

## **1.0 Purpose/Scope**

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- 1.1 The purpose of this procedure is to provide for a system of identification and status of outputs at ACCES I/O Products.
- 1.2 This procedure provides for a system where information regarding the traceability of outputs is controlled and recorded.

## **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 determine the identification and traceability requirements that apply to the product outputs.
- 2.3 Additional responsibilities for the Production Manager and the Quality Team 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 clause 8.5.2 of the ISO 9001:2015 standard, Identification and traceability.
- 3.1.2 MRB – Material Review Board

## **4.0 Resources**

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- 4.1 None

## **5.0 Instructions**

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- 5.1 In support of the procedure P 851-001 for Control of Production and Service Provision, this procedure addresses the identification and traceability requirements.
- 5.2 Product identification. To ensure conformity of products and services, outputs are identified.
  - 5.2.1 Identification of purchased parts
    - Purchased parts are identified with unique part numbers. The unique part number appears on purchase orders, drawings, specifications, bill of materials and other such documents.

- All parts are marked with the unique part number or on the outside of storage bin.

#### 5.2.2 Identification of WIP (Untested assembled boards)

- Upon receipt of untested assembled boards, a work order or a label with the unique part number is present until they are stored.
- Untested assembled boards are stored in anti-static bags and labeled, with unique part number on the outside of the box.

#### 5.2.3 Identification during production

- During all stages of production, parts and boards are identified by the work order. Work orders accompany products as they move thru the production floor.

#### 5.2.4 Identification of Finished Goods

- Finished Goods are stored in anti-static bags and labeled, with unique part number, on the finished good and on the outside of the box.

#### 5.2.5 Identification of returned product

- Products returned for warranty and non-warranty repair are identified by a REPAIR tag and are placed in a designated area for RMA's.
- Products returned for credit will be identified by a RETURN TO STOCK and place in a designated area to be retested.

#### 5.2.6 Products deemed unrepairable

- Returned products that are deemed unrepairable are identified with a Scrap tag and placed in MRB location for disposition
- Products deemed unrepairable during production test are identified with a Scrap tag and placed in MRB location for disposition.

### 5.3 Traceability

5.3.1 Product traceability is maintained when required by applicable laws and regulations, or when specified internally to facilitate corrective actions

5.3.2 When traceability is a customer or regulatory requirement and it differs from normal labeling standards, engineering reviews the contract specifications and/or regulations and specifically identifies the methods to be used.

5.3.3 In the case when traceability is not a regulatory requirement, the standard labeling and serialization process is followed.

#### 5.4 Traceability records

5.4.1 For finished products, the work order is the main traceability record linking the product to its production history.

#### 5.5 Status of measuring and monitoring. The requirements for the measuring and monitoring of outputs are determined with procedure P 910-001 for Monitoring, measurement, analysis and evaluation.

5.5.1 The status of outputs related to monitoring and measurement requirements throughout production and service provision is identified.

5.5.2 Products are deemed accepted, having passed test, by the following:

- Green dot is applied to the front side of assembled board along with tester's initials.
- Work Order Traveler, F 851-002, has been signed off by personnel doing test

5.5.3 Products deemed not accepted, not having passed test, by the following:

- Red dot is applied to the front side of assembled board with tester's initials. A tag indicating date tested, Item Code, Item Description, Revision and a brief description of failure.
- Assembled board is stored in designated area.

### 6.0 Forms and Documented Information

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#### 6.1 Forms and records

6.1.1 F 851-002 Work Order Traveler

#### 6.2 Documented information / Related processes

6.2.1 P 600-001 Planning for the Quality management system

6.2.2 P 820-001 Customer related processes

6.2.3 P 851-001 Control of production and service provision

6.2.4 P 870-001 Control of nonconforming outputs

6.2.5 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) Work Order not present with product on production floor.
- 2) Products not accepted are not identified correctly.
- 3) RMA's are not identified with correct labeling

**Risk Mitigation**

- 1) Ensure all employees are trained to this procedure.
- 2) Train all employees as to the importance of identification.
- 3) Conduct effectivity training and retrain if necessary.

**8.0 Revision History**

Rev	Date	Section	Paragraph	Summary of change	Authorized by
A	3/3/17			Initial issue	