Third-Party Auditor/Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: July 2015

You should submit comments and suggestions regarding this draft document within 75 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the Federal Register.

For questions regarding this document, contact the Center for Food Safety and Applied Nutrition's Office of Compliance at 240-402-3708

Preface

Additional Copies

Additional copies are available from the Internet. You also may send an e-mail request to charlotte.christin@fda.hhs.gov to receive an electronic copy of the draft guidance or send a fax request to 301-436-2717 to receive a hard copy. Please use the document number (XXXX) to identify the draft guidance you are requesting.

Third-Party Auditor/Certification Body Accreditation for Food Safety Audits: Model Accreditation Standards

---

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the number listed on the title page of this guidance.

Table of Contents

I. Introduction

II. Scope

III. Definitions

IV. Authority and responsibility

V. Capacity and competence

VI. Conflicts of interest

VII. Quality assurance

VIII. Records

IX. Regulatory audit reports

X. Miscellaneous

Appendix A – Materials Consulted

Appendix B – Cross-Walk: ISO/IEC 17021:2011 and ISO/IEC 17065:2012

I. Introduction

The FDA Food Safety Modernization Act (FSMA), enacted January 4, 2011, added Section 808 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384d). Section 808 of the FD&C Act directs FDA to establish a program for the recognition of accreditation bodies that accredit third-party auditors/certification bodies to conduct food safety audits to assess compliance with the provisions of the FD&C Act and to issue food and/or facility certifications that FDA may use in certain circumstances to facilitate the entry of foods presented for import. Section 808(b)(2) of the FD&C Act requires FDA to develop Model Accreditation Standards that recognized accreditation bodies shall use to qualify third-party auditors/certification bodies for accreditation, and in so doing, to look to existing standards for certification bodies (as of the date of enactment of FSMA) to avoid unnecessary duplication of efforts and costs.

FDA's standard-setting activities also are guided by the National Technology Transfer and Advancement Act of 1995 (NTTAA), which directs federal agencies to use voluntary consensus standards in lieu of government-unique standards, except where inconsistent with law or otherwise impractical. In developing this draft guidance, FDA considered several voluntary consensus standards for their relevance to the qualifications of third-party auditors/certification bodies that would certify foreign food facilities and/or their foods for conformance with the requirements of the FD&C Act. FDA also sought to identify the standards most commonly used by stakeholders (e.g., other governments, public and private accreditation bodies, the food industry, and the international standards community) in qualifying third-party auditors/certification bodies for conducting food safety audits. As a result, FDA was guided in developing this draft Model Accreditation Standards guidance document by International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) ISO/IEC 17021: *Conformity Assessment – Requirements for bodies providing audit and certification management systems* (2011) ("ISO/IEC 17021:2011").

This draft guidance, if finalized, will constitute the model accreditation standards referred to in section 808(b)(2) of the FD&C Act. In instances where this draft guidance provides different or more specific recommendations than are contained in the ISO/IEC 17021:2011, or conflicts with ISO/IEC 17021:2011, the recommendations of this guidance apply.

This draft guidance document is issued as a companion to the proposed rule "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" ("the proposed rule").[1] This draft guidance document contains FDA recommendations on third-party auditor/certification body qualifications, including recommendations based on relevant provisions in the proposed rule.[2] When finalized, the Model Accreditation Standards will serve as a companion guidance document to the final rule. It will include FDA's final recommendations on third-party auditor/certification body qualifications and will incorporate relevant requirements from the final rule, as permitted in FDA final guidance documents.

---

[1] The proposed rule "Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications" was published in the Federal Register on July 29, 2013 (78 FR 45782).

[2] In this draft guidance sections of the proposed rule are referred to as "proposed [x]."

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 draft guidance document describes the standards for accreditation of third-party auditors/certification bodies under the third-party auditor program as required under section 808 of the FD&C Act and referenced in the proposed rule. In addition, this draft guidance discusses specified clauses of ISO/IEC 17021:2011 and industry practices that are currently being used by third-party auditors/certification bodies, and that FDA recommends accreditation bodies consider as a model when making accreditation decisions. Other documents consulted by FDA are listed in Appendix A.[3] Alternative approaches to those described in the draft guidance may be used if they would meet the standards of the statute and the proposed rule.

