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Title: **ATS Global Quality Policy Manual**

Document Number: C4.3-1M

Effective Date: April 14, 2017

Authorized By: Global Director, Mission Assurance & Compliance





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## 1.0 ATS GLOBAL QUALITY POLICY

ATS is committed to 100% total customer satisfaction and compliance with regulatory requirements.

Every ATS employee is committed to meet Customer Requirements (Cost, Schedule and Quality).

By continuously improving the operation, we will contribute to the success of our customers, employees, suppliers and stakeholders. ***(Applicable to 9001 divisions only)***

By continuously improving our processes and maintaining the effectiveness of the quality system, we will contribute to the success of our customers, employees, suppliers, and stakeholders. ***(Applicable to 13485 divisions only)***

## 2.0 THE ATS VISION

Delivery excellence in innovative manufacturing solutions to the world's most successful companies.

## 3.0 THE ATS MISSION

We will achieve our Vision by providing:

- Outstanding value to our Customers globally.
- Superior financial return to our Shareholders.
- A premier work environment and career opportunities for Employees.

We will accomplish our Mission by:

- Differentiating ourselves by providing outstanding value through the practical and innovative application of state of the art technologies.
- Maintaining focus on our core business of providing automated manufacturing solutions to companies in diverse industries.
- Developing long term relationships with key customers.
- Enhancing our ability to serve key customers by utilizing our technological strengths to manufacture high Quality component parts and assemblies, and provide related services.
- Creating a distinct, high-performance workplace where all employees build success for their customers and for their careers.



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## 4.0 CORE VALUES

We believe that observance of the following **values** is fundamental to the success of our business. These **values** will be reflected in our long-term objectives as well as our current year objectives:

### **Customer Focused**

Our future depends on our contributions to our customers' success. We will exceed our customers' expectations, deliver on our commitments, and treat our customers with professionalism, courtesy and respect.

### **Profitability is Essential**

Long term viability of ATS can only be achieved if adequate profits are generated on a regular basis to make investments for the future in employee training, product development and facilities. This will provide our customers, employees, suppliers and shareholders with security and stability.

### **A Dedication to High Quality**

This must be inherent in all aspects of our operations, products, and services, and reflected in the way we function as an operation. Every employee is responsible for meeting or exceeding the expectations of those who depend upon him/her.

### **Fostering Innovation Through Controlled Risk**

We must continue the entrepreneurial spirit and innovative use of technology that made ATS a leader in its markets. Risk taking will be controlled and undertaken with the understanding that not all innovations are successful.

### **Continuous Improvement**

We believe that in all aspects of our business it is essential to continuously raise the standards of acceptance and efficiency. The search for excellence must never stop.

### **Human Resources Are Our Most Valuable Asset**

Our foremost competitive edge is the Quality of our people. We will promote a sense of teamwork and unity through effective two-way communication, showing respect for the individual along with just and fair management practices.

### **Be A Good Corporate Citizen**

We will be a good corporate citizen. We will take pride in the appearance of our properties, show respect for the environment, and conduct our business in a socially responsible manner. We will join with our employees in supporting the communities where we are located.

### **Ethical Business Practices Will Not Be Compromised**

We will apply the "Golden Rule" and treat others as we wish to be treated. This applies to relationships with customers, suppliers as well as our fellow employees.



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## 5.0 ORGANIZATION AND AUTHORITY FOR QUALITY

The ultimate authority within the ATS management structure shall be the CEO. The management of the Global Quality System has been assigned to the Global Director Mission Assurance & Compliance and is appointed as the Global Quality Management Representative. These responsibilities include:

- The task of ensuring actions have been taken to achieve planned results and overall maintenance to ensure on going effectiveness of the Global QMS
- The promotion of awareness of customer requirements throughout the organization and for liaison with external parties on matters relating to the business management system.
- Initiate, recommend or provide solutions to quality problems in accordance with the Quality Manual
- Verify implementation of quality solutions
- Assure that further processing, delivery, installation or use as is controlled until proper disposition of a nonconformance, deficiency or unsatisfactory condition has occurred
- Stop an operation, test or shipment in order to verify that all Quality and contract requirements have been achieved;
- Notify Executive Management when a stop work order has been issued.
- Ensuring that business operating procedures, to implement the requirements of the ISO 9001, ISO 13485, CSA Z299.1, CSA N285.0, CSA N286 & CSA B51 programs, are developed and maintained

## 6.0 QUALITY MANAGEMENT SYSTEM SCOPE

The organization's business management system conforms to ISO 9001:2015. The global Quality Management system scope is:

