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Quality Management System
Policy Manual
ISO 9001:2015

1-11-21

Date Printed: _____

First-class Metalwork For World-class Brands ❱ btdmfg.com

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1. **Quality Management System Scope**

BTD establishes this quality policy manual to implement and maintain a quality management system meeting the requirements of ISO 9001:2015, to ensure customer satisfaction in the manufacturing of stamped, formed, machined and fabricated metal parts, weldments, subassemblies and painting of metal parts to customer and BTD specifications

  1.1. Non-applicable Clauses of ISO 9001:
    1.1.1. 8.3 Product Design & Development of Products & Services – BTD is a custom manufacturer and designs are provided by our customers.

2. **Quality Policy Statement**
BTD is committed to continually improving all products and services to achieve our customer's expectations.

We do this by:
  1) *Living our values,*
  2) *Providing opportunities for employee involvement, motivation and training,*
  3) *Developing, documenting and following processes.*

3. **Quality Objectives**
BTD's quality management system objectives are to enable BTD to be our customers' first choice by:
  1) *Achieving satisfactory ratings on quality, delivery and other key metrics tracked and reported by our customers through their formal supplier evaluation and performance systems,*
  2) *Achieving a level of 500 ppm as tracked through BTD's RA system.*
  3) *Achieving a 95% on-time delivery for customers without a formal supplier evaluation system for delivery.*

Policy Manual Revisions Log

Date	Summary of Revisions	Made By
3/22/17	Rewrite of Quality Policy Manual to meet ISO 9001:2015.	JGV
8/7/17	1. Revised 4.2 to include "employees", "owners" and "regulators". 2. Added Figure 2 to support to support the BTD QMS Process Flow	JGV
11-8-17	Updated to clarify risk, inputs, out puts and KPI's for Support and Management Process in QMS Process Reference page (page 6)	JGV
12-18-18	1. Updated Figure 2, page 7. 2. Added reference to STD3-005 in section 4.4	JGV
11-26-19	Updated figure 2 on page 6.	JGV
1-17-20	Updated per top management review: 3.) Quality Objectives, objectives 2 & 3.	JGV
1-11-21	Reviewed updated PPM goal to 500 from 700 in Quality Objectives	JGV
8-18-21	Update QMS Reference Processes (page 6)	JGV

Management Approval

Name:	Title:	Signature:	Date:
Paul Gintner	President	_____	_____

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4. **Context of the Organization**
    4.1. **Understanding the Organization & Its Context**
          Top Management determines the external and internal issues that are relevant to our quality management system and its strategic direction, and that affect our ability to achieve the intended results.

          BTD is a contract manufacturer in a competitive market, therefore we must maintain on-time delivery, product quality, and good customer service. Our key internal issues are to maintain production capacities, including competent people, capable processes, and maintained equipment.

          BTD monitors and reviews information relevant to internal and external issues through our management review meetings.

    4.2. **Understanding the Needs and Expectations of Interested Parties**
          Due to their potential effect on the organization's ability to consistently provide products that meet customer requirements, Top Management determines:
          a) The interested parties that are relevant to the quality management system;
          b) The requirements of these interested parties that are relevant to the quality management system.

          BTD's Top Management has determined that our customers, suppliers, employees, owners (Ottertail) and regulators (OSHA) are the interested parties that we need to be concerned with and will strive to meet their needs and expectations.

          Top Management monitors and reviews relevant measurements and information about these interested parties and their relevant requirements through management review meetings.

    4.3. **Determining the Scope of the Quality Management System**
          Top Management determines the boundaries and applicability of the quality management system to establish its scope. (Ref. Section 1.)

          When determining this scope, Top Management has considered:
          a) The external and internal issues referred to in 4.1.
          b) The requirements of relevant interested parties.
          c) The products and services of the organization.

          We apply all the requirements of the standard that are applicable within the scope of the quality management system. With only one exclusion section 8.3 Product Design & Development of Products & Services - (Ref. Section 1.1.1)

          Top Management ensures the scope of the quality management system is available and maintained, as documented in Section 1, including the types of products and services covered by the quality management system, and justification for any requirements determined not applicable to the scope of the quality management system.

