Third-Party Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards: Guidance for Industry and FDA Staff

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Third-Party Certification Body Accreditation for Food Safety: Model Accreditation Standards: Guidance for Industry and FDA Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance listed on the title page.

I. Introduction

This guidance is intended to assist industry and the Food and Drug Administration (FDA) staff by recommending standards for accrediting third-party certification bodies[1] for the voluntary third-party certification program established under the FDA Food Safety Modernization Act (FSMA). The guidance serves as a companion document to the implementing regulations in 21 CFR parts 1, 11, and 16 that establish the framework, procedures, and requirements for accreditation bodies and third-party certification bodies for this program.

By way of background, section 307 of FSMA, Accreditation of Third-Party Auditors, amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add section 808 (21 U.S.C. 384d) under the same name. Section 808 of the FD&C Act directs FDA to establish a voluntary program for the recognition of accreditation bodies that accredit third-party certification bodies to conduct food safety audits and issue food and facility certifications to eligible foreign entities, (including registered foreign food facilities) for the purposes specified in sections 801(q) and 806 of the FD&C Act. The statute specifies that foreign governments, agencies of foreign governments, foreign cooperatives, and other third parties meeting the eligibility criteria in the statute and FDA regulations may be accredited under the third-party certification program by an FDA-recognized accreditation body, except in limited circumstances when FDA may directly accredit third-party certification bodies.[2]

[1] As defined in 21 CFR 1.600(c), a "third-party certification body" has the same meaning as "third-party auditor" as that term is defined in section 808(a)(3) of the FD&C Act. For consistency with the implementing regulations in 21 CFR parts 1, 11, and 16, this final guidance uses the term "certification body."

[2] Section 808(b)(1)(A)(ii) of the FD&C Act allows FDA to directly accredit third-party certification bodies if we have not identified and recognized an accreditation body to meet the requirements of section 808 within 2 years after establishing the third-party certification program.

Pursuant to section 808(b)(2) of the FD&C Act, FDA must develop Model Accreditation Standards that recognized accreditation bodies shall use to qualify third-party certification bodies for accreditation, and in so doing, look to existing standards for certification bodies (as of the date of enactment of FSMA) to avoid unnecessary duplication of efforts and costs.[3]

On November 27, 2015, we finalized the implementing regulations establishing the framework, procedures, and requirements of the third-party certification program, including conflict of interest safeguards and other requirements necessary to ensure the competency and independence of recognized accreditation bodies and of accredited third-party certification bodies, which will help ensure the validity and reliability of certifications and other information resulting from the food safety audits conducted by accredited third-party certification bodies (80 FR 74569) (implementing regulations).[4]

This final guidance document fulfills the statutory mandate under 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. As part of these recommendations, we looked to voluntary consensus standards on accreditation that are widely used in determining the qualifications of third-party bodies that audit and certify the food industry. Specifically, we refer to International Organization for Standardization (ISO)/ International Electrotechnical Commission (IEC) recommendations contained in the ISO/IEC 17021:2011, ISO/IEC 17021: 2015, ISO/IEC 17065:2012, and/or ISO/IEC 17065:2015. In instances where recommendations that are contained in the ISO/IEC 17021:2011, ISO/IEC 17021: 2015, ISO/IEC 17065:2012, and/or ISO/IEC 17065:2015, conflict with the requirements in the statute or implementing regulations, the requirements in the statute and regulations apply.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Scope

This guidance document describes the standards for accreditation of third-party certification bodies as required under section 808 of the FD&C Act and the implementing regulations for the third-party certification program. The guidance discusses specified clauses of ISO/IEC 17021:2011, ISO/IEC 17021:2015, and ISO/IEC 17065:2012, as well as industry practices that are currently being used by third-party certification bodies, and that FDA recommends accreditation bodies consider as a model when making accreditation decisions under the third-

[3] We also note that the National Technology Transfer and Advancement Act of 1995 directs Federal agencies to use voluntary consensus standards in lieu of government-unique standards, except where inconsistent with law or otherwise impractical.

party certification program. Other documents consulted by FDA are listed in the Appendix. Alternative approaches to those described in the guidance may be used if they would meet the standards of the statute and the implementing regulations.