Region	Site Information	Business Scope
CANADA	ATS Automation Inc., Building 1 730 Fountain Street North Cambridge, ON. N3H 4R7	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
CANADA	ATS Automation Inc., Building 3 730 Fountain Street North Cambridge, ON. N3H 4R7	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
CANADA	ATS Test Inc., 600 Chrislea Road, Woodbridge, ON. L4L 8K9	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment



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<b>CANADA</b>	ATS Automation Systems Inc., Building 2, 730 Fountain Street North, Cambridge, ON. N3H 4R7	Manufacture, commission and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
<b>USA</b>	ATS Carolina Inc., 1510 Cedar Line Drive, Rock Hill, SC 29730	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
<b>USA</b>	ATS Ohio Inc., 425 Enterprise Drive, Lewis Center, OH 43035	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
<b>USA</b>	ATS Assembly & Test Inc. 1 ATS Drive, Wixom, MI 48393	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
<b>USA</b>	ATS sortimat USA LLC – 5655 Meadowbrook Industrial Court Rolling Meadows, IL 60008	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
<b>USA</b>	PA Solutions Inc. 25560 Mound Rd. Warren, MI 48091	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
<b>USA</b>	PA Solutions Inc. 1045 Keys Drive Greenville, SC 29615	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
<b>USA</b>	PA Solutions Inc. 3011 Dublin Circle, Bessemer, AL 35022	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
<b>Mexico</b>	PA Solutions Inc. La Martine 115, Piso/Floor 4 Col. Polanco Del Miguel Hidalgo C.p. 11560, Mexico, D.F.	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
<b>GERMANY</b>	ATS Automation Tooling Systems GmbH, Marsstrasse 2 D-85551 Heimstetten, Germany	Providing solutions in the custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
<b>GERMANY</b>	sortimat Assembly & Feeder Technology a branch of ATS Automation Tooling Systems GmbH, Birkenstrasse 1 - 7 71364 Winnenden, Germany	The custom design, manufacture, commission, and service of feeder and assembly technology for the pharmaceutical and medical device industry.



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<b>GERMANY</b>	sortimat International Inc., - Birkenstrasse 1 - 7 71364 Winnenden, Germany	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
<b>GERMANY</b>	sortimat Handling Systems Niederlassung der ATS Automation Tooling Systems GmbH, Am Tannwald 2, St. Georgen, Germany 78112	The design, production, commission and service of handling technology.
<b>GERMANY</b>	IWK Verpackungstechnik GmbH Lorenzstr, 6-D, 76297 Stutensee, Germany	Design & Development, Manufacturing and Sales of Packaging Machines and Packaging Lines for the Pharmaceutical and Cosmetics Industry. <i>THIS SITE IS NOT CONTROLLED UNDER THE GLOBAL CERTIFICATION</i>
<b>GERMANY</b>	ATW Assembly & Test - Europe GmbH - Carl-Borgward Strasse 11 56566, Neuwied, Germany	Design, manufacture, installation, commissioning, and service of assembly and test equipment, including associated software development. <i>THIS SITE IS NOT CONTROLLED UNDER THE GLOBAL CERTIFICATION</i>
<b>MALAYSIA</b>	ATS Automation Malaysia SDN BHD - Plot 221, Lorong Perindustrian Bukit Minyak 11, Mukim 13, Kawasan Perindustrian Bukit Minyak, 14000 Bukit Mertajam, Seberang Perai Tengah, Penang, Malaysia	The manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment
<b>THAILAND</b>	IWK (Thailand) Limited 888/45, Moo 19, Soi Yingcharoen, Bangplee-Tamru Rd, Tamboi Bangpleeyai, Amphur Banglee, Samutprakarn 10540, Thailand	Development and Manufacturing of Packaging Machines. <i>THIS SITE IS NOT CONTROLLED UNDER THE GLOBAL CERTIFICATION</i>
<b>CHINA</b>	ATS Automation Asia (Tianjin) Co., Ltd. -12-2 XEDA Century Road, Xiqing Economic Development Area, Tianjin, China.	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment

The organization's business management system conforms to ISO 13485:2016 as applicable to specific divisions. The Quality Management system scope for these divisions is as follows:

<b>CANADA</b>	ATS Automation Systems Inc - APG <b>Building 2</b> , 730 Fountain Street North Cambridge, ON. N3H 4R7	Manufacture/ contract manufacture, commission, service, functional testing for the pharmaceutical and medical device industry including applications in: <ul style="list-style-type: none"> <li>• Turnkey automation systems &amp; equipment</li> <li>• Assembly technology</li> <li>• Servicing for clinical chemistry systems</li> <li>• Equipment for CT scan systems</li> </ul>
<b>CANADA</b>	ATS Automation Systems Inc., Building 3, 730 Fountain Street North, Cambridge, ON. N3H 4R7	The custom design, manufacture, commission, and service of computerized instrumentation, functional testing, and turnkey automation systems and equipment



