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OTTO

Approval for Issue:



T. J. Roeser
Chairman

2/12/24
Date



Scott Bolanowski
Director of Quality Systems

2-12-24
Date

DISTRIBUTION

Director of Quality Systems

FAA Administrator

Note 1: The Director of Quality Systems shall be responsible for the proper distribution of revised copies of this manual. If the manual is rejected by any of the listed members of the distribution list, the Director of Quality Systems will be responsible for the recall of all unacceptable revisions.

Note 2: OTTO, specifically the Director of Quality Systems, will coordinate document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.

REVISION HISTORY

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INDEX

| | |
|--|-------------------------------|
| REVISION DISCLAIMER / APPROVAL FOR ISSUE | 1 |
| DISTRIBUTION | 2 |
| REVISION HISTORY | 3 |
| INDEX | 4 |
| CROSS REFERENCES | 5 |
| INTRODUCTION..... | 9 |
| QUALITY POLICY & MISSION STATEMENT..... | 9 |
| 1 MANAGEMENT RESPONSIBILITY..... | 11 |
| ORGANIZATIONAL CHART | 14 |
| 2 QUALITY SYSTEM | 14 |
| 3 CONTRACT REVIEW..... | 16 |
| 4 DESIGN CONTROL | 18 |
| 5 DOCUMENT CONTROL..... | 20 |
| 6 PURCHASING | 22 |
| 7 CUSTOMER/EXTERNAL PROVIDER'S PROPERTY | 23 |
| 8 PRODUCT IDENTIFICATION AND TRACEABILITY | 24 |
| 9 PROCESS CONTROL..... | 25 |
| 10 INSPECTION AND TESTING..... | 27 |
| 11 INSPECTION, MEASURING AND TEST EQUIPMENT..... | 29 |
| 12 INSPECTION AND TEST STATUS | 30 |
| 13 CONTROL OF NONCONFORMING PRODUCT | 31 |
| 14 NONCONFORMITY AND CORRECTIVE ACTION | 32 |
| 15 HANDLING, STORAGE, PACKAGING, AND DELIVERY..... | 33 |
| 16 QUALITY RECORDS..... | 34 |
| 17 INTERNAL AUDITS | 35 |
| 18 TRAINING | 36 |
| 18.1 REPAIR STATION TRAINING | 37 |
| 19 SERVICING..... | 38 |
| 20 STATISTICAL TECHNIQUES | 39 |
| 21 CONFIGURATION MANAGEMENT | 40 |
| EASA Supplement | Appendix A (pages I thru VII) |
| Supporting Forms for FAA Repair | Appendix B (pages I thru V) |

CROSS REFERENCES

| | ISO 9001-2000-2015 A9100-2016 | EN ISO/IEC 80079- 34-2011 | ISO/IEC 17025- 2017 (Section 4) | ANSI/ISO 17025- 2017 (Section 5) | ISO 14001-2015 |
|------------------|---------------------------------------|--|---|--|---|
| Distribution | | | | | |
| Index | | | | | |
| Revision History | | | | | |
| Cross Reference | | | | | |
| Introduction | 4.4 | | | | 5.1, 5.2, 5.3, 6.2.1 |
| Quality Policy | 5.2, 5.2.1, 5.2.2, 6.2 | 4.1, 4.2.1, 4.2.2, 5.1, 5.2, 5.3, 5.4.2 | 8.2.1, 8.2.2 | | 4.4, 5.1, 5.2, 5.3, 6.2.1, 10.3 |
| Section 1 | 5.1, 5.1.2, 5.3, 9.3, 9.3.2, 9.3.3 | 4.1, 5.1, 5.3, 5.4.2, 5.5.1, 5.5.2, 5.5.3, 5.6.1, 5.6.2, 5.6.3, 6.1, 7.2.3, 8.2.1, 8.2.3, 8.4, 8.5.1 | | 5.1, 5.4, 5.5, 5.6, 6.2.4, 8.8 | 5.1, 5.2, 5.3, 7.1, 7.2, 9.3 |
| Section 2 | 4.1, 6.1, 6.2 | 4.1, 4.2.2, 5.1, 5.4.1, | 5.5, 5.6, 5.7 | | 5.1, 5.2, 5.3, 6.1.1, 6.1.3, 7.5.1, 8.1, 9.1.1 |
| Section 3 | 6, 6.1, 8.2.3, 8.2.4 | 5.2, 7.2.1, 7.2.2, 7.2.3 | 7.1.1, 7.1.4, 7.1.5, 7.1.6, 7.1.7, 7.1.8, 8.6.2 | 7.1.1, 7.2.2.1 | 6.1.1, 6.1.4 |
| Section 4 | 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5 | 5.4.1, 7.2.1, 7.2.2, | | | 5.1, 5.2, 5.3, 6.1.4, 7.5.1, 7.5.2, 7.5.3, 8.1 |
| Section 5 | 7.5.2, 7.5.3 | 4.2.3 | 7.7.3, 8.3.1, 8.3.2 | | 5.1, 5.3, 6.1.1, 7.5.1 |
| Section 6 | 8.4.1, 8.4.2, 8.4.3, 8.6 | 4.1, 7.4.1, 7.4.2, 7.4.3 | 6.6.1, 6.6.2, 6.6.3, 7.1.1 | | |
| Section 7 | 8.5.3 | 7.5.4 | | | |
| Section 8 | 8.5.2 | 7.5.3 | | 7.4.2 | |
| Section 9 | 8.5.1 | 6.3, 6.4, 7.1, 7.5.1, 7.5.2 | | 6.3.1, 6.3.3, 6.3.4 | 5.1, 5.3, 6.1.2, 7.2, 7.3, 7.4.1, 7.5.1, 7.5.3, 8.1, 8.2, 9.3 |
| Section 10 | 8.4.3, 8.6 | 7.1, 7.4.3, 7.5.1, 8.1, 8.2.4 | | 7.1.1, 7.2.1.1, 7.2.1.2, 7.2.1.6, 7.2.2 | 8.1 |
| Section 11 | 7.1.5, 7.1.5.1, 7.1.5.2 | 7.6 | | 6.1, 6.2.3, 6.2.5, 6.2.6, 6.4.1, 6.4.2, 6.4.3, 6.4.4, 6.4.5, 6.4.6, 6.4.7, 6.4.8, 6.4.9, 6.4.10, 6.4.11, 6.4.12, 6.4.13, 6.5.1, 6.5.2, 6.5.3, 7.1.1, 7.1.2, 7.1.4, 7.2.1.1, 7.2.1.2, 7.2.1.3, 7.2.1.4, 7.2.1.5, 7.2.1.6, 7.2.1.7, 7.2.2, 7.2.2.1, 7.2.2.2, 7.2.2.3, 7.2.2.4, 7.4.2, 7.4.3, 7.6.1, 7.6.2, 7.6.3, 7.7.1, 7.7.2, 7.7.3 | 8.1, 9.1.1 |
| Section 12 | 8.5.2 | 7.5.3 | | | 8.1 |
| Section 13 | 8.7 | 8.3 | 7.10.1, 7.10.3 | | 8.1, 10.2 |
| Section 14 | 6.1, 10.2 | 8.5.2, 8.5.3 | 8.7.1, 8.7.2 | | 7.2, 7.3, 8.1, 10.2 |
| Section 15 | 8.5.4 | 7.5.5 | | 6.4.3, 7.4.1, 7.4.2, 7.4.4 | 8.1 |
| Section 16 | 7.5.2, 7.5.3 | 4.2.4 | 8.4.1, 8.4.2 | 7.8.1.1, 7.8.2.1, 7.8.3.1, 7.8.4.1, 7.8.4.3, 7.8.6.2, 7.8.7.2, 7.8.7.3, 7.8.8.2, 7.8.8.3 | 6.2.1, 6.2.2, 7.4.1, 7.4.2, 7.4.3, 7.5.2, 7.5.3, 8.1, 9.1.2 |

| | ISO 9001-2000-2015 A9100-2016 | EN ISO/IEC 80079- 34-2011 | ISO/IEC 17025- 2017 (Section 4) | ANSI/ISO 17025- 2017 (Section 5) | ISO 14001-2015 |
|----------------------|--|--|------------------------------------|---|--|
| Section 17 | 9.2 | 8.1, 8.2.2 | 8.8.1, 8.8.2 | | 7.2, 7.3, 8.1, 8.2, 9.2.1, 9.2.2 |
| Section 18 | 7.2 | 6.2.1, 6.2.2 | | 6.2.1, 6.2.2, 6.2.3, 6.2.5, 6.2.6, 6.5.1 | 5.1, 6.1.1, 6.1.3, 7.1, 8.2, 9.3 |
| Section 19 | 8.5.5 | 7.5.1 | | | |
| Section 20 | 8.5.1c | 8.1 | | | |
| Section 21 | 8.5.6, 8.6 | | | | 9.1.1 |
| Not applicable | | | | 7.2.1, 7.3.1, 7.3.3, 7.8.1, 7.8.3.1, 7.11 | |
| Approved Vendor List | | | 6.6.1, 6.6.2 | | |
| Internal Audit DB | | | | | 8.2 |
| Internal Portal | | | | | 4.2, 5.2, 6.1.1, 6.1.2, 6.2.1, 7.4.1, 7.4.2 |
| Quality Metrics | 5.4.1 | 5.4.1 | | | |
| Website | 7.2.3 | 7.2.3 | | | 4.2, 5.2, 6.1.1, 6.1.2, 6.2.1, 7.4.1, 7.4.3 |
| 2EN000001 | | | | | |
| 2HR000001 | | | | 6.1, 6.2.1, 6.2.2, 6.2.3, 6.2.5 | |
| 2HR000002 | | | | | 4.4, 6.1.1 |
| 2HR000003 | | | | | 4.1, 4.2, 4.3, 4.4, 6.1.1 |
| 2MT000001 | 5.5.3, 5.6.1, 5.6.2, 5.6.3, 6.1, 7.2.3, 8.2.1, 8.2.3, 8.4, 8.5.1 | 5.5.3, 5.6.1, 5.6.2, 5.6.3, 6.1, 7.2.3, 8.2.1, 8.2.3, 8.4, 8.5.1 | 8.9.1 | | 4.4, 9.3 |
| 2PR000003 | | | | | |
| 2PU000003 | | | 6.6.1 | | |
| 2QA000002 | | | 8.4.1, 8.4.2 | | |
| 2QA000003 | | | 6.6.1 | | |
| 2QA000008 | | | 8.7.1 | | 4.4 |
| 2QA000010 | | | 8.7.1, 8.9.1 | | 4.4 |
| 2QA000011 | | | 8.7.3 | | 4.4 |
| 2QA000016 | | | 8.2.5, 8.3.2 | | |
| 3PM000001 | | | | 6.4.3, 6.4.13 | |
| 3PR000073 | | | | | 4.4 |
| 3QA000002 | | | 8.4.1, 8.4.2 | | 4.4 |
| 2QA000032 | | | 8.6.1, 8.7.1 | | 4.4 |
| 3TL000091 | | | | 5.9, 5.10.1, 5.10.2, 5.10.3.1 7.7.1, 7.8.1.2, 7.8.2.1 | |
| 3QA000141 | | | | 6.4.1, 6.4.3, 6.4.4, 6.4.5, 6.4.6, 6.4.7, 6.4.8, 6.4.9, 6.4.10, 6.4.11, 6.4.12, 6.4.13, 6.5.3, 7.4.2, 7.4.3, 7.4.4, 7.6.1, 7.6.2, 7.6.3, 7.7.1, 7.8.1.1, 7.8.4.1, 7.8.4.1(e), 7.8.6.2, 7.8.7.2, 7.8.4.3, | |
| 3TL000148 | | | | 7.8.8.2, 7.8.8.3 | |
| 3QA000159 | | | 8.3.2 | | 4.4 |
| 3TL000192 | | | | 7.8.1.1, 7.8.2.1 | |

