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Regulatory Alert: FDA Releases Final Guidance on Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards

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On December 6, 2016, the U.S. Food and Drug Administration (FDA) released final guidance intended to assist industry and the FDA staff by recommending standards for accrediting third-party certification bodies for the voluntary third-party certification program established under the FDA Food Safety Modernization Act (FSMA). This final guidance document fulfills section 808(b)(2) of the FD&C Act that FDA must develop Model Accreditation Standards that recognized accreditation bodies shall use to qualify third-party certification bodies for accreditation. This regulatory alert summarizes the guidance.

Third-Party Certification Bodies

A third-party certification body may range from a single person operation to a large organization. One seeking accreditation under the voluntary third-party certification program must demonstrate that it has the resources necessary to fully implement its certification program, including:

1. A documented organizational structure with clear roles, responsibilities, and lines of authority.
2. Staff.
3. Resources necessary to ensure that auditors and managers are adequately trained.
4. Equipment necessary to conduct audits.
5. Resources, other than staff, necessary to accomplish audits.
6. Resources necessary to properly maintain appropriate records.
7. Resources for effective communication with eligible entities, accreditation bodies, and FDA.

Recommended Prerequisites for Auditors and Managers:

A third-party certification body's certification program should define requirements to qualify auditors and managers involved in food safety audit related functions. The requirements should include:

For Entry-Level Auditors:

1. A bachelor's or higher degree in a food-related or relevant scientific discipline; or
2. 30 semester hours of course work or an equivalent level of instruction as described above; or

3. Demonstration of sufficient knowledge and experience to successfully perform the function required and designated tasks.

For Lead Auditors:

1. At least 5 years' full-time experience in food or associated industry, including 2 years' work in quality assurance or food safety functions in food production or manufacturing, retail, inspection, or enforcement.
2. Other formal qualifications as a substitute for a maximum of 3 years of working experience towards 5 years of experience.

Personal attributes, and behaviors of auditors and management should include: High ethical standards, objectivity, reasoning skills, interpersonal skills, analytical skills, communication skills, diligence, adaptability, tenacity, intuition, and observational skills.

Ensuring Competency

The third-party certification body should understand and properly apply FDA's food safety requirements under the FD&C Act and FDA regulations for purposes of auditing and issuing certifications under the third-party certification program.

The third-party certification body should have a documented process for performing initial and on-going evaluations of auditor knowledge, skills, and abilities.

Monitoring: An on-going monitoring of auditors should be implemented to assure consistency in audit performance.

Frequency of evaluation: The third-party certification body should evaluate auditor performance annually, at a minimum, and confirm skills through a witness audit at least once every 2 years.

The third-party certification body should have developed and documented processes to:

1. Initially qualify employees and other agents involved in audit and certification functions, based on demonstrated competence.
2. Establish requirements for necessary advanced and/or technical training required for specific audits.
3. Ensure that the competence of employees involved in audit and decision making functions is maintained.
4. Provide employees and other agents with appropriate support and resources.

Quality Assurance

A third-party certification body must demonstrate that it has a written program for monitoring and evaluating the performance of its employees involved in auditing and certification activities and must be able to meet the quality assurance requirements which include:

1. Periodic self-assessment.
2. Ability to identify deficiencies in complying with the implementing requirements.
3. Ability to quickly implement effective corrective actions to address any deficiencies.
4. Establishment and maintenance of corrective actions.
5. Preparation of a written report in English of the results of the self-assessments.
6. Procedures for annual reviews of its management system to ensure its continued adequacy, effectiveness, and impartiality, including assessment of the results of self-assessments and other internal audits, appeals and complaints, and other relevant input or feedback.

Management System Requirements

A third-party certification body must demonstrate that it has written procedures to establish, control, and retain records to provide an adequate basis for evaluating its program and performance.

An accredited third-party certification body must maintain electronically, for 4 years, records created during its period of accreditation that document compliance with 21 CFR part 1, subpart M, including:

1. Documents resulting from a consultative audit conducted under 21 CFR part 1, subpart M.
2. Any request for a regulatory audit from an eligible entity.
3. Documents resulting from a regulatory audit conducted under 21 CFR part 1, subpart M, including laboratory testing record and results when sampling and analysis is conducted.
4. Notifications by an audit agent to a third-party certification body of a condition that could cause or contribute to a serious risk to the public health.
5. Notification by a third-party certification body to FDA of any condition found during a regulatory or consultative audit of an eligible entity which could cause or contribute to a serious risk to public health.
6. Any food or facility certification issued under subpart M.
7. Any challenge to an adverse regulatory audit decision and the disposition of the challenge.
8. Any monitoring it conducted of an eligible entity to which food or facility certification was issued.
9. Its self-assessments and corrective actions taken.

10. Changes to its auditing or certification program that might affect compliance with subpart M.

Written Program to Protect Against Conflicts of Interest

The third-party certification body must have a written conflict of interest program that:

1. Ensures that a third-party certification body and its agents do not own or have a financial interest in, manage, or control an eligible entity to be certified.
2. Ensures that a third-party certification body and its agents involved in auditing and certification activities are not owned, managed, or controlled by any person that owns or operates an eligible entity to be certified.
3. Ensures that an audit agent of the third-party certification body does not own, operate, have a financial interest in, manage or otherwise controls an eligible entity.
4. Prohibits an employee from accepting any gratuity from the eligible entity to be audited or certified.

After Accreditation

Once accredited, a third-party certification body must ensure that any audit agent it uses to conduct food safety audits:

1. Has relevant knowledge and experience that provides an adequate basis to evaluate compliance with applicable food safety requirements of the FD&C Act and FDA regulations.
2. Has been determined by the accredited third-party certification body to be competent to conduct food safety audits.
3. Has completed annual food safety training that is relevant to activities conducted under 21 CFR part 1, subpart M (§ 1.650(a)(3)).

A third-party certification body must demonstrate that it is capable of exerting any authority necessary to perform its required duties under the third-party certification program, which include:

1. The authority to review relevant records.
2. Grant FDA access to relevant records.
3. Conduct onsite audits.
4. To suspend or withdraw certification for failure to comply with applicable requirements.

Requirements for Regulatory Audit Reports

An accredited certification body must, no later than 45 days after completing a regulatory audit, prepare and submit electronically, in English, to FDA and to its accreditation body a report of such regulatory audit that includes:

1. The identity of the site or location where the regulatory audit was conducted, including:
    a. The name, address, and FDA Establishment Identifier of the facility subject to the regulatory audit.
    b. Where applicable, the FDA registration number assigned to the facility.
2. The identity of the eligible entity, if different from the facility, including:
    a. The name, address, and FDA Establishment Identifier of the facility subject to the regulatory audit.
    b. Where applicable, the FDA registration number.
3. The dates and scope of the regulatory audit.
4. The process(es) and food(s) observed during the regulatory audit.
5. The name(s) and telephone number(s) of the person(s) responsible for the facility's compliance with the applicable requirements of the FD&C Act and FDA regulations.
6. Any deficiencies observed during the audit that present a reasonable probability that it:
    a. Will cause serious adverse health consequences or death.
    b. May cause temporary or medically reversible adverse health consequences.
7. The corrective action plan for addressing each deficiency identified.
8. Whether any sampling and laboratory analysis is used in the facility.
9. Whether the eligible entity has made significant changes to the facility, its process(es), or products during the 2 years preceding the audit.

This guidance does not establish legally enforceable responsibilities, but describe the FDA's current thinking on a topic and should be viewed only as recommendations, unless specific requirements are cited.

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