III. Definitions

For the purposes of this guidance document, the following definitions, which are consistent with the definitions in § 1.600, apply, as follows:

Accreditation means a determination by a recognized accreditation body (or, in the case of direct accreditation, by FDA) that a third-party certification body meets the applicable requirements of 21 CFR part 1, subpart M.

Accreditation body means an authority that performs accreditation of third-party certification bodies.

Accredited third-party certification body means a third-party certification body that a recognized accreditation body (or, in the case of direct accreditation, FDA) has determined meets the applicable requirements of 21 CFR part 1, subpart M and is accredited to conduct food safety audits and to issue food or facility certifications to eligible entities. An accredited third-party certification body has the same meaning as accredited third-party auditor as defined in section 808(a)(4) of the FD&C Act.

Assessment means:

(i) With respect to an accreditation body, an evaluation by FDA of the competency and capacity of the accreditation body under the applicable requirements of 21 CFR part 1, subpart M for the defined scope of recognition. An assessment of the competency and capacity of the accreditation body involves evaluating the competency and capacity of the operations of the accreditation body that are relevant to decisions on recognition and, if recognized, an evaluation of its performance and the validity of its accreditation decisions under the applicable requirements of 21 CFR part 1, subpart M.

(ii) With respect to a third-party certification body, an evaluation by a recognized accreditation body (or, in the case of direct accreditation, FDA) of the competency and capacity of a third-party certification body under the applicable requirements of 21 CFR part 1, subpart M for the defined scope of accreditation. An assessment of the competency and capacity of the operations of the third-party certification body involves evaluating the competency and capacity of the operations of the third-party certification body that are relevant to decisions on accreditation and, if accredited, an evaluation of its performance and the validity of its audit results and certification decisions under the applicable requirements of 21 CFR part 1, subpart M.

Audit means the systematic and functionally independent examination of an eligible entity under 21 CFR part 1, subpart M by an accredited third-party certification body or by FDA. An audit conducted under subpart M is not considered an inspection under section 704 of the FD&C Act.

Audit agent means an individual who is an employee or other agent of an accredited third-party certification body who, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited third-party certification body. An audit agent includes a contractor of the accredited third-party certification body but excludes subcontractors or other agents under outsourcing arrangements for conducing food safety audits without direct control by the accredited third-party certification body.

Consultative audit means an audit of an eligible entity:

(i) To determine whether such entity is in compliance with the applicable food safety requirements of the FD&C Act, FDA regulations, and industry standards and practices;

(ii) The results of which are for internal purposes only; and

(iii) That is conducted in preparation for a regulatory audit; only the results of a regulatory audit may form the basis for issuance of a food or facility certification under 21 CFR part 1, subpart M.

Direct accreditation means accreditation of a third-party certification body by FDA.

Eligible entity means a foreign entity in the import supply chain of food for consumption in the United States that chooses to be subject to a food safety audit under 21 CFR part 1, subpart M conducted by an accredited third-party certification body. Eligible entities include foreign facilities required to be registered under 21 CFR part 1, subpart H.

Facility means any structure, or structures of an eligible entity under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, holds, grows, harvests, or raises animals for food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Non-bottled water drinking water collection and distribution establishments and their structures are not facilities. Facilities for the purpose of 21 CFR part 1, subpart M are not limited to facilities required to be registered under 21 CFR part 1, subpart H.

Facility certification means an attestation, issued for purposes of section 801(q) or 806 of the FD&C Act, by an accredited third-party certification body, after conducting a regulatory audit and any other activities necessary to establish whether a facility complies with the applicable food safety requirements of the FD&C Act and FDA regulations.

Food has the meaning given in section 201(f) of the FD&C Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).

Food safety audit means a regulatory audit or a consultative audit or a consultative audit that is conducted to determine compliance with the applicable food safety requirements of the FD&C Act, FDA regulations, and for consultative audits, also includes conformance with industry standards and practices. An eligible entity must declare that an audit is to be conducted as a

regulatory audit or consultative audit at the time of audit planning and the audit will be conducted on an unannounced basis under 21 CFR part 1, subpart M.

Recognized accreditation body means an accreditation body that FDA has determined meets the applicable requirements of 21 CFR part 1, subpart M and is authorized to accredit third-party certification bodies under 21 CFR part 1, subpart M.