| | ISO 9001-2000-2015 A9100-2016 | EN ISO/IEC 80079- 34-2011 | ISO/IEC 17025- 2017 (Section 4) | ANSI/ISO 17025- 2017 (Section 5) | ISO 14001-2015 |
|-----------|----------------------------------|------------------------------|------------------------------------|--|----------------|
| 3QA000210 | | | | 6.4.4, 6.4.5, 6.4.6, 6.4.7, 6.4.10, 6.4.11, 6.4.12, 6.5.3, 7.4.1, 7.4.2, 7.6.1, 7.6.2, 7.6.3, 7.7.1, 7.8.1.1, 7.8.4.1 | |
| 3TL000259 | | | 7.1.1 | | |
| 2QA000025 | | | | | 6.1.2, 6.2.1 |
| 3SA000029 | | | | | 4.4 |

| FAR Part 145: Repair Station | |
|------------------------------|--|
| Distribution | §145.209; §145.211 |
| Index | §145.209 |
| Revision History | |
| Introduction | |
| Quality Policy | |
| Organizational Chart | §145.151; §145.209 |
| Section 1 | §145.101; §145.103; §145.109; §145.151; §145.209; §145.211; §145.215 |
| Section 2 | |
| Section 3 | §145.205 |
| Section 4 | §145.211 |
| Section 5 | |
| Section 6 | |
| Section 7 | |
| Section 8 | |
| Section 9 | §145.103; §145.109; §145.201; §145.209; §145.211; §145.213; §145.215 |
| Section 10 | §145.157; §145.201; §145.211; |
| Section 11 | §145.109; §145.211 |
| Section 12 | |
| Section 13 | §145.221 |
| Section 14 | §145.211 |
| Section 15 | |
| Section 16 | §145.209; §145.219 |
| Section 17 | |
| Section 18 | §145.211 |
| Section 18.1 | §145.155; §145.157; §145.159; §145.161; §145.209; §145.211; §145.213 |
| Section 19 | §145.155 |
| Section 20 | |
| Section 21 | |
| | |
| 2QA000003 | §145.211 |
| 2QA000005 | §145.211 |
| 2QA000010 | §145.211 |
| 2PR000001 | §145.103; §145.109 |
| | |
| 3HR000019 | §145.155; §145.159; §145.163; §145.209 |
| 3HR000038 | §145.159; §145.213 |
| 3MT000001 | §145.103; §145.109; §145.209 |
| 3QA000002 | §145.163; §145.219 |
| | |
| 3QA000141 | §145.109; §145.211 |
| 3QA000159 | §145.209 |
| 3QA000161 | §145.103; §145.109; §145.211; §145.213 |
| | |
| | |
| 4HR000038 | §145.151; §145.213 |

INTRODUCTION

OTTO designs and manufactures precision switches, controls, audio accessories, used in specialized applications with demanding performance requirements. OTTO's Test Lab, as a part of OTTO, offers various testing services in accordance with ISO/IEC 17025-2017 accreditation.

With OTTO's focus on continuous improvement, OTTO developed a "risk-based thinking" quality management system to better satisfy the needs of our customers, as well as, to improve the management of the company. OTTO's quality system complies with the international standards ANSI/ISO/ASQ 9001, ISO/IEC 17025, EN ISO/IEC 80079-34, ISO 14001, AS9100, and CFR 14 Part 121, 135, and 145, and EASA Part 145. All valid certifications will be displayed in a place that is normally accessible to the public.

This manual governs the systems (and processes) that the following products, as stated in OTTO's various certifications, are produced to: *switches (electro-mechanical, hall-effect and solid state); instrument panels, position sensors, connectors (Conventional and RF), audio accessories, communications systems, cable assemblies, speaker/microphones, headset assemblies, stamped metal components, tooling for stamped metal parts, injection molded components, machined components, engineered assemblies.*

The quality system and procedures referenced herein are written with the intent of meeting the requirement of Federal Aviation Regulation Part 21, Subpart K, paragraph 21.307 (h), and the regulatory requirements of 14 CFR part 145, sections 145.209 and 145.211.

The Quality & Repair Station Manual is divided into sections corresponding to quality system requirements of the ANSI/ISO/ASQ 9001-1994 standard. Each section starts with a policy statement expressing the general principles and commitment to implement specific actions pertaining to the quality system element that is the subject of the section. The policy statement is followed by a general and brief procedure outlining how these activities are carried out.

The purpose of this manual is to document the company's quality system, to instruct and guide employees whose actions affect product quality, and to inform OTTO's customers what controls are implemented to assure product quality.

OTTO's Quality Management System identifies internal and external issues that can impact its strategic objectives. The internal issues include organizational values, culture, knowledge, and company performance to achieve its objectives. The external issues include legal, technological, competitive market, cultural, social, and economic environments.

OTTO Stakeholders include, but not limited to, OTTO Employees, OTTO Customers, OTTO Suppliers, regulatory authorities, certification organizations and the surrounding community.

QUALITY POLICY & MISSION STATEMENT

TO ACHIEVE TOTAL CUSTOMER SATISFACTION THROUGH CONTINUOUS IMPROVEMENT

This policy has been formulated and approved by the Management Team of OTTO. The policy is also posted in conspicuous locations throughout the company, and is printed on employee handouts that are distributed to every OTTO employee. OTTO is committed to Quality as a basic business principle. OTTO believes that Quality is obtained by meeting our customer's requirements, and/or fulfilling the needs and expectations of the customer. To achieve this, the following objectives have been established:

- Reduce cycle time on everything we do
- On-time delivery performance
- Reduce customer returns

ISO 14001 is a management system that empowers an organization to address the environmental impact of its activities, services, products and people. It then provides a framework for companies to take steps to identify issues significant to them, and implement environmental management programs to achieve improved performance. OTTO's Environmental policy states that we are committed to assure that the operations, products and services do not adversely affect the environment.

In accordance with ISO 14001; OTTO has developed the following Environmental Objectives:

- Provide the best available products and services, considering the needs of our customers, employees, environment, and all other interested parties;
- Prevent pollution and comply with all environmental, safety and quality requirements to which we subscribe;
- Continually improve our product quality, workplace safety, and environmental performance.

OTTO recognizes and accepts its responsibility for the environment as an integral part of its services and operations. OTTO is committed to excellence and leadership in protecting the environment and will strive to achieve this objective through an effective Environmental Management System which adheres to the following principles:

Compliance – We will manage all of our activities to meet or surpass the standards of all relevant environmental laws and regulations and other requirements.

Continuous Improvement – We will establish measurable environmental improvement goals and targets and regularly audit and review environmental performance; continually monitor and improve environmental performance in existing and new operations; strive for cost-effectiveness in environmental management by improving operations, and by promoting the reform of ineffective environmental regulations or laws

Pollution Prevention – We will take into account the impact of our environmental aspects when making decisions; ensure that our facility develops and implements a pollution prevention plan.

Communication – We will provide training and education to our employees to ensure that they can work safely, efficiently, and in an environmentally sound manner; communicate openly with employees, clients, the public, government, and regulatory agencies concerning the company's environmental performance and improvement plans

In accordance with ISO/IEC 17025-2017; OTTO's Test Lab has added the below objective specific to the Lab:

- Provide Proficient, Reliable Service
- Services Performed with Accuracy, Integrity, and Impartiality

Goals have been established throughout the organization, such that our progress to meet the stated objectives are quantified and are constantly monitored to assure the desired continuous improvement.

The Director of Quality Systems, who reports directly to me (as stated in 1.4.5), is hereby assigned the responsibility and the authority to organize, maintain, and administer the Quality Program and to assure its effective implementation. Further, all OTTO employees are given the responsibility and authority to identify problems, implement solutions to these problems, and to control further processing of affected product, this includes preventing shipment of non-conforming, deficient, or unsatisfactory materials or product, until the entire problem has been corrected.

I fully support and approve this program.

