1.0 Purpose/Scope

1.1 This procedure describes the process at ACCES I/O Products for dealing with nonconformity using a system for corrective action.

1.2 The procedure applies to the process of dealing with non-conformances and determining effective corrective action.

2.0 Responsibilities and Authorities

2.1 The ISO Representative has the prime responsibility and approval authority for this procedure.

2.2 In support of the ISO Representative, the Quality Team is responsible for dealing with the consequences of non-conformances and to determine effective corrective action.

2.3 Additional responsibilities are detailed in relevant paragraphs of section 5.0 below.

3.0 References and Definitions

3.1 Reference

3.1.1 This document relates to clause 10.2 of the ISO 9001:2015 standard, Nonconformity and corrective action.

3.2 Definitions

3.2.1 Corrective Action: Action taken to eliminate the cause of a non-conformance that has occurred, and prevent reoccurrence of the nonconformance.

3.2.2 CAR – Corrective Action Request

4.0 Resources

4.1 None

5.0 Instructions

5.1 In support of the procedure P 1010-001 for Improvement, this procedure addresses nonconformity and corrective action.

5.1.1 The ISO Representative ensures that non-conformances are dealt with as they occur, and that corrective action is taken to eliminate the cause or to reduce the likelihood of recurrence.

5.2 Nonconformity and corrective action requests.

5.2.1 Any employee discovering a nonconformance, relating to an

internal problem, or when a complaint is received from an external party or a customer, should fill out a Corrective Action Request, form F 1020-001 and add any pertinent attachments. The CAR is automatically logged into the CAR Log, F 1020-005 and a number is assigned.

- Customer satisfaction / dissatisfaction / complaint issues are further addressed with the procedure P 912-001 for Customer satisfaction.
- The identification and segregation of nonconforming outputs is carried out as described in the procedure P 870-001 for the Control of nonconforming outputs.

5.2.2 The ISO Representative will receive a notification that a CAR has been initiated and will identify and advise the responsible party with the details.

5.2.3 The CAR is automatically logged into the CAR Log, F 1020-005, and a number is assigned.

5.2.4 The CAR is assigned, using F 1020-012, to the responsible party for evaluation.

- After thorough review, analysis and determination of the root cause, the responsible party completes a CAR Action Report, F 1020-002.
- If additional resources are needed, the corrective action is forwarded to the ISO Representative who will assign it to another person with responsibility and authority to implement the action.

5.2.5 The ISO Representative is responsible for the follow-up and close-out of the CAR Closeout, F 1020-003.

5.2.6 The ISO Representative updates, if required, the risks and opportunities identified during the planning process.

5.2.7 The ISO Representative shall discuss with Quality Manager if changes to the QMS are required as the result of the action.

5.2.8 The ISO Representative prepares a summary of the corrective actions to be reviewed with the procedure P 930-001 for management review.

5.3 Documented information is retained with the procedure, P 750-001 Control of documented information, as evidence of the nature of the nonconformities, of any subsequent actions taken, and of the results of any corrective action.

6.0 Forms and Documented Information

6.1 Forms

6.1.1 F 1020-001 Corrective Action Request (CAR)

6.1.2 F 1020-002 CAR Action Report

6.1.3 F 1020-003 CAR Closeout

6.1.4 F 1020-005 CAR Log

6.1.5 F 1020-012, CAR Action Assignment

6.2 Documented information / Related processes

6.2.1 P 600-001 Planning for the Quality management system

6.2.2 P 750-001 Control of documented information.

6.2.3 P 870-001 Control of nonconforming outputs

6.2.4 P 912-001 Customer satisfaction.

6.2.5 P 930-001 Management review

6.2.6 P 1010-001 Improvement

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 of those risks:

Potential Risks:

1) Nonconformities are not reported

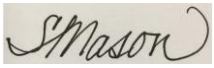
2) No follow-up on CAR's

Risk Mitigation:

1) Ensuring employees are properly trained and conduct verification of effectivity of training to ensure training and processes are understood.

2) Ensuring employees are properly trained and conducting verification of effectivity of training.

8.0 Revision History

Rev	Date	Section	Paragraph	Summary of change	Authorized by
A	2-13-17			Initial issue	
B	11-28-17	2.1 & 5.2	Multiple	The owner of this process changed from Quality Manager to ISO Rep. Added the assignment step using google docs.