Regulatory audit means an audit of an eligible entity:

(i) To determine whether such entity is in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations; and

(ii) The results of which are used in determining eligibility for certification under section 801(q) or under section 806 of the FD&C Act.

Self-assessment means an evaluation conducted by a recognized accreditation body or by an accredited third-party certification body of its competency and capacity under the applicable requirements of 21 CFR part 1, subpart M for the defined scope of recognition or accreditation. For recognized accreditation bodies this involves evaluating the competency and capacity of the entire operations of the accreditation body and the validity of its accreditation decisions under the applicable requirements of 21 CFR part 1, subpart M. For accredited third-party certification bodies this involves evaluating the competency and capacity of the entire operations of the third-party certification body and the validity of its audit results under the applicable requirements of 21 CFR part 1, subpart M.

Third-party certification body has the same meaning as third-party auditor as that term is defined in section 808(a)(3) of the FD&C Act and means a foreign government, agency of a foreign government, foreign cooperative, or any other third party that is eligible to be considered for accreditation to conduct food safety audits and to certify that eligible entities meet the applicable requirements of the FD&C Act and FDA regulations. A third-party certification body may be a single individual or an organization. Once accredited, a third-party certification body may use audit agents to conduct food safety audits.

IV. Legal authority and responsibility

Under 21 CFR 1.641, 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. These necessary authorities include the authority to review relevant records; grant FDA access to relevant records; conduct onsite audits; and to suspend or withdraw certification for failure to comply with applicable requirements.

To this end, a third-party certification body should make available to the recognized accreditation body information about its organizational structure, ownership, and the legal or natural persons exercising control over the third-party certification body. If the third-party certification body is a legal entity that is wholly or partly owned by a larger organization, the third-party certification body should clearly document the activities, structure, and governance of that larger organization. If the third-party certification body wholly or partly owns other legal entities, the third-party certification body should clearly define and document the activities and

responsibilities of those other entities, as well as their legal and operational relationships with the third-party certification body.

For additional guidance on demonstrating necessary legal authority, we recommend that recognized accreditation bodies and third-party certification bodies refer to the following, as applicable:

- ISO/IEC 17021:2011, subclause 5.1.1, "Legal responsibility;"
- ISO/IEC 17021:2015, subclause 5.1.1, "Legal responsibility;" and
- ISO/IEC 17065:2012, subclause 4.1.1, "Legal responsibility."

Additionally, the third-party certification body must demonstrate that it has the authority, if accredited, to:

> (1) Conduct an unannounced audit to determine whether the facility, process(es), and food of the eligible entity (within the scope of the audit) comply with the applicable food safety requirements of the FD&C Act and FDA regulations and, for consultative audits, also includes conformance with applicable industry standards and practices (§1.651(b)(1));
> (2) Access any records and any area of the facility, process(es), and food of the eligible entity relevant to the scope and purpose of such audit (§1.651(b)(2));
> (3) When, for a regulatory audit, sampling and analysis is conducted, use a laboratory that is accredited in accordance with (i) ISO/IEC 17025:2005; or (ii) Another laboratory accreditation standard that provides at least a similar level of assurance in the validity and reliability of sampling methodologies, analytical methodologies, and analytical results (§1.651(b)(3));
> (4) Notify FDA immediately if, at any time during a food safety audit, the accredited third-party certification body (or its audit agent, where applicable) discovers a condition that could cause or contribute to a serious risk to the public health and provide information required by §1.656(c) (§1.651(b)(4));
> (5) Prepare reports of audits conducted 21 CFR part 1, subpart M, as follows: (i) For consultative audits, reports that contain the elements specified in § 1.652(a) and maintain such records, subject to FDA access in accordance with section 414 of the FD&C Act; and (ii) for regulatory audits, reports that contain the elements specified in § 1.652(b) and submit them to FDA and to its recognized accreditation body (where applicable) under § 1.656(a) (§1.651(b)(5)) ; and
> (6) Allow FDA and the recognized accreditation body that accredited such third-party certification body, if any, to observe any food safety audit conducted under 21 CFR part 1, subpart M, for purposes of evaluating the accredited third-party certification body's performance under §§ 1.621 and 1.662 or, where appropriate, the recognized accreditation body's performance under §§ 1.622 and 1.633 (§ 1.651(b)(6)).