Top Management ensures conformity to the standard(s) referred to in Section 1, and that any requirements determined as not applicable do not affect our ability or responsibility to ensure the conformity of our products and services and the enhancement of customer satisfaction.

4.4.   Quality Management System and Its Processes

4.4.1. Top Management establishes, implements, maintains, and continually improves a quality management system, including the processes needed and their interaction, in accordance with the requirements of the standard.

Top Management determines the processes needed for the quality management system and their application throughout the organization, and:

a) Determines the inputs required and the outputs expected from these processes;

b) Determines the sequence and interaction of these processes (Ref. Figure 1);

c) Determines and applies the criteria and methods (including monitoring, measurements, and related performance indicators) needed to ensure the effective operation and control of these processes; (STD3-005 BTD Function & Process KPI Matrix)

d) Determines the resources needed for these processes and ensures their availability;

e) Assigns the responsibilities and authorities for these processes;

f) Addresses the risks and opportunities as determined in accordance with Section 6.1;

g) Evaluates these processes and implements any changes needed to ensure that these processes achieve their intended results;

h) Improves the processes and the quality management system.

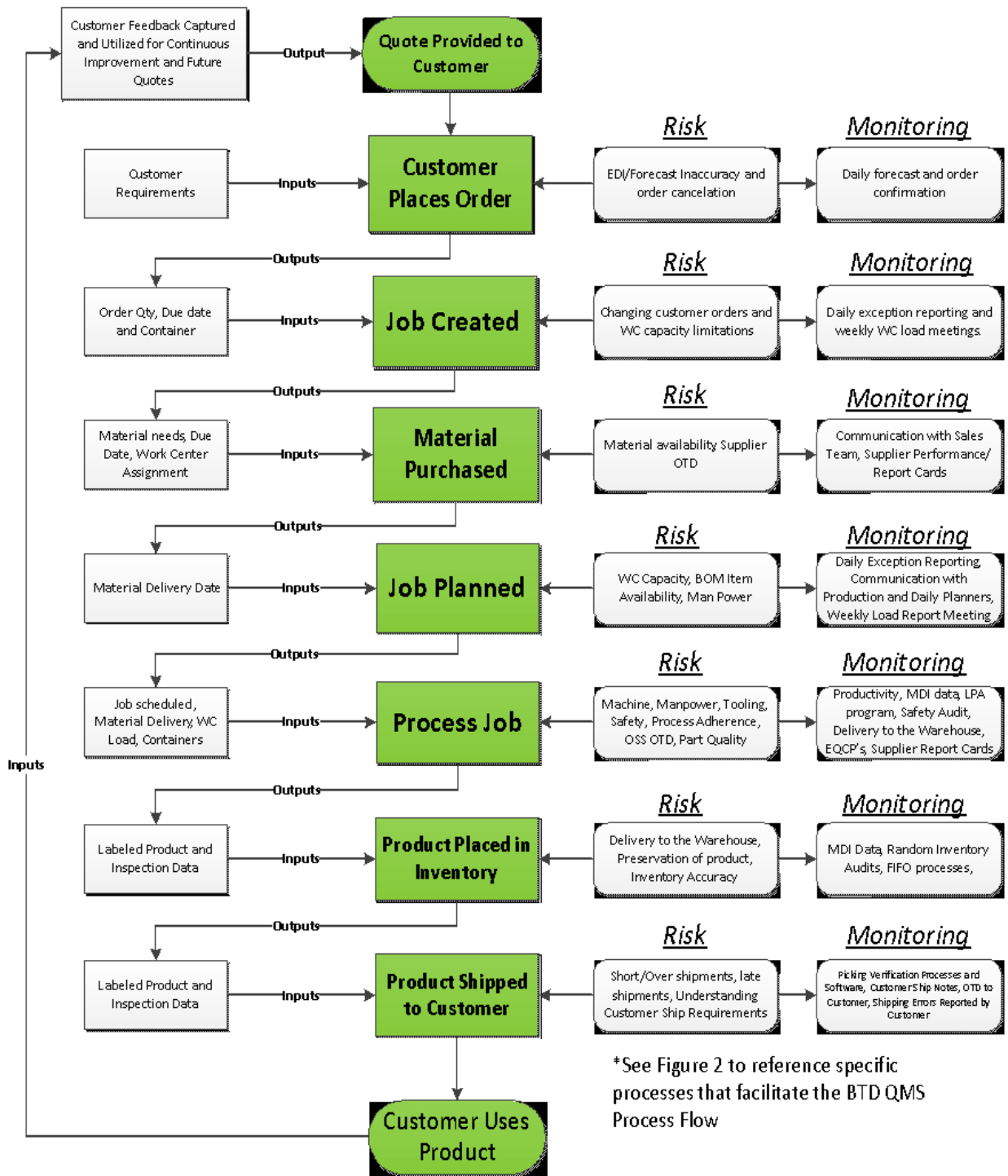**Figure 1 – Quality Management System Processes**