III. Definitions

For the purposes of this draft guidance document, the following definitions that are consistent with the definitions in proposed § 1.600, subpart M of part 1 apply:

Accreditation means a determination by an accreditation body recognized by FDA (or, in the case of direct accreditation, by FDA) that a third-party auditor/certification body meets the applicable requirements of proposed subpart M.

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

Accredited third-party auditor/certification body means a third-party auditor/certification body that a recognized accreditation body (or, in the case of direct accreditation, FDA) has determined meets the applicable requirements of proposed subpart M and is authorized to conduct food safety audits and to issue food or facility certifications to eligible entities.

Audit means:
(1) with respect to a third-party auditor/certification body, the systematic, independent, and documented examination (through observation, investigation, and records review) by a recognized accreditation body (or, in the case of direct accreditation, FDA) to assess the third-

[3] We understand that the food industry also uses ISO/IEC 17065:2012, Conformity Assessment – Requirements for Bodies Certifying Products, Processes and Services and ISO/IEC 19011:2011, Guidelines for auditing management systems. Therefore, we have provided Appendix B, which cross-references comparable clauses among ISO/IEC 17021:20011, ISO/IEC 17065:2012, and ISO/IEC 19011:2011. However, ISO/IEC 17065:2012, and ISO/IEC 19011:2011 are not referenced for purposes of the Model Accreditation Standards.

party auditor's/certification body's authority, qualifications (including its expertise and training program), and resources; its procedures for quality assurance, conflicts of interest, and records; its performance in auditing and certification activities; and its capability to meet the applicable requirements of proposed subpart M; and
(2) with respect to an eligible entity (see the definition below), the systematic, independent, and documented examination (through observation, investigation, records review, and as appropriate, sampling and laboratory analysis) by an accredited third-party auditor/certification body to assess the entity, its facility, system(s), and food using audit criteria for consultative or regulatory audits (see the definitions below), including compliance with any applicable requirements for sanitation, monitoring, verification, corrective actions, and recalls, and, for consultative audits, also includes an assessment of compliance with applicable industry standards and practices.

Audit agent means an individual who is an employee or other agent of an accredited third-party auditor/certification body who, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited auditor/certification body. An audit agent includes a contractor of the accredited third-party auditor/certification body.

Certification body 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 applicable requirements of the FD&C Act. A certification body may be a single individual or an organization. A certification body may use audit agents to conduct food safety audits. *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 in proposed subpart M.

Consultative audit means an audit of an eligible entity to determine whether such entity is in compliance with applicable requirements of the FD&C Act and industry standards and practices; and the results of which are for the entity's internal purposes only.

Eligible entity means a foreign entity that chooses to be subject to a food safety audit by an accredited third-party auditor/certification body.

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, or holds 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.

Facility certification means an attestation, issued for purposes of section 806,Voluntary Qualified Importer Program (VQIP), of the FD&C Act (21 U.S.C. 384b) by an accredited third-party auditor/certification body, after conducting a regulatory audit and any other activities necessary to establish that a facility meets the applicable requirements of the FD&C Act.

Food certification means an attestation, issued for purposes of section 801(q), Certifications Concerning Imported Foods, of the FD&C Act (21 U.S.C. 381) by an accredited third-party auditor/certification body, after conducting a regulatory audit and any other activities necessary to establish that a food meets the applicable requirements of the FD&C Act.

Food safety audit means a regulatory audit or a consultative audit.

Recognized accreditation body means an accreditation body that FDA has determined meets the applicable requirements of proposed subpart M and is authorized to accredit third-party auditors/certification bodies.

Regulatory audit means an audit of an eligible entity to determine whether such entity is in compliance with the provisions of the FD&C Act; and the results of which are used in determining eligibility for food certification under section 801(q) of the FD&C Act or facility certification under section 806 of the FD&C Act, and may be used by an importer in meeting the requirements for an on-site audit of a foreign supplier under the requirements of section 805 of the FD&C Act (21 U.S.C. 384a).

Self-assessment means a systematic assessment conducted by an accreditation body or by a third-party auditor/certification body to determine whether it meets the applicable requirements of proposed subpart M.

