ASC-AOP-05: Competence and Qualification of Assessors

Title: Competence and Qualification of Assessors
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Approved by: [Second Chairman Name]
Applies to: All personnel involved in assessment, accreditation, and decision-making activities

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1. Purpose

This procedure establishes the requirements for competence, qualification, selection, training, and performance monitoring of ASC personnel, assessors, technical experts, and decision-makers involved in the accreditation of third-party certification bodies under the FDA Accredited Third-Party Certification Program and ISO/IEC 17011.

2. Scope

This procedure applies to all ASC personnel including: - Lead Assessors - Assessment Team Members - Technical Experts - Accreditation Decision Committee Members - Quality Manager - Administrative Officers - Chairmen (Authorized Partners)

3. References

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

- ISO/IEC 17021-1:2015: Requirements for Bodies Providing Audit and Certification of Management Systems
- ASC-MS-01: Accreditation & Certification Management System Manual
- ASC-SOP-AB-01: Accreditation and Oversight Procedure
- SOP-05: Auditor Competence and Qualification

4. Definitions

Competence: Demonstrated ability to apply knowledge and skills to achieve intended results.

Qualification: Formal recognition that a person meets specified competence requirements for a particular role.

Lead Assessor: Senior assessor responsible for planning, conducting, and reporting assessments of certification bodies.

Assessment Team Member: Qualified assessor who participates in assessment activities under direction of Lead Assessor.

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

Assessor-in-Training: Individual undergoing training and qualification process to become qualified assessor.

Continuing Professional Development (CPD): Ongoing learning and development activities to maintain and enhance competence.

5. Responsibilities

Role	Responsibility
Chairmen (Authorized Partners)	Approve personnel qualifications; authorize assessor certifications; ensure adequate resources for competence development.
Quality Manager	Manage competence framework; maintain personnel records; coordinate training; monitor performance; conduct competence evaluations.
Lead Assessors	Mentor assessors-in-training; evaluate team member performance; recommend qualifications.
Human Resources	Recruit qualified candidates; maintain personnel files; coordinate onboarding.

6. Procedure

6.1 Competence Requirements

6.1.1 Lead Assessor Competence

Education: - Bachelor's degree in food science, microbiology, chemistry, engineering, quality management, or related field - Advanced degree (Master's or PhD) preferred

Experience: - Minimum 5 years professional experience in one or more of the following: - Food safety management and regulation - Quality management systems - Regulatory compliance and auditing - Certification or accreditation activities - Minimum 2 years experience conducting audits or assessments - Experience with FDA regulations and food safety requirements

Knowledge: - Thorough understanding of: - 21 CFR Part 1 Subpart M (FDA Third-Party Certification Program) - ISO/IEC 17011 (Accreditation Body Requirements) - ISO/IEC 17065 (Certification Body Requirements) - FDA Food Safety Modernization Act (FSMA) - Preventive Controls for Human Food (21 CFR Part 117) - Good Manufacturing Practices (21 CFR Part 110) - Hazard Analysis and Risk-Based Preventive Controls - Working

knowledge of: - ISO 9001 Quality Management Systems - ISO 22000 Food Safety Management Systems - HACCP principles - Audit and assessment methodologies

Skills: - Assessment planning and execution - Evidence collection and analysis - Report writing and documentation - Effective communication (written and oral) - Team leadership and coordination - Conflict resolution and diplomacy - Critical thinking and problem-solving - Time management and organization

Personal Attributes: - Ethical and professional conduct - Objectivity and impartiality - Attention to detail - Cultural sensitivity - Adaptability and flexibility - Commitment to continuous learning

Training: - Successful completion of ASC Lead Assessor Training Program (minimum 40 hours) - ISO/IEC 17011 training (minimum 16 hours) - FDA FSMA and Third-Party Certification Program training (minimum 16 hours) - Assessment techniques and methodology training - Report writing training

Language: - Fluent in English (reading, writing, speaking) - Additional languages beneficial based on CB locations

6.1.2 Assessment Team Member Competence

Education: - Bachelor's degree in relevant field - Associate degree with additional experience may be acceptable

Experience: - Minimum 3 years professional experience in food safety, quality management, or regulatory compliance - Minimum 1 year experience in auditing or assessment activities - Experience with FDA regulations preferred

Knowledge: - Good understanding of: - FDA food safety requirements - ISO/IEC 17011 and 17065 - Food safety management principles - Audit and assessment techniques

Skills: - Document review and analysis - Interviewing and communication - Evidence collection and documentation - Teamwork and collaboration

Training: - ASC Assessment Team Member Training (minimum 24 hours) - ISO/IEC 17011 awareness training (minimum 8 hours) - FDA FSMA overview training (minimum 8 hours)

