ASC-SOP-AB-01: Accreditation and Oversight Procedure

Title: Accreditation and Oversight of Third-Party Certification Bodies
Document No.: ASC-SOP-AB-01
Revision: 01
Effective Date: October 2025
Prepared by: Muhammad Fahmy, Chairman
Approved by: [Second Chairman Name]
Applies to: All accreditation and oversight activities conducted by American Standardization Council LLP (ASC) under the FDA Accredited Third-Party Certification Program

---

1. Purpose

This procedure defines how the American Standardization Council LLP (ASC) performs the assessment, accreditation, surveillance, and reassessment of third-party certification bodies (CBs) to ensure compliance with the FDA Accredited Third-Party Certification Program requirements (21 CFR Part 1, Subpart M) and ISO/IEC 17011 principles.

2. Scope

This SOP applies to all ASC personnel, assessors, and committees involved in the accreditation, oversight, and monitoring of CBs performing food safety audits under FDA-recognized scopes such as Preventive Controls for Human Food, Dietary Supplements, and other applicable categories.

3. References

- 21 CFR Part 1, Subpart M: Accreditation of Third-Party Certification Bodies

- ISO/IEC 17011:2017: Conformity Assessment – Requirements for Accreditation Bodies
- ASC-MS-01: Accreditation & Certification Management System Manual
- ASC-AGM-01: Accreditation Governance Manual
- ASC-QMS-01: Quality Management System Manual
- ASC-AOP-02: Onsite Assessment and Witness Audit Procedure
- ASC-AOP-03: Surveillance and Reassessment Procedure
- ASC-AOP-04: Suspension, Withdrawal, and Scope Reduction Procedure
- ASC-AOP-05: Competence and Qualification of Assessors
- SOP-01: Accreditation Application and Contract Review
- SOP-03: Decision-Making and Impartiality Control

4. Definitions

Accreditation: Formal recognition by ASC that a certification body is competent to carry out specific conformity assessment tasks.

Certification Body (CB): An organization seeking or maintaining accreditation under ASC to perform FDA-recognized audits.

Surveillance: Ongoing oversight activities conducted to ensure continuing compliance of accredited CBs.

Reassessment: Comprehensive review and reevaluation of a CB's compliance and performance, conducted at least once every four years.

Witness Audit: Observation of a CB's audit by ASC assessors to verify auditor competence and methodology.

Third-Party Certification Body: A foreign government, agency of a foreign government, foreign cooperative, or any other third party eligible for accreditation to conduct food safety audits and certify eligible entities under FDA regulations.

Regulatory Audit: An audit conducted to determine compliance with applicable food safety requirements of the FD&C Act and FDA regulations, the results of which are used for certification under sections 801(q) or 806.

5. Responsibilities

Role	Responsibility
Chairmen (Authorized Partners)	Oversee implementation of the accreditation program; approve accreditation and enforcement decisions.
Accreditation Decision Committee (ADC)	Review assessment results and make impartial accreditation decisions independent from assessment teams.
Lead Assessors and Technical Experts	Conduct assessments, surveillance, witness audits, and prepare comprehensive assessment reports.
Quality Manager	Maintain QMS documentation, records, notifications, and communication with FDA.
Administrative Officer	Manage scheduling, application processing, recordkeeping, and coordination of assessment activities.
Impartiality and Risk Committee	Monitor conflicts of interest, review impartiality declarations, and oversee risk management.

6. Procedure

6.1 Application and Contracting

1. **Application Submission**
2. CB submits an application for accreditation specifying requested FDA scope(s) using the official application form.
3. Application must include documentation of legal authority, competence, capacity, and quality assurance procedures.
4. **Application Review**
5. ASC reviews the application for completeness and eligibility under 21 CFR 1.640-1.642.
6. Administrative Officer logs application in tracking system and assigns unique reference number.

7. Technical review conducted to verify CB's scope is within ASC's recognition scope.
8. **Accreditation Agreement**
9. ASC issues a formal Accreditation Agreement outlining legal authority, confidentiality, record access, and financial terms.
10. The Agreement must include ASC's authority to:
    - Review all relevant records
    - Conduct onsite assessments and witness audits
    - Perform surveillance and reassessment
    - Suspend, withdraw, or reduce scope
11. Agreement signed by both parties before assessment commences.
12. **Reference:** See SOP-01 for detailed application and contract review procedures.