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<b>GERMANY</b>	sortimat Assembly & Feeder Technology a branch of ATS Automation Tooling Systems GmbH Birkenstrasse 1 - 7 71364 Winnenden, Germany	The custom design, manufacture, commissioning and service of feeder and assembly technology for the pharmaceutical and medical device manufacturing industry
<b>USA</b>	ATS sortimat USA LLC – 5655 Meadowbrook Industrial Court Rolling Meadows, IL 60008	The custom design, manufacture, commission, service, spare parts and functional testing for the pharmaceutical and medical device industry including applications in: Turnkey automation systems & equipment, Feeder technology and Assembly technology.

## 7.0 PERMISSIBLE EXCLUSIONS & NON APPLICABLE ITEMS

The ATS management system scope conforms to the requirements of ISO 9001:2015 & ISO 13485:2016 with the following permissible exclusions and non-applicable items:

### 7.1 CANADA – APG (BUILDING 2):

#### Exclusions:

ISO 13485:2016 (E):

- Clause 7.3..... Design and development Planning
- Clause 7.3.1.....General
- Clause 7.3.2.....Design and development planning;
- Clause 7.3.3.....Design and development inputs;
- Clause 7.3.4.....Design and development outputs;
- Clause 7.3.5.....Design and Development Review;
- Clause 7.3.6.....Design and development verification;
- Clause 7.3.7.....Design and development validation
- Clause 7.3.8.....Design and Development Transfer
- Clause 7.3.9.....Control of Design and Development Changes
- Clause 7.3.10..... Design and Development Files

#### Non Applicable Items:

ISO 9001:2015 (E):

- Clause 8.3.1.....General
- Clause 8.3.2.....Design and Development Planning
- Clause 8.3.3.....Design and Development Inputs
- Clause 8.3.4.....Design and Development Controls
- Clause 8.3.5.....Design and Development Outputs
- Clause 8.3.6.....Design and Development Changes





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The Automation Products Group – Cambridge Division of ATS Automation Tooling Systems does not design or develop products. Customers specify all tooling and product requirements. Engineering activities are limited to design and development of manufacturing processes, and thus ISO 9001 clause 8.3 and ISO 13485 clause 7.3 are not applicable.

### **NON-APPLICABLE ITEMS, ISO 13485:2016(E)**

- Clause 6.4.2.....Contamination Control (sterile medical device requirement only)
- Clause 7.5.2.....Cleanliness of Product
- Clause 7.5.3.....Installation activities
- Clause 7.5.5.....Particular Requirements for Sterile Medical Devices
- Clause 7.5.7.....Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems
- Clause 7.5.9.2.....Particular Requirements for Implantable Medical Devices
- Clause 8.2.6.....Monitoring & Measurement of Product (implantable device requirement only)

#### **Justification for no applicable sections:**

APG - Cambridge Division of ATS does not have any customer or regulatory obligations to support cleanliness of product, installation, requirements to support particular requirements for sterile medical devices or for the validation of processes for sterilization/sterile and implantable medical devices thus clauses 6.4.2, 7.5.2, 7.5.3, 7.5.5, 7.5.7 and 7.5.9.2 and 8.2.6 (implantable device requirement only) under the ISO 13485 standard are not applicable.

### **7.2 CANADA – CAMBRIDGE: BUILDING #3**

#### **NON-APPLICABLE ITEMS, ISO 13485:2016(E)**

The following sections of the ISO 13485:2016 standard are not applicable to the scope of registration:

- Clause 4.2.3.....Medical Device File
- Clause 6.4.2.....Contamination Control (sterile medical device requirement only)
- Clause 7.3.10.....Design and Development Files
- Clause 7.5.2.....Cleanliness of Product
- Clause 7.5.3.....Installation activities
- Clause 7.5.4.....Servicing Activities
- Clause 7.5.5.....Particular Requirements for Sterile Medical Devices
- Clause 7.5.7.....Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems
- Clause 7.5.9.2.....Particular Requirements for Implantable Medical Devices
- Clause 7.5.11.....Preservation of Product



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- Clause 8.2.6.....Monitoring & Measurement of Product (implantable device requirement only)

**Justification for exclusion of specified sections:** ATS Cambridge is not a medical device manufacturer and only provides equipment/tooling to this industry. ATS does not have any customer or regulatory obligations to support cleanliness of product, installation, requirements to support particular requirements for sterile medical devices or for the validation of processes for sterilization/sterile and implantable medical devices thus clauses 4.2.3, 6.4.2, 7.3.10, 7.5.2, 7.5.3, 7.5.4, 7.5.5, 7.5.7, 7.5.9.2 and 8.2.6 (implantable devices requirement only) under the ISO 13485 standard are not applicable.

