ASC-AOP-03: Surveillance and Reassessment Procedure

Title: Surveillance and Reassessment Procedure
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Prepared by: Muhammad Fahmy, Chairman
Approved by: [Second Chairman Name]
Applies to: All surveillance and reassessment activities for accredited third-party certification bodies

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1. Purpose

This procedure establishes the methodology for conducting ongoing surveillance and periodic reassessment of accredited third-party certification bodies (CBs) to ensure continued compliance with FDA Accredited Third-Party Certification Program requirements and ISO/IEC 17011 principles.

2. Scope

This procedure applies to all ASC personnel involved in monitoring, surveillance, and reassessment of CBs maintaining accreditation 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
- ASC-MS-01: Accreditation & Certification Management System Manual
- ASC-SOP-AB-01: Accreditation and Oversight Procedure

- ASC-AOP-02: Onsite Assessment and Witness Audit Procedure
- ASC-AOP-04: Suspension, Withdrawal, and Scope Reduction Procedure

4. Definitions

Surveillance: Ongoing monitoring and oversight activities conducted annually to verify continued compliance of accredited CBs.

Reassessment: Comprehensive evaluation conducted at least every four years to reconfirm CB's competence, capacity, and compliance.

Self-Assessment: CB's internal evaluation of its own performance and compliance, submitted annually to ASC.

Desk Review: Evaluation of documents and records without onsite visit.

Onsite Surveillance: Physical visit to CB's facilities as part of surveillance activities.

Witness Audit: Observation of CB's auditor conducting a food safety audit, required biennially.

5. Responsibilities

Role	Responsibility
Quality Manager	Maintain master surveillance schedule; assign surveillance activities; ensure timely completion.
Lead Assessor	Conduct surveillance reviews; prepare surveillance reports; coordinate witness audits.
Assessment Team	Participate in reassessment activities; document findings.
Administrative Officer	Schedule surveillance and reassessment activities; maintain records; coordinate logistics.
Accreditation Decision Committee	Review reassessment reports; make accreditation renewal decisions.

6. Procedure

6.1 Master Surveillance Schedule

6.1.1 Schedule Development

1. **Annual Planning**
2. Quality Manager develops master surveillance schedule at beginning of each calendar year.
3. Schedule includes all accredited CBs with:
    - CB name and accreditation number
    - Accreditation scope(s)
    - Accreditation expiration date
    - Last assessment/surveillance date
    - Planned surveillance activities and dates
    - Reassessment due date (if within planning period)
    - Assigned Lead Assessor
4. **Schedule Distribution**
5. Master schedule reviewed and approved by ASC management.
6. Schedule shared with all Lead Assessors and Administrative Officer.
7. CBs notified of planned surveillance activities at least 60 days in advance.
8. **Schedule Monitoring**
9. Quality Manager monitors schedule compliance quarterly.
10. Delays or changes documented with justification.
11. Schedule updated as needed for new accreditations, withdrawals, or changes.

6.1.2 Surveillance Frequency

1. **Annual Surveillance**
2. All accredited CBs subject to annual surveillance.

3. First annual surveillance conducted within 12 months of initial accreditation.
4. Subsequent surveillance conducted annually thereafter.
5. **Biennial Witness Audits**
6. Onsite witness audit conducted no later than 1 year after initial accreditation.
7. Subsequent witness audits conducted every 2 years.
8. Additional witness audits may be conducted based on risk or performance.
9. **Four-Year Reassessment**
10. Full reassessment conducted at least every four years.
11. Reassessment may be conducted sooner if:
    - Significant nonconformities identified
    - Major changes to CB's operations
    - Complaints or performance concerns
    - Scope expansion requested
    - FDA requests reassessment

6.2 Annual Surveillance

6.2.1 CB Self-Assessment

1. **Self-Assessment Requirements**
2. CB submits annual self-assessment report to ASC at least 30 days before surveillance due date.
3. Self-assessment must include:
    - Evaluation of CB's compliance with accreditation requirements
    - Performance of auditors and certification personnel
    - Changes to organization, personnel, or procedures
    - Summary of audits conducted (number, scope, locations)
    - Summary of certifications issued
    - Complaints received and resolution

- Internal audit and management review results
- Corrective actions from previous surveillance
- Conflict of interest monitoring results
- Training and competence development activities