BTD QMS Process Flow

Input boxes	Process	Risk	Monitoring
Customer Feedback Captured and Utilized for Continuous Improvement and Future Quotes — Output →	Quote Provided to Customer		
Customer Requirements — Inputs →	Customer Places Order	EDI/Forecast Inaccuracy and order cancelation	Daily forecast and order confirmation
Order Qty, Due date and Container — Inputs →	Job Created	Changing customer orders and WC capacity limitations	Daily exception reporting and weekly WC load meetings
Material needs, Due Date, Work Center Assignment — Inputs →	Material Purchased	Material availability Supplier OTD	Communication with Sales Team, Supplier Performance/ Report Cards
Material Delivery Date — Inputs →	Job Planned	WC Capacity, BOM Item Availability, Man Power	Daily Exception Reporting, Communication with Production and Daily Planners, Weekly Load Report Meeting
Job scheduled, Material Delivery, WC Load, Containers — Inputs →	Process Job	Machine, Manpower, Tooling, Safety, Process Adherence, OSS OTD, Part Quality	Productivity, MDI data, LPA program, Safety Audit, Delivery to the Warehouse, EQCP's, Supplier Report Cards
Labeled Product and Inspection Data — Inputs →	Product Placed in Inventory	Delivery to the Warehouse, Preservation of product, Inventory Accuracy	MDI Data, Random Inventory Audits, FIFO processes,
Labeled Product and Inspection Data — Inputs →	Product Shipped to Customer	Short/Over shipments, late shipments, Understanding Customer Ship Requirements	Picking Verification Processes and Software, Customer Ship Notes, OTD to Customer, Shipping Errors Reported by Customer
	Customer Uses Product		

*See Figure 2 to reference specific processes that facilitate the BTD QMS Process Flow

Figure 2 – Quality Management System Reference Processes

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Core Flow Processes

	Quote Provided to Customer
SLS2-001	Quoting
CHN2-005	Obsolete Part

*Launch (New Product) if applicable

	Customer Places Order
SLS2-002	Process Customer Orders

Job Created

	Material Purchased
PLN2-003	Master Planning of Direct Materials
SHP2-002	Receive Material or Service
SCH2-004	Purchase Indirect Materials or Services

	Job Planned
PLN2-002	Daily Production Planning
PLN2-004	Expedite Customer Orders
CHN2-006	Temporary Outsourcing

Process Job
Product Placed in Inventory

PRO2-003	Part Production
CHN2-002	NSM Non-Standard Manufacturing
CHN2-004	QAD Addition
FAE2-007	Work Center Transfer
LAU2-004	Container Designation Process
PRO3-010	Monitoring and Measuring of Product
PLN2-001	Transfer of Temporary Work