### **7.3 SORTIMAT GERMANY – WINNENDEN**

#### **NON-APPLICABLE ITEMS, ISO 13485:2016(E)**

- Clause 4.2.3.....Medical Device File
- Clause 6.4.2.....Contamination Control (sterile medical device requirement only)
- Clause 7.3.10.....Design and Development Files
- Clause 7.5.2.....Cleanliness of Product
- Clause 7.5.3.....Installation activities
- Clause 7.5.4.....Servicing Activities
- Clause 7.5.5.....Particular Requirements for Sterile Medical Devices
- Clause 7.5.7.....Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems
- Clause 7.5.9.2.....Particular Requirements for Implantable Medical Devices
- Clause 7.5.11.....Preservation of Product
- Clause 8.2.6.....Monitoring & Measurement of Product (implantable device requirement only)

**Justification for exclusion of specified sections:** sortimat is not a medical device manufacturer and only provides equipment/tooling to this industry. sortimat does not have any customer or regulatory obligations to support cleanliness of product, installation, requirements to support particular requirements for sterile medical devices or for the validation of processes for sterilization/sterile and implantable medical devices thus clauses 4.2.3, 6.4.2, 7.3.10, 7.5.2, 7.5.3, 7.5.4, 7.5.5, 7.5.7, 7.5.9.2, 7.5.11 and 8.2.6 (implantable devices requirement only) under the ISO 13485 standard are not applicable.



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## 7.4 SORTIMAT USA:

### NON-APPLICABLE ITEMS, ISO 13485:2016(E)

- Clause 4.2.3.....Medical Device File
- Clause 6.4.2.....Contamination Control (sterile medical device requirement only)
- Clause 7.3.10.....Design and Development Files
- Clause 7.5.2.....Cleanliness of Product
- Clause 7.5.3.....Installation activities
- Clause 7.5.4.....Servicing Activities
- Clause 7.5.5.....Particular Requirements for Sterile Medical Devices
- Clause 7.5.7.....Particular Requirements for Validation of Processes for Sterilization and Sterile Barrier Systems
- Clause 7.5.9.2.....Particular Requirements for Implantable Medical Devices
- Clause 7.5.11.....Preservation of Product
- Clause 8.2.6.....Monitoring & Measurement of Product (implantable device requirement only)

**Justification for non applicable of specified sections:** sortimat is not a medical device manufacturer and only provides equipment/tooling to this industry. sortimat does not have any customer or regulatory obligations to support cleanliness of product, installation, requirements to support particular requirements for sterile medical devices or for the validation of processes for sterilization/sterile and implantable medical devices thus clauses 4.2.3, 6.4.2, 7.3.10, 7.5.2, 7.5.3, 7.5.4, 7.5.5, 7.5.7, 7.5.9.2, 7.5.11 and 8.2.6 (implantable devices requirement only) under the ISO 13485 standard are not applicable.

## 7.5 Malaysia, Penang:

### Non Applicable Items:

ISO 9001:2015 (E):

- ISO 9001:2015 (E):
- Clause 8.3.1.....General
- Clause 8.3.2.....Design and Development Planning
- Clause 8.3.4.....Design & Development Controls
- Clause 8.3.5.....Design and Development Outputs
- Clause 8.3.6.....Design and Development Changes

The Penang, Malaysia Division of ATS Automation Tooling Systems does not design or develop products or tooling. Customers specify all tooling and product requirements. The engineering activities are limited to design and development of manufacturing processes, and thus ISO 9001 clause 8.3 will not apply.



