ASC-AOP-02: Onsite Assessment and Witness Audit Procedure

Title: Onsite Assessment and Witness Audit Procedure
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Prepared by: Muhammad Fahmy, Chairman
Approved by: [Second Chairman Name]
Applies to: All onsite assessment and witness audit activities conducted by ASC for third-party certification bodies

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1. Purpose

This procedure establishes the methodology for conducting onsite assessments and witness audits of third-party certification bodies (CBs) seeking or maintaining accreditation under the FDA Accredited Third-Party Certification Program and ISO/IEC 17011 requirements.

2. Scope

This procedure applies to all ASC assessment team members conducting onsite assessments and witness audits of CBs performing food safety audits under FDA-recognized scopes.

3. References

- 21 CFR Part 1, Subpart M: Accreditation of Third-Party Certification Bodies
- ISO/IEC 17011:2017: Requirements for Accreditation Bodies

- ISO/IEC 17065:2012: Requirements for Bodies Certifying Products, Processes and Services
- ASC-MS-01: Accreditation & Certification Management System Manual
- ASC-SOP-AB-01: Accreditation and Oversight Procedure
- ASC-AOP-05: Competence and Qualification of Assessors
- SOP-02: Assessment and Witness Audit Procedure

4. Definitions

Onsite Assessment: Physical evaluation of a CB's facilities, operations, personnel, and systems at the CB's location(s).

Witness Audit: Observation of a CB's auditor(s) conducting a food safety audit at an eligible entity's facility to verify competence and methodology.

Assessment Team: Group of qualified assessors and technical experts assigned to conduct the assessment.

Lead Assessor: Senior assessor responsible for planning, conducting, and reporting the assessment.

Technical Expert: Subject matter specialist providing expertise in specific FDA scopes or technical areas.

Eligible Entity: Foreign facility subject to FDA food safety requirements that may be audited and certified by accredited CBs.

5. Responsibilities

Role	Responsibility
Lead Assessor	Plan and conduct assessment; prepare assessment report; coordinate team activities.
Assessment Team Members	Participate in assessment activities; document findings; support Lead Assessor.
Technical Experts	Provide specialized knowledge; evaluate technical competence in specific scopes.
Quality Manager	Review assessment plans and reports; ensure procedural compliance.
Administrative Officer	Coordinate logistics; schedule assessments; maintain records.

6. Procedure

6.1 Assessment Planning

6.1.1 Team Selection

1. **Lead Assessor Assignment**
2. Quality Manager assigns qualified Lead Assessor based on:
    - CB's scope of accreditation
    - Geographic location
    - Language requirements
    - Assessor availability and competence
3. Lead Assessor must meet requirements in ASC-AOP-05.
4. **Team Composition**
5. Lead Assessor recommends team composition including:
    - Additional assessors (if needed for scope or complexity)
    - Technical experts for specialized FDA scopes

    - Observers or assessors-in-training (if applicable)
6. Team size appropriate to CB's size, scope, and complexity.
7. All team members must be free from conflicts of interest.
8. **Conflict of Interest Check**
9. All team members complete conflict of interest declaration.
10. Quality Manager reviews declarations for potential conflicts.
11. Team members with conflicts replaced or recused from specific activities.

6.1.2 Document Review

1. **Pre-Assessment Documentation**
2. CB provides documentation at least 30 days before onsite assessment:
    - Quality Management System manual
    - Organizational chart and personnel qualifications
    - Audit procedures and checklists
    - Sample audit reports and certifications
    - Training records and competence evaluations
    - Conflict of interest management procedures
    - Complaint and appeal procedures
    - List of current and planned audits
3. **Document Analysis**
4. Lead Assessor reviews documentation to:
    - Verify completeness and adequacy
    - Identify areas requiring detailed examination
    - Prepare assessment questions and focus areas
    - Determine witness audit opportunities
5. Document review findings documented in assessment plan.

