such as policy statements, announcements, memoranda, and so forth.

10.2 Nonconformity and corrective action

10.2.1 Nonconformity Response

When a nonconformity occurs York Haven Fabricators plans to react to the extent required to take action to control and correct the issue and deal with the potential consequences. Appropriate action is taken to prevent recurrence as defined by Section 8.7.

10.2.2 Preventive versus corrective action

Preventive actions are requested and implemented when there are trends of decreasing quality capability and/or effectiveness of the quality system that create a risk for a potential nonconformity. Corrective actions are used when an actual nonconformity is identified.

The need for corrective action is determined on the basis of identified actual nonconformities. Corrective action requests are typically triggered by such events as a failed inspection, customer complaint and/or product return, nonconforming delivery from a supplier, or a quality system audit finding.

The need for preventive action is determined on the basis of information and data regarding capability and performance of processes, product nonconformity rates, post-production experience feedback, service records, customer complaints, in responses to risk analysis and quality system audit findings. Such information and data are collected and analyzed to detect unfavorable trends that, if not checked, will increase the risk of nonconformities.

10.2.3 Processing of corrective and preventive actions

Preventive and corrective actions are initiated, processed and followed up Per SOP 10.2 Corrective and Preventive Action.

10.3 Continual improvement

Continual improvement actions are often defined as corrective and preventive actions. This is especially true for preventive actions.

Revision History and Approval

Rev.	Nature of changes	Approval	Date

D	Updated to Match ISO9001:2015 standard from ISO9001:2008	MS	12/05/16