SYSTEM SENSOR	QP 17 Internal Quality Audits
STANDARD OPERATING PROCEDURE	Sheet 1 of 4

ISSUE NO. A	ISSUE NO. B	ISSUE NO.	ISSUE NO.	ISSUE NO.	ISSUE NO.	ISSUE NO.	PREPARED BY
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DATE 03/21/97	DATE 12/23/97	DATE	DATE	DATE	DATE	DATE	DATE 12/23/97

0 PURPOSE

Define quality audits to verify whether quality activities comply with planned arrangements and to determine the effectiveness of the quality system.

1.0 RESPONSIBILITY

The Quality Assurance Manager shall be responsible to ensure that the requirements of this procedure are being met. The QA Manager may choose to have the primary function of this procedure performed by an Internal Audit Coordinator.

2.0 TYPES OF AUDITS, SCOPE, AND SCHEDULE

2.1 QUALITY SYSTEM AUDITS

Internal quality system audits shall be carried out on all sections of the System Sensor Quality Manual. These audits shall verify that the requirements of the manual are met and that quality activities comply with the planned arrangements set up to meet those requirements.

2.2 PRODUCT, DEPARTMENT, AND PROCESS AUDITS

Audits of a particular process, department, product line shall be scheduled based on the status and importance of that activity. (i.e., verification of corrective actions required by the internal quality system audit or criticality of the activities such as process or calibration control).

3.0 AUDIT SCHEDULE

The Internal Audit Coordinator shall prepare an annual schedule of audits. The schedule shall ensure that the period between audits of any element of the Quality Manual does not exceed one year. It shall detail the type of audit and when it is scheduled to be performed. Should any audits be deferred, the reason for such shall be documented either by the Internal Audit Coordinator or Quality Assurance Manager.

4.0 AUDIT PREPARATION

Auditors shall be assigned to perform an audit and shall not be responsible for the activities being audited. A set of audit checklists shall be prepared for each audit defining the key elements of the audit and, if appropriate, indicate any sampling plan for a specific activity. These shall be distributed to the auditors prior to the scheduled audit. All checklists shall be reviewed by the Lead Auditor and shall include verification of actions to correct and prevent non-complying conditions including those documented during previous audits.

5.0 PERFORMANCE AND REPORT

Each audit shall begin with a brief meeting between the audit team and the management of the area to be audited. The audit shall be performed such that listed elements are evaluated for conformance and effectiveness against specified requirements. Objective evidence shall be examined to the degree necessary to determine if the control elements are being implemented effectively. The results shall be recorded on the checklist pages, or on supplemental notes. Every effort should be made to inform the auditee of the progress of the audit and concerns of the audit team.

Each audit shall conclude with a brief closing (exit) meeting between the audit team and management of the area audited. The closing meeting shall be scheduled at the end of the audit within one day of audit completion. In the event that the closing meeting has to be deferred more that one more than one day after completing the audit, it shall be documented by the Internal Audit Coordinator or Quality Assurance Manager. Any non-compliance forms shall be acknowledged at the closing meeting by the person having responsibility and authority to implement corrective action. Copies of acknowledged non-compliance forms and/or observations shall be provided to those in attendance.

After completion of the audit, an audit report shall be prepared in the form of a memo from the Lead Auditor. The audit shall contain the following information:

1. Audit title, number, and other identifying information.

2. Background information, such as audit, purpose, scope, dates, and audit team members.

3. Summary and overall conclusions of the effectiveness of the quality system implemented in the audited area(s).

4. Listing of those who participated in the audit. This is normally presented as an attachment.

5. Specific non-compliance or observations as attachments.

Audit non-compliance's shall be presented as a generic statement of the non-conforming condition followed by discussion (or explanation) points, the first of which should be a description of the specific requirement(s) for the control item under question. This should be then be followed by examples of specific objective evidence, found during the course of the audit. To assist management in tracking and developing corrective action, each non-compliance of an audit shall include audit identifying information (audit title and number), be sequentially numbered, and presented on a separate sheet of paper attached to the report.

Audit observations shall be presented in a fashion similar to audit noncompliance and indicate situations that could lead to a non-compliance. Audit observations shall also be sequentially numbered and identify the party responsible to review the situation and shall be attached to the report.

The audit report shall be provided to all affected managers from the Lead Auditor. A response shall be requested within thirty days of the audit. If more than thirty days are requested for a response, the approval from the Internal Audit Coordinator shall be obtained and documented. Additional copies of the report should be provided to other interested parties, the audit team members.

6.0 FOLLOW-UP

Response shall be evaluated by the Internal Audit Coordinator for effective corrective action which addresses the concerns expressed by the audit report. Specifically, replies to audit non-compliance's shall be evaluated to verify that:

1. The cause of the problem has been identified.
2. Actions have been taken to correct the specific problem areas.
3. Actions to prevent recurrence have been identified.
4. Specific responsibilities and dates have been identified.
5. These actions have been or will be taken in a timely manner.

Once obtained and after any follow-up verification has been completed, the Internal Audit Coordinator shall document on the audit report or response that the audit finding has been closed. Audit observation responses shall be reviewed to determine that they were evaluated for validity/applicability and potential improvement. The Internal Audit Coordinator shall ensure that corrective actions have been taken and shall verify and document acceptance of each non-compliance and observation response.

The Internal Audit Coordinator shall prepare a log of open issues and periodically review the status of outstanding audit non-compliance and observations. The Internal Audit Coordinator shall communicate corrective action responses not completed by the agreed upon date to the Quality Assurance Manager and Vice President of Quality and Regulatory Assurance. Appropriate steps shall be taken to resolve outstanding issues.

7.0 AUDITOR TRAINING

All auditors shall be trained to perform the tasks required by the internal audits. Training shall include, but is not limited to the following topics:

1. The purpose of Quality Assurance and an audit.
2. The audit process, including preparation, performance, reporting, and closure.
3. Definitions of Audit Non-compliance and Audit Observation.
4. Audit checklists and their use.
5. Any special areas of concern.

Records of auditor training shall be kept.

8.0 RECORDS

The following items are considered to be official audit records and shall be maintained by the Quality Assurance Manager or Internal Audit Coordinator for two years:

1. Audit notification memo and audit plan.
2. Blank audit checklists used.
3. Audit report and forwarding memo.
4. Audit responses.

The following items are considered to be working audit records and shall be maintained by the Internal Audit Coordinator, for a period of one year, after which time they may be discarded:

1. Completed Audit checklists and auditor's working papers.
2. Related miscellaneous correspondence.
3. Annual audit schedules and any revisions.

System Sensor Quality System Internal Audit Nonconformance Report	Audit Date:	Control #:

Details of the Nonconformance:

Responsible Party:

Acknowledged: _____

Completion Date: _____

Lead Auditor: _____

Complete this section and return to lead auditor by above date.

Corrective Action:

Corrective Action Accepted by:

_____ _____

Lead Auditor or QA Manager Date

System Sensor Quality System Internal Audit Observation Report	Audit Date:	Control #:

Details of Conditions Which Might Lead to a Non-conformance:

System Sensor Internal Audit Plan -

Scope :

Objective :

Applicable Standards : ISO9001

Lead Auditor/Audit Team :

Activities to be audited :

Personnel to be notified :

Applicable documents :

Audit schedule :
Opening Meeting :
Audit :
Closing Meeting :

Checklist - Procedure :
QP17, Rev A : Internal Quality Audits

Prepared by :
Date :

Approved by :
Date :