Third-Party Auditor 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. A third-party auditor may be a single individual or an organization. A third-party auditor may use audit agents to conduct food safety audits. *Third-Party Auditor* has the same meaning as *Certification Body* as that term is defined in proposed subpart M.

IV. Authority and responsibility

A. Legal authority

A third-party auditor/certification body must demonstrate that it is capable of exerting any authority necessary to meet the accreditation requirements of proposed § 1.641, which addresses the legal authorities that we believe are necessary for thorough and credible audits and certifications under the program. This includes adequate authority to access records; conduct onsite audits; and to issue, suspend or withdraw certification. To this end, a third-party auditor/certification body should make available to the accreditation body information about its organizational structure, ownership, and the legal or natural persons exercising control over the third-party auditor/certification body. If the third-party auditor/certification body is a legal entity that is wholly or partly owned by a larger organization, the third-party auditor/certification body should clearly document the activities, structure, and governance of that larger organization. If the third-party auditor/certification body wholly or partly owns other legal entities, the third-

party auditor/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 auditor/certification body.

For additional guidance, we recommend that accreditation bodies and third-party auditors/certification bodies refer to ISO/IEC 17021:2011, clause 5.1.1, "Legal responsibility."

B. Certification authority and responsibility for certification decisions

A third-party auditor/certification body seeking accreditation must demonstrate that it has the authority (as a governmental entity or through contractual rights) to perform such assessments of facilities, their process(es), and food(s) as are necessary to determine compliance with the FD&C Act and with industry standards and practices and to issue certifications where appropriate based on a review of the findings of such assessments (proposed § 1.641(a)). Contractual rights should be legally enforceable.

We recommend that accreditation bodies and third-party auditors/certification bodies generally refer to ISO/IEC 17021:2011, clause 5.1.3, "Responsibility for certification decisions," for guidance on a third-party auditor's/certification body's responsibility for decisions relating to certification. However, although ISO/IEC 17021:2011, clause 5.1.3, states that a certification body shall be responsible for and shall retain authority for, its decisions relating to certification, this particular provision is not entirely consistent with FDA's statutory authority. FDA has authority under section 801(q) to refuse to accept a certification under section 801(q), if FDA reasonably believes that the certification is not valid or reliable. Under such circumstances, the third-party auditor/certification body might not retain authority for its decisions related to certification.

A third-party auditor/certification body must demonstrate that it has the authority (as a governmental entity or through contractual rights) to review any relevant records of the audited facility (proposed § 1.641(a)(1)). Records and other information relevant to an audit could include SOPs, raw material controls, analytical results, maintenance records, consumer complaint files, corrective actions plans, self-assessments, supply chain records, and, as applicable, master production records and batch production records.

A third-party auditor/certification body must demonstrate that it has the authority (as a governmental entity or through contractual rights) to conduct onsite audits of the eligible entity (proposed § 1.641(a)(2)).

A third-party auditor/certification body must demonstrate that it has the authority (as a governmental entity or through legally enforceable contractual rights) to suspend or withdraw certification for failure to comply with applicable requirements (proposed § 1.641(a)(3)).

The third-party auditor/certification body should have authority to allow personnel from the accreditation body to observe its audits, including providing access to the audited

facility and its records, as a means to assess the third-party auditor's/certification body's qualifications for accreditation.

We recommend that accreditation bodies and third-party auditors/certification bodies generally refer to ISO/IEC 17021:2011, clause 5.1.2, "Certification agreement," for guidance on legally enforceable agreements for the provision of certification activities. We further recommend that accreditation bodies and third-party auditors/certification bodies refer to ISO/IEC 17021:2011, clause 7.3 "Use of individual external auditors and external technical experts," for guidance on agreements with external auditors and external technical experts.

V. Capacity and competence

A. Capacity

A third-party auditor/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 a several factors such as the scope of accreditation and the volume of work. In general, a third-party auditor/certification body seeking accreditation must demonstrate that it has the resources necessary to fully implement its third-party auditor program, including:

(1) Adequate numbers of personnel (e.g., audit agents, managers) with relevant knowledge, skills, and experience to effectively audit and assess compliance with applicable FDA requirements and industry standards and practices and to issue valid and reliable certifications (proposed § 1.642(a)(1)).
(2) Adequate financial resources for its operations (proposed § 1.642(a)(2)).

