Elite Engineering & Manufacturing (Elite) Quality Manual

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Revision History and Approval

Rev.	Nature of changes	Approval	Date
1.0	Original release.		4/1/2025

1.0 Welcome

The adoption of a quality management system is a strategic decision for Elite that can help to improve overall performance, provide a sound basis for consistently meeting requirements and help address future needs and expectations.

The benefits to Elite of implementing a quality management system based on **ISO 9001:2015** are:

a) The ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements.
b) Facilitating opportunities to enhance customer satisfaction.
c) Addressing risks and identifying opportunities.
d) Help to define objectives.
e) The ability to demonstrate conformity to specified quality management system requirements.

Elite's application of **ISO 9001:2015** employs the **P**lan, **D**o, **C**heck and **A**ct (**PDCA**) approach to achieve the intended results. The **PDCA** cycle enables Elite to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

Risk-based thinking demonstrates that risk was considered (**Risk Registry – QF 6.1.1-1**) and enables Elite to determine the factors that could cause its processes and its quality management system to deviate from the planned results and to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise.

Elite's Quality management principles

Elite has adopted the following quality management principles:

a) customer focus
b) engagement of people
c) process approach
d) continuous improvement
e) evidence-based decision making
f) relationship management

See Appendix 'A' below for the Elite Company Organizational Chart

2.0 Quality Policy

The Senior Management Team at Elite. has developed the following Quality Policy which governs day-to-day operations to ensure quality. The Quality Policy is communicated and implemented throughout the organization.

The Elite Quality Policy:

The Elite strategic direction is our commitment to meeting our customer's requirements by continually improving the effectiveness of our Quality Management System (QMS).

Context of the Elite Organization (COTO Context of the Organization)

Elite has reviewed and analyzed key aspects of itself and its stakeholders to determine the strategic direction of the company. This requires understanding internal and external issues that are of concern to Elite and its interested parties.

COTO analysis begins with the **SWOT Worksheet - QF 4.1.1-1**.

SWOT issues are monitored and updated as appropriate and discussed as part of management reviews. The issues determined above are identified through an analysis of risks facing Elite and its interested parties. "Interested parties" are those stakeholders who receive our Products or Services, those who may be impacted by them, or those parties who may otherwise have a significant interest in our company. These parties are identified in the document **Interested Parties, Internal - External issues - QF 4.2.1-1**.

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.

3.0 Scope of the Elite Quality Management System

Based on an analysis of the above issues of concern, interests of stakeholders, and in consideration of its products and services, Elite has determined the scope of the management system as follows:

Providing Precision CNC Machining, Production & Prototypes for a Variety of Industries

The ISO 9001 EA Code is **17** (Basic metals and fabricated metal products)

The quality system applies to all processes, activities and employees within the company.

The Production facility is located at:

340 Martin Avenue

Santa Clara, California 95050 USA

www.eliteem.com

4.0 QMS Processes and Objectives

Elite has adopted a process approach for its management system. Identifying and managing the company's top-level processes individually, minimizes the likelihood of nonconforming products or services being detected during final stages or post-delivery. By addressing nonconformities and risks in real time within each top-level process, these issues can be proactively managed.

The following top-level processes have been identified for Elite:

- Sales / Customers
- Purchasing / Receiving
- Production
- Calibration & Maintenance
- Corrective Actions, Internal Audits & Management Review
- Design & Development

Each process may be supported by other activities, such as tasks or sub-processes. Monitoring and control of these top-level processes ensures effective implementation and control of all subordinate tasks or sub-processes.

Each top-level process has been identified in the **Risk Register - QF 6.1.1-1** and the **YTD Metrics & Objectives - QF 9.3.1-1** which together define:

a) applicable inputs and outputs
b) process owner(s)
c) applicable responsibilities and authorities
d) applicable risks and opportunities
e) critical and supporting resources
f) criteria and methods employed to ensure the effectiveness of the process
g) quality objectives related to that process

The sequence of interaction of these processes is illustrated in **Appendix B**.

QMS documented procedures have been developed to support the QMS and its processes; these are listed in **Appendix C**. This list only provides some top-level procedures and may not reflect the entirety of all QMS documentation.

Each process has at least one objective established for it. 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(s).

Throughout the year, metrics data is measured and gathered by process owners in order to present the data to the Senior Management Team. This data is analyzed during Management Review meetings in order that goals may be set and / or adjustments made for the purposes of long-term continual improvement.

The specific quality objectives for each process are defined in the applicable **YTD Metrics & Objectives - QF 9.3.1-1.** Metrics, along with current standings and goals for each objective, are recorded in this document and reviewed in management review.