For additional guidance on legally enforceable agreements for the provision of certification activities, we recommend that accreditation bodies and third-party certification bodies refer to the following, as applicable:

- ISO/IEC 17021:2011, subclause 5.1.2, "Certification agreement;"
- ISO/IEC 17021:2015, subclause 5.1.2, "Certification agreement;" and

- ISO/IEC 17065:2012, subclause 4.1.2, "Certification agreement."

For additional guidance on authority for certification decisions, we recommend that recognized accreditation bodies and third-party certification bodies refer to the following, as applicable:

- ISO/IEC 17021: 2011, subclause 5.1.3, "Responsibility for certification decisions;"
- ISO/IEC 17021:2015, subclause 5.1.3, "Responsibility for certification decisions;" and
- ISO/IEC 17065:2012, subclause, 4.1.2, "Certification agreement, and subclause 4.1.3, "Use of license, certificates, and marks of conformity."

V. Capacity and competence

A. Capacity

A third-party certification body may range in size from a single person operation to a large organization with offices across the globe. Capacity demands vary depending on several factors such as the scope of accreditation and the volume of work. A third-party certification body must have the capacity to meet all of the applicable requirements under the implementing regulations (§ 1.642(b)). Specifically, a third-party certification body 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) Adequate numbers of employees and other agents to examine for compliance with applicable FDA food safety requirements of the FD&C Act and FDA regulations, conformance with applicable industry standards and practices, and issuance of valid and reliable certification (§ 1.642(a)(1)); and
(2) Adequate financial resources for its operations; and (§ 1.642(a)(2)).

To be adequate, a third-party certification body's resources should include:

- A documented organizational structure with clear roles, responsibilities, and lines of authority;
- Staff (i.e., employees and other agents) necessary to provide support services for the certification program and to conduct quality assurance activities;
- The resources necessary to ensure that auditors and managers are adequately trained;
- The equipment necessary to conduct audits;
- The resources, other than staff, necessary to accomplish audits and, as appropriate, sampling and analysis by a laboratory accredited under ISO/IEC 17025:2005 or other standard as described in § 1.651(b)(3);
- The resources necessary to properly maintain appropriate records; and
- The resources for effective communication with eligible entities (e.g., foreign food facilities that are required to register under section 415 of the FD&C Act), accreditation bodies, and FDA

For additional guidance on capacity, we recommend that recognized accreditation bodies and third-party certification bodies refer to the following, as applicable:

- ISO/IEC 17021:2011, subclause 5.3.2, "Liability and Financing" and subclause 7.2.2, "Personnel involved in the certification activities""

- ISO/IEC 17021:2015, subclause 5.3.2, "Liability and Financing" and subclauses 7.2.1 and 7.2.2, "Personnel involved in the certification activities"; and
- ISO/IEC 17065:2012, subclause 4.3.2, "Liability and Financing" and subclause 6.1.1.1, "Certification body personnel"

B. Competency

To qualify for accreditation under 21 CFR part 1, subpart M, a third-party certification body must demonstrate that its employees and other agent(s) have relevant knowledge, skills, and experience to effectively examine for compliance with applicable FDA food safety requirements of the FD&C Act and FDA regulations, conformance with applicable industry standards and practices, and decisions on issuance of valid and reliable certifications (§ 1.642(a)(1)).

Where a third-party certification body is a single individual, such individual must have the relevant knowledge, skills, and experience both to conduct food safety audits and to issue valid and reliable certifications, in the manner described in this document. Where a third-party certification body uses employees or other agents to conduct food safety audits, relevant knowledge, skills, and experience may be divided among various individuals. FDA recommends that the knowledge, skills, and experience of employees and agents of third-party certification bodies be assessed using objective criteria, such as through a written test or oral questions on the food safety requirements of the FD&C Act and FDA regulations.

