

1.0 Purpose/Scope

- 1.1 This procedure describes the process used at ACCES I/O Products to ensure that outputs that do not conform to product requirements are identified and controlled to prevent its unintended use or delivery.

2.0 Responsibilities and Authorities

- 2.1 The Quality Manager has the prime responsibility and approval authority for this procedure.
- 2.2 In support of the Quality Manager, the Quality Team is responsible for identifying the appropriate methods for the control of nonconformities.
- 2.3 The ISO Management Representative is responsible for the processing of nonconforming reports and associated corrective action requests.
- 2.4 Additional responsibilities are detailed in relevant paragraphs of section 5.0 below.

3.0 References and Definitions

3.1 References

- 3.1.1 This document relates to clause 8.7 of the ISO 9001:2015 standard, Control of nonconforming process outputs, products and services.

3.2 Definition

- 3.2.1 Nonconformity: Non-fulfillment of a requirement.
- 3.2.2 NCR – Product Nonconformity Report
- 3.2.3 CAR – Corrective Action Report

4.0 Resources

- 4.1.1 None

5.0 Instructions

- 5.1 In support of the procedure P 851-001 for Control of production and service provision, this procedure addresses the control of nonconforming process outputs.
- 5.2 The Quality Team ensures that the methods for the control of nonconformities are identified and controlled.

5.3 Nonconforming process outputs are handled with the following actions:

- Correction
- Segregation, containment, return shipments or suspension of provision of products,
- Informing the customer,
- Disposition,
- Obtaining authorization for acceptance with a concession.

5.4 When a process output, material, part or product is identified as nonconforming it is immediately segregated and processed as follows:

Note: If necessary, a where-used report should be obtained to ensure all assemblies are identified.

Purchased parts:

- A REJECTED tag is attached to product with the following:
 - Current Date
 - Item Code
 - Purchase Order number, if known
 - Description of non-conformity
 - Initiate a Product Nonconformity Material Report, F 870-001.
 - List the Report number from the Product Nonconformity Report (NCR) on the tag.
 - Place on MRB shelf for disposition

Incoming assembled boards

- A tag is attached to product with the following:
 - Current Date
 - Item Code
 - Item Description
 - Revision
 - Purchase Order number, if known
 - Original Work Order number, if known

- Brief description of non-conformity
- Initiate a Product Nonconformity Report, F 870-001.
- List the Report number from the Product Nonconformity Material Report (NCR) on the tag.
- Place on MRB shelf for disposition

Assembled board non-conformity discovered in test

- Note: An assembled board non-conformity in this context would be material not installed per BOM. For instance, if a wrong part is installed or if the part is installed in the wrong direction.
- A tag is attached to product with the following:
 - Current Date
 - Item Code
 - Item Description
 - Revision
 - Original (XXX-XXXX-B) Work Order number, if known
 - Brief description of non-conformity
 - Place on MRB shelf for disposition

Finished Goods

- Non-conformity is noted on Work Order Traveler, F 851-006.
- Production Manager and/or Quality Manager is notified for immediate disposition.
- A CAR may be initiated, depending on the severity, to investigate root cause.

5.5 A member of the Quality Team reviews the NCR form and identify the disposition of the product(s).

Disposition can include:

- Correct nonconformity immediately

Note: A where-used report should be obtained in order to identify

- Rework to correct
- Re-grade
- Scrap

- Return to provider
- Use as is.

When the disposition is Use-as-is, Quality Manager or designee is responsible for notifying the customer and obtaining a concession, if deemed appropriate.

Records describing the nonconformity, the actions taken, concessions obtained and identification of the authority for action related to the nonconformity are retained with the procedure P 750-001 for Control of documented information.

- If product is released under a customer concession, documented approval by a customer authority is required.

The manager of the department holding the material is responsible for the disposition of the product as designated on the NCR form where:

- Rework is sent to the appropriate / original process.
- Corrected product or material is subject to all product inspection required by the process to verify and demonstrate conformity to requirements.
- Return product to provider with the Corrective Action Report (CAR), F 1020-001, if necessary.
- Product is scraped and reported on the Product Nonconformity Material Report (NCR), F 870-001.
- If disposition is use as is the item is placed back in the process.
- If customer concession or inappropriate uses have been identified on the NCR form, the report will stay with the item throughout production and to shipping and will be filed with the associated work order traveler.
- Authority to release products for shipment is described in the procedure P 851-001 for Control of production and service provision.
- When completed, a copy of the NCMR form is sent to the Quality Manager to be filed.

The manager of the department holding the material is responsible to complete Product Nonconformance Material Disposition, F 870-004.

5.6 The Production Manager is responsible to complete the Product Nonconformance Material Closeout, F 870-005.

5.7 A member of the Quality Team will determine if a corrective action, based

on the nature of the nonconformity and its impact on the conformity of the product, is required.

Criteria of a corrective action:

- A corrective action may not be required if a nonconformance is a one-time incident and does not affect product quality to existing product, product in WIP or product that has shipped to the customer.
- A corrective action will be required should it be determined that the nonconformity has affected other product quality
- If a trend is identified or if the individual nonconformance is serious enough to warrant a corrective action.

5.7.1 When required, corrective action is requested on CAR form F 1020-001 as defined in procedure P 1020-001 for Nonconformity and corrective action.

5.8 If nonconforming product is detected after delivery or use, customer will be contacted and appropriate remedial action will be taken, and a corrective action will be initiated.

5.9 Documented information of actions taken dealing with decisions regarding nonconforming outputs is controlled and retained as quality records.

The documented information includes:

- Description of the nonconformity,
- Description of the action taken,
- Details of any concession obtained,
- Identification of the authority for decisions on action regarding the nonconformity.

5.10 MRB Authority

5.10.1 The Quality Manager, Production Manager and VP of Engineering have the authority for MRB disposition.

6.0 Forms and Documented Information

6.1 Forms

F 870-001, Nonconformance Material Report

F 870-002 Nonconformity Material Report Log

F 870-004 Nonconformance Material Disposition

F 870-005 Nonconformance Material Closeout

F 1020-001 Corrective action request (CAR)

F 851-012, In Process Data

6.2 Documented information / Related processes

P 600-001 Planning for the Quality management system

P 750-001 Control of documented information

P 840-001 Control of external providers

P 851-001 Control of production and service provision

P 1020-001 Nonconformity and corrective action.

7.0 Opportunities and Risks

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:

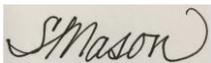
Potential Risks:

- 1) Nonconforming parts are not tagged
- 2) Nonconformance is not reported

Risk Mitigation

- 1) Ensure all employees have been trained on this procedure
- 2) Ensure all employees have been trained on this procedure and conduct verification of effectivity.

8.0 Revision History

Rev	Date	Section	Paragraph	Summary of change	Authorized by
A	03/03/17			Initial issue	
B	01/30/18	5	5.4	Note added	