STANDARD OPERATING PROCEDURE
Internal Audit

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1. Purpose

This procedure defines the requirements for planning, conducting, reporting, and following up on internal audits to ensure the Quality Management System (QMS) conforms to ISO 13485:2016, FDA 21 CFR 820, and applicable regulatory requirements.

2. Scope

This procedure applies to all internal audits of the QMS, including process audits, system audits, and audit preparation activities. It covers all departments and functions within the organization.

3. Responsibilities

3.1 Quality Management Representative

- Establish and maintain the annual audit schedule
- Assign qualified auditors to each audit
- Review and approve audit reports
- Present audit results to management review

3.2 Internal Auditor

- Prepare audit plan and checklist
- Conduct audits objectively and impartially
- Document findings accurately
- Issue audit report within defined timeline

3.3 Auditee / Process Owner

- Provide access to relevant documentation and records
- Ensure personnel availability during audit
- Implement corrective actions for findings

4. Definitions

Term	Definition
Audit	Systematic, independent examination to determine if activities comply with planned arrangements
Finding	Result of evaluation of audit evidence against audit criteria (NC, Observation, OFI)
Nonconformity (NC)	Non-fulfillment of a specified requirement
Observation	Statement of fact based on evidence, may indicate potential risk
OFI	Opportunity for Improvement - suggestion without compliance concern

4.1 Classification of Audit Findings

The following criteria shall be used to classify audit findings consistently:

Classification	Criteria	Examples
Major Nonconformity	• Systemic failure affecting product quality or patient safety • Absence or total breakdown of a required process • Direct regulatory impact • Repetitive failures (pattern of non-compliance)	• Missing CAPA system • No document control • Complete absence of required records
Minor Nonconformity	• Isolated instance of non-compliance • Single deviation from procedure • No direct impact on product quality • First occurrence	• Single missing signature • One undocumented training • Minor record keeping error
Observation	• Potential weakness identified • No current requirement violated • Could lead to NC if not addressed	• Process could be improved • Documentation gaps
OFI	• Best practice recommendation • No regulatory requirement violated • Efficiency improvement suggestion	• Streamline process • Add guidance notes

Decision Tree for Classification:

1. Is the finding systemic (affects multiple products/processes)? → Major NC
2. Does it directly violate a regulatory requirement? → Major NC
3. Could it affect product quality or patient safety? → Major NC
4. Is it an isolated, single occurrence? → Minor NC
5. Is it a suggestion for improvement only? → Observation or OFI

5. Procedure

5.1 Annual Audit Planning

6. The QM Representative establishes an annual audit schedule covering all QMS processes.
7. Audit frequency is determined based on process risk, previous audit results, and process changes.
8. High-risk processes and those with previous findings are audited more frequently.
9. The schedule is reviewed and updated as needed throughout the year.

5.2 Auditor Qualification

Internal auditors must meet the following criteria:

- Completed internal auditor training (ISO 19011 or equivalent)
- Knowledge of ISO 13485 and applicable regulatory requirements

- Independence from the area being audited
- Documented in training records

5.3 Audit Preparation

10. Review previous audit reports, CAPAs, and relevant documentation.
11. Define audit scope, objectives, and criteria using the Audit Plan template.
12. Prepare audit checklist based on applicable requirements.
13. Notify auditee at least 5 business days in advance.
14. Confirm availability of key personnel and documentation.

5.4 Audit Execution

Opening Meeting:

- Confirm audit scope and schedule
- Explain audit process and finding categories
- Address any questions or concerns

Audit Activities:

- Review documents and records for compliance
- Interview personnel using open-ended questions
- Observe processes and activities
- Document objective evidence for all findings

Closing Meeting:

- Present preliminary findings
- Clarify any misunderstandings
- Agree on timeline for corrective actions

5.5 Audit Reporting

15. Complete the Audit Report within 5 business days after audit completion.
16. Classify findings per Section 4.1 (Major NC, Minor NC, Observation, OFI).
17. Include objective evidence for each finding.
18. Obtain QM Representative approval.
19. Distribute report to auditee and management.

5.6 Follow-up and Closure

20. Nonconformities require CAPA per SOP-007 (CAPA Procedure).
21. Observations and OFIs are tracked and addressed as appropriate.
22. Verify effectiveness of corrective actions.
23. Close audit findings when evidence confirms resolution.

5.7 Audit Results as Input to Management Review

Per ISO 13485:2016 clause 5.6.2, audit results are mandatory inputs to Management Review.

Required Inputs to Management Review:

- Summary of all audits conducted in the review period
- Number and classification of findings (Major/Minor/Observation/OFI)
- CAPA status and effectiveness verification results
- Trend analysis (recurring findings, systemic issues)

Key Performance Indicators (KPIs):

KPI	Target	Frequency
Audit completion rate	100%	Per schedule
Finding closure rate	>90% within 90 days	Quarterly

KPI	Target	Frequency
Overdue CAPAs	0	Monthly
Repeat findings	<10%	Annual

The Quality Manager shall provide a written summary of audit activities for each Management Review meeting.

6. Records

Record	Location	Retention
Annual Audit Schedule	QMS Database	Device Lifetime + 5y
Audit Plans	Audit Records	Device Lifetime + 5y
Audit Reports	Audit Records	Device Lifetime + 5y
Auditor Training Records	HR/Training	Employment + 3y

7. References

- ISO 13485:2016, Clause 8.2.4 - Internal Audit
- ISO 13485:2016, Clause 5.6.2 - Management Review Input
- FDA 21 CFR 820.22 - Quality Audit
- ISO 19011:2018 - Guidelines for Auditing Management Systems
- SOP-006 - Nonconformity Control
- SOP-007 - CAPA Procedure

8. Revision History

Version	Date	Author	Description
1.0	[Date]	[Name]	Initial release
1.1	[Date]	[Name]	Added Section 4.1 (NC Classification) and 5.7 (Management Review Input)

9. Approval

Role	Signature	Date
Prepared by:		
Reviewed by:		
Approved by:		

Compliant with ISO 13485:2016 and FDA 21 CFR 820.22