Before assigning an audit agent to conduct a specific food safety audit, a third-party certification body must determine that the agent is qualified to conduct the audit under the criteria established in § 1.650(a), considering the scope and purpose of the audit and the type of facility, its process(es), and food (§ 1.650(b)). Specifically, once accredited, a third-party certification body must ensure that any audit agent it uses to conduct food safety audits under the third-party certification program meets the following competency requirements:

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

1. Recommended Prerequisites for Auditors (e.g., Audit Agents) 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 the following elements:

Education and/or Experience--Entry Level Auditor

- A full course of study at an accredited college or university leading to a bachelor's or higher degree in a food-related or relevant scientific discipline; or
- 30 semester hours of course work or an equivalent level of instruction as described above, plus appropriate experience or additional education; or
- Demonstration of sufficient knowledge and experience to successfully perform the function required and designated tasks.

Education and/or Experience--Lead Auditor

- At least five years' full-time experience in food or associated industry, including two years' work in quality assurance or food safety functions in food production or manufacturing, retail, inspection, or enforcement, or the equivalent;
- Other formal qualifications (e.g., an advanced degree) as a substitute for a maximum of three years of working experience towards five years of experience.

Personal Attributes and Code of Conduct

Skills, 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
- Observational skills

2. Training for Auditors and Managers

Training in FDA's food safety requirements: The third-party certification body, its managers, and its auditors 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. Technical training may vary depending on the processes and products being audited and should address any gaps in trainees' knowledge or changes in applicable FDA requirements.

Continuing professional development: To help keep the audit agent's knowledge current. Training methods may include classroom training, annual food safety training, and joint audits with a qualified trainer to help the audit agent apply classroom learning.

3. Ensuring competency of employees and other agents

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

documented evaluation criteria that includes requirements for witness audits (i.e., observations of audits).

Monitoring: The third-party certification body should have a documented process for on-going monitoring of auditors to assure consistency in audit performance. Monitoring methods may include review of records of audits; feedback from audited firms, supervisors, and peers; and periodic witness audits.

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 two years.

For additional guidance on competency, we recommend that recognized accreditation bodies and third-party certification bodies refer to the following, as applicable:

- ISO/IEC 17021:2011, subclause 7.1, "Competence of management and personnel," subclause 7.2, "Personnel involved in the certification activities;"
- ISO/IEC 17021:2015, subclause 7.1, "Competence of personnel," and subclause 7.2, "Personnel involved in the certification activities;" and
- ISO/IEC 17065:2012, subclause 6.1, "Certification body personnel"

VI. Conflicts of interest

A third-party certification body seeking accreditation must demonstrate that it has implemented written measures to protect against conflicts of interest between the third-party certification body (and its officers, employees, and other agents involved in auditing and certification activities) and clients seeking examinations or certification from, or audited or certified by, such third-party certification body (§ 1.643(a)).

Further, a third-party certification body must have the capability to meet the conflict of interest requirements in proposed § 1.657, if accredited (§ 1.643(b)). Section 1.657 requires a written program to protect against conflicts of interest between the accredited third-party certification body (and its officers, employees and other agents involved in auditing and certification activities) and an eligible entity seeking a food safety audit or food or facility certification from, or audited or certified by, such accredited third-party certification body. Such a program should include measures for promoting independence, objectivity, and impartiality in third-party certification body activities and should include procedures for effectively identifying, investigating, and resolving conflicts of interest. The required elements of the written conflict of interest program are described in the "Records" section below (section VIII).

For additional guidance on impartiality, objectivity, and conflict of interest safeguards, we recommend that recognized accreditation bodies and third-party certification bodies refer to the following, as applicable:

- ISO/IEC 17021:2011, subclause 5.2, "Management of impartiality;"
- ISO/IEC 17021:2015, subclause 5.2, "Management of impartiality;" and
- ISO/IEC 17065:2012, subclause 4.2 "Management of impartiality."

We note that for purposes of the third-party certification program, an accredited third-party certification body may allow its audit agents to conduct both consultative audits and regulatory audits of the same eligible entity within a 13-month period, if the third-party certification body demonstrates to FDA under § 1.663 that there is insufficient access to accredited third party certification bodies in the country or region where the eligible entity is located. If the accredited third-party certification body is an individual, that individual is also subject to such limitations (§ 1.650(c)).

