ASC-Accredit Compliance with FDA 21 CFR Part 1 Subpart M

Overview

This document demonstrates how ASC-Accredit meets the requirements of FDA regulation 21 CFR Part 1 Subpart M for recognition as an accreditation body to accredit third-party certification bodies conducting food safety audits.

Key Requirements from 21 CFR Part 1 Subpart M

§ 1.611 Legal Authority

Requirement: An accreditation body must demonstrate authority (as governmental entity or legal entity with contractual rights) to: 1. Review relevant records 2. Conduct onsite assessments and witness audits 3. Perform reassessments and surveillance 4. Suspend, withdraw, or reduce scope of accreditation

ASC-Accredit Compliance: - **Legal Status:** ASC-Accredit is an independent legal entity registered as a non-profit organization with full contractual authority - **Documented Authority:** Section 6 of ASC-MS-01 Manual establishes structural requirements and authority - **Contractual Rights:** All accreditation agreements grant ASC-Accredit authority to conduct assessments, surveillance, and enforcement actions - **Enforcement Powers:** SOP-03 documents decision-making authority including suspension and withdrawal procedures

§ 1.612 Competency and Capacity

Requirement: An accreditation body must demonstrate: 1. Competent personnel with knowledge of food safety systems 2. Capacity to perform assessments and monitoring 3. Technical expertise in applicable standards

ASC-Accredit Compliance: - **Competence Framework:** Annex B (ASC Competence Matrix) defines qualification requirements for all roles - **Personnel Qualifications:** SOP-05 establishes auditor competence and qualification procedures - **Technical Expertise:** Lead Assessors require minimum 5 years healthcare experience with quality management background - **Capacity Documentation:** Section 7 (Resource Management) demonstrates adequate staffing and infrastructure - **Training Programs:** Comprehensive training requirements documented in SOP-05

§ 1.613 Conflict of Interest Protections

Requirement: An accreditation body must demonstrate: 1. Written program to identify and manage conflicts of interest 2. Independence from accredited bodies 3. Prohibition on financial interests in accredited entities 4. Safeguards against undue influence

ASC-Accredit Compliance: - **Impartiality Policy:** Publicly available policy addressing conflict of interest management - **Independent Committee:** Annex C establishes Risk & Impartiality Committee with independent oversight - **Conflict Declaration:** Conflict of Interest Declaration Form required for all personnel - **SOP-07:** Impartiality and Risk Management Procedure provides systematic approach - **Financial Independence:** Section 5 commits to preventing commercial pressures from influencing decisions - **Separation of Functions:** SOP-03 ensures decision-makers are independent from assessment teams

§ 1.614 Quality Assurance Procedures

Requirement: An accreditation body must demonstrate: 1. Written program for monitoring and evaluating performance 2. Procedures to identify deficiencies 3. Corrective action processes

ASC-Accredit Compliance: - **Quality Management System:** Section 10 establishes management system requirements - **Internal Audit Program:** SOP-06 requires regular internal audits - **Management Review:** SOP-06 establishes annual management review process - **Continual Improvement:** Section 10 commits to ongoing improvement - **Performance Monitoring:** SOP-05 includes assessor performance evaluation procedures - **Corrective Actions:** Documented procedures for identifying and addressing deficiencies

§ 1.615 Records Procedures

Requirement: An accreditation body must demonstrate: 1. Written procedures to establish, control, and retain records 2. Adequate record retention periods 3. Capability to meet reporting and notification requirements

ASC-Accredit Compliance: - **Document Control:** Section 9 (Information Management & Record Control) establishes comprehensive system - **Record Retention:** All accreditation records maintained for minimum 5 years - **Electronic Systems:** Application tracking system and document management system - **Reporting Capability:** SOP-04 establishes reporting procedures for complaints and appeals - **Notification Procedures:** SOP-03 requires timely notification of accreditation decisions

Additional FDA Requirements for Recognized Accreditation Bodies

§ 1.620 Evaluation of Third-Party Certification Bodies

ASC-Accredit Procedures: - **SOP-01:** Application and Contract Review ensures thorough evaluation before accreditation - **SOP-02:** Assessment and Witness Audit Procedure includes onsite observation requirements - **Witness Audits:** Assessment teams observe representative sample of audits conducted by applicants - **Documentation Review:** Comprehensive review of training, qualifications, and internal systems

§ 1.621 Monitoring Performance of Accredited Bodies

ASC-Accredit Procedures: - **Annual Assessments:** SOP-02 requires annual comprehensive performance assessments - **Surveillance Activities:** Regular surveillance visits documented in Section 8 (Process Requirements) - **Onsite Observations:** Biennial onsite observations of regulatory audits - **Records Review:** Continuous monitoring of audit reports and compliance history

