



LAI Quality Manual (BMS) Rev. S

Written By: Kevin Tate

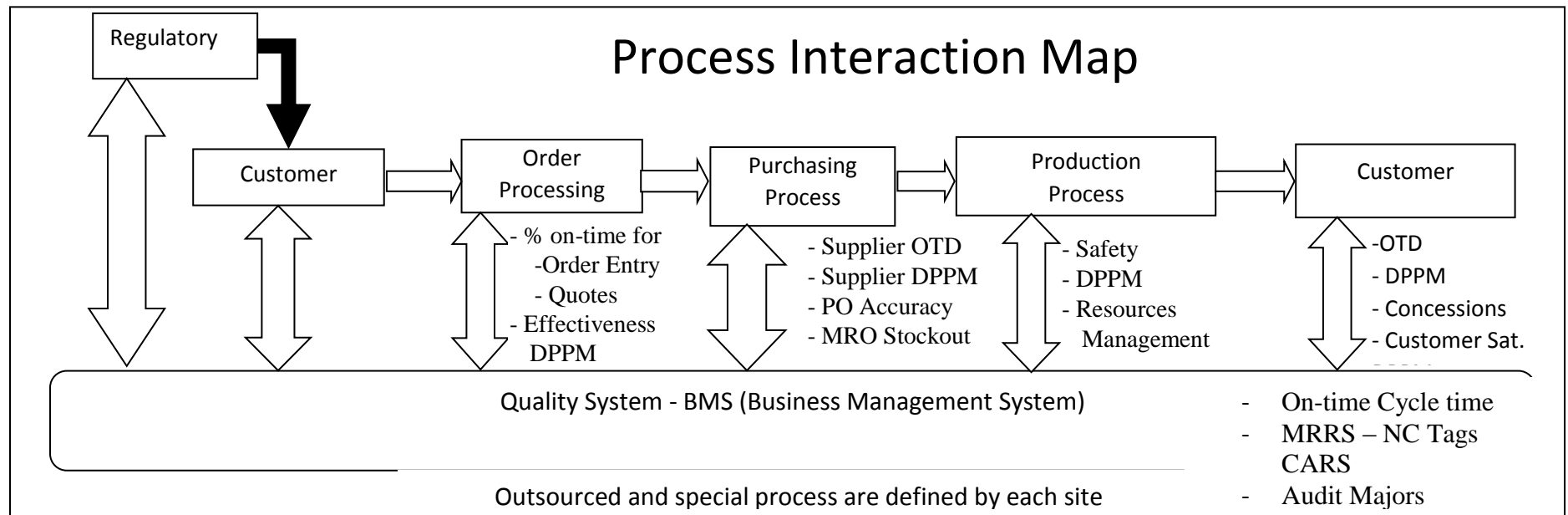
Approved By: Joe Beauchemin

Date: 01/31/18

The quality manual provides the foundation for achieving the company's evolving mission, while remaining committed to our core values and purpose. LAI's BMS (Business Management System) is made up of this Quality Manual, Procedures, Work Instructions and Forms.

LAI's Quality Policy: Provide competitive value in a safe environment with exceptional quality, delivery, and effectiveness. We will measure and continuously improve processes using the LAI Business System tool.

(ISO 13485): LAI's undertaken role to produce medical devices is as a "contract manufacturer". The processes indicated in the Process Interaction Map take into account LAI's role as a contract manufacturer.



See P 4.01 (Document Control) for documented procedures related to these processes.



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LAI's Interested Parties

- LAI's Customers
- LAI's Associates
- LAI's Suppliers
- LAI's Ownership
- Regulatory (Local and Countries)
- AS9100, ISO13485 and NADCAP certification bodies

LBS Leadership – Leading Performance

Documentation Structure and Information Flow

Inputs: Regulatory, Customer, Internal Needs, *AS9100, *ISO 9001, **ISO 13485, and NADCAP (Depending on Site Certifications)

- ↳ Level 1 is Quality Manual – BMS (Business Management System)
 - ↳ Level 2 Procedures support Level 1 BMS documents
 - ↳ Level 3 Documents (Work Instructions and Forms) support Level 2 documents
 - ↳ Level 4 Documents that are quality records



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Scope of the Quality Management System

Top management in conjunction with its Site Management have determined the scope for each sites quality management system by considering the external and internal issues from its strategic planning, the requirements of its interested parties and the products and services it provides to its customer.

- Scope for LAI Southwest site (Tempe, AZ):
 - Contract provider of Water Jet Processing, Laser Processing, Additive Manufacturing and Assembly for the Aerospace and Commercial Industries.
- Scope for LAI Northeast site (Scarborough, ME):
 - Precision conventional and non-conventional machining and fabrication of complex military commercial components for the aerospace and power generation industries.
- Scope for LAI East site (Westminster, MD):
 - Provider Conventional Machining, Laser and Water-Jet Processing.
- Scope for LAI New York site (Green Island, NY):
 - Precision CNC machining, conventional machining, welding and fabrication of components for power generation, aerospace, defense and specialty melting industries.
- The BMS is structured to comply with regulatory requirements and conform to Customer, Patients and the conditions set forth in the International Standards ISO 9001, SAE AS9100, ISO 13485 (for our medical customers) and NADCAP.
- LAI manufactures product for numerous markets. The application of AS9100 requirements within the BMS applies to work in the aviation, space, and defense industries and may be extended to work in other business sectors. Each LAI facility may maintain other certifications or qualifications to address requirements of the various market sectors served, such as ISO 13485 for those facilities who provide components for medical device customers.
- In the event that a change to LAI's certification, registration or accreditation, site level management shall notify the effected Customers within 48 hours of receiving notification of change.
- Clauses determined to be not applicable to the Quality System for ISO/AS9100 and ISO 13485 requirements are justified and do not affect LAI's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction are defined in the LAI Quality Manual (BMS).

Clauses Not Applicable to LAI's Quality System

*ISO/AS9100D requirements:

- Clause 8.3 Design and development: There are no design activities being performed with product being manufactured to customer specifications.