Additionally, in order to meet the conflict of interest requirements of § 1.657, a third-party certification body must be capable of maintaining a Web site with an up-to-date list of the eligible entities to which it has issued food or facility certifications under 21 CFR part 1, subpart M, as required under § 1.657(d). For each such eligible entity on the list, the Web site must also identify the duration and scope of the certification and the date(s) on which the eligible entity paid the third-party certification body any fee or reimbursement associated with the certification (§ 1.657(d)).

For additional guidance, we recommend that recognized accreditation bodies and third-party certification bodies refer to the following, as applicable:

- ISO/IEC 17021:2011, subclause 8.1, "Publicly accessible information;"
- ISO/IEC 17021;2015, subclause 8.1, "Public information;" and
- ISO/IEC 17065:2012, subclause 4.6, "Publicly available information," and subclause 7.8, "Directory of certified products."

VII. Quality assurance

A third-party certification body must demonstrate that it has implemented a written program for monitoring and evaluating the performance of its officers, audit agents, and managers involved in auditing and certification activities (§ 1.644(a)).

A third-party certification body also must demonstrate the capability to meet the quality assurance requirements of § 1.655 (§ 1.644(b)). These requirements include periodic self-assessment; the ability to identify deficiencies in complying with the implementing requirements; the ability to quickly implement effective corrective actions to address any deficiencies; establishment and maintenance of corrective actions; and preparation of a written report in English of the results of the self-assessments (see § 1.655).

Additionally, we recommend that the third-party certification body establish 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. We recommend that the review includes:

- Identification of areas for improvement in auditing activities and certification decision-making and the root cause(s) for any deficiencies;
- Identification and implementation of appropriate corrective action(s) for any deficiency;

- Assessment of the effectiveness of corrective actions taken for any deficiencies identified during the preceding year's review including external complaints;
- Evaluation of the compliance of officers, personnel and other agents with conflict of interest measures; and
- Identification of any resource needs.

For additional guidance on establishing and maintaining a management system that is capable of meeting quality assurance requirements, we recommend that recognized accreditation bodies and third-party certification bodies refer to the following, as applicable:

- ISO/IEC 17021:2011, clause 10, "Management system requirements for certification bodies;"
- ISO/IEC 17021:2015, clause 10, "Management system requirements for certification bodies;" and
- ISO/IEC 17065:2012, clause 8, "Management system requirements."

VIII. Records

A. Records procedures

A third-party certification body seeking accreditation must demonstrate that it has implemented written procedures to establish, control, and retain records (including documents and data) for a period of time necessary to meet its contractual and legal obligations and to provide an adequate basis for evaluating its program and performance (§ 1.645(a)).

A third-party certification body seeking accreditation must demonstrate that it is capable of meeting the records requirements of § 1.658, if accredited (1.645(b)). Section 1.658(a) states that 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 subpart M;
(2) Any request for a regulatory audit from a 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; and

(10) Significant changes to its auditing or certification program that might affect compliance with subpart M.

B. 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 officers, personnel, or agents (other than audit agents subject to the provision below) do not own or have a financial interest in, manage, or otherwise control an eligible entity to be certified, or any affiliate, parent, or subsidiary of the entity (§ 1.657(a)(1));

(2) Ensures that a third-party certification body and, its officers, employees, or other 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 (§ 1.657(a)(2));

(3) Ensures that an audit agent of the accredited third-party certification body does not own, operate, have a financial interest in, manage or otherwise controls an eligible entity or any affiliate, parent, or subsidiary of the entity that is subject to a consultative or regulatory audit by the audit agent (§ 1.657(a)(3)); and

(4) Prohibits an officer, employee, or other agent of the third-party certification body from accepting any money, gift, gratuity, or item of value from the eligible entity to be audited or certified. (§ 1.657(a)(4)).

To assist accreditation bodies in documenting a written conflict of interest program, we recommend that third-party certification bodies identify in writing their officers, personnel, agents, committee members, lines of authority, and relationships to other parts of the business entity (if applicable) in an organizational chart, referring to ISO/IEC 17021:2015, subclause 6.1.1, "Organizational structure and top management" ISO/IEC 17065:2012, subclause 5.1.2, "Organizational structure and top management," and ISO/IEC 17065:2012, subclause 5.2.2, "Mechanism for safeguarding impartiality," as applicable, for guidance on documenting organizational structure and identification of top management.