Product Shipped to the Customer
SHP2-001	Ship Customer Orders

Supporting Processes and Systems

Supporting Processes

*	LAU2-001	Product Realization		STD2-001	BMS Document Revision
*	LAU2-002	Part Manufacturing Qualification		STD3-015	BMS Document Control
*	LAU2-003	Proto Process		STD2-003	Internal Audit
*	LAU2-006	Customer Supplier Guide Review		STD3-014	Risk Assessment Matrix
*	LAU2-010	New Customer Onboarding		STD2-006	Records Control
				STD2-007	Layered Process Audit
	SCH1-002	BTD Partner Supplier Guide		STD2-008	BTD Management Review
	SCH2-001	Establish New Vendor		STD2-004	Monitoring and Measuring of Processes
	SCH2-005	Supplier Assessment and Selection			
				FAE2-004	Maintain and Repair Capitalized Assets
	PRO2-002	Non-Conforming Product			
	PRO2-004	Production Part Deviation		HRE2-004	Onboarding Employees
	PRO2-005	Corrective Action		HRE2-005	Assess Job Performance
	PRO3-021	Calibration			
				CHN2-001	ECN Engineering Change Notification
	CIP2-001	Planning and conducting a Kaizen Blitz or Kaizen Event		CHN2-003	Request for Operation or Rate Change

Key Supporting Systems

Maintenance: PM Software
Safety: Safety Software
L&D: "Career Paths" (SharePoint: Training Public)
        "Employee Development" (SharePoint: L&D Public)
Customer Satisfaction: Top Customer Satisfaction Score Card

Color Key:
Key ISO Processes
QMS Processes Flow Steps

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4.4.2. Top Management ensures the organization:
   a) Maintains documented information to support the operation of its processes;
   b) Retains documented information to have confidence that the processes are being carried out as planned.

This documentation includes the "Quality Manual", which consists of this Quality System Policy Manual, as well as the quality system procedures, which are located and controlled as defined under documentation requirements per Section 7.5.

5. Leadership
5.1. Leadership & Commitment
5.1.1. General
Top Management demonstrates leadership and commitment with respect to the quality management system by:
   a) Taking accountability for the effectiveness of the quality management system;
   b) Ensuring the quality policy statement and objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
   c) Ensuring the integration of the quality management system requirements into the organization's business processes;
   d) Promoting the use of the process approach and risk-based thinking;
   e) Ensuring that the resources needed for the quality management system are available;
   f) Communicating the importance of effective quality management and of conforming to the quality management system requirements;
   g) Ensuring that the quality management system achieves its intended results;
   h) Engaging, directing, and supporting personnel to contribute to the effectiveness of the quality management system;
   i) Promoting improvement;
   j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2. Customer Focus
Top Management demonstrates leadership and commitment with respect to customer focus by ensuring that:
   a) Customer and applicable statutory and regulatory requirements are determined, understood, and consistently met;
   b) The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
   c) The focus on enhancing customer satisfaction is maintained.

5.2. Policy
5.2.1. Establishing the Quality Policy
Top Management establishes, implements, and maintains a quality policy statement that:

a)   Is appropriate to the purpose and context of the organization and supports its strategic direction;
b)   Provides a framework for setting quality objectives;
c)   Includes a commitment to satisfy applicable requirements;
d)   Includes a commitment to continual improvement of the quality management system.

5.2.2. Communicating the Quality Policy

Top Management ensures the quality policy statement is:
a)   Available and maintained as documented information, ref. Section 2;
b)   Communicated, understood, and applied within the organization;
c)   Available to relevant interested parties, as appropriate.

5.3. Organizational Roles, Responsibilities, & Authorities

Top Management ensures that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the organization.

Top Management assigns responsibility and authority for:
a)   Ensuring that the quality management system conforms to the requirements of the standard, per Section 1;
b)   Ensuring that the processes are delivering their intended outputs;
c)   Reporting on the performance of the quality management system and on opportunities for improvement , in particular to top management;
d)   Ensuring the promotion of customer focus throughout the organization;
e)   Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

6. Planning
6.1. Actions to Address Risks & Opportunities

6.1.1. When planning for the quality management system, Top Management considers the issues referred to in 4.1 and the requirements referred to in 4.2, and determines the risks and opportunities that need to be addressed to:
a)   Give assurance that the quality management system can achieve its intended result(s);
b)   Enhance desirable effects;
c)   Prevent, or reduce, undesired effects;
d)   Achieve improvement.