6.1.3 Technical Expert Competence

Education: - Bachelor's degree or higher in specific technical field - Advanced degree preferred for complex scopes

Experience: - Minimum 5 years specialized experience in specific FDA scope area: - Preventive Controls for Human Food - Preventive Controls for Animal Food - Dietary Supplements (21 CFR Part 111) - Seafood HACCP (21 CFR Part 123) - Juice HACCP (21 CFR Part 120) - Low-Acid Canned Foods (21 CFR Part 113) - Other FDA-recognized scopes - Industry or regulatory experience in specific scope - Recognized expertise demonstrated through publications, presentations, or professional recognition

Knowledge: - Deep technical knowledge of specific FDA scope - Current industry practices and technologies - Regulatory requirements and guidance documents - Hazards and controls specific to scope

Skills: - Technical evaluation and analysis - Expert consultation and guidance - Communication of complex technical concepts

Training: - ASC Technical Expert Orientation (minimum 8 hours) - Scope-specific technical training as needed

6.1.4 Accreditation Decision Committee Member Competence

Education: - Bachelor's degree in relevant field - Advanced degree preferred

Experience: - Minimum 7 years senior-level experience in: - Accreditation or certification activities - Food safety regulation or compliance - Quality management - Auditing or assessment - Experience in decision-making or governance roles

Knowledge: - Comprehensive understanding of: - Accreditation principles and practices - FDA Third-Party Certification Program - ISO/IEC 17011 and 17065 - Impartiality and conflict of interest management - Decision-making methodologies

Skills: - Critical analysis and evaluation - Independent judgment - Deliberation and consensus-building - Documentation and justification of decisions

Personal Attributes: - High ethical standards - Impartiality and independence - Sound judgment - Confidentiality and discretion

Training: - ASC Decision-Maker Training (minimum 16 hours) - Impartiality and conflict of interest training (minimum 4 hours) - Decision-making methodology training

6.1.5 Quality Manager Competence

Education: - Bachelor's degree in quality management, food science, or related field - Quality management certification (e.g., ASQ CQM, CQA) preferred

Experience: - Minimum 5 years experience in quality management systems - Minimum 2 years experience in accreditation or certification - Experience with ISO management systems and FDA regulations

Knowledge: - Expert knowledge of: - Quality management principles and practices - ISO/IEC 17011 requirements - Document and record control - Internal auditing - Management review processes - Continuous improvement methodologies

Skills: - QMS development and maintenance - Internal auditing and assessment - Training and competence management - Process improvement - Stakeholder communication

Training: - Quality management system training - ISO/IEC 17011 implementation training - Internal auditor training - FDA regulatory training

6.2 Selection and Qualification Process

6.2.1 Recruitment and Selection

1. **Position Requirements**
2. Quality Manager develops position description with:
    - Role and responsibilities
    - Competence requirements (education, experience, knowledge, skills)
    - Training requirements
    - Performance expectations
3. Position description approved by Chairmen.
4. **Candidate Sourcing**
5. Positions advertised through:
    - Professional associations (IAS, ANAB, ANSI)
    - Industry networks and conferences
    - Online job platforms

    - University partnerships

6. Referrals from current assessors and industry contacts.

7. **Application Review**

8. Quality Manager reviews applications for:
    - Minimum education and experience requirements
    - Relevant knowledge and skills
    - Professional references
    - Conflict of interest potential

9. Shortlisted candidates invited for interview.

10. **Interview and Evaluation**

11. Structured interview conducted by Quality Manager and Lead Assessor.

12. Evaluation of:
    - Technical knowledge (FDA regulations, food safety, quality management)
    - Assessment experience and methodology
    - Communication and interpersonal skills
    - Ethical conduct and professionalism
    - Cultural fit with ASC values

13. Technical knowledge test may be administered.

14. **Reference Checks**

15. Professional references contacted to verify:
    - Work history and performance
    - Technical competence
    - Professional conduct
    - Suitability for role

16. Minimum 2 professional references required.

17. **Background Verification**

18. Education credentials verified

19. Professional certifications verified
20. Background check conducted (criminal history, credit check if applicable)
21. Conflict of interest declaration completed
22. **Selection Decision**
23. Quality Manager makes selection recommendation to Chairmen.
24. Chairmen approve selection.
25. Offer extended to selected candidate.