§ 1.622 Self-Assessment Requirements

ASC-Accredit Procedures: - **Annual Self-Assessment:** SOP-06 requires annual management review including self-assessment - **Performance Evaluation:** Assessment of officers, employees, and agents - **Conflict of Interest Monitoring:** Annual review of compliance with impartiality requirements - **Corrective Actions:** Documentation and implementation of improvements

§ 1.623 Reporting and Notifications to FDA

ASC-Accredit Capability: - **Electronic Submission:** Systems in place for electronic reporting in English - **Timely Reporting:** Procedures for immediate notification of accreditation actions - **Assessment Reports:** 45-day reporting timeline for assessment results - **Self-Assessment Reports:** Annual submission of self-assessment results

§ 1.624 Conflict of Interest Program

ASC-Accredit Implementation: - **Written Program:** Comprehensive Anti-Bribery and Integrity Policy (ISO 37001-aligned) - **Financial Independence:** Prohibition on ownership or financial interest in accredited bodies - **Gift Policy:** Clear restrictions on accepting money, gifts, or items of value - **Monitoring:** Impartiality Committee oversight of conflict management

§ 1.625 Records Requirements

ASC-Accredit System: - **5-Year Retention:** All accreditation records maintained electronically for minimum 5 years - **Comprehensive Records:** Documents include applications, assessments, decisions, appeals, and monitoring - **Electronic Format:** Modern document management system with backup and security - **Accessibility:** Records available for FDA review and audit

Scope of Accreditation

ASC-Accredit is prepared to accredit third-party certification bodies for:

1. **Food Safety Audits** of eligible entities including:
2. Foreign food facilities

3. Food manufacturing and processing operations
4. Food packing and holding facilities
5. **Certification Services** for:
6. Facility certifications under section 806 (Voluntary Qualified Importer Program)
7. Food certifications under section 801(q) (Import admissibility)
8. **Geographic Scope:**
9. International operations with cross-frontier accreditation capability
10. Cooperation with foreign accreditation bodies and regulatory authorities

Documentation System

Systems Documentation

- **ASC-MS-01 Manual:** Complete management system documentation
- **Seven SOPs:** Detailed operational procedures
- **Quality Records:** Comprehensive record-keeping system
- **Electronic Systems:** Application tracking and document management

Competence Documentation

- **Annex B:** Competence Matrix defining requirements for all roles
- **SOP-05:** Auditor qualification and training procedures
- **Personnel Files:** Qualifications, training records, and performance evaluations
- **Continuous Development:** Ongoing training and competence assessment

Independence Documentation

- **Impartiality Policy:** Public commitment to independence
- **Annex C:** Risk & Impartiality Committee Charter
- **SOP-07:** Risk management procedures

- **Conflict Declarations:** Required from all personnel

Monitoring and Auditing Capacity

- **SOP-02:** Assessment and witness audit procedures
- **SOP-06:** Internal audit and management review
- **Surveillance Program:** Regular monitoring of accredited bodies
- **Performance Metrics:** Key performance indicators and reporting

Compliance Summary

FDA Requirement	ASC-Accredit Documentation	Status
§ 1.611 Legal Authority	ASC-MS-01 Sections 4, 6; Accreditation Agreements	✓ Compliant
§ 1.612 Competency & Capacity	ASC-MS-01 Section 7; Annex B; SOP-05	✓ Compliant
§ 1.613 Conflict of Interest	Impartiality Policy; Annex C; SOP-07; COI Form	✓ Compliant
§ 1.614 Quality Assurance	ASC-MS-01 Section 10; SOP-06	✓ Compliant
§ 1.615 Records Procedures	ASC-MS-01 Section 9; All SOPs	✓ Compliant
§ 1.620 Evaluation Procedures	SOP-01; SOP-02	✓ Compliant
§ 1.621 Performance Monitoring	SOP-02; ASC-MS-01 Section 8	✓ Compliant
§ 1.622 Self-Assessment	SOP-06	✓ Compliant
§ 1.623 Reporting to FDA	SOP-03; SOP-04; Electronic systems	✓ Compliant
§ 1.624 COI Program	Anti-Bribery Policy; Annex D; SOP-07	✓ Compliant
§ 1.625 Records Requirements	ASC-MS-01 Section 9; Document control system	✓ Compliant

Implementation Readiness

ASC-Accredit has established comprehensive systems, procedures, and documentation to meet all requirements of 21 CFR Part 1 Subpart M. The organization is prepared to:

1. **Apply for FDA Recognition** with complete documentation package
2. **Undergo FDA Assessment** demonstrating competency and capacity
3. **Accredit Third-Party Certification Bodies** following FDA recognition
4. **Report to FDA** on accreditation activities and performance
5. **Maintain Compliance** through ongoing monitoring and improvement

References

- 21 CFR Part 1 Subpart M - Accreditation of Third-Party Certification Bodies
- ISO/IEC 17011:2017 - Conformity assessment - Requirements for accreditation bodies
- ISO 37001:2016 - Anti-bribery management systems
- FDA Guidance for Industry: Accreditation of Third-Party Certification Bodies