6.1.2. Top Management plans:
a)   Actions to address these risks and opportunities;
b)   How to:
1)   Integrate and implement the actions into its quality management system processes;
2)   Evaluate the effectiveness of these actions.

Top Management ensures actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

Top Management has addressed risks and opportunities through the implementation of the quality management system, specifically through the procedures and processes we've defined with the intention to prevent risks and address opportunities.

6.2.   Quality Objectives & Planning to Achieve Them

6.2.1. Top Management establishes quality objectives at relevant functions, levels, and processes needed for the quality management system.

Top Management ensures the quality objectives:
a)   Are consistent with the quality policy statement;
b)   Are measureable;
c)   Take into account applicable requirements;
d)   Are relevant to conformity of products and services and to enhancement of customer satisfaction;
e)   Are monitored;
f)   Are communicated;
g)   Are updated as appropriate.

Top Management maintains documented information on the quality objectives.

6.2.2. When planning how to achieve its quality objectives, Top Management determines:
a)   What will be done;
b)   What resources will be required;
c)   Who will be responsible;
d)   When it will be completed;
e)   How the results will be evaluated.

Top Management plans to achieve objectives by defining our quality management system procedures and processes. Top Management evaluates results and improvement actions through the management review process, including document and tracking actions.

6.3.   Planning of Changes

When the need for changes to the quality management system are determined, Top Management ensures the changes are carried out in a planned manner, considering:
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.

7.   Support

7.1.   Resources

7.1.1.   General

Top Management determines and provides the resources needed for the establishment, implementation, maintenance, and continual improvement of the quality management system, considering:

a) The capabilities of, and constraints on, existing internal resources;
b) What needs to be obtained from external providers.

7.1.2. People
Top Management determines and provides the personnel resources necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3. Infrastructure
Top Management determines, provides, and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

7.1.4. Environment for the Operation of Processes
Top Management determines, provides, and maintains the environment necessary for the operation of its process and to achieve conformity of products and services.

7.1.5. Monitoring & Measuring Resources
7.1.5.1. General
Top Management determines and provides resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements, ensuring the resources provided:
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.

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

7.1.5.2. Measurement Traceability
When measurement traceability is a requirement, or is considered to be an essential part of providing confidence in the validity of measurement results, the Quality Department ensures 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 used for calibration or verification are retained as documented information;
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.

Assigned personnel determine if the validity of previous measurement results have been adversely affected when measuring equipment is found to be unfit for its intended purpose, and take appropriate action as necessary.

7.1.6. Organizational Knowledge

Top Management determines the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

Top Management ensures this knowledge is maintained and made available to the extent necessary.

When addressing changing needs and trends, Top Management ensures current knowledge is considered and determines how to acquire or access any necessary additional knowledge and required updates.

Top Management has addressed this requirement through the documented processes and procedures of the quality management system, as well as through the retained information supporting the quality management system processes.

7.2. Competence
Management:
a) Determines the necessary competence of personnel doing work under its control that affects the performance and effectiveness of the quality management system;
b) Ensures that these persons are competent on the basis of appropriate education, training, or experience;
c) Where appropriate, takes actions to ensure the necessary competence, and evaluates the effectiveness of the actions taken;
d) Retains appropriate documented information as evidence of competence.

7.3. Awareness
Management ensures personnel doing work under the organization's control are aware of:
a) The quality policy statement;
b) Relevant quality objectives;
c) Their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
d) The implications of not conforming with the quality management system requirements.

7.4. Communication
Top Management determines the internal and external communications relevant to the quality management system, including what, when, with whom, and how it will communicate, and who communicates.

Top Management addresses communications through the quality management system procedures and processes, including management review, competency processes, operational meetings, routine daily supervision and management activities, etc.