Chairman: _____
T. J. Roeser

1 MANAGEMENT RESPONSIBILITY

Company Policy

The Management Team (see 1.6.2 Management Team Members) is ultimately responsible for establishing, implementing and maintaining the quality system. The members are ultimately accountable for the effectiveness of the quality management system and ensuring the integration of it into OTTO's business processes. Specific responsibilities comprise: formulating the quality policy, defining organization, assigning authorities and responsibilities, appointing the management representative, periodically reviewing the effectiveness of the quality system, and making available the resources and personnel necessary to understand and maintain the system as documented within this manual.

1.1 General

- 1.1.1 It is the policy of OTTO that the assurance of quality is fundamental to the work undertaken by all employees.
- 1.1.2 It is accepted that consistent high quality can only be achieved by working in a systematic way to pre-defined, formalized procedures.
- 1.1.3 To achieve uniformity of working methods, certain fundamental procedures shall be documented and followed without unauthorized deviation.
- 1.1.4 It shall be the responsibility of individual departmental managers to initiate, document, implement and maintain work instructions and ensure they are fully integrated into OTTO's quality management system.
- 1.1.5 The quality management system established and operated by OTTO shall be reviewed by the Management Team. Any revisions will be properly distributed to the list of qualified recipients described in the Distribution section of this manual.
- 1.1.6 It shall be the responsibility of the Quality Systems Department to continuously monitor and report on the quality management system, both through audits and observations, for the application and efficiency of the necessary systems and procedures.
- 1.1.7 The Quality Systems Department shall represent OTTO on all matters relating to quality assurance and shall be organized in a manner to promote independence of commercial or production influences.
- 1.1.8 All OTTO personnel will have access to quality system documentation and will be made aware of all relevant procedures. Customer and/or regulatory authority representatives will be provided viewing access to this documentation.

1.2 Organizational Chart

- 1.2.1 The OTTO Organizational Chart identifies the departments and departmental managers that are responsible for the quality in products, services or equipment.

1.3 Authority and Responsibility

- 1.3.1 The *Chairman* shall serve as ISO Management Representative and is responsible for ensuring that the requirements of this Quality & Repair Station Manual are implemented and maintained. The *Chairman* authorizes the release of the Quality & Repair Station Manual.
- 1.3.2 The Director of Quality Systems shall serve as Deputy ISO Management Representative, as well as, the Laboratory Authorized Representative.

MANAGEMENT RESPONSIBILITY

1.4 Job Descriptions / Duties and Responsibilities

The following are job descriptions for departmental Managers whose departments affect the quality of the services (including OTTO's FAA Repair Station), products or equipment at OTTO.

- 1.4.1 Chairman - *The Chairman has the ultimate responsibility for all activities at OTTO. The duties include supporting the President in Operational decisions while having direct responsibilities of non-operational Directors.*
- 1.4.2 President - *The President has the ultimate responsibility for all operational activities at OTTO. The duties include maintaining an adequate and knowledgeable staff to plan, perform, supervise, and inspect the work being performed. The President may delegate all duties to qualified persons however such delegation does not relieve the President of the overall responsibility.*
- 1.4.3 General Manager, Controls Division – *The General Manager of the Controls Division is responsible for all activities within the Controls Division. This position reports directly to the President.*
- 1.4.4 General Manager, Communications Division – *The General Manager of the Communications Division is responsible for all activities within the Communications Division. This position reports directly to the President.*
- 1.4.5 Director of Operations - *The Director of Operations is responsible for the manufacture, and repair, of all products originating within the production department, and the equipment manufactured at OTTO. This position reports directly to the President.*
- 1.4.6 Director of Quality Systems - *The Director of Quality Systems is responsible for monitoring the quality systems at OTTO and shall have final authority on all matters relating to the quality system as established by OTTO including contractual or regulatory requirements. This includes responsibility for managing the various quality departments and for the quality and technical related activities these departments perform and coordination of activities of all applicable standards. The Director of Quality Systems shall be the Accountable Manager for the company's FAA Repair Station and manufacturing facilities. Additional responsibilities pertaining to the FAA repair station include: supervision of all inspection personnel, and maintaining a current list of all pertinent data. This position shall also maintain the companies Facility Clearance License (FCL) while performing the duties set forth as the Facility Security Officer (FSO), as well as the duties as defined of the Insider Threat Program Senior Official (ITPSO). In addition, the Director of Quality Systems is responsible for the direction and performance of the company Environmental program. The title of Ex authorized person, for the manufacturing of Ex products, is also held within this role. This position reports directly to the General Manager, Controls Division, coupled with additional reporting structure (regarding the above responsibilities) to the *Chairman*.*
- 1.4.7 Director of Human Resources - *The Director of Human Resources is responsible for compensation, benefits, training activities and all associated records at OTTO. In addition, the HR Director is responsible for the direction and performance of the company Safety Program, as well as, various personnel testing systems. This position reports directly to the *Chairman*.*
- 1.4.8 Director of Finance – *The Director of Finance is responsible for all activities within the Accounting Department. This position reports directly to the *Chairman*.*
- 1.4.9 Director of IT – *The Director of Information Technology (IT) is responsible for all activities within the IT Department. This position reports directly to the *Chairman*.*
- 1.4.10 Business Unit Manager - *The Business Unit Manager is responsible for all activities in OTTO's Tech Center. This position reports directly to the *Chairman*.*

1.5 Other Management Responsibilities

- 1.5.1** Individual departmental managers shall also be responsible for; but not limited to:
- Ensuring that all staff is adequately qualified experienced and trained to perform their assigned tasks.
 - The quality of work performed by personnel within their respective departments.
 - Initiating, implementing and maintaining work instructions for their departments.
 - Ensuring that all staff are familiar with, and have ready access to company and departmental procedures, and that the relevant procedures are effectively implemented.
 - The provision and maintenance of an infrastructure required to achieve product conformity. This infrastructure includes;
 - Buildings, workspaces and associated utilities (including temperature, cleanliness, lighting), process equipment (both hardware and software), supporting services (such as transport or communication), and Identification of resources to support operation and maintenance of the product.

MANAGEMENT RESPONSIBILITY

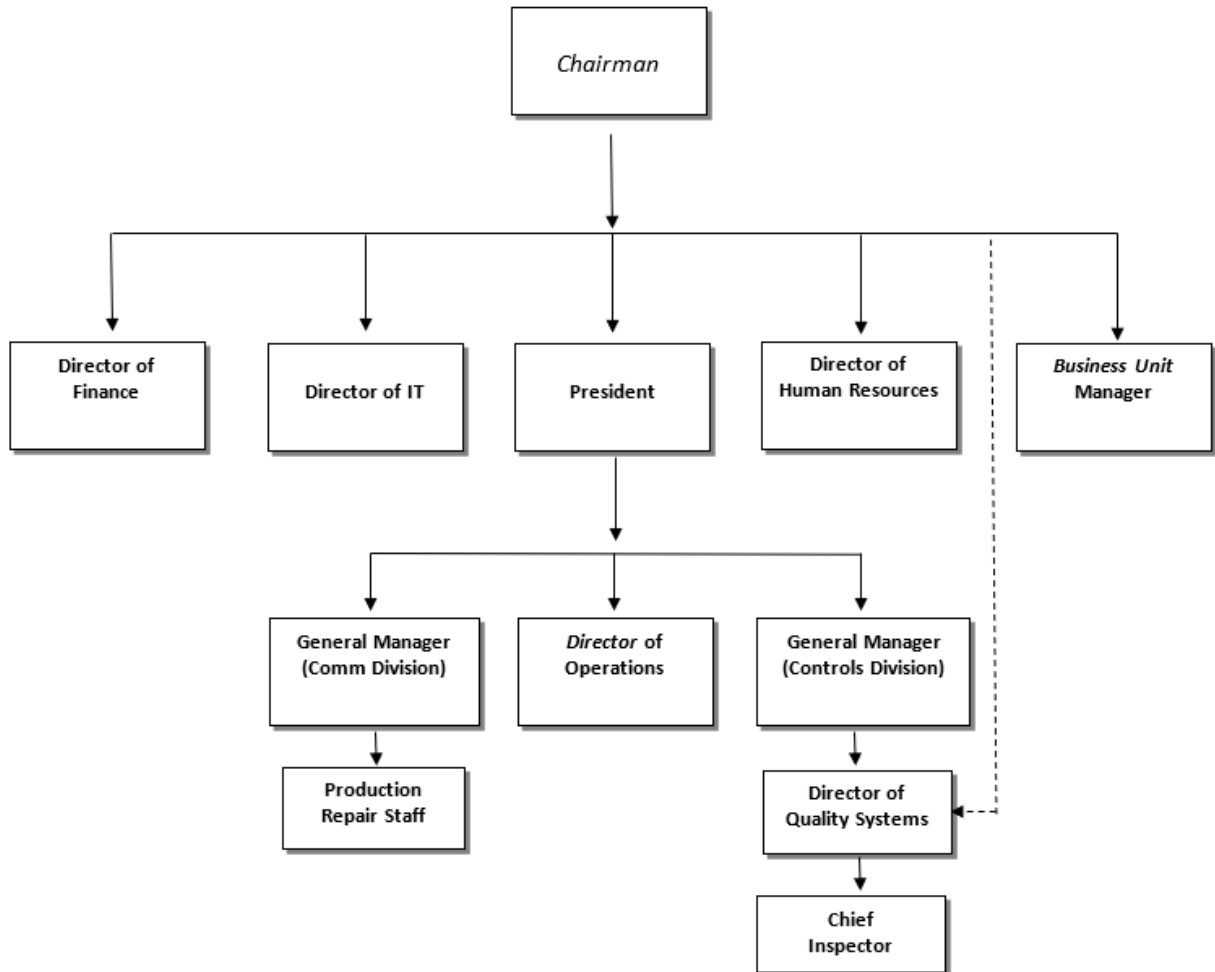
1.6 Management Review

- 1.6.1** The Management Team reviews the quality system at least once a year. The purpose of the reviews is to assess the effectiveness and continuing suitability of the quality system. The Director of Quality Systems is responsible for scheduling and conducting the reviews. Conclusions of the reviews are recorded.
- 1.6.2** Management (Executive) Team members are:
- *Chairman*
 - *President*
 - *General Manager, Controls Division*
 - *General Manager, Communications Division*
 - *Director of Operations*
 - *Director of Quality Systems*
 - *Director of Human Resources*
 - *Director of Finance*
 - *Director of IT*
 - *Business Unit Manager*

1.7 Reference Procedure

- 1.7.1** Management Review (2MT000001)
- 1.7.2** Organizational Charts (4HR000037)
- 1.7.3** ANSI/ISO/ASQ 9001
- 1.7.4** SAE AS9100
- 1.7.5** ISO/IEC 17025

ORGANIZATIONAL CHART



2 QUALITY SYSTEM

Company Policy

OTTO has documented and implemented a quality management system that satisfies the requirements of ANSI/ISO/ASQ 9001. The quality system is documented in the quality manual, quality procedures, work instructions, process specifications, company technical standards, national and international standards, and associated production documentation. The documented Quality Procedures are consistent with the requirements of the ANSI/ISO/ASQ 9001 standard, and with the policies stated within this Quality & Repair Station Manual. Implementation of the quality system is regularly audited and reviewed.