6.2.2 Onboarding and Initial Training

1. **Orientation**
2. New personnel receive comprehensive orientation including:
    - ASC organizational structure and governance
    - Mission, vision, and values
    - Policies and procedures
    - Code of conduct and ethics
    - Confidentiality and impartiality requirements
    - IT systems and document management
    - Health and safety
3. **Role-Specific Training**
4. Personnel complete training specific to their role:
    - **Lead Assessors:** ASC Lead Assessor Training Program (40 hours)
    - **Assessment Team Members:** Assessment Team Member Training (24 hours)
    - **Technical Experts:** Technical Expert Orientation (8 hours)
    - **ADC Members:** Decision-Maker Training (16 hours)
    - **Quality Manager:** QMS and ISO 17011 Implementation Training
5. **Regulatory and Standards Training**

6. All personnel complete:
    - ISO/IEC 17011 training (8-16 hours depending on role)
    - FDA FSMA and 21 CFR Part 1 Subpart M training (8-16 hours)
    - Food safety fundamentals (if needed)
7. **Practical Training**
8. Assessors-in-training participate in:
    - Observation of experienced assessor conducting assessment
    - Co-assessment with Lead Assessor supervision
    - Witness audit observation
    - Report writing practice
9. Minimum 2 supervised assessments required before independent qualification.
10. **Competence Evaluation**
11. Knowledge test administered covering:
    - FDA regulations and FSMA
    - ISO/IEC 17011 and 17065
    - ASC procedures and requirements
    - Assessment methodology
12. Minimum passing score: 80%
13. Practical competence evaluated by supervising Lead Assessor.
14. **Qualification Approval**
15. Quality Manager reviews training records and competence evaluation.
16. Recommendation for qualification submitted to Chairmen.
17. Chairmen approve qualification.
18. Qualified personnel added to ASC assessor registry.

6.2.3 Assessor-in-Training Program

1. **Program Structure**

2. Structured program for developing Lead Assessor competence:
    - Phase 1: Classroom training and knowledge development (40 hours)
    - Phase 2: Observation and shadowing (minimum 2 assessments)
    - Phase 3: Supervised practice (minimum 2 assessments as team member)
    - Phase 4: Independent assessment with review (1 assessment)
    - Phase 5: Final evaluation and qualification
3. **Mentorship**
4. Each assessor-in-training assigned experienced Lead Assessor mentor.
5. Mentor provides:
    - Guidance and coaching
    - Feedback on performance
    - Assessment of competence development
    - Recommendation for qualification
6. **Performance Criteria**
7. Assessor-in-training evaluated on:
    - Assessment planning and preparation
    - Document review and analysis
    - Interviewing and communication
    - Evidence collection and documentation
    - Finding identification and classification
    - Report writing quality
    - Professionalism and ethics
8. **Qualification Decision**
9. Mentor submits qualification recommendation to Quality Manager.
10. Quality Manager reviews training records and performance evaluations.
11. Chairmen approve Lead Assessor qualification.

12. Typical program duration: 6-12 months.

6.3 Continuing Professional Development

6.3.1 Annual CPD Requirements

All qualified personnel must complete minimum continuing professional development annually:

Role	Minimum CPD Hours
Lead Assessor	24 hours
Assessment Team Member	16 hours
Technical Expert	16 hours
ADC Member	12 hours
Quality Manager	20 hours

6.3.2 CPD Activities

Acceptable CPD activities include:

1. **Formal Training**
2. Courses, workshops, webinars on relevant topics
3. Professional certification programs
4. University courses
5. **Professional Activities**
6. Conducting assessments and witness audits
7. Participation in technical committees
8. Peer review and calibration exercises
9. Internal auditing
10. **Self-Study**

11. Reading technical publications and regulatory updates
12. Online learning modules
13. Research and analysis
14. **Knowledge Sharing**
15. Presenting at conferences or workshops
16. Publishing articles or papers
17. Mentoring assessors-in-training
18. Developing training materials
19. **Regulatory Updates**
20. FDA guidance document reviews
21. ISO standard updates
22. Industry best practice developments

6.3.3 CPD Documentation

- Personnel maintain CPD log documenting:
- Activity description
- Date and duration
- Learning outcomes
- Evidence (certificates, attendance records)
- CPD records submitted to Quality Manager annually.
- Quality Manager reviews CPD compliance during annual performance review.

6.4 Performance Monitoring and Evaluation

6.4.1 Ongoing Performance Monitoring

1. **Assessment Quality Review**
2. Quality Manager reviews sample of assessment reports for:
    - Completeness and accuracy

- Compliance with procedures
- Quality of findings and evidence
- Report writing quality
- Timeliness

3. Minimum 20% of reports reviewed annually.
4. **Witness Audit Observation**
5. Quality Manager or senior Lead Assessor observes assessors conducting witness audits.
6. Evaluation of:
   - Assessment methodology
   - Interviewing and communication
   - Professional conduct
   - Technical competence
7. Each assessor observed at least once every 2 years.
8. **CB Feedback**
9. CBs invited to provide feedback on assessor performance after each assessment.
10. Feedback reviewed by Quality Manager.
11. Patterns or concerns addressed with assessor.
12. **Peer Review**
13. Assessors participate in peer review and calibration exercises.
14. Discussion of findings, interpretations, and consistency.
15. Conducted at least annually.