7.5. Documented Information
7.5.1. General
Management ensures the organization's quality management system includes:
a) Documented information required by the standard(s);
b) Documented information determined to be necessary for the effectiveness of our quality management system.

7.5.2. Creating & Updating
When creating and updating documented information, Management ensures appropriate:
a) Identification and description (title, date, authority, or reference number);
b) Format and media types;
c) Review and approval for suitability and adequacy.

7.5.3. Control of Documented Information
7.5.3.1. Management ensures documented information required by the quality management system and by the standard(s) is controlled to ensure:
   a) It is available and suitable for use, where and when it is needed;
   b) It is adequately protected from loss of confidentiality, improper use, or loss of integrity.

7.5.3.2. Management ensures control of documented information address the following activities, as applicable:
   a) Distribution, access, retrieval, and use;
   b) Storage and preservation, including preservation of legibility;
   c) Revision control of changes;
   d) Retention and disposition.

Management ensures documented information of external origin necessary for the planning and operation of the quality management system is identified as appropriate, and controlled.

Management ensures documented information retained as evidence of conformity is protected from unintended alterations.

8. Operation
8.1. Operational Planning & Control
Management ensures the organization plans, implements, and controls the processes needed to meet the requirements for supplying products and services, and to implement the actions determined in Section 6, by:
a) Determining the requirements for the products and services;
b) Establishing criteria for:
   1) The processes;
   2) The acceptance of products and services;
c) Determining the resources needed to achieve conformity to the products and services requirements;
d) Implementing control of the processes in accordance with the criteria;
e) Determining, maintain, and retaining documented information to the extent necessary:
   1) To have confidence that the processes have been carried out as planned;
   2) To demonstrate the conformity of products and services to their requirements.

Management ensures the output of this planning is suitable for the organization's operations.

Management ensures planned changes are controlled and the consequences of unintended changes reviewed, taking action to mitigate any adverse effects, as necessary (reference Section 10.2).

Management ensures outsourced processes are controlled.

8.2. Requirement for Products & Services

8.2.1. Customer Communication
Sales and Customer Service ensures communication with customers includes:
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 & Services
When determining the requirements for the products and services to be offered to customer, Sales ensures that:
a) The requirements for the products and services are defined, including:
    1) Any applicable statutory and regulatory requirements;
    2) Those requirements we consider necessary.
b) We can meet the claims for the products and services we offer.

8.2.3. Review of the Requirements for Products & Services
8.2.3.1. Sales ensures we have the ability to meet the requirements of products and services to be offered to customers, and ensures review is conducted before committing to supply products and services to a customer, including:
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 the specified or intended use, when known;
c) Requirements specified by our organization;
d) Statutory and regulatory requirements applicable to the products and services;
e) Contract or order requirements differing from those previously expressed.

Sales and Customer Service ensures that contract or order requirements differing from those previously defined are resolved.

Sales and Customer Service ensures customer's requirements are confirmed before acceptance, when the customer does not provide a documented statement of their requirements.

8.2.3.2. Sales ensures documented information is retained, as applicable:
a) On the results of the review;
b) On any new requirements for the products and services.

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8.2.4. Changes to Requirements for Products & Services
Sales ensures that relevant documented information is amended, and that relevant personnel are made aware of the change, when the requirements for products and services are changed.

8.3. Design & Development of Products & Services
As a contract manufacturer, this clause is not applicable to our quality management system.

8.4. Control of Externally Provided Processes, Products, & Services
8.4.1. General
Purchasing and Quality ensures externally provided processes, products, and services conform to the requirements.

Purchasing and Quality determines the controls to be applied to externally provided processes, products, and services when:
a) Products and services from external providers are intended for incorporation into our products and services;
b) Products and services are provided directly to the customer(s) by the external providers on our behalf;
c) A process, or part of a process, is provided by an external provider.

Purchasing and Quality 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. Purchasing retains documented information of these activities and any necessary actions arising from the evaluations.