6.1.3 Assessment Plan Development

1. **Plan Contents**
2. Lead Assessor develops comprehensive assessment plan including:
    - Assessment objectives and scope
    - Team composition and roles
    - Assessment schedule and timeline
    - Locations to be visited
    - Personnel to be interviewed
    - Processes and documents to be examined
    - Witness audit schedule (if applicable)
    - Assessment criteria and methodology
    - Resource requirements
3. **Witness Audit Planning**
4. Lead Assessor selects representative audit(s) to witness based on:
    - FDA scope(s) being assessed
    - Auditor competence to be verified
    - Geographic accessibility
    - Timing and availability
    - Risk and complexity
5. Minimum one witness audit required for initial accreditation.
6. Additional witness audits may be needed for multiple scopes or locations.
7. **Plan Approval and Communication**
8. Assessment plan reviewed and approved by Quality Manager.
9. Plan shared with CB at least 30 days before onsite assessment.
10. CB confirms logistics, personnel availability, and witness audit arrangements.
11. Any changes to plan documented and communicated promptly.

6.2 Onsite Assessment Execution

6.2.1 Opening Meeting

1. **Meeting Objectives**
2. Confirm assessment scope, objectives, and schedule.
3. Introduce assessment team and CB personnel.
4. Explain assessment methodology and confidentiality.
5. Address CB questions and concerns.
6. Confirm logistics and access arrangements.
7. **Meeting Documentation**
8. Attendance list signed by all participants.
9. Key discussion points documented.
10. Any changes to assessment plan noted and agreed.

6.2.2 Assessment Activities

1. **Facility Tour**
2. Assessment team tours CB's facilities to observe:
    - Office layout and organization
    - Document and record storage
    - IT systems and security
    - Meeting and training facilities
3. Observations documented with photographs (if permitted).
4. **Personnel Interviews**
5. Structured interviews conducted with:
    - Management and leadership
    - Lead auditors and audit team members
    - Technical specialists
    - Administrative and support staff

    - Decision-makers for certification

6. Interviews assess:
    - Knowledge of FDA requirements and CB procedures
    - Understanding of roles and responsibilities
    - Competence and qualifications
    - Impartiality and independence

7. **Document and Record Examination**

8. Review of:
    - Quality management system documentation
    - Personnel qualification and training records
    - Audit planning and execution records
    - Audit reports and certification decisions
    - Complaint and appeal records
    - Internal audit and management review records
    - Conflict of interest declarations
    - Contracts with clients and auditors

9. Sample size based on CB's volume and risk.

10. **Process Observation**

11. Observation of CB processes such as:
    - Audit planning and preparation
    - Auditor briefings and debriefings
    - Report writing and review
    - Certification decision-making
    - Internal quality checks

12. Observations verify procedures are followed in practice.

13. **IT Systems Review**

14. Evaluation of:

- Audit scheduling and tracking systems
- Document management and version control
- Record retention and backup procedures
- Data security and confidentiality controls
- Reporting systems for FDA submissions

6.2.3 Findings Documentation

1. **Finding Classification**
2. **Conformity:** CB meets requirements; no action needed.
3. **Observation:** Opportunity for improvement; no immediate action required; monitored in surveillance.
4. **Minor Nonconformity:** Isolated lapse or weakness; does not prevent accreditation; corrective action required.
5. **Major Nonconformity:** Significant failure to meet requirements; prevents accreditation until resolved; immediate corrective action required.
6. **Finding Documentation**
7. Each finding documented with:
    - Finding number and classification
    - Requirement reference (regulation, standard, or procedure)
    - Objective evidence (documents, records, observations, interviews)
    - Description of nonconformity or observation
    - Potential impact on CB's competence or impartiality
8. Findings reviewed daily by assessment team for consistency.
9. **Evidence Collection**
10. Objective evidence collected and documented:
    - Copies of relevant documents (with CB permission)
    - Photographs of facilities or processes
    - Interview notes and responses
    - Observation records

11. Evidence organized and referenced to findings.

6.2.4 Closing Meeting

1. **Meeting Objectives**
2. Present assessment findings to CB management.
3. Explain finding classifications and evidence.
4. Discuss corrective action requirements and timelines.
5. Address CB questions and clarifications.
6. Outline next steps in accreditation process.
7. **Meeting Documentation**
8. Attendance list signed by all participants.
9. Findings presented and discussed.
10. CB acknowledgment of findings (not necessarily agreement).
11. Corrective action timeline confirmed (typically 30 days).
12. Meeting minutes prepared and signed.

