1.0 Purpose/Scope

1.1 This procedure describes the process for performing Internal Audits at ACCES I/O Products.

1.2 The procedure applies to internal audits that are conducted to ensure that the QMS conforms to the requirements, is effectively implemented and maintained, and continues to be suitable, adequate and effective.

2.0 Responsibilities and Authorities

2.1 The VP of Operations has the prime responsibility and approval authority for this procedure.

2.2 In support of the VP of Operations the Quality Team is responsible to ensure that internal audits are conducted at planned intervals.

2.3 Additional responsibilities for the 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 9.2 of the ISP 9001:2015 standard, Internal audit.

3.2 Definition

3.2.1 Audit Team: May be one or more auditors, including the lead auditor and outside consultant.

4.0 Resources

4.1 None

5.0 Instructions

5.1 In support of the procedure P 910-001 for Monitoring, measuring, analysis and evaluation, this procedure addresses the internal audits of the QMS.

5.1.1 The VP of Operations and/or ISO Management Representative ensure that internal audits are conducted at planned intervals at a minimum of once per year.

- At the call of the VP of Operations, internal audits may be conducted more frequently based on performance and results observed during

previous audits.

5.2 The ISO Management Representative works with the Quality Team to plan and prepare a master schedule, F 920-001, for internal audits.

5.2.1 The schedule includes all areas of the facility and is based on the status and importance of the area being audited.

5.2.2 Other considerations include the results of previous audits and changes impacting on the company.

5.2.3 The schedule identifies when the audits will take place and what areas will be audited.

- Each area of the facility is audited once per year.
- The master schedule is evaluated with the procedure P 930-001 for Management review and is updated based on:
  - The results of the audits.
  - The number of corrective actions generated as a measure of the status of the area.
  - System problems identified by corrective actions
  - Other relevant information.

5.2.4 The ISO Management Representative initiates the internal audits based on the master schedule.

- The ISO Management Representative schedules the audit with the manager of the area to be audited.
- The ISO Management Representative identifies an audit by selecting trained auditors, independent of the area to be audited and available on the scheduled day or days.
- The ISO Management Representative schedules the opening meeting for the auditors and representative(s) of the area to be audited.

5.3 The auditor documents the scope of the audit on the audit plan. The scope is based on the area to be audited and the procedures of the quality system that apply to that area.

5.3.1 The auditor prepares the audit plan on form F 920-003 and reviews appropriate documentation.

5.4 The auditor reviews previous audit reports for the area. All corrective

actions that have been completed from previous audits that require follow-up are identified on the audit reports.

5.4.1 The auditor will follow-up on the corrective actions.

5.4.2 The auditor holds an opening meeting with the management person with responsibility for the area being audited.

5.5 The auditor performs the audit per the audit plan and the checklist.

5.5.1 Compliance to the QMS requirements and to the ISO 9001:2015 standard is determined by observation, interview and review of records using the Internal Audit Checklist, F 920-002, as a guide.

5.5.2 Complete notes are taken to provide ample details of observations if nonconformance is noted and can be readily located for correction action.

5.5.3 Auditors document all non-conformances on the Internal Audit Checklist, F 920-002.

5.6 As the internal audit is conducted, the auditors record audit results on the audit checklists.

5.7 After the audit, the auditor holds a review meeting with the Quality Manager and the process owner to agree on and write up corrective action requests.

5.7.1 The Quality Manager is responsible for initiating corrective actions.

5.7.2 The auditor holds a closing meeting with the management person with responsibility for the area audited.

- All observed non-conformances are explained and the status of the area audited is summarized.

5.7.3 The auditor prepares an Internal Audit Report, form F 920-004. The report includes:

- A summary of the findings

5.7.4 The audit report is distributed to the management person with the responsibility for the area audited and the ISO Management Representative.

5.8 The auditor submits all audit records to the ISO Management Representative.

5.8.1 The records included are the Internal Audit Plan, F 920-003, Audit Checklist, F 920-002, and the Internal Audit Report, F 920-004.

5.8.2 The records are retained, with the procedure P 750-001 for Control of documented information, as evidence of the implementation of the audit program and the audit results.

5.9 ACCES I/O Products qualifies internal auditor through providing internal auditor training. Upon completion of training, the internal auditors must be observed by the Lead Auditor/Team Lead Auditor to ensure proficiency. Once the Lead Auditor/Team Lead Auditor determines competency through witness audits, the internal auditor will be qualified to conduct internal audits. No auditor will be assigned to their department or are a process owner.

6.0 Forms and Documented Information

6.1 Forms

6.1.1 F 920-001 Internal Audit Schedule & Audit Plan

6.1.2 F 920-002 Audit Checklist

6.1.3 F 920-003 Internal Audit Plan

6.1.4 F 920-004 Internal Audit Report

6.1.5 F 1020-001 Corrective action request - CAR

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 910-001 Monitoring, measuring, analysis and evaluation

6.2.4 P 930-001 Management review

6.2.5 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 of those risks:

Potential Risks:

1) Audits are not conducted timely and properly

2) Follow-ups are not conducted on CAR's,

Risk Mitigation:

1) Management shall effectively support the internal audit program by being notified of internal audit program status on a monthly basis.

2) Ensuring employees are properly trained and conducting verification of effectivity of training to ensure training and processes are understood

8.0 Revision History

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