C. Documentation of competence

A third-party certification body's written procedures should include procedures for the maintenance of current and accurate records relevant to the competence of its audit agents and others involved in certification activities.

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

- Initially qualify employees and other agents involved in audit and certification functions, based on demonstrated competence;
- Establish requirements for necessary advanced and/or technical training required for specific audits;

- Ensure that the competence of employees and other agents involved in audit and decision making functions is maintained on a continuing basis; and
- Provide employees and other agents with appropriate support and resources where needed.

For additional guidance, we recommend that recognized accreditation bodies and third-party certification bodies refer to the following, as applicable;

- ISO/IEC 17021:2011, subclause 7.4, "Personnel records;"
- ISO/IEC 17021:2015, subclause 7.4, "Personnel records;" and
- ISO/IEC 17065:2012, subclause 6.1.2.2, "Certification body personnel."

IX. Requirements for regulatory audit reports

Section 808(b)(2) of the FD&C Act requires FDA to include in the model accreditation standards, requirements for regulatory audit reports. Under § 1.652(b), 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 (or, in the case of direct accreditation, only to FDA) a report of such regulatory audit that includes the following information:

- The identity of the site or location where the regulatory audit was conducted, including:
  - The name, address, and FDA Establishment Identifier of the facility subject to the regulatory audit and a unique facility identifier, if designated by FDA; and
  - Where applicable, the FDA registration number assigned to the facility under 21 CFR part 1, subpart H;
- The identity of the eligible entity, if different from the facility, including:
  - The name, address, and FDA Establishment Identifier of the facility subject to the regulatory audit and a unique facility identifier, if designated by FDA; and
  - Where applicable, the FDA registration number under 21 CFR part 1, subpart H;
- The dates and scope of the regulatory audit;
- The process(es) and food(s) observed during such regulatory audit;
- 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;
- Any deficiencies observed during the audit that present a reasonable probability that the use of or exposure to a violative product:
  - Will cause serious adverse health consequences or death; or
  - May cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote;
- The corrective action plan for addressing each deficiency identified, as discussed above, unless corrective action was implemented immediately and verified onsite by the accredited third-party certification body (or its audit agent, where applicable);
- Whether any sampling and laboratory analysis (e.g., under a microbiological sampling plan) is used in the facility; and
- Whether the eligible entity has made significant changes to the facility, its process(es), or products during the 2 years preceding the audit.

Appendix

We consulted the following additional materials in developing this guidance:

- *FDA's Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, Proposed Rule,* 78 FR 45782, and *Final Rule,* 80 FR 74570, (issued on November 27, 2016 and codified at 21 CFR part 1, subpart M);
- *FDA's Manufactured Foods Regulatory Program Standards (MFRPS),* which establish a uniform foundation for the design and management of State programs responsible for the regulation of facilities manufacturing, packaging, labeling, or holding human food;
- *FDA's draft International Comparability Assessment Tool,* an objective framework, based on the MFRPS, for determining the robustness of a foreign trading partner's overall food safety system;
- *FDA's Animal Feed Regulatory Program Standards*, which help promote uniformity and consistency among animal food regulatory programs;
- *FDA's Guidance on Voluntary Third-Party Certification Programs for Foods and Feeds*, issued in January 2009, which provided FDA's thinking at that time on general certification program attributes necessary to provide verification of food product safety;
- *International Medical Device Regulators Forum's Competence and Training Requirements for Auditing Organizations*, which specifies competence and training requirements for personnel involved in medical device regulatory audits and decision making;
- *International Medical Device Regulators Forum's Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition;*
- ISO/IEC Guide 65:1996, General Requirements for Bodies Operating Product Certification Systems;
- ISO/IEC 17065:2012, Conformity Assessment – Requirements for Bodies Certifying Products, Processes and Services;
- ISO/IEC 17021:2011, Conformity assessment—Requirements for bodies providing audit and certification of management systems, which is referenced in the 21 CFR part 1, subpart M;
- ISO/IEC 17021:2015, Conformity assessment—Requirements for bodies providing audit and certification of management systems—Part 1: Requirements;
- ISO/IEC 19011:2011, Guidelines for auditing management systems; and
- Codex Alimentarius, Guidelines for the Design, Operations, Assessment, and Accreditation of Food Import and Export Inspection and Certification Systems.