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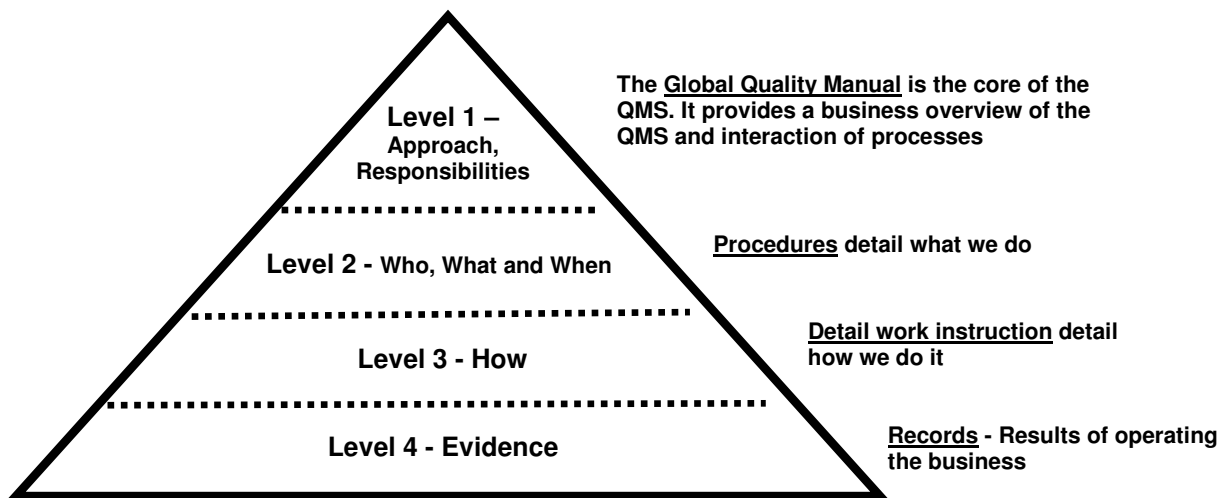
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## 7.6 CANADIAN GOVERNING REGULATIONS (as required by contract)

The Canadian Medical Device Regulations – SOR/98-282, FDA GMP 21 CFR part 820 regulations govern the components and assemblies produced by ATS APG for the medical device industry. Audits will be conducted in accordance with the ISO13485 Standard. The following reference documents could be used for guidance, the Canadian Medical Device Conformity Assessment System - CMDCAS and FDA regulations.

## 8.0 ATS BUSINESS AND QUALITY MANAGEMENT SYSTEM STRUCTURE

### 8.1 QMS STRUCTURE



The organization’s quality system supports its policy and objectives and is focused on delivering products and services that enhance customer satisfaction.

The organization’s identified processes are operated under controlled conditions and are monitored, measured and analyzed to ensure ongoing effectiveness and efficiency. The effectiveness of the implemented system is determined by (not limited to): achieving objectives, customer satisfaction and continual improvement. Corporate scorecards shall be submitted monthly to the Global Director, Mission Assurance & Compliance. An action plan shall be submitted for any scores identified as red to mitigate risk in accordance with C8.5.1-2P, Global KPI Requirements.



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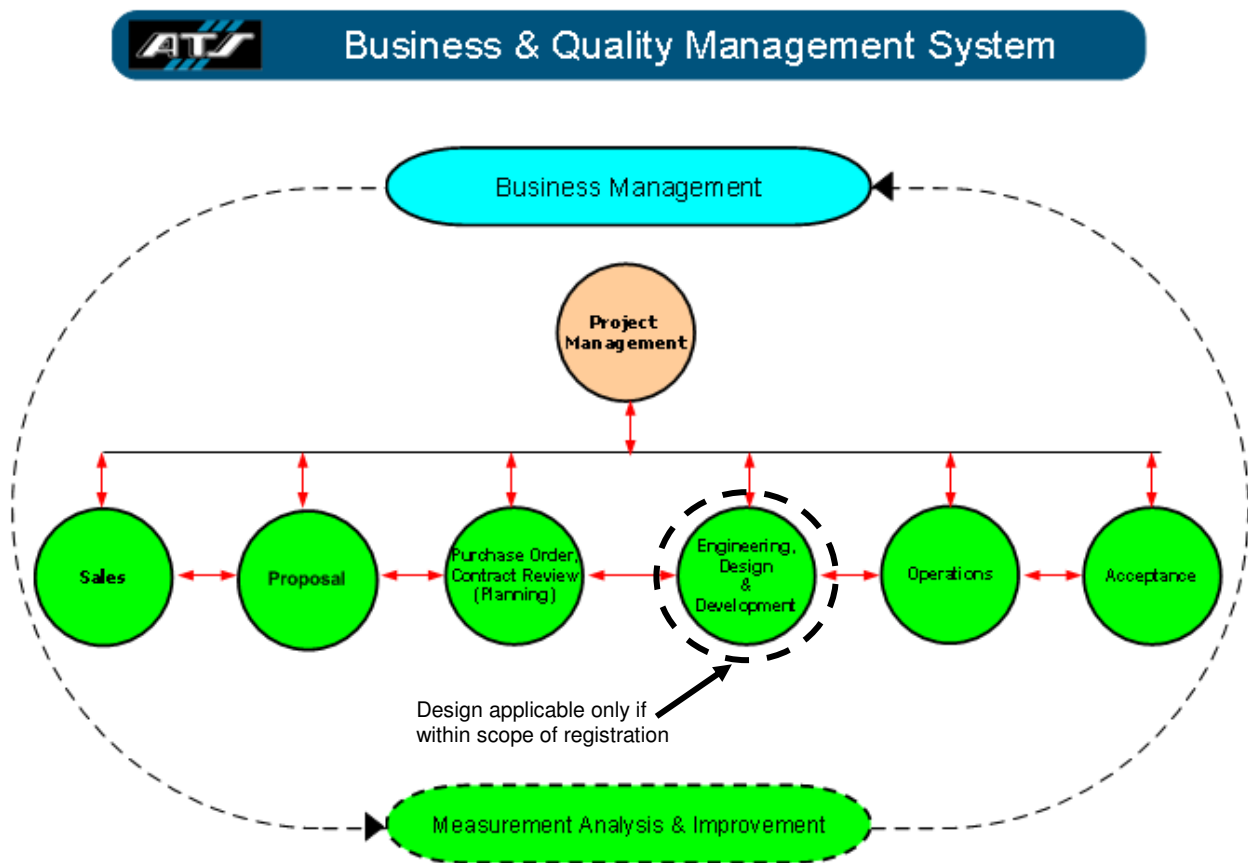
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Corporate Quality communications and updates shall be the responsibility of the Global Director, Mission Assurance & Compliance. Communications specific to the division shall be managed by the General Manager as defined by internal requirements.