6.2 Assessment Process

1. **Document Review**
2. ASC conducts comprehensive document review to confirm the CB's:
    - Quality Management System (QMS)
    - Competence and qualification of personnel
    - Procedures for conducting food safety audits
    - Conflict of interest protections
    - Quality assurance procedures
3. **Assessment Planning**
4. Lead Assessor develops assessment plan specifying:
    - Assessment team composition
    - Onsite assessment dates and locations
    - Witness audit schedule
    - Assessment criteria and methodology
5. Assessment plan shared with CB at least 30 days in advance.

6. **Onsite Assessment**
7. Performed at the CB's headquarters and/or key operational locations.
8. Assessment team evaluates:
    - Organizational structure and governance
    - Personnel competence and training records
    - Internal procedures and quality controls
    - Record-keeping and reporting systems
    - Impartiality and conflict of interest management
9. **Witness Audit**
10. ASC witnesses at least one representative audit performed by the CB.
11. Witness audit evaluates:
    - Auditor competence and professionalism
    - Audit methodology and thoroughness
    - Compliance with FDA requirements and CB procedures
    - Report writing and decision-making processes
12. Additional witness audits may be conducted based on scope and risk.
13. **Findings and Nonconformities**
14. Findings recorded and classified as:
    - **Conformity:** Meets requirements
    - **Observation:** Area for improvement, no immediate action required
    - **Minor Nonconformity:** Isolated lapse, does not prevent accreditation
    - **Major Nonconformity:** Significant failure, must be corrected before accreditation
15. Nonconformities documented with evidence and regulatory references.
16. **Corrective Actions**
17. CB must submit corrective action plan within 30 days for all nonconformities.
18. ASC reviews and verifies effectiveness of corrective actions.

19. Major nonconformities must be fully resolved before accreditation decision.
20. **Assessment Report**
21. Lead Assessor prepares comprehensive assessment report including:
    - Executive summary
    - Assessment scope and methodology
    - Findings and evidence
    - Corrective actions and verification
    - Recommendation for accreditation decision
22. Report reviewed by Quality Manager for completeness and accuracy.
23. **Reference:** See ASC-AOP-02 for detailed onsite assessment and witness audit procedures.

6.3 Accreditation Decision

1. **Independent Review**
2. The Accreditation Decision Committee (ADC) reviews the assessment report.
3. ADC members must be independent from the assessment team.
4. ADC may request additional information or clarification.
5. **Decision-Making**
6. ADC makes one of the following decisions:
    - **Grant Accreditation:** CB meets all requirements
    - **Deny Accreditation:** CB fails to meet requirements or resolve major nonconformities
    - **Defer Decision:** Additional information or corrective actions needed
7. Decision documented with clear justification and regulatory references.
8. **Approval**
9. Accreditation decisions approved by the Chairmen (Authorized Partners).
10. Approval signatures required on decision documentation.

11. **Notification**
12. CB notified of decision in writing within 10 business days.
13. For denials, notification includes reasons and appeal rights.
14. **Accreditation Certificate**
15. Successful CBs receive an official ASC Accreditation Certificate indicating:
    - FDA scope(s) of accreditation
    - Effective date and expiration date
    - Unique accreditation number
    - Validity period (maximum four years)
16. Certificate includes authorization to use ASC accreditation mark.
17. **FDA Notification**
18. ASC notifies FDA electronically of all accreditation decisions within required timeframes per 21 CFR 1.623:
    - Immediate notification for granting, expanding, suspending, withdrawing, or reducing scope
    - Include CB name, contact information, scope, and effective dates
19. **Reference:** See SOP-03 for detailed decision-making and impartiality control procedures.

