



1.0 Purpose

- 1.1 This procedure describes the process for performing Internal Audits.

2.0 Responsibilities

- 2.1 The management representative and lead auditor are responsible for scheduling and initiating the audits and maintaining the master schedule.
- 2.2 Top management is responsible for reviewing all corrective actions resulting from internal audits.
- 2.3 Management is responsible for selecting an audit coordinator.
- 2.4 The audit coordinator is responsible for selecting the audit team, communicating with the auditee to arrange the audit, and preparing the final audit report.
- 2.5 A management staff person is responsible to attend the opening and closing meetings.
- 2.6 The *audit coordinator or management staff person* is responsible for initiating corrective actions.
- 2.7 The audit team is responsible for planning, organizing, performing and reporting results for the internal audit.

3.0 Definitions

- 3.1 *Audit Team: May be one or more auditors, including the lead auditor.*

4.0 Equipment/Software

- 4.1 No additional equipment or software required.

5.0 Instructions

- 5.1 The management representative works with management to prepare a master schedule for internal audits. The schedule includes all areas of the facility, and is based on the status and importance of the area being audited.
- 5.1.1 The schedule identifies when the audits will take place and what areas will be audited.
- 5.1.2 *Each area of the facility will be audited a minimum of two times per year.*
- 5.1.3 The associated table, Applicable Procedures by Work Area (F-822-003) identifies which procedures of the quality management system apply to each work area of the facility.



- 5.1.4 The master schedule is evaluated at management review. It is revised based on:
- a) The results of the audits.
 - b) The number of corrective actions generated. (*As a measure of the status of the area*)
 - c) System problems identified by corrective actions
 - d) Other relevant information.
- 5.2 The audit coordinator initiates the internal audits based on the master schedule.
- 5.2.1 The audit coordinator schedules the audit with the manager of the area to be audited.
- 5.2.2 The audit coordinator identifies an audit team and lead auditor by selecting trained auditors, independent of the area to be audited and available on the scheduled day or days.
- 5.2.3 The audit coordinator schedules the opening meeting for the auditors and representative(s) of the area to be audited.
- 5.3 The lead 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 lead auditor prepares the audit plan. The audit team reviews appropriate documentation.
- 5.4 The audit team 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 lead auditor assigns follow-up on the corrective actions to the members of the audit team.
- 5.4.2 The auditors get the appropriate corrective action forms from the corrective action coordinator.
- 5.5 The *lead auditor* leads the opening meeting with the representative(s) of the area to be audited.
- 5.6 The audit team performs the audit according to the audit plan and approved checklists. Auditors document all non-conformances on the checklist. (F-822-004)
- 5.7 Compliance to the quality system requirements and to the ISO 9000 2000 standard is determined by observation, interview and record review using the internal audit checklist as a guide.
- 5.8 Follow-up on corrective actions is completed. The auditor documents the results