SUBJECT: Accreditation Program for FDA Food Safety Modernization Act (FSMA) Accredited Third-Party Certification

APPLIES TO: FSMA Management Systems ANAB-Accredited and Applicant Certification Bodies

PREFACE
This Accreditation Rule is to inform certification bodies (CBs) of ANAB requirements for accreditation to certify organizations under the FDA Final Rule on Accredited Third-Party Certification.

ACCREDITATION RULE
1. Requirement Documents (current versions unless specified)
   1.1. Code of Federal Regulations Title 21 (21 CFR) Part 1, Subpart M – Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications
   1.2. FD&C Act and FDA regulations applicable to the scope of accreditation food safety requirements
   1.3. ISO/IEC 17021-1, Conformity assessment – Requirements for bodies providing audit and certification of management systems
   1.4. MA 5000, ANAB Management Systems Accreditation Manual, and applicable ANAB Accreditation Rules
   1.5. IAF Mandatory Documents as applicable

2. Application Process
   2.1. CBs can obtain applications for informational use at www.anab.org.
   2.2. The application process outlined at www.anab.org must be completed via ANAB’s Enterprise Quality Manager (EQM) database when the CB is ready to apply for accreditation.
   2.3. The application fee includes the cost of one assessor day for the off-site documentation review. ANAB will invoice the CB for any additional days.

3. Initial Assessments for Accreditation
   3.1. An ANAB accreditation assessor shall conduct a full documentation review.
   3.2. After the documents are found acceptable, ANAB shall conduct an office assessment and required witnessed audits.
      3.2.1. The office assessment shall be conducted on site or remotely (at ANAB’s discretion) and is conducted to ensure the CB’s certification process conforms with ISO/IEC 17021-1 and the FDA Final Rule on Accredited Third-Party Certification and is effective.
      3.2.2. ANAB shall witness the CB conducting a two-stage audit process (stages 1 and 2).
         3.2.2.1. The ANAB assessment team shall have the same number of members as the CB audit team.
         3.2.2.2. Because of the level of expertise needed, ANAB may use technical experts for witnessed audits under FDA FSMA program. ANAB will invoice the CB for the fees and expenses of the technical expert.
4. Surveillance Assessments

4.1. ANAB shall conduct an annual office assessment and at least annually witness a CB team conducting a regulatory audit under the FDA FSMA Accredited Third-Party Certification program, with a minimum of one percent coverage of the CB’s clients certified under this program.

4.1.1. At least every two years, ANAB shall conduct an on-site assessment of all CB locations that manage auditors who conduct food safety audits under the FDA FSMA Third-Party Accredited Certification program, if different than head office and in accordance with IAF MD 12 and ANAB Accreditation Rule 6.

4.1.2. When possible, the office assessment shall be conducted concurrently with assessments for other ANAB accreditation programs for which the CB is accredited.

4.1.3. ANAB will select witnessed audits in accordance with this Accreditation Rule, Accreditation Rule 18, and MA 5000.

4.1.3.1. ANAB shall evaluate the CB’s full system audit process during every annual witnessed audit (stages 1 and 2 certification audit or recertification).

4.1.3.2. ANAB may witness additional audits, based on the number of CB clients certified under this program. A sample size of one percent shall be witnessed annually. When selecting additional audits to witness in the accreditation cycle, ANAB will consider the scopes (listed in Annex 1 below) for which the CB is accredited, scopes previously witnessed by ANAB, the criticality of the scopes within the CB’s scope of accreditation, the CB’s audit activity, and management system findings, and will include audit types such as special, multi-site, scope expansion, transfer, and/or integrated.

4.1.3.3. The CB’s process for unannounced audits shall include notifying the client that ANAB may accompany the CB to an audit. The CB shall ensure the client’s commitment to allow ANAB access. Refusal of entry to ANAB will result in immediate withdrawal of certification, in accordance with MA 5000.

4.1.4. All FSMA assessments shall be planned for and recorded on the ANAB assessment program (per MA 5000).

4.1.5. Because of the level of expertise needed, ANAB may use technical experts for witnessed audits under FDA FSMA program. ANAB will invoice the CB for the fees and expenses of the technical expert.

5. Reaccreditation Assessments

5.1. ANAB shall conduct a document review and an on-site full system office assessment at approximately six months prior to the expiration of accreditation.