2.1 Quality System Scope

- 2.1.1** Scope of the quality system is defined in the following documents:
- Quality & Repair Station Manual,
 - Quality procedures,
 - Work instructions, process specifications, internal standards and records,
 - Applicable military, national, and international standards,
 - Product technical specifications and drawings, and
 - Production Control Plans, Routings and associated documentation.
- 2.1.2** The typical sequences of interaction of key OTTO Quality Management System processes are illustrated within 2QA000025.

2.2 Quality System Implementation

- 2.2.1.** All personnel who manage, perform, and verify work affecting quality are responsible for implementing the quality system. The Director of Quality Systems is responsible for coordinating, monitoring and auditing the system.
- 2.2.2.** Implementation of the quality system is assessed regularly by way of internal and third party audits and management reviews.
- 2.2.3.** All changes to the Quality System will be planned and implemented to ensure the integrity of the Quality Management System.
- 2.2.4.** OTTO's Environmental Management System will consist of, at a minimum, one meeting per year to discuss the development, tracking, and implementation of company environmental objectives and procedures. Records of these findings, along with the meeting information, will be recorded.
- 2.2.5.** Technical Standard Orders (TSO) will be submitted to FAA Engineering in accordance with FAA Orders, Advisory Circulars and Regulations in conjunction with OTTO Procedures.

2.3 Reference Procedure

- 2.3.1** Product Development (2EN000004)
- 2.3.2** Sequence and Interaction of Key QMS Processes (2QA000025)
- 2.3.3** Environmental Management System (2HR000003)
- 2.3.4** ANSI/ISO/ASQ 9001
- 2.3.5** SAE AS9100
- 2.3.6** ISO/IEC 17025

3 CONTRACT REVIEW

Company Policy

All contracts and orders are reviewed to assess if customer's requirements are adequately defined, are well understood, and if the company has the capacity to meet the contract requirements.

3.1 Application

- 3.1.1 There are two processes for contract reviews. One is applicable to OTTO's standard products, and the other to custom engineered products. The Sales Department, specifically the Director of Sales, is responsible for conducting contract reviews for both types of products.
- 3.1.2 The Sales Department will be responsible for all customer communication ranging from initial contact/contract review to customer feedback, including customer complaints.

3.2 Scope of Review

- 3.2.1 Contract reviews comprise verification that the customer's requirements are adequately defined and documented, and that OTTO understands, and has the capacity to meet the contract requirements. These risk-based requirements include, but are not limited to:
 - 3.2.1.1 Requirements specified by the customer, including the requirements for delivery and post-delivery activities.
 - 3.2.1.2 Requirements not stated by the customer but necessary for specified or intended use, where known,
 - 3.2.1.3 Statutory and regulatory requirements related to the product, and
 - 3.2.1.4 Risk evaluation (i.e. new technology, short delivery time scale).
 - 3.2.1.4.1 OTTO Mitigates risk in the various forms including, but not limited to:
 - 3.2.1.4.1.1 Contract Review,
 - 3.2.1.4.1.2 Product Development, including lessons learned,
 - 3.2.1.4.1.3 Production Processes, and
 - 3.2.1.4.1.4 On-Going Testing.
- 3.2.2 If any discrepancies or ambiguities are observed, Sales personnel will contact the customer for clarification.
- 3.2.3 Contract modifications and/or amendments are reviewed as above, and information is furnished to the applicable functions as necessary based on the scope of the modification/amendment.
- 3.2.4 Flow Down (thru) requirements to OTTO's Vender base will originate during this review, but be governed by applicable departmental specifications.

3.3 FAA Repair Station Review

- 3.3.1 OTTO may perform maintenance for an air carrier or commercial operator that has a continuous airworthiness maintenance program under Part CFR 14 part 43, 121, 135 and 145. In accordance with the carrier's requirements, the details from such review will be flowed down to OTTO Repair Station in conjunction with 9.4.5 of this manual.

3.4 Records

- 3.4.1 Sales personnel conducting contract reviews make a record of each review. In the case of standard products, the record is made by signing and *returning* the order. For custom products, it is a copy of an offer, acknowledged by Sales, that constitutes a record of the contract review.

CONTRACT REVIEW

- 3.4.2** Records are also maintained for verbal orders placed for standard items. The complete order entered into the OTTO's ERP system indicates that the customer's requirements are adequately defined and documented, and that the capacity to meet the contract requirements exists.

3.5 Customer Satisfaction

- 3.5.1** OTTO will monitor information, using various methods, relating to customer perception as to whether OTTO has met customer requirements.

3.6 Reference Procedures

- 3.6.1** Contract Review Standard(2SA000001)
3.6.2 ANSI/ISO/ASQ 9001
3.6.3 SAE AS9100
3.6.4 ISO/IEC 17025

4 DESIGN CONTROL

Company Policy

The design process is planned, controlled, and verified to ensure input requirements are met. Design activities are identified, responsibilities for carrying them out are assigned, and organizational interfaces are defined and controlled. The design input is identified, and the design output is documented and verified that it meets the design input requirements. The final design is reviewed and approved. Design changes are controlled.

4.1 General

- 4.1.1** OTTO designs its own standard products, as well as, customer specified products and modifications. The Engineering department, and specifically the Director of Engineering, is responsible for establishing and maintaining design procedures and work instructions.

4.2 Design Planning

- 4.2.1** Design planning, activity assignment and control of organizational and technical interfaces are carried out by Engineering Directors, or their supervisory staff.
- 4.2.2** Plans are documented and updated as the design evolves.
- 4.2.3** Design activities are assigned to qualified staff equipped with adequate resources.

4.3 Design Input

- 4.3.1** Design input for products comes from the Sales Department in the form of a Project. The Project is reviewed by Directors, or their designated staff, to determine if the selected requirements are adequate. The input shall include, but not be limited to:
- 4.3.1.1** functional and performance requirements,
 - 4.3.1.2** applicable statutory, regulatory and environmental requirements,
 - 4.3.1.3** information derived from previous similar designs, and
 - 4.3.1.4** risk analysis.
- 4.3.2** Incomplete, ambiguous, or conflicting requirements are resolved by Sales and Engineering before the commencement of design activities.

4.4 Design Output

- 4.4.1** Design output is documented and expressed in terms of requirements, calculations and analyses.
- 4.4.2** Design output is documented on two levels: Primary output consists of documents defining the product, while the secondary output supports the design with calculations, analysis, etc. Design output is verified to determine if it;
- meets design input requirements,
 - contains or references acceptance criteria, drawings, part lists, specifications,
 - conforms to appropriate regulatory requirements whether or not these have been stated,
 - identifies the characteristics of the design crucial to the safe and proper functioning of the product,
 - contains the appropriate information for purchasing, production, and service, and
 - contains information on material, processes, type of manufacturing and assembly of the product necessary to ensure product conformity.

DESIGN CONTROL**4.5 Design Verification**

- 4.5.1** Design verification is planned, documented and assigned to competent personnel.
- 4.5.2** Design verification establishes that the design output meets the design input requirements.
- 4.5.3** As a minimum, the design is verified by holding and recording design reviews and undertaking qualification tests and demonstrations. Other forms of verification, such as carrying out alternative calculations and comparing the new design with a similar proven design, may also be used when appropriate.

4.6 Design Validation

- 4.6.1** Design validation follows design verification, and is performed on the final product under defined operating conditions, to ensure that the product conforms to the defined user needs and/or requirements.

4.7 Design Changes

- 4.7.1** Design changes are initiated by an Engineering Change Notice. The Engineering Change Notice provides design input for defining the change. Planning, design output, and design verification and validation activities follow the same rules as apply to the original design. Design changes that are developed and implemented by a major project team are documented within the various OTTO Databases, and relevant Project folders held on the company network drive.
- 4.7.2** When required, the Engineering Change Notice will be distributed and approved by a customer and/or regulatory authority.
- 4.7.3** Revalidation (see section 4.6).

4.8 Reference Procedure

- 4.8.1** Design Control (2EN000001)
- 4.8.2** ANSI/ISO/ASQ 9001
- 4.8.3** Document Control (2QA000017)
- 4.8.4** SAE AS9100
- 4.8.5** Product Development Procedure (2EN000004)
- 4.8.6** System Documentation (2QA000016)
- 4.8.7** Engineering Change Notice Procedure (3QA000159)
- 4.8.8** ISO/IEC 17025

5 DOCUMENT CONTROL

Company Policy

The purpose and scope of quality system documents are defined. All documents (as outlined in 5.1.1) are reviewed and approved prior to issue. Appropriate documents are available at locations where they are intended to be used. Obsolete documents are removed from points of use. The Director of Quality Systems is responsible for auditing, coordinating, and enforcing the document control related activities.