6.4 Surveillance and Reassessment

1. **Annual Surveillance**
2. Conducted annually to verify continued compliance of accredited CBs.
3. Surveillance activities include:
    - Review of CB's self-assessment reports
    - Review of regulatory audit reports submitted to FDA
    - Review of complaints and corrective actions
    - Monitoring of personnel changes and competence
    - Review of any changes to QMS or procedures

4. Surveillance may include onsite visits and witness audits.
5. **Biennial Witness Audits**
6. ASC conducts onsite observations of representative sample of regulatory audits performed by CB.
7. Conducted no later than 1 year after initial accreditation and every 2 years thereafter.
8. Includes visit to CB's headquarters or audit management location.
9. **Surveillance Reporting**
10. Lead Assessor prepares surveillance report documenting findings and recommendations.
11. Report submitted to FDA within 45 days of completing surveillance per 21 CFR 1.623(a).
12. **Full Reassessment**
13. Comprehensive reassessment conducted at least every four years.
14. Reassessment follows same process as initial assessment.
15. May be conducted sooner if:
    - Significant nonconformities identified during surveillance
    - Major changes to CB's operations or personnel
    - Complaints or concerns about CB performance
    - FDA requests reassessment
16. **Master Surveillance Schedule**
17. ASC maintains master surveillance schedule ensuring all accredited CBs reviewed on time.
18. Schedule reviewed quarterly and updated as needed.
19. Administrative Officer responsible for scheduling and coordination.
20. **Reference:** See ASC-AOP-03 for detailed surveillance and reassessment procedures.

6.5 Suspension, Withdrawal, or Scope Reduction

1. **Grounds for Enforcement Action**
2. ASC may suspend, withdraw accreditation, or reduce scope when CB:
    - Fails to correct nonconformities within specified timeframe
    - Violates contractual terms or accreditation requirements
    - Poses risk to food safety or public health
    - Fails to maintain competence or capacity
    - Violates impartiality or conflict of interest requirements
    - Fails to pay accreditation fees
    - Requests voluntary relinquishment
3. **Decision Process**
4. Enforcement decisions made by Accreditation Decision Committee.
5. Decisions follow procedures in ASC-AOP-04.
6. Decisions approved by Chairmen before implementation.
7. **Notification to CB**
8. ASC notifies CB in writing of enforcement action including:
    - Effective date of action
    - Reasons and evidence supporting decision
    - Requirements for reinstatement (if applicable)
    - Appeal rights and procedures
9. CB must immediately cease use of ASC accreditation mark.
10. **FDA Notification**
11. ASC notifies FDA immediately of any suspension, withdrawal, or scope reduction per 21 CFR 1.623(c)(2).
12. Notification includes:
    - Basis for action

- Effective date
- Updated accreditation information

13. **Public Disclosure**
14. ASC updates public directory of accredited bodies to reflect enforcement action.
15. Information posted on ASC website within 5 business days.
16. **Reinstatement**
17. CB may apply for reinstatement after addressing deficiencies.
18. Reinstatement requires full reassessment.
19. Decision made by ADC following normal accreditation procedures.
20. **Reference:** See ASC-AOP-04 for detailed suspension, withdrawal, and scope reduction procedures.

6.6 Reporting and Notification

1. **Records Maintained**
2. ASC prepares and maintains the following records:
    - Application forms and accreditation agreements
    - Assessment plans, reports, and corrective action records
    - Accreditation decision minutes and justifications
    - Surveillance and reassessment reports
    - Complaints, appeals, and resolution documentation
    - Annual self-assessment and monitoring summaries
    - Communications with FDA
    - Enforcement action documentation
3. **FDA Reporting Requirements**
4. ASC reports to FDA electronically in English per 21 CFR 1.623:
    - **Immediate notification:** Granting, expanding, suspending, withdrawing, or reducing accreditation

- **Within 30 days:** Denying accreditation or significant changes to ASC operations
- **Within 45 days:** Surveillance assessment results and annual self-assessment reports

5. Reports submitted through FDA's designated electronic system.
6. **Annual Self-Assessment**
7. ASC conducts annual self-assessment of its own performance per 21 CFR 1.622.
8. Self-assessment includes:
    - Performance of officers, employees, and agents
    - Consistency in conducting accreditation activities
    - Compliance with conflict of interest requirements
    - Onsite observation of representative sample of witness audits
9. Report submitted to FDA within 45 days of completion.
10. **Public Information**
11. ASC maintains public directory of accredited CBs on website including:
    - CB name and contact information
    - Scope(s) of accreditation
    - Accreditation status and effective dates
    - Accreditation number
12. Directory updated within 5 business days of any changes.

6.7 Record Control

1. **Retention Period**
2. All records retained for minimum of **10 years** in accordance with 21 CFR 1.625.
3. Records include documents and data created during ASC's recognition period.
4. **Storage and Security**
5. Records maintained in secure digital and physical formats.