4. **Self-Assessment Review**

5. Lead Assessor reviews self-assessment for:
   - Completeness and adequacy
   - Compliance with requirements
   - Trends or patterns requiring attention
   - Areas requiring detailed examination during surveillance

6. Review findings documented in surveillance plan.

6.2.2 Desk Review Surveillance

1. **Document Review**

2. Lead Assessor conducts desk review of:
   - CB's self-assessment report
   - Sample of regulatory audit reports submitted to FDA
   - Sample of food and facility certifications issued
   - Complaints and appeals received and resolved
   - Personnel changes and qualification records
   - Changes to QMS, procedures, or scope
   - Internal audit and management review records
   - Corrective actions from previous surveillance
   - FDA notifications and correspondence

3. **Sample Selection**

4. Sample size based on:
   - CB's volume of audits and certifications
   - Risk and complexity of scopes

- Previous performance and compliance history
- Changes since last surveillance

5. Minimum sample: 5% of audits/certifications or 5 files, whichever is greater.
6. **Evaluation Criteria**
7. Documents evaluated for:
    - Compliance with FDA requirements and CB procedures
    - Audit thoroughness and methodology
    - Appropriate certification decisions
    - Accurate and complete reporting to FDA
    - Proper handling of nonconformities
    - Evidence of auditor competence
8. **Findings Documentation**
9. Findings classified as conformity, observation, or nonconformity.
10. Nonconformities documented with evidence and requirement references.
11. Trends or patterns identified and documented.

6.2.3 Onsite Surveillance (if applicable)

1. **Triggers for Onsite Surveillance**
2. Nonconformities identified in desk review
3. Significant changes to CB's operations or personnel
4. Complaints or concerns about CB performance
5. Risk-based selection (e.g., new scopes, high-volume operations)
6. Biennial witness audit due
7. **Onsite Activities**
8. Abbreviated version of initial assessment focusing on:
    - Areas of concern from desk review
    - Changes since last assessment

- Verification of corrective actions
- Personnel interviews and competence verification
- Document and record examination

9. Onsite surveillance typically 1-2 days depending on scope and issues.
10. **Onsite Surveillance Procedure**
11. Follow procedures in ASC-AOP-02 adapted for surveillance scope.
12. Opening and closing meetings conducted.
13. Findings documented and presented to CB.

6.2.4 Witness Audit Surveillance

1. **Witness Audit Planning**
2. Conducted biennially as part of surveillance per 21 CFR 1.621(b).
3. Lead Assessor coordinates with CB to select representative audit.
4. Audit selection criteria:
    - Represents CB's typical scope and methodology
    - Auditor competence to be verified
    - Geographic accessibility
    - Timing aligns with surveillance schedule
5. **Witness Audit Execution**
6. Follow procedures in ASC-AOP-02 Section 6.3.
7. Observation of complete audit cycle (opening through closing).
8. Evaluation of auditor competence and methodology.
9. Review of audit report and certification decision.
10. **Witness Audit Reporting**
11. Witness audit results included in surveillance report.
12. Findings related to auditor competence documented.
13. Recommendations for training or corrective action if needed.

6.2.5 Surveillance Reporting

1. **Report Preparation**
2. Lead Assessor prepares surveillance report including:
    - Surveillance scope and activities conducted
    - CB self-assessment summary
    - Documents and records reviewed
    - Witness audit results (if conducted)
    - Findings and evidence
    - Corrective actions required
    - Recommendation for continued accreditation
    - Next surveillance due date
3. **Report Review and Approval**
4. Report reviewed by Quality Manager for completeness.
5. Report finalized and approved by Lead Assessor.
6. Report distributed to CB within 15 business days of surveillance completion.
7. **FDA Reporting**
8. Surveillance report submitted to FDA electronically in English per 21 CFR 1.623(a).
9. Submission within 45 days of completing surveillance.
10. Report includes up-to-date list of CB's audit agents.