8.4.2. Type & Extent of Control
Purchasing and Quality ensure externally provided processes, products, and services do not adversely affect our ability to consistently deliver conforming products and services to our customers

Purchasing and Quality Assurance:
a) Ensure externally provided processes remain within the control of its quality management system;
b) Define the controls we intend to apply to external providers and/or to their resulting outputs;
c) Take into consideration the potential impact of the externally provided processes, products, and services on our ability to consistently meet customer and applicable statutory and regulatory requirements, and the effectiveness of the controls applied by the external provider;
d) Determine 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

Purchasing ensures the adequacy of requirements prior to their communication to the external provider.

Purchasing communicates requirements to external providers for:
a) The processes, products and services to be provided;
b) The approval of: products and services; methods, processes, and equipment; and the release of products and services;
c) Competence, including any required qualification of personnel;
d) The external providers' interactions with our organization;
e) Control and monitoring to be applied to the external providers' performance;
f) Verification or validation activities that we, or our customer, intends to perform at the external providers' premises.

8.5.   Production & Service Provision
8.5.1.   Control of Production & Service Provision
Operations implements production and service under controlled conditions, which includes, as applicable:
a) The availability of documented information that defines:
  1) The characteristics of the products to be produced, the services to be provided, or the activities to be performed;
  2) The results to be achieved;
b) The availability and use of suitable monitoring and measuring resources;
c) The implementation of monitoring and measurement activities at appropriate stages to verify that the criteria for control of processes or outputs, and the acceptance criteria for products and services, have been met;
d) The use of suitable infrastructure and environment for the operation of processes;
e) The appointment of competent personnel, including any required qualification;
f) The validation, and periodic revalidation, of the ability to achieve planned results of the processes for products and services provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
g) The implementation of actions to prevent human error;
h) The implementation of release, delivery, and post-delivery activities.

8.5.2.   Identification & Traceability
Operations uses suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

Operations identifies the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

Operations 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 Customer or External Providers
BTD exercises care with property belonging to customers or external providers while it is under our control or being used in our processes.

BTD identifies, verifies, protects, and safeguards customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged, or otherwise found to be unsuitable for use, BTD ensures this is reported to the customer or external provider and retains documented information on what has occurred.

8.5.4. Preservation
Operations preserves the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

8.5.5. Post-delivery Activities
BTD ensures requirements for post-delivery activities associated with the products and services are met.

In determining the extent of post-delivery activities that are required, BTD considers:
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.

8.5.6. Control of Changes
BTD reviews and controls changes for product and service provision, to the extent necessary to ensure continuing conformity with requirements.

BTD retains documented information describing information describing the results of the review of changes, the personnel authorizing the change, and any necessary actions arising from the review.

8.6. Release of Products & Services
Operations and Quality Assurance implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

Operations and Quality Assurance ensure the release of products and services to the customer does not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

Operations and Quality Assurance retain documented information on the release of products and services, including:
a)   Evidence of conformity with the acceptance criteria;
b)   Traceability to the person authorizing the release.

8.7. Control of Nonconforming Outputs
8.7.1.   BTD ensures outputs that do not conform to their requirements are identified and controlled to prevent unintended use or delivery.

BTD ensures appropriate actions are taken based on the nature of the nonconformity and its effect on the conformity of products and services, including nonconforming products and services detected after delivery of products, and during or after the provision of services.

BTD ensures nonconforming outputs are dealt with in one or more of the following ways:
a) Correction;
b) Segregation, containment, return, or suspension of provision of products and services;
c) Informing the customer;
d) Obtaining authorization for acceptance under concession.

BTD ensures conformity to requirements is verified when nonconforming outputs are corrected.

8.7.2. BTD retains documented information that:
a) Describes the nonconformity;
b) Describes the actions taken;
c) Describes any concessions obtained;
d) Identities the authority deciding the action in respect to the nature of the nonconformity.

9. Performance Evaluation
9.1. Monitoring, Measurement, Analysis, & Evaluation
9.1.1. General
Top Management determines:
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 is to be performed;
d) When the results from monitoring and measurement are analyzed and evaluated.