6. Electronic records backed up regularly with offsite storage.
7. Physical records stored in locked, climate-controlled facility.
8. **Access Control**
9. Access to records limited to authorized personnel.
10. Access log maintained for all record retrievals.
11. Confidential information protected per ASC Confidentiality Policy (POL-02).
12. **FDA Access**
13. FDA granted access to relevant records during oversight or verification activities.
14. Records provided electronically in English within requested timeframe.
15. ASC cooperates fully with FDA monitoring and assessment activities.
16. **Document Control**
17. All documents version-controlled with revision history.
18. Obsolete documents archived and clearly marked.
19. Current versions available to authorized personnel through document management system.

6.8 Confidentiality and Impartiality

1. **Confidentiality Requirements**
2. All ASC staff and assessors sign confidentiality agreements annually.
3. Confidential information includes:
    - CB proprietary information
    - Assessment findings and reports
    - Audit reports and certifications
    - Personnel information
4. Information protected under ASC Data Protection Policy.
5. **Impartiality Management**

6. All personnel sign impartiality declarations annually.
7. Conflicts of interest identified and managed per SOP-07.
8. Impartiality and Risk Committee monitors compliance.
9. Personnel recuse themselves from decisions involving conflicts.
10. **Independence Requirements**
11. Assessment team members independent from decision-making.
12. ADC members independent from assessment activities.
13. No financial interests in accredited CBs.
14. Separation of consulting and accreditation activities.

7. Competence and Capacity

7.1 Personnel Qualifications

ASC maintains qualified personnel to perform all required activities:

- **Lead Assessors:** Minimum 5 years experience in food safety, quality management, or regulatory compliance; training in ISO/IEC 17011 and 21 CFR Part 1 Subpart M
- **Technical Experts:** Subject matter expertise in specific FDA scopes (e.g., Preventive Controls, Dietary Supplements)
- **ADC Members:** Senior professionals with accreditation or certification experience; trained in impartial decision-making
- **Quality Manager:** Quality management system expertise; knowledge of FDA and ISO requirements

7.2 Training and Development

- All personnel receive initial training on FDA requirements, ISO/IEC 17011, and ASC procedures.
- Annual refresher training on regulatory updates and procedural changes.
- Competence assessed and documented per ASC-AOP-05.

- Ongoing professional development encouraged and supported.

7.3 Financial Resources

- ASC maintains adequate financial resources to:
- Conduct all assessment and surveillance activities
- Employ qualified personnel
- Maintain facilities and equipment
- Fulfill reporting and notification obligations
- Maintain professional liability insurance

7.4 Reference

See ASC-AOP-05 for detailed competence and qualification requirements.

8. Records

Records generated from this SOP include:

- Application forms and accreditation agreements
- Assessment plans, reports, and corrective action records
- Witness audit observation reports
- Accreditation decision minutes and certificates
- Surveillance and reassessment reports
- Enforcement action documentation
- Notifications to FDA
- Annual monitoring and self-assessment summaries
- Confidentiality and impartiality declarations
- Training and competence records

9. References to Regulations

- **21 CFR 1.611(a)(1)-(4):** Legal Authority
- **21 CFR 1.612(a)(1)-(b):** Competency and Capacity
- **21 CFR 1.613:** Conflict of Interest Protections
- **21 CFR 1.614:** Quality Assurance Procedures
- **21 CFR 1.615:** Records Procedures
- **21 CFR 1.620:** Evaluation of Third-Party Certification Bodies
- **21 CFR 1.621:** Monitoring Performance of Accredited CBs
- **21 CFR 1.622:** Self-Assessment Requirements
- **21 CFR 1.623:** Reporting and Notifications to FDA
- **21 CFR 1.624:** Conflict of Interest Program
- **21 CFR 1.625:** Records Requirements
- **ISO/IEC 17011:2017:** Conformity Assessment – Requirements for Accreditation Bodies

10. Revision History

Revision	Date	Description of Change	Approved By
01	October 2025	Initial Issue – Created to align ASC with FDA FSMA Accreditation Body requirements and integrate with existing ASC-MS-01 management system	Muhammad Fahmy, Chairman

---

Document Control:
This document is controlled and maintained by the ASC Quality Manager. Printed copies are uncontrolled and may not reflect the current version. Always refer to the electronic document management system for the latest approved version.