

## **1.0 Purpose/Scope**

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- 1.1 The purpose of this procedure is to describe the system that provides controlled conditions under which the key product realization processes are performed at ACCES I/O Products.
- 1.2 The procedure also applies to the release of products and services, the post-delivery activities, the control of customer or external provider property, and the control of changes.

## **2.0 Responsibilities and Authorities**

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- 2.1 The Production Manager has the prime responsibility and approval authority for this procedure.
- 2.2 In support of the Production Manager, the Quality Team is responsible to ensure that processes are performed under controlled conditions.
- 2.3 Additional responsibilities are detailed in relevant paragraphs of section 5.0 below.

## **3.0 References and Definitions**

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### **3.1 References**

3.1.1 This document relates to the following requirements of ISO 9001:2015:

- Sub-clause 8.5.1, Control of production and service provision,
- Sub-clause 8.5.3, Property belonging to customers or external providers,
- Sub-clause 8.5.5, Post-delivery activities,
- Sub-clause 8.5.6, Control of changes,
- Clause 8.6, Release of products and services.

### **3.2 Definitions**

3.2.1 Key product realization processes: Processes that contribute or result in the product being produced or the product being provided.

3.2.2 Product Realization: Processes, from customer input through delivery and service that lead to the creation of the final product or service.

## **4.0 Resources**

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- 4.1 None

## 5.0 Instructions

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- 5.1 In support of the planning procedures P 810-001 for Operational planning and control, and P 910-001 for Monitoring, measurement, analysis and evaluation, this procedure addresses the control of production and service provision.
- 5.1.1 The ISO Management Representative ensures that production and service provision is implemented under controlled conditions.
- 5.1.2 The ISO Management Representative ensures that documented information for production and service provision are included in the Document Matrix, F 750-003.
- 5.2 A suitable infrastructure and process environment are provided where product realization processes are controlled and managed to achieve product conformance and continual improvement.
- 5.3 Product realization processes are planned or designed with the procedure P 810-001 for Operational planning and control and procedure P 830-001 for Design and development.
- 5.3.1 The planning includes the identification and implementation of actions to prevent human error.
- 5.3.2 The design output identifies the required controls for the processes.
- 5.4 Documented information, such as product specifications and criteria for workmanship, define the characteristics of the products and services and results to be achieved using F 851-006, Work Order Traveler, F 851-007, Work Order Picking list and/or F 851-008 Bill of Materials Picking Sheet.
- 5.4.1 Resulting production documentation consists of information packages which may include:
- Documented information, such as routers, drawings, parts lists or process flow charts that define the sequence of operations and activities required to be performed and the results to be achieved. Clear and practical instructions are provided for the assembly, test, inspect, and accept and release of production or service.
- 5.5 Monitoring and measurement resources are provided. Related activities at appropriate stages are performed to verify that criteria for control of processes and process outputs, and acceptance criteria for products and services are met.
- 5.5.1 The procedure P 910-001 for Monitoring, measurement, analysis, and evaluation identifies process inspection and test points, process monitoring requirements, tests performed, responsible person, and action criteria.
- 5.6 Production and/or Engineering reviews all processes and equipment and

- approves all quality plans, procedures, or work instructions.
- 5.7 Competent persons are appointed and all processes are performed by employees qualified with the procedure P 720-001 for Competence and awareness. Additional information is provided to employees with the procedure P 740-001 for Communication.
- 5.8 Processes where resulting output cannot be verified by subsequent monitoring or measurement are validated to demonstrate the ability of the process to achieve planned results.
- 5.8.1 The need for validation and periodic revalidation of such special processes is identified during the planning phase with procedure P 810-001 for Operational planning and control.
- 5.9 Release of products and services is performed after the verification activities at the appropriate stages ensure that product and service requirements are met.
- 5.9.1 Product release criteria and product release authority are documented on the Work Order Traveler, F 851-006.
- 5.9.2 Products and services are not released for shipment to the customer until evidence indicates that the product has been inspected and/or tested to documented requirements by qualified personnel.
- Records are maintained to provide evidence that the products or services have passed test and/or final inspection with defined acceptance criteria.
  - Records provide traceability to the person authorizing the release for delivery.
- 5.10 Trained personnel make use of documented work instructions and identified customer delivery requirements to provide the delivery services.
- 5.11 Post-delivery activities include warranty and non-warranty repairs.
- 5.11.1 The post-delivery activities that are required are determined with consideration given to the:
- Potential undesired consequences associated with the product and services,
  - Nature, use and intended lifetime of the product and services,
  - Customer feedback,
  - Statutory and regulatory requirements.
- 5.12 When property is provided from customers for service, due care is