The global process map document #4.1-1-1PFM located on divisional Business & Quality Management sites shall identify and correlate all QMS related procedures. All divisional specific relationships between ISO 9001:2015/ISO 13485:2016 (applicable to 13485 business units only) shall be maintained by each respective site to supplement this manual.

Document # PFM 4.1-1-1PFM:



Global ATS procedures shall be implemented and enforced by each site. Key Quality objectives will be reported to the Global Director, Mission Assurance & Compliance on monthly intervals and monitored for performance.



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The ATS Global Director, Mission Assurance & Compliance reserves the right to audit any ATS facilities as required or deemed necessary by Executive Management.

## 8.2 DOCUMENTATION REQUIREMENTS

The Quality System documentation includes:

- A Quality Policy Statement
- Business Plan, including Quality Objectives
- Global Quality Management System manual
- Documents needed by the organization to ensure the effective planning, operation and control of its processes (defined by each division), including work instructions and forms
- Records required by ATS, ISO 9001:2015 and ISO 13485:2016

8.2.1 The **Global** Quality System documentation includes the following documented procedures required **ISO 13485:2016** (reference section 10):

- **C4.2.3 Global Document Management** (ISO 13485:2016, section 4.2.4 Control of Documents)
- **C4.2.4 Global Record Control Requirements** (ISO 13485:2016, section 4.2.5 Control of Records)
- **C7.4.1-2P Global Supplier Development and Evaluation** (ISO 13485:2016, section 7.4.1, Purchasing Process)
- **C8.2.2 Global Quality Management System Program** (Internal Audit) (refer to ISO 13485:2016, section 8.2.4 Internal Audit)
- **C8.3 Global Control of Non-Conforming Material** (ISO 13485:2016, section 8.3 Control of Non-Conforming Product)
- **C8.5.1 Global Continual Improvement Process** (refer to ISO 13485:2016, section 8.5.2 Corrective Action)
- **C8.5.1-2P Global KPI Requirements** (refer to ISO 13485:2016, section 8.5.2 Corrective Action)
- **C8.5.1 Global Continual Improvement Process** (refer to ISO 13485:2016, section 8.5.3 Preventive Action)
- **C8.5.1-2P Global KPI Requirements** (refer to ISO 13485:2016, section 8.5.3 Preventive Action)
- **C8.5.1 Global Continual Improvement Process** (refer to ISO 13485:2016, section 8.2.1 Feedback)
- **C8.5.1 Global Continual Improvement Process** (refer to ISO 13485:2016, section 8.4 Analysis of Data)



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8.2.2 The **Global** Quality System documentation includes the following documented processes as required **ISO 9001:2015/ISO 13485:2016** (reference section 10):

- **C6.1-1P ATS Risk Management Process** (refer to ISO 9001:2015, section 6.1/ISO13485:2016, section 7.1)
- **C4.1-1P Global Gate Review Process** (refer to ISO 9001:2015, section 6.1/ISO13485:2016, section 7.1)
- **C4.2.1-1P Organizational Context & Interested Parties**