5.1 Quality System Documentation

5.1.1 Quality system documentation comprises the following types of documents:

- Quality & Repair Station Manual,
- Quality procedures,
- Work instructions, process specifications, internal standards and records,
- Applicable military, national, and international standards,
- Product technical specifications and drawings, and
- Production control plans, routings and associated documentation.

5.1.2 All drawings, including those for all FAA-PMA/TSOA items, are maintained by Engineering per specification 2EN000001. Drawings are made available to production personnel as needed through Document Control.

5.1.3 Inspection personnel will use the controlled drawing file to make inspection acceptance as needed.

5.1.4 The following schedule dictates the proper notification body responsible for each examination certificate held by OTTO. The Director of Quality Systems is responsible for coordinating communication to the below applicable parties. Notifications of substantial changes to OTTO's quality system (i.e. equipment, personnel, products, and processes) which have occurred (or will occur) will be communicated accordingly.

- ISO 9001 National Quality Assurance (NQA)
- AS9100 National Quality Assurance (NQA)
- ISO 14000 National Quality Assurance (NQA)
- EN ISO/IEC 80079-34 ATEX/IS – Underwriters Laboratories
- ISO/IEC 17025 A2LA
- CFR 14:256 FAA: Rosemont, IL Office
- EASA European Aviation Safety Agency, Germany

5.2 Document Approval, Issue and Re-approval.

5.2.1 Documents and document changes may be initiated by anyone in the organization. All documents (as outlined in 5.1.1) are reviewed and approved prior to issue. The originator of the change is responsible for selecting the appropriate approval path for the change.

5.2.2 All documented Level 2 procedures shall be periodically reviewed and re-approved for adequacy. OTTO's recurring training program shall serve as means for this re-approval process.

5.3 Document Placement

5.3.1 Current revisions of ISO Level 1 through 4 documents are available to all personnel via the PLM database.

DOCUMENT CONTROL**5.4 Document Changes**

- 5.4.1** Document changes are reviewed and authorized according to the ECN procedure (3QA000159). Obsolete documents are removed from the system. A master list specifying the latest issues and revisions of all documents is maintained in the PLM database.
- 5.4.2** It is the responsibility of the Director of Quality Systems to obtain approval of changes in the engineering data for all FAA-PMA parts or assemblies. Major changes of FAA-PMA/TSO parts will be FAA Engineering approved prior to implementation of the change. Minor changes to FAA-PMA parts will be submitted to the FAA Aircraft Certification office location at 2300 E. Devon, Des Plaines, IL. 60018, within 6 months of OTTO engineering department approval. All OTTO specifications for FAA-PMA/TSOA parts are considered as extension of the drawings and are maintained and controlled in the same manner
- 5.4.3** No changes will be incorporated in this manual and Quality Procedures, applicable to FAA-PMA/TSOA parts repair, prior to an acceptance of the change by an appropriate FAA office. Exceptions to this are for correction of typographic error or additions of information to improve the level of quality control.
 - 5.4.3.1** PMA's are not transferrable.
- 5.4.4** Documents are reissued after a change.
- 5.4.5** OTTO's system for informing company inspectors of current changes in engineering drawings, specifications, and quality control procedures is outlined in 3QA000159 and 3QA000327.

5.5 Reference Procedures

- 5.5.1** System Documentation (2QA000016)
- 5.5.2** Document Control (2QA000017)
- 5.5.3** Engineering Change Notice Procedure (3QA000159)
- 5.5.4** ISO Change Notice Procedure (3QA000327).
- 5.5.5** Design Control (2EN000001)
- 5.5.6** ANSI/ISO/ASQ 9001
- 5.5.7** SAE AS9100
- 5.5.8** ISO/IEC 17025

6 PURCHASING

Company Policy

OTTO assesses its suppliers and subcontractors and purchases only from those that can satisfy the company's quality requirements. Purchasing documents describe ordered products, including quality requirements as applicable. Purchasing documents are reviewed and approved prior to release.

6.1 Assessment of Suppliers/Subcontractors

- 6.1.1 OTTO's suppliers and subcontractors consist of those vendors who deliver their standard catalogue products, and/or those who design and/or manufacture products from OTTO's drawings.
- 6.1.2 Assessments of suppliers and subcontractors are conducted jointly by Purchasing, Quality, and Engineering, if deemed necessary. Final recommendations are performed using "risk-based" analysis.
- 6.1.3 Quality performance of component part suppliers and subcontractors is monitored. Vendors showing inadequate performance are required to implement corrective actions and are replaced if there is no improvement.
- 6.1.4 Purchasing maintains an approved supplier/subcontractor list for component parts. Orders may only be placed with vendors that are on the approved list.
- 6.1.5 Control of purchased products is achieved through quality questionnaires, supplier/subcontractors audits, and/or records of supplier/subcontractor performance.

6.2 Purchasing Data

- 6.2.1 Purchasing documents are prepared by the Purchasing department. The documents describe ordered products. They include precise identification of the products, reference applicable standards and state quality requirements. The Purchaser reviews purchasing documents prior to release.

6.3 Verification of Purchased Product

- 6.3.1 When applicable and appropriate, OTTO's customers are given the right to verify that the purchased product conforms to specified requirements. Customer verification does not absolve OTTO from the responsibility to approve suppliers and subcontractors or to deliver a quality product. Verification activities may include:
 - 6.3.1.1 Review of objective evidence of the conformity of the processes, products, and services from the external provider (e.g., accompanying documentation, certificate of conformity, test reports, statistical documentation, process control documentation, results of production process verification and assessment of changes to the production process thereafter),
 - 6.3.1.2 Review of the required documentation,
 - 6.3.1.3 Review of production part approval process data,
 - 6.3.1.4 Inspection of products upon receipt,
 - 6.3.1.5 Inspection and audit at the supplier's premises, and
 - 6.3.1.6 Review of delegations of product verification to the external provider.

6.4 Reference Procedures

- 6.4.1 Component Part and Services Purchases (3PU000004)
- 6.4.2 Supplier Performance Assessment and Rating(2QA000013)
- 6.4.3 Maintenance, Repair and Operation _MRO Purchases (3PU000003)
- 6.4.4 Supplier Selection and Review (2PU000003)
- 6.4.5 Material Department – Supplier Performance Report (3PU000012)
- 6.4.6 Supplier Quality Manual (2QA000018)
- 6.4.7 ANSI/ISO/ASQ 9001
- 6.4.8 SAE AS9100
- 6.4.9 ISO/IEC 17025

7 CUSTOMER/EXTERNAL PROVIDER'S PROPERTY

Company Policy

Customer or external provider's property shall be identified, verified, protected and safeguarded. Customer supplied products are handled in the same manner as other products that are purchased for incorporation into end products. When specified in a contract, special handling instructions from customers or external providers will take precedent over the company's standard procedures. Loss, damage, deterioration or unsuitability of a customer's products is recorded and reported to the customer.

7.1 General

- 7.1.1 Customer's or external provider's property can include materials, components, tools/equipment, intellectual property, including customer furnished data used for design, test equipment and software, production and/or inspection.
- 7.1.2 Customer's or external provider's products are verified by inspection or testing as required. The products, materials, tools/equipment are identified, marked and stored in the same manner as other purchased products, materials and tools/equipment.
- 7.1.3 Verification by OTTO Engineering does not absolve the customer of the responsibility to provide acceptable product.

7.2 Loss or Damage

- 7.2.1 The customer is contacted in the event of loss, damage, deterioration or unsuitability of products. This contact is documented.

7.3 Reference Procedure

- 7.3.1 Customer Owned Tooling, Property or Intellectual Property (2SA000005)
- 7.3.2 ANSI/ISO/ASQ 9001
- 7.3.3 SAE AS9100
- 7.3.4 ISO/IEC 17025

8 PRODUCT IDENTIFICATION AND TRACEABILITY

Company Policy

Materials, components, subassemblies and products are identified by a part number correlated to corresponding drawings, specifications and/or other technical documents.

8.1 Part and Product Identification

- 8.1.1** All purchased and in-house manufactured materials and parts are identified with OTTO's internal part numbers assigned by the Engineering department. The part numbers provide for a correlation between a part and its technical documentation.
- 8.1.2** When required by contract, finished products are labeled with a unique serial number to allow for traceability of product configurations. Otherwise, all products are date coded for purposes of traceability.
- 8.1.3** All completed FAA-PMA parts and/or assemblies will be identified by part number and inspection approval means.
 - 8.1.3.1** The parts and/or assemblies will be permanently and legibly marked with:
 - 8.1.3.2** The letters "FAA-PMA",
 - 8.1.3.3** The name, trademark, or symbol of the holder of the Parts Manufacturer Approval,
 - 8.1.3.4** The part number, and
 - 8.1.3.5** The date code.
- 8.1.4** The name and model designation for each type certified product on which the part is eligible for installation will be included on a label affixed to bags containing the product. Each part will be individually bagged and labeled.
- 8.1.5** TSO parts will be marked per the requirements of the specific order.
- 8.1.6** Servicing of returned product for rework or replacement shall be traceable by its original date code, or serial number when such serial number was a contract requirement. It is also possible to identify or trace a product by the customer's name.

8.2 Records

- 8.2.1** The Engineering department maintains the part number lists and associated technical documentation.
- 8.2.2** Date codes used on products are maintained as a record, and records of the unique serial numbers used as a result of specific contract requirements are maintained as a quality record.

8.3 Reference Procedure

- 8.3.1** Product Identification and Traceability (2QA000001)
- 8.3.2** ANSI/ISO/ASQ 9001
- 8.3.3** SAE AS9100
- 8.3.4** ISO/IEC 17025

9 PROCESS CONTROL

Company Policy

Production and individual operations are planned and documented under control conditions. The characteristics of the products produced are defined and documented. Personnel performing complex or critical operations are provided with work instructions, workmanship criteria and criteria for product acceptance and rejection. Special processes are controlled and performed in accordance with written procedures. Production and process equipment are regularly checked and maintained. Production areas are clean and provide a suitable working environment. Test Lab areas are controlled to make sure that the environmental conditions do not invalidate the results of the tests performed.