Top Management evaluates the performance and the effectiveness of the quality management system.

Top Management retains appropriate documented information as evidence of the results.

9.1.2. Customer Satisfaction
Sales and Top Management monitors customers' perceptions of the degree to which their needs and expectation have been fulfilled. Sales and Top Management determines the methods for obtaining, monitoring, and reviewing this information.

9.1.3. Analysis & Evaluation
Top Management analyzes and evaluates appropriate data and information arising from monitoring and measurement.

Top Management ensures the results of analysis are used to evaluate:
a) Conformity of products and services;
b) The degree of customer satisfaction;
c) The performance and effectiveness of the quality management system;
d) If planning has been implemented effectively;
e) The effectiveness of actions taken to address risks and opportunities;
f) The performance of external providers;
g) The need for improvements to the quality management system.

9.2. Internal Audit
9.2.1. Quality Assurance ensures internal audits are conducted at planned intervals to provide information on whether the quality management system:
a) Conforms to:
    1) Our quality management system requirements;
    2) The requirements of the quality management system standard(s);
b) Is effectively implemented and maintained.

9.2.2. Quality Assurance:
a) Plans, establishes, implements, and maintains an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which takes into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
b) Defines the audit criteria and scope for each audit;
c) Selects auditors and conducts audits to ensure objectivity and the impartiality of the audit process;
d) Ensures the results of audits are reported to top management;
e) Takes appropriate correction and corrective actions without undue delay;
f) Retains documented information as evidence of the implementation of the audit program and the audit results.

9.3. Management Review
9.3.1. General
Top Management reviews the quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of the organization.

9.3.2. Management Review Inputs
Top Management ensures management reviews are planned and carried out taking into consideration:
a) The status of actions from previous management reviews;
b) Changes in external and internal issues that are relevant to the quality management system;
c) Information on the performance and effectiveness of the quality management system, including trends in:
    1) Customer satisfaction and feedback from relevant interested parties;
    2) The extent to which quality objectives have been met;
    3) Process performance and conformity of products and services;

4) Nonconformities and corrective actions;
5) Monitoring and measurement results;
6) Audit results;
7) The performance of external providers;
d) The adequacy of resources;
e) The effectiveness of actions taken to address risks and opportunities;
f) Opportunities for improvement.

9.3.3. Management Review Outputs

Top Management ensures the outputs of the management review include decisions and actions related to:
a) Opportunities for improvement;
b) Any need for changes to the quality management system;
c) Resource needs.

Top Management retains documented information as evidence of the results of management reviews.

10. Improvement

10.1. General

Top Management determines and selects opportunities for improvement and implements any necessary actions to meet customer requirements and enhance customer satisfaction, including:
a) Improving products and services to meet requirements as well as to address future needs and expectations;
b) Correcting, preventing, and reducing undesired effects;
c) Improving the performance and effectiveness of the quality management system.

10.2. Nonconformity and Corrective Action

10.2.1. When a nonconformity occurs, including any arising from complaints, Top management and Quality Assurance ensures the organization:
a) Reacts to the nonconformity and, as applicable:
1) Takes action to control and correct it;
2) Deals with the consequences;
b) Evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
1) Reviewing and analyzing the nonconformity;
2) Determining the cause(s) of the nonconformity;
3) Determining if similar nonconformities exist, or could potentially occur;
c) Implements any actions needed;
d) Reviews the effectiveness of any corrective action taken;
e) Updates risks and opportunities determined during planning, if necessary;
f) Makes changes to the quality management system, if necessary.

Top Management and Quality Assurance ensures corrective actions are appropriate to the effects of the nonconformities encountered.

10.2.2. Quality Assurance retains documented information as evidence of:
   a) The nature of the nonconformities and any subsequent actions taken;
   b) The results of any corrective action.

10.3. Continual Improvement
Top Management ensures the organization continually improves the suitability, adequacy, and effectiveness of the quality management system.

Top Management considers the results of analysis and evaluation, and the outputs form management review, to determine if these are needs or opportunities that need to be addressed as part of continual improvement.