6.3 Witness Audit Execution

6.3.1 Witness Audit Preparation

1. **Audit Selection**
2. Witness audit selected to represent:
    - CB's typical audit scope and methodology
    - FDA requirements for the accreditation scope
    - Auditor competence to be verified
    - Facility type and complexity
3. Eligible entity notified and consents to witness audit.
4. **Pre-Audit Briefing**
5. Lead Assessor reviews with CB auditor:

- Audit plan and objectives
- Facility background and scope
- ASC's role as observer
- Confidentiality and non-interference
- Observation criteria and methodology

6. **Observation Plan**

7. Lead Assessor develops observation plan covering:
   - Audit phases to be observed (opening, execution, closing)
   - Specific activities to evaluate
   - Auditor competencies to assess
   - Documentation to review

6.3.2 Witness Audit Observation

1. **Observation Activities**

2. ASC assessor observes CB auditor conducting:

   - **Opening Meeting:** Introduction, scope confirmation, logistics
   - **Facility Tour:** Observation of operations and conditions
   - **Document Review:** Examination of records and documentation
   - **Interviews:** Questioning of facility personnel
   - **Process Observation:** Verification of food safety controls
   - **Nonconformity Documentation:** Recording of findings
   - **Closing Meeting:** Presentation of findings and next steps

3. **Evaluation Criteria**

4. ASC assessor evaluates:

   - **Technical Competence:** Knowledge of FDA requirements, food safety principles, and audit standards
   - **Audit Methodology:** Systematic approach, sampling, evidence collection

- **Communication Skills:** Clear questioning, active listening, professional demeanor
- **Objectivity:** Impartial evaluation, evidence-based findings
- **Report Writing:** Accurate documentation, clear findings, appropriate conclusions
- **Professionalism:** Ethical conduct, confidentiality, respect

5. **Non-Interference Principle**

6. ASC assessor observes without interfering in audit process.
7. Questions or clarifications addressed during breaks or after audit.
8. ASC assessor does not direct audit activities or findings.
9. Eligible entity informed of ASC's observer role.

6.3.3 Post-Audit Review

1. **Debriefing with CB Auditor**
2. ASC assessor debriefs with CB auditor after audit completion.
3. Discussion of:
    - Audit performance and methodology
    - Strengths and areas for improvement
    - Compliance with CB procedures and FDA requirements
    - Any concerns or nonconformities observed
4. **Audit Report Review**
5. ASC assessor reviews CB's audit report when completed.
6. Verification that:
    - Report accurately reflects audit findings
    - Findings supported by objective evidence
    - Conclusions appropriate and justified
    - Report format and content meet FDA requirements
    - Certification decision (if applicable) is appropriate

7. **Witness Audit Documentation**

8. ASC assessor prepares witness audit observation report including:
    - Audit details (date, location, auditor, scope)
    - Observation activities and duration
    - Evaluation of auditor competence
    - Findings and evidence
    - Strengths and weaknesses identified
    - Recommendation regarding auditor qualification

9. Report included in overall assessment documentation.

6.4 Assessment Reporting

6.4.1 Report Preparation

1. **Report Structure**

2. Lead Assessor prepares comprehensive assessment report with:

    - **Executive Summary:** Overview of assessment, key findings, recommendation
    - **Assessment Details:** Scope, dates, locations, team composition
    - **CB Information:** Organization, scope, personnel, facilities
    - **Assessment Methodology:** Activities conducted, documents reviewed, interviews
    - **Findings:** Detailed findings with evidence and classification
    - **Corrective Actions:** CB's responses and ASC's verification
    - **Witness Audit Results:** Summary of witness audit observations
    - **Competence Evaluation:** Assessment of CB's competence and capacity
    - **Impartiality Evaluation:** Assessment of conflict of interest management
    - **Recommendation:** Grant, deny, or defer accreditation with justification
    - **Annexes:** Finding details, evidence, attendance lists, photographs

3. **Report Review**

4. Assessment report reviewed by:
    - Quality Manager for completeness and procedural compliance
    - Technical experts for technical accuracy
    - Lead Assessor for final approval
5. Report revised as needed based on review comments.
6. **Report Distribution**
7. Final report distributed to:
    - CB (within 15 business days of assessment completion)
    - Accreditation Decision Committee
    - ASC management
    - ASC records (retained for 10 years)

6.4.2 Corrective Action Verification

1. **Corrective Action Plan**
2. CB submits corrective action plan within 30 days addressing all nonconformities.
3. Plan must include:
    - Root cause analysis
    - Corrective actions (immediate and long-term)
    - Implementation timeline
    - Responsibility assignments
    - Evidence of effectiveness
4. **ASC Review**
5. Lead Assessor reviews corrective action plan for adequacy.
6. Plan may be:
    - **Accepted:** Addresses nonconformity effectively
    - **Rejected:** Inadequate or incomplete; CB must revise
7. Feedback provided to CB within 10 business days.
8. **Verification**