9.1 Production Plan

- 9.1.1 The production plan is specified on a Routing/Control Plan prepared by Production Planning.
- 9.1.2 The manufacturing work order lists all production and inspection operations necessary to manufacture and verify a product. This includes, but is not limited to:
 - 9.1.2.1 Key characteristics to the product,
 - 9.1.2.2 In-process inspection/verification points,
 - 9.1.2.3 Criteria for product acceptance and rejection,
 - 9.1.2.4 Applicable tooling used to aide in the manufacturing and inspection of the product,
 - 9.1.2.5 Prevention, detection and removal of foreign objects, and
 - 9.1.2.6 Special processes.

9.2 Production Control

- 9.2.1 Where their absence would adversely affect quality, production personnel are provided with approved work instructions. Approved workmanship standards are also utilized for manufacture of product when appropriate. Production equipment, tools, software programs, test equipment, processes, product characteristics and production environment are controlled and maintained.

9.3 Production Process Verification

- 9.3.1 All new production processes and changes to existing processes are verified to ensure the production is able to produce products that meet requirements.
- 9.3.2 The results of production process validation are documented.

9.4 Special Processes

- 9.4.1 OTTO flows down the requirements for validation and control of special processes (e.g. heat treatment, chemical processing, composites, nonconventional machining, non-destructive testing, joining, coating, surface enhancement) which may include:
 - 9.4.1.1 Criteria for process review and approval (e.g. technical requirements, verification and validation activity), approval arrangements (process, documents, persons etc.).
 - 9.4.1.2 Customer or Third party certification, i.e. ISO9000, A9100, NADCAP of facilities and equipment.
 - 9.4.1.3 Conditions to maintain process approval e.g. compliance checks, process oversight, special process audits, requalification of persons, planned maintenance, process monitoring, process surveillance, change control.
 - 9.4.1.4 Qualification of persons e.g. skills matrices, training, oversight, workplace assessment, competency assessment, levels of authorization.
 - 9.4.1.5 Methods and procedures e.g. techniques, instructions, data cards, standard operating procedures, diagrams, set up sheets, acceptance criteria.
 - 9.4.1.6 Retained documented information to demonstrate that processes have been carried out as planned (e.g. person qualification, process cards, route cards, furnace charts, laboratory reports, test pieces, test results, x-ray film, maintenance records, calibration records, consumable traceability, verification results).

PROCESS CONTROL

- 9.4.2** Quality Systems, Engineering, and Production are responsible for identifying special processes used in production and for prescribing methods and procedures for performing, controlling and, if required, recording such processes. The requirements of 9.1 and 9.2 apply as appropriate.
- 9.4.3** The Department Supervisor maintains the list of process specifications for manufacturing, the associated records of equipment qualifications and training matrices for personnel associated with the applicable manufacturing area.
- 9.4.4** OTTO shall strive to develop, maintain and improve processes with consideration for the latest environmental friendly practices.
 - 9.4.4.1** When specific direction is required to be documented, all appropriate procedures, control plans, and any other applicable documentation will be maintained.
 - 9.4.4.2** Flow Down of all product specifications, including environmental requirements, will be communicated to both the vendor and customer base.
- 9.4.5** The Repair Station Operations has a dedicated production area, with dedicated equipment. OTTO's FAA Repair Station(s) shall be located:
 - 9.4.5.1** 2 East Main location; in the West wing (of the production area) on the 2nd Floor.
 - 9.4.5.2** 10 West Main location; in the South corner (of the production area) of the 3rd Floor.
 - 9.4.5.3** Any location changes altering the above statements will require FAA approval prior to implementation.
 - 9.4.5.3.1** Other than having a designated area, OTTO's repair station will operate as normal (original) production – using all existing housing, facilities, equipment, and like-material, unless otherwise noted. OTTO is the OEM for the item being repaired.
 - 9.4.5.3.2** Specific Repair Station instruction are as follows:
 - 9.4.5.3.2.1** Product will be flagged for repair,
 - 9.4.5.3.2.2** Initial consult will be done to corroborate customers need for repair (see example of Repair Station Matrix in Appendix B),
 - 9.4.5.3.2.3** In-depth consult will be done to check for specific reasons for repair need, as well as any other undocumented (by customer) requirements for repair (see example of RMA in Appendix B), and
 - 9.4.5.3.2.4** Repairs, and acceptance of repairs (with appropriate tagging), will be conducted prior to release (see example of 8130 on page VII of Appendix A, and example of an ATP in Appendix B).
 - 9.4.5.3.3** Only those products which are controlled via the company PLM database with the designation of "FAA" may be repaired. Any additions to this list will be distributed to the FAA upon initiation of the change.
 - 9.4.5.3.3.1** The FAA Repair Station Capabilities list, or products which OTTO is allowed to repair, will be kept within the PLM database.

9.5 Reference Procedure

- 9.5.1** Process Control (2PR000001)
- 9.5.2** Quality Functions for Product/Process Development (2QA000021)
- 9.5.3** Update/Modify Production and Machine Shop Control Plans and Routings (3QA000161)
- 9.5.4** Engineering Change Notice Procedure (3QA000159)
- 9.5.5** Processing of Return Material (2QA000033)
- 9.5.6** Manufacturing Equipment Maintenance (3PM000001)
- 9.5.7** Emergency/Disaster Recovery Program (3MT000003)
- 9.5.8** Guidelines to Avoid Particulate Contamination – FOD (3PR000039)
- 9.5.9** ANSI/ISO/ASQ 9001
- 9.5.10** SAE AS9100
- 9.5.11** ISO/IEC 17025

10 INSPECTION AND TESTING

Company Policy

Inspection and testing are conducted when purchased materials and components are received, at significant stages of production, and prior to dispatch of finished products. The objective of inspections and testing is to verify conformance with specified requirements. Materials, components and products are prevented from use, assembly and dispatch until the required inspections are completed. Records of inspections are established and maintained to evidence that products comply with stated requirements.

10.1 Receiving Inspection

- 10.1.1** Purchased products and services, when they affect the quality of the product, are subjected to receiving inspection and First Article Inspection (FAI) reporting. This includes the inspection and detection of suspected unapproved parts according to FAR Part 145. The products, and where appropriate, services, are inspected visually. Critical products or those products that have been manufactured from OTTO's drawings are subjected to a more detailed and technical inspection.
- 10.1.2** Repair station inspections will be performed by only those inspectors who are qualified and are on the current FAA inspection roster.
 - 10.1.2.1** Preliminary inspection of a repairable item shall be thorough and include an inspection for hidden damage.
 - 10.1.2.2** Preliminary inspection shall also include proper research of return item with respect to any/all Airworthiness Directives (AD's)
 - 10.1.2.3** The inspectors shall approve repairs for "Return for Service." All products contained on the companies Capability List (see Section 9.0), in accordance of Part 145.

10.2 In-process Inspections

- 10.2.1** In-process inspections are specified on a manufacturing control plan accompanying a product during its manufacturing phases. The inspections are normally carried out by the production personnel.
- 10.2.2** The quality of product during manufacture shall be controlled by monitoring the process and/or by inspections.
- 10.2.3** Products shall not be released for further processing until all the required inspections and tests have been completed.
- 10.2.4** Each inspection and test shall be recorded as appropriate for the product. Prior inspections and tests shall be verified as completed before the start of the next operation.
- 10.2.5** Inspection criteria for each operation are identified in the manufacturing control plan.
- 10.2.6** Where traceability is required, it shall be achieved as described in Section 8, Product Identification and Traceability.
- 10.2.7** Nonconforming items shall be processed in accordance with the non-conformance procedures.

10.3 Final Inspection

- 10.3.1** All finished products are subjected to final inspection (by Quality Systems if product line is not certified, by the product line itself if it is line certified), as specified on the manufacturing control plan. Only those products that pass the final inspection can be shipped.
- 10.3.2** Acceptance of finished parts or products shall be indicated by the signing of the relevant document by authorized personnel after verifying that all previous process and inspection stages have been completed.
- 10.3.3** No product shall be permitted to be shipped until all the activities specified in the relevant test procedures have been satisfactorily completed along with associated documentation.

INSPECTION AND TESTING**10.4 Inspection and Test Records**

- 10.4.1** All three types of inspections are recorded and signed off by the personnel performing the inspections if they conform to the acceptance criteria for the operation being performed. The records of acceptance are kept in accordance with the requirements in Quality Records (2QA000002).

10.5 Reference Procedures

- 10.5.1** Materials Dept. - Receiving (3SR000004)
- 10.5.2** Receiving Inspection (2QA000003)
- 10.5.3** In-Process Inspection (2QA000004)
- 10.5.4** Final Inspection (2QA000005)
- 10.5.5** Quality Records (2QA000002)
- 10.5.6** Special Inspection/Customer Requirements (3QA000042)
- 10.5.7** ANSI/ISO/ASQ 9001
- 10.5.8** SAE AS9100
- 10.5.9** ISO/IEC 17025

11 INSPECTION, MEASURING AND TEST EQUIPMENT

Company Policy

Inspection, measuring and test equipment is controlled, calibrated, validated and maintained to demonstrate the conformance of the product to required specifications. Inspection, measuring and test equipment are calibrated to nationally recognized standards. Inspection, measuring and test equipment is used in a manner that measurement uncertainty is known and is consistent with the required measurement capability. Calibration records are maintained and the calibration status of inspection, measuring and test equipment is identified.

11.1 Measurement Identification

- 11.1.1 Product measurements and the required tolerances are identified on documents by the Engineering Department. Selection and verification of the inspection, measuring and test equipment, for the required accuracy and precision to perform those measurements are defined.