To be adequate, resources should also include:

- Staff necessary to provide support services for the audits and certification program, and to oversee field activities, and conduct quality assurance activities;
- The resources, other than staff, necessary to accomplish audits and/or sampling;
- The equipment necessary to conduct audits;
- The resources necessary to properly maintain records;
- The resources necessary to ensure appropriate auditor competencies; and
- The resources for effective communication with eligible entities, accreditation bodies, and regulatory authorities.

B. Management and audit agent competence

To qualify for accreditation, the third-party auditor/certification body must demonstrate that its audit agent(s) have the relevant knowledge, skills, and experience to effectively audit and assess compliance with applicable FDA requirements and industry standards

and practices (proposed § 1.642(a)(1)). FDA recommends that audit agent knowledge be assessed using objective criteria such as a written test or oral questions on FDA's food safety requirements. The third-party auditor/certification body also must demonstrate that its personnel, including management, have the appropriate knowledge, skills, and experience for decisions on issuance of valid and reliable certifications (proposed § 1.642(a)(1)). Where a third-party auditor/certification body is a single individual, such individual must have the relevant knowledge, skills, and experience for both audit agents and managers involved in certification activities, in the manner described in this document.

A third-party auditor/certification body that uses audit agents to conduct food safety audits must ensure that each audit agent meets the following competency requirements:

(a) Has relevant knowledge and experience that provides an adequate basis for the agent to assess compliance with the FD&C Act (proposed § 1.650(a)(1));
(b) Has been determined by the third-party auditor/certification body, through observations of a representative number of audits, to be competent to conduct food safety audits under proposed subpart M (proposed § 1.650(a)(2));
(c) Participates in annual food safety training under the third-party auditor's/certification body's training plan (proposed § 1.650(a)(3)); and
(d) Agrees to notify the third-party auditor/certification body immediately upon discovering, during a food safety audit, any condition that could cause or contribute to a serious risk to the public health (proposed § 1.650(a)(5)).

Before assigning an audit agent to conduct a specific food safety audit, a third-party auditor/certification body must determine that the agent is qualified to conduct the audit under the criteria established in proposed § 1.650(a), considering the scope and purpose of the audit and the type of facility, its process(es), and food (proposed § 1.650(b)).

We recommend that accreditation bodies and third-party auditors/certification bodies refer to ISO/IEC 17021:2011, clause 7.1, "Competence of management and personnel," for guidance on competence criteria, and demonstration, evaluation, and monitoring of the competence of auditors, management, and supporting personnel.

1. Prerequisites for Audit Agents and Managers:

A third-party auditor's/certification body's certification program should define requirements to initially qualify audit agents and managers involved in food safety audit and related decision-making functions. The requirements should include the following elements:

a. 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.

b. 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;
- Completion of other formal qualifications (e.g., an advanced degree) can substitute for a maximum of three years of working experience towards the required five years of experience.

c. Personal Attributes and Code of Conduct:

Skills, personal attributes, and behaviors of audit agents 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 Audit Agents and Managers:

- *Initial training in FDA program requirements:* To help ensure that the auditor/certification body, its managers, and its audit agents comply with the requirements of FDA's 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).

- *Field training:* By observing an experienced auditor or trainer knowledgeable in FDA requirements. Before an audit agent serves as a sole auditor or the lead auditor under the FDA program, the third-party auditor/certification body should ensure that the audit agent has been field trained and through observation by an experienced auditor or trainer has been determined to be competent in the areas described in the sections of this draft guidance regarding competence.

- *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.

C. Audit agent evaluation and monitoring

- *Evaluation criteria:* The third-party auditor/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 auditor/certification body should have a documented process for on-going monitoring of audit agents to assure consistency in audit performance and compliance with conflict of interest, annual food safety training, and other program requirements. Monitoring methods may include review of records of audits or inspection, education, training, etc.; feedback from audited firms, supervisors, and peers; and periodic witness audits.