8.2.3 The Quality System documentation includes the following documented procedures/processes required by **ISO 13485:2016** and shall be maintained by each applicable division:

***Documented Procedures (ISO 13485):***

- Project Management; Electrical Design; Mechanical Design; Software Design; System Engineering (refer to ISO 13485:2016, section 7.3 Design and Development Planning – excluding 7.3.10)
- Purchasing (refer to ISO 13485:2016, section 7.4.1 Purchasing Information)
- Documentation of Procedures and Methods for the Control of Production (refer to ISO 13485, section 7.5.1, Control of Production and Service Provision)
- Validation (refer to ISO 13485:2016, section 7.5.6 Validation of Processes for Production and Service Provision)
- Identification; (refer to ISO 13485:2016, section 7.5.8 Identification)
- Traceability; (refer to ISO 13485:2016, section 7.5.9 Traceability)
- Shelf Life Materials (refer to ISO 13485:2016, section 7.5.11 Preservation of Property)
- Calibration (refer to ISO 13485:2016, section 7.6 Control of Monitoring and Measuring Equipment)
- Advisory Notice (refer to ISO 13485:2016, section 8.2.3 Reporting to Regulatory Authorities)

***Documented Requirements/Arrangements:***

- Monitoring of Product (refer to ISO 13485:2016, section 8.2.6)
- Preventive Maintenance (refer to ISO 13485:2016, section 6.3 Infrastructure)
- Work Environment, Health & Safety (refer to ISO 13485:2016, section 6.4.1, Work Environment)



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#### 8.2.4 **ATS Procedure Requirements for ISO 9001 registered divisions:**

Divisions shall maintain documented procedures and associated templates for the following processes at minimum:

- Design & Development, Design Verification, Design Review, Design Revisions and Change Control (refer to ISO 9001:2015, section 8.3, Design & Development of Products and Services)
- Process Maps (utilized for the BQMS navigation)
- Assembly, Machining (refer to ISO 9001:2015, section 8.5, Production and Service Provisions, section 8.6 Release of Product and Services)
- Identification & Traceability, Storage, Preservation (refer to ISO 9001:2015, section 8.5.2, Identification and Traceability, 8.5.4. Preservation)
- Purchasing, Verification of Purchased items (refer to ISO 9001:2015, section 8.4, Control of Externally Provided Processes, Products and Services)
- Control of Nonconforming Product (disposition authorities) (refer to ISO 9001:2015, section 8.7, Control of Nonconforming Outputs)
- Service Processes (refer to ISO 9001:2015, section 8.5, Production and Service Provisions)
- Training Requirements, Competence, Roles, Responsibilities and Authority (refer to ISO 9001:2015, section 7.1.6, Organizational Knowledge, 7.2, Competence, 7.3 Awareness)
- Calibration Requirements (refer to ISO 9001:2015, section 7.1.5.2, Measurement Traceability)
- Program Management (refer to ISO 9001:2015, section 8.1, Operational Planning and Control)
- Preventative Maintenance of equipment/building (refer to ISO 9001:2015, section 7.1.3, Infrastructure - documented process is required)