11.2 Calibration and Maintenance of Equipment

- 11.2.1 Inspection, measuring and test equipment used to judge the quality of the product is identified and calibrated to a nationally recognized standard. When no such standard exists, the basis of the calibration is documented. The calibration status of inspection, measuring and test equipment is identified with a suitable indicator or approved identification record.
- 11.2.2 Calibration work instructions include the location of the calibration activity and action to be taken when unsatisfactory results are achieved. If the calibration is performed in-house, the equipment used, standards used, identification number and acceptance criteria are documented. Inspection, measuring and test equipment requiring checks is documented as to the check method and frequency. Actions to be taken from unsatisfactory results of calibrations or checks are documented in the calibration work instructions.
- 11.2.3 To ensure the accuracy and precision necessary for the inspection, measuring and test equipment, gage reliability and repeatability studies are performed when the equipment manufacturer's documented precision exceeds 25% of the characteristics total tolerance.
- 11.2.4 Calibration records of the inspection, measuring and test equipment are maintained. Data includes gage type, gage identification number, status, location, date last calibrated, next calibration date, who performed the calibration, and the calibration results.
- 11.2.5 When inspection, measuring and test equipment is found to be out of tolerance, an Status Change Form (4QA000153) is issued to the Director of Quality Systems. Possible nonconforming product is addressed by Control of Non-Conforming Product, Section 13.
- 11.2.6 Environmental conditions are recorded and controlled to the extent necessary to insure proper calibration of the inspection, measuring and test equipment. Work instructions address environmental variables.
- 11.2.7 The inspection, measuring and test equipment is handled, preserved, and/or stored to maintain accuracy. These requirements are documented and maintained accordingly.
- 11.2.8 Fixtures, jigs, and test software used to inspect product quality are verified as to their accuracy prior to use and checked at prescribed intervals, as required. These verifications are documented. All fixtures, jigs and test software used for inspection have supporting design data available for use by the purchaser or the purchaser's representative, for verification that it is functionally adequate.

11.3 Reference Procedure

- 11.3.1 Control of Inspection, Measuring, and Test Equipment (2QA000006)
- 11.3.2 ANSI/ISO/ASQ 9001
- 11.3.3 Calibration Procedure for Measurement and Test Equipment (3QA000141)
- 11.3.4 General Test Sequence Guideline (3TL000091)
- 11.3.5 SAE AS9100
- 11.3.6 ISO/IEC 17025

12 INSPECTION AND TEST STATUS

Company Policy

Inspection status of a product is identified to assure that only product that has passed inspection is used.

12.1 Identification System

- 12.1.1 Products that pass receiving inspection are identified.
- 12.1.2 Status of an in-process inspection is identified on a manufacturing work order accompanying the product.
- 12.1.3 Associated documents that pass the final inspection are identified, signed and dated by qualified personnel.
- 12.1.4 Products that fail any one of the three inspections are identified.

12.2 Authority to Release Product

- 12.2.1 Qualified personnel performing final inspection have the authority to release product for shipment. Records are kept as evidence that the product has been released for shipment.

12.3 Reference Procedure

- 12.3.1 Inspection and Test Status (2QA000007)
- 12.3.2 OTTO Inspector Stamp Control (3QA000078)
- 12.3.3 ANSI/ISO/ASQ 9001
- 12.3.4 SAE AS9100
- 12.3.5 ISO/IEC 17025

13 CONTROL OF NONCONFORMING PRODUCT

Company Policy

Nonconforming product, including customer returned product, is identified, documented, evaluated and prevented from being used or shipped. Responsibility for disposition of nonconforming product is defined and, when required, the customer is contacted for concession. Reworked product is re-inspected.

13.1 Identification and Documentation

- 13.1.1 It is a policy of OTTO to identify and document nonconformities.
- 13.1.2 Documentation of nonconformity is made on a Material Review Report. Nonconforming products are labeled and segregated. Counterfeit product is also covered under this section.

13.2 Nonconformity Review and Disposition

- 13.2.1 In the event of a nonconformity, OTTO will:
 - 13.2.1.1 Take appropriate action to correct the nonconforming process,
 - 13.2.1.2 Evaluate whether the nonconforming process has resulted in nonconforming product, and
 - 13.2.1.3 Identify and control the nonconforming product, which includes types originated from the inspection of suspected unapproved parts.
- 13.2.2 The disposition decision may be:
 - Rework,
 - Sort,
 - Use as is,
 - Scrap.
- 13.2.3 When required, the customer is contacted for acceptance by concession of a nonconforming product. The description of the accepted nonconformance (including results of rework operations) shall be documented on the appropriate form.
- 13.2.4 If finished goods are found to be out of specification, the Director of Quality, or delegate, will determine severity of issue and if necessary, recall finished goods from customer.
 - 13.2.4.1 Defects that are determined to be un-airworthy, the Director of Quality Systems, or delegate, will report such situations within 72 hours of discovery, in writing, to EASA, the aircraft/component design organization, and the customer or operator.
 - 13.2.4.1.1 At a minimum, the notification will include the following:
 - 13.2.4.1.1.1 Aircraft Registration Number,
 - 13.2.4.1.1.2 Type, make, and model of the article,
 - 13.2.4.1.1.3 Date of discovery of the failure, malfunction, or defect,
 - 13.2.4.1.1.4 Nature of the failure, malfunction, or defect,
 - 13.2.4.1.1.5 Time since last overhaul, and
 - 13.2.4.1.1.6 Apparent cause of the failure.
 - 13.2.4.2 Product dispositioned for scrap shall be conspicuously marked, and positively controlled, until physically deemed unusable.

13.3 Re-inspection

- 13.3.1 Repaired or reworked products are re-inspected.

13.4 Reference Procedures

- 13.4.1 Nonconforming Product and Testing Control (2QA000008)
- 13.4.2 Material Review Board Process (2QA000009)
- 13.4.3 Counterfeit Control Plan (2QA000023)
- 13.4.4 ANSI/ISO/ASQ 9001
- 13.4.5 SAE AS9100
- 13.4.6 ISO/IEC 17025

14 NONCONFORMITY AND CORRECTIVE ACTION

Company Policy

Processes, work operations, quality records, and customer complaints are analyzed to detect sources of potential nonconformity. Causes of nonconformities are investigated and corrective actions are initiated to prevent recurrence. Controls are applied to ensure that corrective actions are implemented and that they are effective.

14.1 Initiation of Corrective Actions

- 14.1.1** Anyone in the company may propose a corrective action.
- Corrective actions are initiated as a result of (but not limited to): Identification of product nonconformity
 - Process quality problems
 - Concessions
 - Non-compliance observed during audits
 - Service and warranty claims
 - Customer complaints
- 14.1.2** When a nonconformity is identified, the cause of its occurrence is investigated, including, as applicable, those related to human factors, and corrective action is taken. The nonconformity is documented, all information that defines the nonconformity and corrective action are maintained, and preventative measures are initiated.
- 14.1.2.1** Once the root cause and possible effects are identified, the likelihood of any reoccurrence is assessed, a risk assessment (including, but not limited to associated costs) is to be performed to substantiate any/all reduction of the nonconformity.
- 14.1.3** When corrective action is necessary, procedures ensure that the intended action has been taken and is effective.
- 14.1.4** Changes to existing procedures are implemented, verified and recorded.
- 14.1.5** Processes, work operations, concessions, warranty claims, quality records, service reports and customer complaints are analyzed to detect and eliminate potential causes of nonconforming product.
- 14.1.6** Corrective action requirements are flowed down to external provider when it is determined that the external provider is responsible for the nonconformity.

14.2 Reference Procedure

- 14.2.1** Nonconformity and Corrective Action (2QA000010)
- 14.2.2** Customer Satisfaction (2SA000004)
- 14.2.3** Supplier Quality Manual (2QA000018)
- 14.2.4** ANSI/ISO/ASQ 9001
- 14.2.5** SAE AS9100
- 14.2.6** ISO/IEC 17025

15 HANDLING, STORAGE, PACKAGING, AND DELIVERY

Company Policy

Methods and means of handling that prevent product damage and/or deterioration is provided. Receipt to, and dispatch from, storage areas is controlled. The condition of stored products is assessed regularly. Packaging, including those for sensitive products, is specified and controlled. Products are protected prior to and, where required, during delivery.

15.1 Handling

- 15.1.1 Measures are taken to ensure products are protected from damage and deterioration during handling, storage, packaging, repair, and delivery.

15.2 Storage

- 15.2.1 Only products that are properly identified and that have passed any required inspections (unless line certified) are authorized to enter and leave the storage areas. Periodically, the storage areas are inspected to assess the condition of stock.
- 15.2.2 Products are stored in clearly identified storage areas.
- 15.2.3 Receipt and dispatch from storage areas is controlled by the supervisor.

15.3 Packaging and Delivery

- 15.3.1 Packaging is specified during product design or by contract, and is communicated in the form of Bill of Materials, and/or work instructions. Packaging is designed and suitable for the intended means of delivery to preserve the product until OTTO's responsibility ceases.
- 15.3.2 After the final inspection, products are protected and stored in adequate conditions to prevent damage and deterioration.
- 15.3.3 Exterior marking of packages is determined by Sales (in accordance with Section 3, Contract Review), and specified on the shipping order.

15.4 Reference Procedures

- 15.4.1 Product Handling (2PR000002)
- 15.4.2 Product Storage (2PR000003)
- 15.4.3 Product Packaging and Delivery (2PR000004)
- 15.4.4 Contract Review Standard (2SA000001)
- 15.4.5 ANSI/ISO/ASQ 9001
- 15.4.6 SAE AS9100
- 15.4.7 ISO/IEC 17025

16 QUALITY RECORDS

Company Policy

Quality records demonstrate achievement of the required quality and effective operation of the quality system. The records are identified, indexed and stored in a suitable environment to minimize deterioration and to ensure they are readily retrievable. Records are normally stored by the department that is responsible for their establishment. Retention periods for quality records are defined.