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

We recommend that accreditation bodies and third-party auditors/certification bodies refer to ISO/IEC 17021:2011, clause 7.2, "Personnel involved in the certification activities," for guidance on selecting, training, monitoring, and managing audit agents and others involved in certification activities to ensure their continuing competence.

For discussion of recordkeeping relating to competence, see the "Records" section below.

VI. Conflicts of interest

A third-party auditor/certification body must demonstrate that it has the capability to meet the conflict of interest requirements in proposed § 1.657, if accredited (proposed § 1.643(b)). Proposed § 1.657 requires a written program to protect against conflicts of interest between the third-party auditor/certification body (and its officers, personnel, and other agents) and eligible entities certified or seeking certification. Such a program should include measures for promoting independence, objectivity, and impartiality in third-party auditor/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.

We recommend that accreditation bodies and third-party auditors/certification bodies generally refer to ISO/IEC 17021:2011, clause 5.2, "Management of impartiality," for guidance on

impartiality, objectivity, and management of conflict of interest, except that, for purposes of the third-party auditor program, an accredited third-party auditor/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 auditor/certification body demonstrates to FDA that there is insufficient access to accredited third party auditors/certification bodies in the country or region where the eligible entity is located or in the country of export (proposed § 1.650(c)).

Further, we recommend that accreditation bodies and third-party auditors/certification bodies refer to ISO/IEC 17021:2011, clause 5.3, "Liability and financing," for guidance on having adequate arrangements to cover potential liabilities arising from their activities and adequate resources so that resource limitations do not cause compromise of impartiality.

VII. Quality assurance

A third-party auditor/certification body must demonstrate the capability to meet the quality assurance requirements of § 1.655 (proposed § 1.644(b)). These requirements include periodic self-assessment; the ability to quickly implement effective corrective actions, if areas needing improvement are identified; and preparation of a written report in English of the results of the self-assessment (see proposed § 1.655).

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

Additionally, we recommend that the third-party auditor/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.

We recommend that accreditation bodies and third-party auditors/certification bodies refer to ISO/IEC 17021:2011, clause 10.0, "Management system requirements for certification bodies," for guidance on establishing and maintaining a management system that will support and show that the third-party auditor/certification body meets the requirements of the third-party auditor program.

VIII. Records

A. Records procedures

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

A third-party auditor/certification body seeking accreditation must demonstrate that it is capable of meeting the records requirements of proposed § 1.658, if accredited (proposed 1.645(b)). Proposed § 1.658(a) states that an accredited third-party auditor/certification body must maintain electronically, for 4 years, records in English that document compliance with proposed subpart M, including:

1. Documents resulting from a consultative audit conducted under proposed subpart M;
2. Any request for a regulatory audit from a eligible entity;
3. Documents resulting from a regulatory audit conducted under proposed subpart M;
4. Notifications by an audit agent to a third-party auditor/certification body of a condition that could cause or contribute to a serious risk to the public health;
5. Notification by a third-party auditor/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 proposed 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 proposed subpart M.

The records described above must be available for inspection and copying promptly upon written request of an authorized FDA officer or employee at the place of business of the third-party auditor/certification body or at a reasonably accessible location. If the records are requested by FDA electronically, they must be submitted electronically, in English, not later than 10 business days after the date of the request (proposed 1.658(c)). This may require that third-party auditors/certification bodies modify confidentiality provisions of their contracts with eligible entities. Third-party auditors/certification bodies should demonstrate that they have the legal authority to grant FDA access to the relevant records.

B. Written program to protect against conflicts of interest

The third-party auditor's/certification body's written conflict of interest program must:

> (1) Ensure that a third-party auditor/certification body and its officers, personnel, or agents (other than audit agents subject to the proposed 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 (proposed § 1.657(a)(1));
>
> (2) Ensure that an audit agent of the third-party auditor/certification body does not own or operate an eligible entity, or any affiliate, parent, or subsidiary of the entity to be subject to consultative or regulatory audit by such agent (proposed § 1.657(a)(2)); and
>
> (3) Prohibit an officer, employee, or other agent of the third-party auditor/certification body from accepting any money, gift, gratuity, or item of value from the eligible entity to be audited or certified. This does not include payment of fees for accreditation services, reimbursement of direct costs associated with an onsite audit or assessment, and meals of de minimis value provided on the premises where the audit or assessment is conducted (proposed § 1.657(a)(3) and (4).