6.2.6 Corrective Actions

1. **Corrective Action Requirements**
2. CB must address all nonconformities identified during surveillance.
3. Corrective action plan submitted within 30 days.
4. Plan must include root cause analysis, actions, timeline, and evidence.
5. **Verification**

6. Lead Assessor reviews and verifies corrective actions.
7. Verification methods based on severity:
    - Document review for minor nonconformities
    - Onsite verification for major nonconformities
8. Verification results documented.
9. **Escalation**
10. Failure to submit adequate corrective actions may result in:
    - Suspension of accreditation
    - Scope reduction
    - Withdrawal of accreditation
11. Enforcement actions follow ASC-AOP-04.

6.3 Reassessment

6.3.1 Reassessment Planning

1. **Reassessment Triggers**
2. **Scheduled:** At least every four years from initial accreditation date.
3. **Early Reassessment:** May be conducted sooner if:
    - Significant nonconformities during surveillance
    - Major organizational changes (ownership, management, structure)
    - Scope expansion requested
    - Substantial changes to procedures or systems
    - Serious complaints or performance issues
    - FDA requests reassessment
4. **Notification**
5. CB notified of reassessment at least 90 days in advance.
6. Notification includes:

- Reassessment scope and objectives
- Tentative schedule
- Documentation requirements
- Team composition
- Witness audit requirements

7. **Reassessment Scope**

8. Comprehensive evaluation of all aspects of CB's operations:
    - Organizational structure and governance
    - Personnel competence and qualifications
    - Quality management system
    - Audit and certification procedures
    - Impartiality and conflict of interest management
    - Complaint and appeal handling
    - Record-keeping and FDA reporting
    - Performance since last reassessment

6.3.2 Reassessment Execution

1. **Assessment Methodology**
2. Reassessment follows same methodology as initial assessment per ASC-AOP-02.
3. Comprehensive onsite assessment at CB's headquarters.
4. Witness audit(s) of representative regulatory audits.
5. Document and record review.
6. Personnel interviews and competence verification.
7. Process observation and evaluation.
8. **Focus Areas**
9. Reassessment emphasizes:
    - Performance trends since last reassessment
    - Resolution of previous nonconformities

- Changes to organization, personnel, or procedures
- Compliance with ongoing surveillance findings
- Effectiveness of quality management system
- Continued competence of auditors and personnel

10. **Duration**

11. Reassessment typically requires 3-5 days onsite depending on:
    - CB's size and complexity
    - Number of scopes
    - Number of locations
    - Performance history

12. Additional time for witness audits and report preparation.

6.3.3 Reassessment Reporting

1. **Report Structure**

2. Comprehensive reassessment report similar to initial assessment report.

3. Report includes:
    - Executive summary
    - Reassessment details and methodology
    - Findings and evidence
    - Witness audit results
    - Performance evaluation since last reassessment
    - Corrective actions and verification
    - Recommendation for accreditation renewal

4. Report prepared per ASC-AOP-02 Section 6.4.

5. **Report Distribution**

6. Report distributed to:
    - CB (within 15 business days)
    - Accreditation Decision Committee

- ASC management

7. Report retained for 10 years.

6.3.4 Accreditation Renewal Decision

1. **Decision-Making Process**
2. Accreditation Decision Committee reviews reassessment report.
3. Committee makes one of following decisions:
   - **Renew Accreditation:** CB continues to meet requirements
   - **Renew with Conditions:** Minor nonconformities must be resolved within specified timeframe
   - **Suspend Accreditation:** Major nonconformities require resolution before renewal
   - **Withdraw Accreditation:** CB fails to meet requirements; accreditation terminated
4. Decision follows procedures in ASC-SOP-AB-01 Section 6.3.
5. **Renewal Certificate**
6. If accreditation renewed, new certificate issued indicating:
   - Renewed accreditation scope(s)
   - New effective date and expiration date (maximum 4 years)
   - Updated accreditation number (if applicable)
7. Certificate replaces previous certificate.
8. **FDA Notification**
9. ASC notifies FDA of renewal decision per 21 CFR 1.623.
10. Immediate notification for renewal, suspension, or withdrawal.
11. Updated accreditation information provided.