16.1 Identification and Storage

- 16.1.1** Records are identified to the product, person or activity involved. When relevant, they are signed and dated. The indexing system facilitates retrieval. Subcontractor quality records which may include records in the form of Test Reports, Certifications, or Materials Analysis are included as a part of Quality Records. When contractually required, records will be made available to the purchaser or their representative for an agreed period of time.
- 16.1.2** All inspection and test records indicating FAA-PMA/TSOA part acceptance will be retained for at least ten (10) years after the part has been completed.

16.2 Reference Procedure

- 16.2.1** Quality Records (2QA000002)
- 16.2.2** ANSI/ISO/ASQ 9001
- 16.2.3** SAE AS9100
- 16.2.4** ISO/IEC 17025

17 INTERNAL AUDITS

Company Policy

Comprehensive, planned and documented internal audits are carried out at least once a year. The internal audits verify the effectiveness of the quality management system, and verify that the quality activities comply with the established, planned arrangements. With sufficient notice, outside audits, by any bodies (i.e. suppliers, customers, regulatory) are welcomed at any time.

17.1 General

- 17.1.1** Audits are scheduled on the basis of the status and importance of the activity.
- 17.1.2** In addition to the applicable standards, internal audits are designed to meet contractual and/or regulatory requirements.
- 17.1.3** Audits are conducted by individuals independent of the area being audited.
- 17.1.4** Management having responsibility for the audited area, shall review, agree, and correct any deficiencies highlighted by the audit within an agreed time period.
- 17.1.5** Sections 17.1.1 thru 17.1.4 will encompass all internal departments, Environmental systems and OTTO's FAA Repair Station.

17.2 Follow Up

- 17.2.1** Nonconforming conditions are followed up as a result of corrective action. The corrective action process will be in accordance with Section 14, Corrective Action.

17.3 Reference Procedure

- 17.3.1** Internal/External Quality Audits (2QA000011)
- 17.3.2** Outgoing Final Inspection (3QA000040)
- 17.3.3** Production Line Certification Procedure (3QA000135)
- 17.3.4** ANSI/ISO/ASQ 9001
- 17.3.5** SAE AS9100
- 17.3.6** ISO/IEC 17025

18 TRAINING

Company Policy

OTTO identifies training needs of all personnel and provides the required training. Personnel performing specific tasks which affect quality are qualified. Records of personnel qualifications and training are maintained.

18.1 Training Needs

- 18.1.1** Tasks and activities are assessed to determine education, training and/or experience qualifications.
- 18.1.2** Employees are assessed initially and periodically by their managers to determine if their qualifications are adequate or if additional training is needed.

18.2 Training

- 18.2.1** OTTO provides new employee orientation. Other training is provided as required.

18.3 Training Record

- 18.3.1** The Human Resources department maintains records of all internal and external training provided to employees.

18.4 Reference Procedures

- 18.4.1** Training (2HR000001)
- 18.4.2** ANSI/ISO/ASQ 9001
- 18.4.3** SAE AS9100
- 18.4.4** ISO/IEC 17025

18.1 REPAIR STATION TRAINING

Company Policy

OTTO Engineering identifies training needs of all personnel and provides the required training. Personnel performing specific tasks which affect quality are qualified. Records of personnel qualifications and training are maintained.

18.1.1 Training Needs

- 18.1.1.1 Tasks and activities are assessed to determine education, training and/or experience qualifications.
- 18.1.1.2 Employees are assessed initially and periodically by their managers to determine if their qualifications are adequate or additional training is needed.
- 18.1.1.3 Inspection personnel are trained thoroughly with all inspection methods, techniques and equipment.
- 18.1.1.4 OTTO provides new employee orientation. Other training is provided as required.
- 18.1.1.5 Where required, Human Factors training shall be incorporated within all related inspection activities.

18.1.2 Training Records

- 18.1.2.1 The Human Resources department maintains records of all internal and external training provided to employees.
 - 18.1.2.1.1 Employees who are associated with the company's FAA Repair Station are also a part of the company's random drug testing program described in 3HR000038 (OTTO's FAA Random Drug Testing Program).
 - 18.1.2.1.2 FAA Rosters are maintained by Human Resources via a Network database system. These records will include, but not be limited to:
 - 18.1.2.1.2.1 A roster with all the names of all inspection personnel,
 - 18.1.2.1.2.2 A roster of personnel authorized to sign a maintenance release for approving a maintained or altered article for return to service,
 - 18.1.2.1.2.3 A summary of employment of each individual on the roster,
 - 18.1.2.1.2.4 Present title,
 - 18.1.2.1.2.5 Total years of experience and the type of maintenance work performed, and
 - 18.1.2.1.2.6 Type of certificate held.
 - 18.1.2.1.3 Employees who are responsible for returning all FAR Part 145 product to service will be required to comply with the requirements set forth in FAR Part(s) 43, 65, and 145.
 - 18.1.2.1.4 If changes shall occur to the roster, due to termination, reassignment, change in duties or scope of assignment, or addition of personnel, notification shall be submitted to the FAA district office in accordance with the procedures stated in 145.209 (e) of Part 14.

18.1.3 Reference Procedures

- 18.1.3.1 Training (2HR000001)
- 18.1.3.2 Training System (3HR000019)
- 18.1.3.3 FAA Roster and Drug Testing Program (3HR000038)
- 18.1.3.4 ANSI/ISO/ASQ 9001
- 18.1.3.5 SAE AS9100
- 18.1.3.6 ISO/IEC 17025

19 SERVICING

Company Policy

When servicing is specified by contract, OTTO shall perform and verify that the serviced item has met the specified requirements.

19.1 F.A.A Regulations

19.1.1 In accordance with Federal Aviation Regulations 21.3, the FAA Engineering office will be informed within 24 hours by the Director of Quality Systems, of any failure, malfunctions, or defects that have occurred in OTTO Engineering, Inc. manufactured products that he has determined will, or could, result in a hazardous flight. All users will be notified, when possible.

19.1.2 Airworthiness Directives will be handled with Local Aircraft Certification Office in accordance with 14 CFR Part 39.

19.2 Reference Procedures

19.2.1 ANSI/ISO/ASQ 9001

19.2.2 SAE AS9100

19.2.3 ISO/IEC 17025

19.2.4 Contract Review Standard (2SA000001)

20 STATISTICAL TECHNIQUES

Company Policy

Statistical techniques are employed to verify the acceptability of product characteristics, and to control and verify process capability.

20.1 Process Analysis and Statistical Sampling

- 20.1.1** When appropriate, process analysis and statistical sampling are applied to verify acceptability. Personnel using statistical techniques are provided with charts, tables and other instructions.
- 20.1.2** Statistical Process Control (SPC) is employed as a tool to control processes, and to aid in establishing and verifying process capabilities. Personnel using SPC techniques are trained and provided with instructions as to the use of such. This program will: demonstrate conformity of the product, ensure conformity of the quality management system, and continually improve the effectiveness of the quality management system.
- 20.1.3** According to the nature of the product, and depending on the specified requirements, statistical techniques may be used to support:
- 20.1.4** Design Verification.
- 20.1.5** Process Control.
 - 20.1.5.1** Selection and inspection of key characteristics,
 - 20.1.5.2** Process capability measurements,
 - 20.1.5.3** Statistical process control, and
 - 20.1.5.4** Design of Experiment.
- 20.1.6** Inspection – matching sampling rate to the criticality of the product and to the process capability.
- 20.1.7** Failure mode and effects analysis.

20.2 Reference Procedure

- 20.2.1** ANSI/ISO/ASQ 9001
- 20.2.2** SAE AS9100
- 20.2.3** ISO/IEC 17025

21 CONFIGURATION MANAGEMENT

Company Policy

The activities to direct and control the interrelated functional and physical characteristics of requirements for product design, realization, verification, operation and support are coordinated through various departments, and their related procedures. Each of OTTO's products, processes, machinery, and procedures (termed configurable items, hereafter) have an established baseline. This serves as a reference for activities throughout the life cycle of the given configurable item.

21.1 General

- 21.1.1** Changes to any of the configurable items shall be reviewed, and approved by the applicable dispositioning authorities as defined by the applicable procedures for the given configurable item.
- 21.1.2** Dependent on the configurable item, a timeline for implementation is to be established, managed, and maintained to completion.
- 21.1.3** Changes are controlled by the opposing system as listed below:
 - Documents/Drawings
 - Control Plan/Routings
 - Vendors/Tooling / Process
 - New Products/Design Control
 - ISO Change Notice
 - ECN – Engineering Change Notice
 - RCN – Router Change Notice
 - VOC – Validation of Change
 - New Product Development Procedure
- 21.1.4** Established baselines for product will be governed in document 2EN000004

21.2 Configuration Identification

- 21.2.1** Employees who are establishing, and approving changes to the configurable items shall use any related tool/resource to make the most appropriate change.
 - 21.2.1.1** Those items which have been flagged as a controlled item, shall also seek the guidance of the controlling source (i.e. a customer, or regulatory agency).
- 21.2.2** Configurable items which have been changed shall have appropriate revision control indicating that a change has been approved for use. The latest revision will be available within OTTO's ERP system.
 - 21.2.2.1** All employees shall have the ability to have access to the latest documentation.

21.3 Reference Procedures

- 21.3.1** System Documentation (2QA000016)
- 21.3.2** Update/Modify Production and Machine Shop Control Plan and Routings (3QA000161)
- 21.3.3** Quality Functions for Product/Process Development (2QA000021)
- 21.3.4** Product Development Procedure (2EN000004)
- 21.3.5** Design Control (2EN000001)
- 21.3.6** Engineering Change Notice Procedure (3QA000159)
- 21.3.7** Document Control (2QA000017)
- 21.3.8** Part Numbering and BOM Guidelines (3EN000015)
- 21.3.9** Management of Customer Documentation and Control Documentation (3SA000029)
- 21.3.10** Sequence and Interaction of Key QMS Processes (2QA000025)
- 21.3.11** ISO Change Notice Procedure (3QA000327)
- 21.3.12** SAE AS9100
- 21.3.13** ISO/IEC 17025