




*Steps of an
ISO 13485:2003
Internal Audit
(Audit of Sticky Bubble Gum Company)*

Sticky Bubble Gum

Internal Audit Procedure



	QP-822-A Internal Audits
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 <i>audit coordinator or management staff person</i> 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 <i>Audit Team: May be one or more auditors, including the lead auditor.</i>	
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 <i>Each area of the facility will be audited a minimum of two times per year.</i>	
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. <i>(As a measure of the status of the area)</i> c) System problems identified by corrective actions	

Internal Audit Procedure



13485store.com

QP-822-A
Internal Audits

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 13485 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 of the corrective action on the corrective action form.

5.8.1 If the corrective action has been effective, the auditor closes the corrective action by checking the "Effective" box, and signing and dating the date closed line.

5.8.2 If the corrective action was not effective, the auditor will check the "Not Effective Box".

5.8.3 The auditors note on the appropriate audit report if corrective actions have been effective, or if they will be reissued.

5.8.4 The auditors return the corrective action forms to the corrective action coordinator.


5.8.5 The corrective action coordinator will handle the corrective actions according to the Corrective and Preventive Action Procedure.

5.9 Auditors record audit results on the checklists.

5.10 The audit team holds a review meeting to agree on and write up corrective action requests.

Internal Audit Procedure



		QP-822-A Internal Audits
5.11	The <i>audit team</i> holds a closing meeting with the representatives of the area audited, including a management person with responsibility for the area being audited.	
5.11.1	All nonconformances are explained.	
5.11.2	The status of the area audited is summarized.	
5.12	The lead auditor prepares a final report including:	
5.12.1	A summary of the findings	
5.12.2	A table of corrective action requests	
5.12.3	A copy of each corrective action request	
5.13	The lead auditor puts all audit records into the audit file.	
5.14	The records included are:	
	<ul style="list-style-type: none">• Internal audit plan• Auditors checklists• Internal audit report, including the table of corrective action requests	
6.0	Forms and Records	
6.1	F-822-001 Internal Audit Plan	
6.2	F-822-002 Internal Audit Report	
6.3	F-822-003 Applicable Procedures by Work Area	
6.4	F-822-004 Audit Checklist	
7.0	Attachments	
7.1	None	
8.0	Related Documents	
8.1	QP-852 Corrective Action	
8.2	QP-853 Preventive Action	
9.0	References	
9.1	None	

Write up the Nonconformance



- Identify the requirement
 - Identify the procedure and what it requires
- Identify the nonconformance
 - What is happening that does not follow the procedure?

The Final Report



- The Lead Auditor prepared the final report
- The report summarizes:
 - Nonconformances
 - Any changes to the scope of that audit
 - The affectivity of implementing and maintaining the quality management system