6.4 Special Circumstances

6.4.1 Scope Expansion

1. **Expansion Request**
2. CB may request expansion of accreditation scope at any time.
3. Request must include:
    - Proposed new scope(s)
    - Justification and business need
    - Evidence of competence in new scope
    - Personnel qualifications for new scope
    - Procedures for new scope
4. **Scope Expansion Assessment**
5. ASC conducts focused assessment of new scope:
    - Document review of procedures and competence
    - Personnel interviews and qualification verification
    - Witness audit in new scope (if available)
    - Evaluation of capacity and resources
6. Assessment may be combined with scheduled surveillance or reassessment.
7. **Decision and Notification**
8. Accreditation Decision Committee reviews scope expansion request.
9. Decision to approve, deny, or defer expansion.
10. If approved, updated certificate issued with expanded scope.
11. FDA notified of scope expansion per 21 CFR 1.623(c)(1).

6.4.2 CB-Initiated Changes

1. **Notification Requirements**
2. CB must notify ASC within 30 days of significant changes:

- Organizational structure or ownership
- Key personnel (management, lead auditors, decision-makers)
- Procedures or quality management system
- Facilities or locations
- Scope of operations
- Legal status or name

3. **Change Evaluation**

4. ASC evaluates impact of changes on CB's accreditation:
   - Document review of changes
   - Assessment of continued compliance
   - Verification of competence (for personnel changes)
   - Onsite visit if needed

5. Evaluation may be conducted as special surveillance or incorporated into scheduled surveillance.

6. **Action Based on Changes**

7. ASC may:
   - Accept changes with no action
   - Require additional documentation or verification
   - Conduct special surveillance or reassessment
   - Suspend accreditation pending verification
   - Reduce scope or withdraw accreditation if changes compromise competence

6.4.3 Complaint-Triggered Surveillance

1. **Complaint Evaluation**
2. Complaints about accredited CB's performance evaluated by Quality Manager.
3. Evaluation determines if special surveillance needed based on:
   - Severity and credibility of complaint

- Potential impact on food safety or public health
- Pattern of similar complaints
- CB's response to complaint

4. **Special Surveillance**
5. Unscheduled surveillance conducted to investigate complaint.
6. Focused on specific issues raised in complaint.
7. May include onsite visit, witness audit, or document review.
8. Results documented in special surveillance report.
9. **Follow-Up Actions**
10. Based on surveillance findings:
    - No action if complaint unsubstantiated
    - Corrective actions required if issues confirmed
    - Enforcement actions per ASC-AOP-04 if serious nonconformities found
11. Complainant notified of outcome (maintaining confidentiality).

6.5 Surveillance and Reassessment Records

1. **Records Maintained**
2. Master surveillance schedule
3. CB self-assessment reports
4. Surveillance plans and reports
5. Witness audit observation reports
6. Reassessment reports
7. Corrective action plans and verification records
8. FDA submission confirmations
9. Accreditation renewal certificates
10. Correspondence with CBs
11. **Record Retention**

12. All records retained for minimum 10 years per 21 CFR 1.625.
13. Records maintained in secure electronic and physical formats.
14. Access limited to authorized personnel.
15. FDA granted access upon request.

7. Performance Monitoring

7.1 Key Performance Indicators

ASC monitors surveillance and reassessment performance using:

- Percentage of surveillance activities completed on schedule
- Average time from surveillance completion to report issuance
- Percentage of surveillance reports submitted to FDA within 45 days
- Number and severity of nonconformities identified
- Percentage of corrective actions verified on time
- Number of enforcement actions (suspension, withdrawal, scope reduction)
- Number of complaints about accredited CBs

7.2 Continuous Improvement

- Performance data reviewed quarterly by ASC management.
- Trends analyzed to identify improvement opportunities.
- Surveillance procedures updated based on experience and feedback.
- Assessor training adjusted to address common findings.

8. References to Regulations

- **21 CFR 1.621:** Monitoring Performance of Accredited Third-Party Certification Bodies
- **21 CFR 1.622:** Self-Assessment Requirements for Accreditation Bodies
- **21 CFR 1.623:** Reporting and Notifications to FDA

- **21 CFR 1.625:** Records Requirements
- **ISO/IEC 17011:2017 Clause 7.9:** Surveillance of Accredited Conformity Assessment Bodies
- **ISO/IEC 17011:2017 Clause 7.10:** Reassessment

9. Revision History

Revision	Date	Description of Change	Approved By
01	October 2025	Initial Issue – Procedures for ongoing surveillance and periodic reassessment of accredited certification bodies	Muhammad Fahmy, Chairman

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