6. Additional FDA FSMA Requirements

6.1. ANAB’s accreditation cycle is a maximum of four years.

6.2. Certification issued under the FDA FSMA Accredited Third-Party Certification program shall not exceed 12 months.

6.3. The initial audit of a new client seeking certification shall be an initial certification audit (stages 1 and 2) as defined in ISO/IEC 17021-1. Subsequent audits of a client for this program are considered recertification audits as defined in ISO/IEC 17021-1.

6.3.1. The stage 1 should be performed prior to providing the 30-day operating schedule (in accordance with the FDA Final Rule on Accredited Third-Party Certification, section 1.651.a.1.ii. The stage 1 can be an announced audit and conducted on site or off site in accordance with the CB’s processes and ISO/IEC 17021-1.

6.3.2. The stage 2 is considered the unannounced audit per the FDA Final Rule on Accredited Third-Party Certification, section 1.651.b.1, within the required 30-day operating schedule provided by the CB to the facility.
6.4. FDA requires that the audit witnessed for the CB’s initial accreditation (including scope extensions) shall not be used for certification. The CB shall repeat the audit (stage 2 only) of its client following accreditation using its process for 30-day notification for an unannounced audit.

6.5. As required by (21 CFR) Part 1, Subpart M, accredited third-party CBs must conform with the reports and notification requirements of 1.652 and 1.656 and submit specific documentation to FDA and ANAB within specified timeframes.

6.5.1. The CB shall submit required documentation to ANAB through ANAB’s ShareFile system.
6.5.2. The CB shall submit required documentation to FDA through FDA’s specified channels.
6.5.3. Access to submit required documentation to ANAB and FDA will be granted upon accreditation.

7. Acknowledgements

7.1. ANAB acknowledges that FDA is the regulatory body with authority over FSMA Accredited Third-Party Certification program.

7.2. ANAB acknowledges that FDA has the authority to withdraw accreditation per section 1.664 of the FDA FSMA Rule on Third-Party Accredited Certification. If FDA initiates the withdrawal of a CB’s accreditation, ANAB’s Management Systems Accreditation Council has authorized ANAB management staff to withdraw the CB’s accreditation without initiating a hearing.

8. Scope of Accreditation

8.1. The scope of accreditation shall be for scopes specified by FDA and in Annex 1 (following), based on assessment of the CB in accordance with this Accreditation Rule.

8.2. A witnessed audit is required for each scope prior to initial accreditation.

8.2.1. Because of the nature of FSMA applicant facilities, a witnessed audit could encompass more than one scope, and the CB must demonstrate competence for all applicable scopes during facility certification audits. ANAB’s witnessed audit will include all applicable scopes.

8.3. Witnessing of an initial stage 2 audit is required for scope extensions. ANAB will decide during the scope extension process if witnessing of a stage 1 audit is required.

8.4. To expand the scope of accreditation, the CB shall provide a completed scope extension application (via EQM) that includes evidence demonstrating an appropriate level of competence for the desired scopes.

8.4.1. A competent accreditation assessor or technical reviewer will review the application and documentation, including the CB’s competencies and processes for the specific scopes, and prepare a written response on the CB’s conformance. When the application has been accepted by the assessor, ANAB will schedule the witnessed audit. ANAB will notify the CB if the scope extension application is rejected.

9. Reduction of Scope

9.1. When there is evidence that the CB no longer possesses the necessary competence for auditing and certification for a specific scope, ANAB staff is authorized by the Management Systems Accreditation Council to make a scope reduction decision, per MA 5000.

9.1.1. Because scopes may be dependent on other scopes, a reduction in scope may include related scopes.

9.1.2. ANAB shall make public notice of the reduction in scope on ANAB’s website.
## Annex 1. Scopes per Code of Federal Regulation (CFR) Title 21*

<table>
<thead>
<tr>
<th>Scope</th>
<th>Corresponding CFR</th>
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<tbody>
<tr>
<td>Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption</td>
<td>112</td>
</tr>
<tr>
<td>Thermally processed low-acid foods packaged in hermetically sealed containers</td>
<td>113</td>
</tr>
<tr>
<td>Acidified foods</td>
<td>114</td>
</tr>
<tr>
<td>cGMPs, Hazard Analysis and Risk Based Preventive Controls for Human Food</td>
<td>117</td>
</tr>
<tr>
<td>Hazard Analysis and Critical Control Point (HACCP) Systems</td>
<td>120</td>
</tr>
<tr>
<td>Fish and Fishery Products</td>
<td>123</td>
</tr>
<tr>
<td>cGMPs, Hazard Analysis and Risk Based Preventive Controls for Animal Food</td>
<td>507</td>
</tr>
</tbody>
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*Includes only scopes for which ANAB is recognized by FDA.