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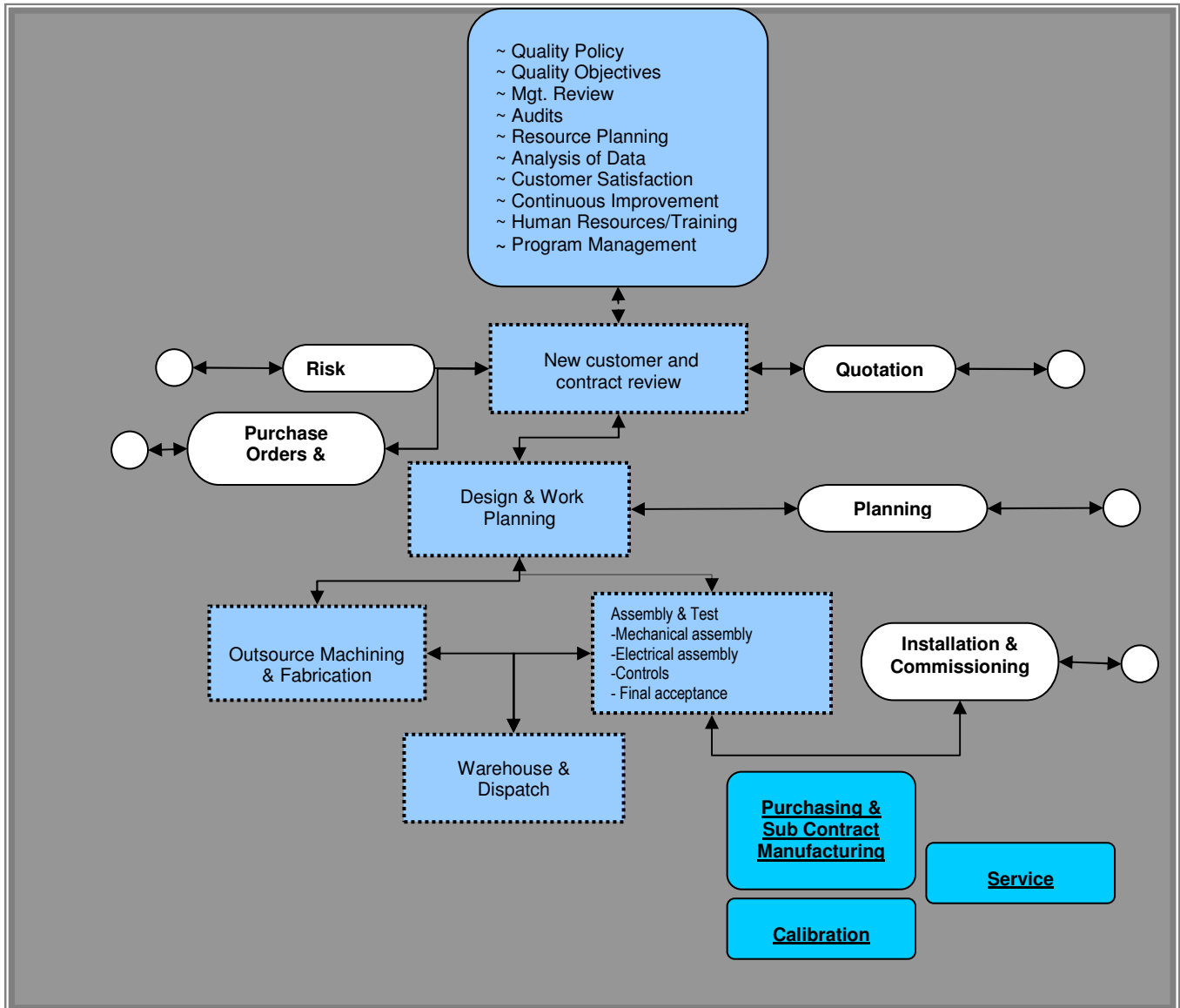
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## 9.0 PROCESS INTERACTIONS OVERVIEW (Reference scope for applicable items per division)





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## 10.0 DOCUMENT MATRIX FOR KEY GLOBAL DOCUMENTATION

The relationship between the organizations's documented procedures and the requirements of ISO 9001:2015 & ISO 13485:2016 are described below. These procedures are mandatory unless otherwise approved by the Global Director, Mission Assurance & Compliance.

Document Ref No.	Global Quality Management Procedures	Standard Cross Reference	Standard Cross Reference
		ISO9001	ISO 13485
C4.3-1M	Global Quality Policy Manual	ATS Requirement	4.2.2
C7.4.1-1M	Global Supplier Quality Manual	7.4.1, 7.4.2	7.4.1, 7.4.2
C4.2.3	Global Document Management	7.5	4.2.4
C4.2.4	Global Record Control Requirements	4.2.4	4.2.5
C5.6	Global Management Review Process	9.3	5.6
C7.4.1	Global Supplier Performance System	8.4, 9.1.3, 10.0	7.4, 8.4, 8.5.2, 8.5.3
C7.4.1-2P	Global Supplier Development & Evaluation	8.4.1	7.4.1
C8.2.2	Global Quality Management System Program	9.2	8.4
C8.3	Global Control of Nonconforming Product	8.7	8.3
C8.5.1 C8.5.1-2P	Global Continual Improvement Process Global KPI Requirements	9.1.1, 9.1.2, 10.1, 10.2, 10.3	8.5.2, 8.5.3, 8.5.1, 8.2.1, 8.4
C7.3.6-1P	Global Acceptance Test Plan	8.2.4, 7.3.6, 7.5.1	8.2.6, 7.3.7,
C4.1-1P	Global Gate Review Process	6.1, 4.4.1	4.1.2, 7.1
C6.1-1P	ATS Risk Management Process	6.1, 4.4.1	4.1.2, 7.1
C4.2.1-1P	Organizational Context & Interested Parties	4.1, 4.2	NA