exercised to protect and safeguard this property while it is under the control or being used by the company.

5.12.1 Property provided by customers or external providers is identified as described in the procedure P 852-001 for Identification and traceability.

5.12.2 Property is preserved and protected from damage per the procedure P 854-001 for Preservation and handling.

5.12.3 Any lost, damaged or unusable property is documented reported to the customer.

5.12.4 Intellectual property belonging to the customer or external providers is protected per confidentiality agreements with the customer.

5.13 Unplanned changes essential for production or service provision are reviewed and controlled to ensure continuing conformity with specified requirements.

5.13.1 Changes to production process instructions are controlled as follows:

- Engineering reviews and approves all changes to production processes. Affected persons are trained when processes are changed.
- Customer or statutory and regulatory authority approvals are obtained as required by contracts or regulations.
- Changes are recorded in production documentation and documented and dated in routers, drawings, parts lists, process flow charts, procedures and instructions as appropriate.
- Production Process changes are verified following implementation by inspection and/or test to assure changes have been implemented and the changes meet the desired effect, without adverse effect on product quality.

5.13.2 Documented information describing the results of the review of changes, the personnel authorizing the change, and any necessary actions are controlled and retained with the procedure P 750-001 for Control of documented information.

## **6.0 Forms and Documented Information**

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### **6.1 Forms**

6.1.1 F 440-001 QMS-Process Interaction

6.1.2 F 810-002 Project planning worksheet

6.1.3 F 851-003 Packing List

- 6.1.4 F 851-004 Invoice
- 6.1.5 F 851-005 Proforma Invoice
- 6.1.6 F 851-006 Work Order Traveler
- 6.1.7 F 851-007 Work Order Picking List
- 6.1.8 F 851-008 Bill of Materials Picking Sheet
- 6.2 Documented information / Related processes
  - 6.2.1 WI 851-001 Final Assembly Instructions
  - 6.2.2 WI 851-002 WO Production Process
  - 6.2.3 WI 851-003 SO Verification and WO Issuance
  - 6.2.4 WI 851-004 Finished Goods Label Printing
  - 6.2.5 WI 851-005 Processing kits for Outside Assembly
  - 6.2.6 WI 851-006 Shipping
  - 6.2.7 WI 851-007 Final Inspection
  - 6.2.8 P 600-001 Planning for the Quality management system
  - 6.2.9 P 720-001 Competence and awareness
  - 6.2.10 P 740-001 Communication
  - 6.2.11 P 750-001 Control of documented information
  - 6.2.12 P 810-001 Operational planning and control
  - 6.2.13 P 830-001 Design and development
  - 6.2.14 P 852-001 Identification and traceability
  - 6.2.15 P 854-001 Preservation and handling
  - 6.2.16 P 910-001 Monitoring, measurement, analysis, and evaluation

## **7.0 Opportunities and Risks**

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- 7.1 The planning procedure P 600-001 for Planning for the Quality management system addresses opportunities and risks (risk-based thinking).
- 7.2 ACCES I/O has identified the following risks and mitigation to those risks:


**Potential Risks:**

- 1) Parts are not labeled correctly
- 2) Preprogrammed parts are sent before programming

**Risk Mitigation:**

- 1) Assembly house may install parts incorrectly and when parts are returned, locating the bin is challenging
- 2) Rework of assembled boards

**8.0 Revision History**

Rev	Date	Section	Paragraph	Summary of change	Authorized by
A	03/03/17			Initial issue	

Uncontrolled document when printed