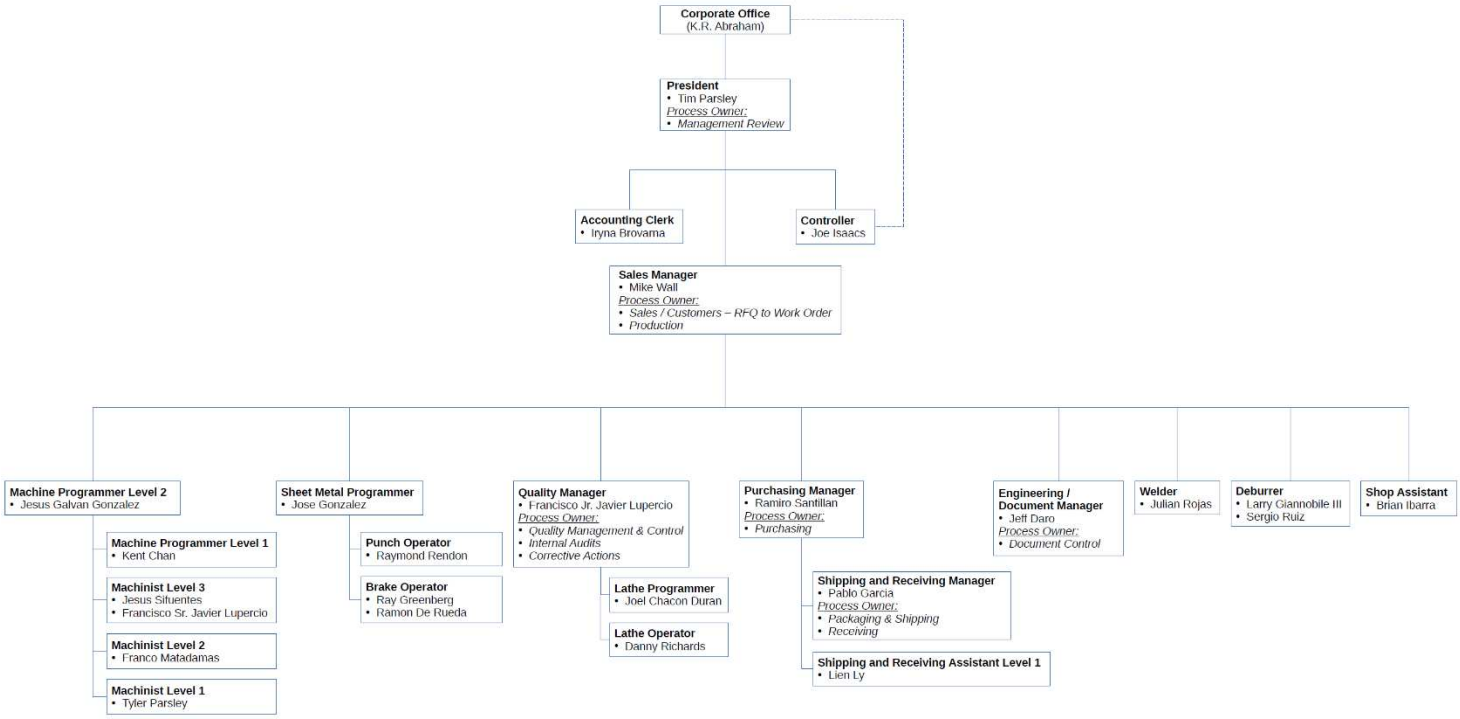
When a process does not meet a goal, or an unexpected problem is encountered with a process, the corrective and preventive action process is implemented to research and resolve the issue. In addition, opportunities for improvement are sought and implemented, for the identified processes.

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 **Purchasing, Supplier Control & Supplier Verification - SOP 8.4.2-1**.