6.4.2 Annual Performance Review

1. **Review Process**
2. Quality Manager conducts annual performance review for each assessor.
3. Review includes:

- Number and types of assessments conducted
- Quality of assessment reports
- Timeliness and productivity
- CPD compliance
- CB feedback
- Peer review results
- Adherence to procedures and ethics
- Areas of strength and improvement

4. **Performance Rating**
5. Overall performance rated as:
    - **Exceeds Expectations:** Consistently high quality; role model
    - **Meets Expectations:** Satisfactory performance; meets all requirements
    - **Needs Improvement:** Performance gaps; development needed
    - **Unsatisfactory:** Significant deficiencies; qualification at risk
6. **Development Planning**
7. Individual development plan created for each assessor.
8. Plan includes:
    - Performance goals for coming year
    - Training and development needs
    - CPD objectives
    - Mentoring or coaching (if needed)
9. **Review Documentation**
10. Performance review documented and signed by assessor and Quality Manager.
11. Approved by Chairmen.
12. Maintained in personnel file.

6.4.3 Corrective Actions for Performance Issues

1. **Performance Improvement Plan**
2. For assessors rated "Needs Improvement":
    - Specific performance gaps identified
    - Improvement actions and timeline defined
    - Additional training or mentoring provided
    - Progress monitored monthly
    - Re-evaluation after 6 months
3. **Suspension of Qualification**
4. Qualification may be suspended if:
    - Serious performance deficiencies identified
    - Ethical violations or misconduct
    - Failure to complete required CPD
    - Failure to improve after performance improvement plan
5. Assessor cannot conduct assessments while suspended.
6. Reinstatement requires demonstration of competence.
7. **Withdrawal of Qualification**
8. Qualification withdrawn for:
    - Continued unsatisfactory performance
    - Serious ethical violations
    - Fraud or misrepresentation
    - Refusal to participate in improvement activities
9. Withdrawal decision made by Chairmen.
10. Former assessor may reapply after minimum 1 year.

6.5 Impartiality and Conflict of Interest

6.5.1 Annual Declarations

All personnel must complete annually:

1. **Impartiality Declaration**
2. Commitment to conduct activities impartially
3. No bias or prejudice
4. Decisions based on objective evidence
5. No undue influence from commercial or other interests
6. **Conflict of Interest Declaration**
7. Disclosure of:
    - Current and recent employment (past 3 years)
    - Financial interests in CBs or food companies
    - Personal relationships with CB personnel
    - Consulting or advisory roles
    - Other potential conflicts
8. Declarations reviewed by Quality Manager and Impartiality Committee.

6.5.2 Assignment-Specific Declarations

Before each assessment assignment:

- Assessor reviews CB information and declares any conflicts
- Conflicts include:
- Worked for or consulted with CB in past 3 years
- Personal relationship with CB personnel
- Financial interest in CB or its clients
- Other circumstances affecting impartiality
- Assessor with conflict not assigned to that CB
- Conflicts documented in assignment records

6.6 Records

6.6.1 Personnel Records Maintained

For each qualified person, ASC maintains:

- Application and resume
- Education credentials and certifications
- Training records and certificates
- Competence evaluation results
- Qualification approval documentation
- Assessment assignment history
- Performance reviews and evaluations
- CPD logs and evidence
- Impartiality and conflict of interest declarations
- Correspondence and communications

6.6.2 Record Retention

- Personnel records retained for minimum 10 years after person leaves ASC per 21 CFR 1.625
- Active personnel records maintained in secure electronic and physical formats
- Access limited to authorized personnel (Quality Manager, Chairmen, HR)
- Confidentiality protected

6.7 Competence Matrix

ASC maintains competence matrix documenting:

- Personnel name and role
- Education and qualifications
- FDA scopes of competence
- Languages
- Geographic regions

- Specialized expertise
- Qualification status and date
- CPD compliance status
- Performance rating

Matrix used for: - Assessment team selection - Capacity planning - Training needs identification - Competence gap analysis

7. References to Regulations

- **21 CFR 1.612:** Competency and Capacity Requirements
- **21 CFR 1.613:** Conflict of Interest Protections
- **21 CFR 1.624:** Conflict of Interest Program
- **21 CFR 1.625:** Records Requirements
- **ISO/IEC 17011:2017 Clause 6.1:** Personnel Competence Requirements
- **ISO/IEC 17011:2017 Clause 6.2:** Personnel Involved in Accreditation Activities

8. Revision History

Revision	Date	Description of Change	Approved By
01	October 2025	Initial Issue – Comprehensive competence and qualification requirements for all ASC personnel involved in accreditation activities	Muhammad Fahmy, Chairman

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