9. Verification methods based on nonconformity severity:
    - **Document Review:** For minor nonconformities; review of evidence
    - **Follow-up Visit:** For major nonconformities; onsite verification
    - **Witness Audit:** For competence-related issues; observe implementation
10. Verification results documented and added to assessment report.
11. **Closure**
12. Nonconformities closed when:
    - Corrective actions implemented effectively
    - Evidence demonstrates sustained compliance
    - Lead Assessor approves closure
13. Closure documented in assessment report.

6.5 Special Circumstances

6.5.1 Multi-Site Assessments

1. **Scope Determination**
2. For CBs with multiple offices or locations:
    - Headquarters always assessed
    - Representative sample of other locations based on risk and scope
    - Remote/virtual locations assessed through IT systems review
3. **Sampling Methodology**
4. Sample size based on:
    - Number of locations and personnel
    - Scope diversity across locations
    - Risk and complexity
    - Previous assessment results
5. Minimum 30% of locations for initial accreditation.

6.5.2 Remote Assessment Activities

1. **Acceptable Remote Activities**
2. Document review
3. Personnel interviews (video conference)
4. IT systems demonstration
5. Follow-up verification for minor nonconformities
6. **Required Onsite Activities**
7. Initial accreditation assessment (headquarters)
8. Witness audits (at eligible entity's facility)
9. Major nonconformity verification
10. Reassessment (at least headquarters)

6.5.3 Assessment Suspension or Termination

1. **Grounds for Suspension**
2. CB fails to provide access to records or personnel
3. CB misrepresents information or provides false documentation
4. Safety or security concerns for assessment team
5. CB requests postponement
6. **Suspension Procedure**
7. Lead Assessor consults with Quality Manager
8. Decision documented with reasons
9. CB notified immediately
10. Rescheduling or termination determined based on circumstances
11. **Assessment Termination**
12. Assessment terminated if:
    - CB cannot demonstrate basic competence
    - Major nonconformities cannot be resolved

    - CB withdraws application
    - Fraud or misrepresentation discovered
13. Termination reported to Accreditation Decision Committee
14. Application denied or withdrawn as appropriate

7. Competence Requirements

7.1 Lead Assessor Qualifications

- Minimum 5 years experience in food safety, quality management, or regulatory compliance
- Training in ISO/IEC 17011, ISO/IEC 17065, and 21 CFR Part 1 Subpart M
- Successful completion of ASC Lead Assessor training program
- Demonstrated competence in assessment methodology and report writing
- Knowledge of FDA food safety requirements and FSMA regulations

7.2 Assessment Team Member Qualifications

- Minimum 3 years relevant experience
- Training in assessment techniques and FDA requirements
- Technical knowledge appropriate to CB's scope
- Satisfactory performance in previous assessments

7.3 Technical Expert Qualifications

- Subject matter expertise in specific FDA scope (e.g., Preventive Controls, Dietary Supplements)
- Minimum 5 years industry or regulatory experience
- Understanding of audit and accreditation principles
- Ability to evaluate technical competence of CB auditors

8. Records

Records generated from this procedure include:

- Assessment plans and schedules
- Conflict of interest declarations
- Assessment findings and evidence
- Witness audit observation reports
- Assessment reports and recommendations
- Corrective action plans and verification records
- Meeting minutes (opening and closing)
- Attendance lists and interview notes
- Photographs and document copies

All records retained for minimum 10 years per 21 CFR 1.625.

9. References to Regulations

- **21 CFR 1.620(a)(1)-(3):** Evaluation of Third-Party Certification Bodies
- **21 CFR 1.621(b):** Onsite Observations and Witness Audits
- **21 CFR 1.625:** Records Requirements
- **ISO/IEC 17011:2017 Clause 7.6:** Assessment of Conformity Assessment Bodies
- **ISO/IEC 17065:2012:** Requirements for Certification Bodies

10. Revision History

Revision	Date	Description of Change	Approved By
01	October 2025	Initial Issue – Detailed procedures for onsite assessment and witness audits aligned with FDA and ISO requirements	Muhammad Fahmy, Chairman

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