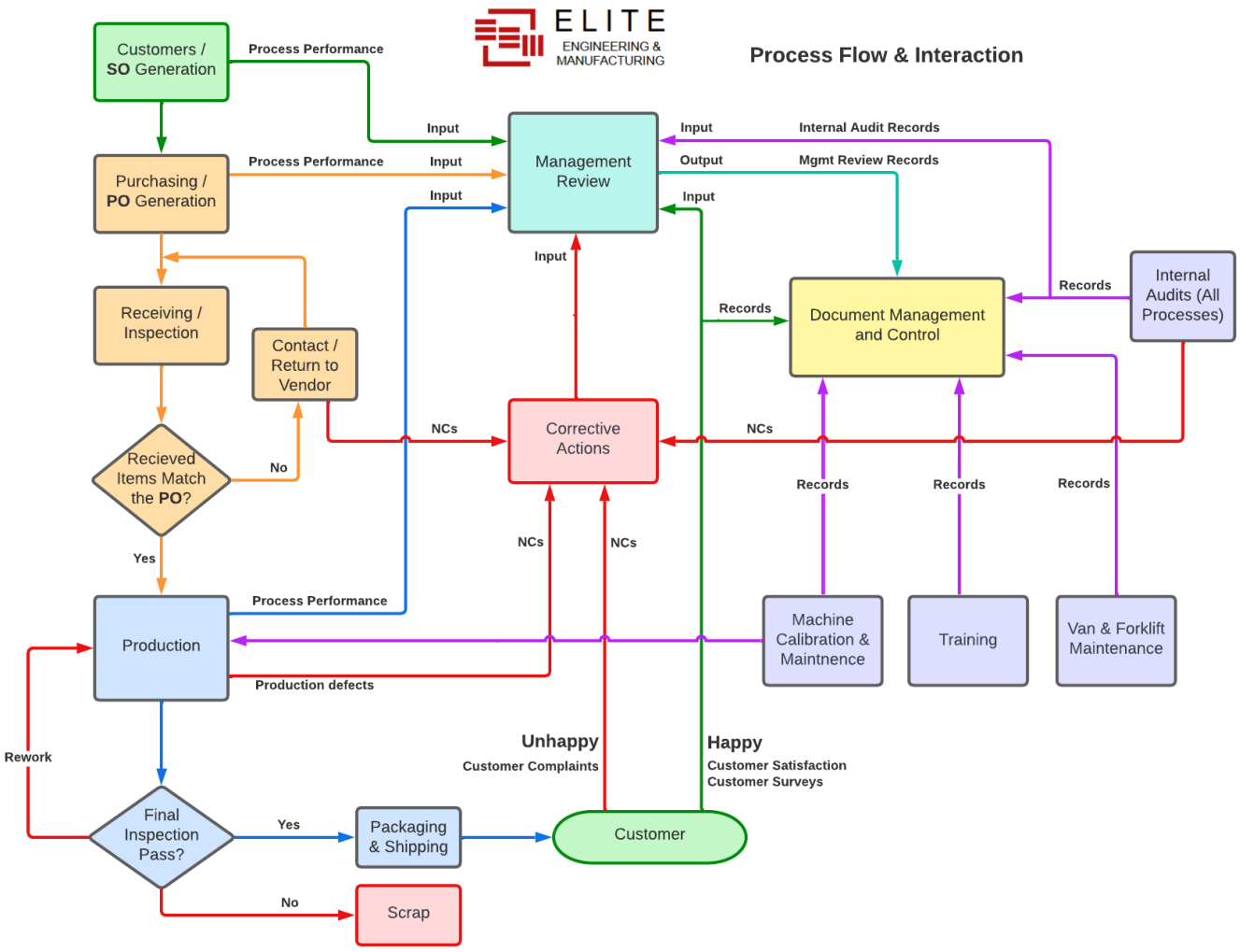
5.0 Anti-Counterfeit Policy

Elite has in place an Anti-Counterfeit Policy to which strict adherence is part of the QMS. The Policy has been reviewed and approved by executive management and is documented in the Elite **Anti-Counterfeit Policy & Control Plan - SOP 8.4.1-2**. Elite has adopted this Anti-Counterfeit Policy to eliminate the impact of counterfeit products on Elite and its customers. This is a **zero tolerance** Policy against knowingly (unknowingly) and / or intentionally (unintentionally) trafficking in counterfeit goods. Should a suspect counterfeit product be discovered, anywhere within the QMS, Elite shall quarantine such material and report the findings to the supplier and appropriate authorities. This policy shall be communicated, understood, implemented, and maintained at all levels of the Organization by **all** employees.

Appendix A
Elite Company Organizational Chart



Appendix B
Process Sequence & Interaction



Appendix C
Subordinate QMS Procedures

Standard Operating Procedures - (SOPs)

- SOP 6.1.1-1 Risk and Opportunities Management
- SOP 7.1.3-1 Plant and Equipment Maintenance
- SOP 7.1.5-1 Control of Monitoring & Measuring Devices
- SOP 7.2.0-1 Competency, Awareness & Communication
- SOP 7.5.3-1 Control of Quality Documents & Records
- SOP 7.5.3-2 Data Backup & Restore
- SOP 8.1.1-1 Product (Production) Planning
- SOP 8.2.1-1 The Management of Customer Communications
- SOP 8.2.2-1 RFQ to Sales Order Generation Procedure
- SOP 8.3.1-1 Design & Development
- SOP 8.4.1-1 Supplier Evaluation, Selection & Performance Monitoring
- SOP 8.4.2-1 Purchasing, Supplier Control & Supplier Verification
- SOP 8.5.1-1 Production Management (Job Travelers)
- SOP 8.5.1-2 Control of Production
- SOP 8.5.2-1 Identification and Traceability
- SOP 8.5.3-1 Customer or Supplier Property
- SOP 8.5.4-1 Preservation
- SOP 8.5.6-2 Customer Engineering Change
- SOP 8.6.1-1 Release of Product
- SOP 8.7.2-1 Control of Nonconforming Product
- SOP 9.1.1-1 Measuring and Monitoring of Product
- SOP 9.1.2-1 Customer Satisfaction
- SOP 9.1.3-1 Performance Evaluation
- SOP 9.2.2-1 Internal Audit
- SOP 10.2.1-1 Corrective Action