To assist accreditation bodies in assessing conflict of interest, we recommend that third-party auditors/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 17021:2011, clause 6.1, "Organizational structure and top management," for guidance on documenting organizational structure and identification of top management.

C. Documentation of competence

A third-party auditor/certification body must demonstrate that it has implemented written procedures to establish and maintain records to provide a basis for assessing its third-party auditor program and performance (see proposed § 1.645(a)). This should include maintenance of current and accurate records relevant to the competence of its audit agents and others involved in certification activities.

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

- Initially qualify personnel involved in audit and decision making functions to conduct audits as specified in this draft guidance, based on demonstrated competence;
- Establish requirements for necessary advanced and/or technical training required for specific audits;
- Ensure that the competence of personnel involved in audit and decision making functions is maintained on a continuing basis; and

- Provide personnel with appropriate support and resources where needed.

We recommend that accreditation bodies and third-party auditors/certification bodies refer to ISO/IEC 17021:2011, clause 7.4, "Personnel records," for guidance on maintaining up-to-date personnel records.

IX. Regulatory audit reports

Under proposed § 1.652(b), an accredited auditor/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 name and address of the audited facility and, where applicable, the FDA food facility registration number;
- The name and address of the eligible entity(if different than that of facility);
- The dates and scope of the regulatory audit;
- The process(es) and food(s) observed during such audit;
- The identity of the person(s) responsible for the facility's compliance with the applicable requirements of the FD&C Act;
- 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 auditor/certification body (or its audit agent);
- Whether any sampling and laboratory analysis (e.g., under a microbiological sampling plan) is used in the facility;
- Whether the entity has issued a food safety-related recall of an article of food from the facility during the 2 years preceding the audit and, if so, the identity of any such article(s) of food recalled and the reason(s) for the recall(s);
- Whether the entity has made significant changes to the facility, its process(es), or products during the 2 years preceding the audit; and
- Any food or facility certifications issued to the entity during the 2 years preceding the audit, including the scope and duration of each such certification.

X. Miscellaneous

A. Publicly accessible information and directory of certified clients

An accredited third-party auditor/certification body must maintain on its Web site an up-to-date list of the eligible entities to which it has issued food or facility certifications under proposed subpart M. For each such eligible entity, 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 auditor/certification body any fee or reimbursement associated with the certification (proposed § 1.657(d)).

We recommend that accreditation bodies and third-party auditors/certification bodies refer to ISO/IEC 17021:2011, clauses 8.1, "Publicly accessible information," and 8.3, "Directory of certified clients," for guidance on information that a third-party auditor/certification body should make publicly accessible or provide upon request, such as information about certifications granted or the validity of a certification.

B. Certification documents

For purposes of submission to FDA under proposed subpart M, a third-party auditor/certification body must issue food or facility certifications electronically and in English (proposed § 1.653(b)(1)). The certification must contain the following elements:

a. name and address of the accredited third-party auditor/certification body and the scope and date of its accreditation (proposed § 1.653(b)(2)(i));
b. name, address of the eligible entity to which certification was issued (proposed § 1.653(b)(2)(ii));
c. name, address of the facility where the audit was conducted, if different than the eligible entity (proposed § 1.653(b)(2)(iii));
d. the scope and date(s) of the audit (proposed § 1.653(b)(2)(iv));
e. the name of the audit agent(s) conducting the audit (proposed § 1.653(b)(2)(v)); and
f. the scope of the food or facility certification, date of issuance, and date of expiration (proposed § 1.653(b)(2)(vi)).

We recommend that accreditation bodies and third-party auditors/certification bodies refer to ISO/IEC 17021:2011, clause 8.1, "Certification documents," for guidance on issuing, dating, and the contents of certification documents.

Appendix A

Additional materials we consulted in developing this draft guidance are as follows:

- *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 (ICAT)*, 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 (AFRPS)*, 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, and its successor ISO/IEC 17065:2012, Conformity Assessment – Requirements for Bodies Certifying Products, Processes and Services;
- ISO/IEC 19011:2011, Guidelines for auditing management systems; and
- Codex Guidelines for the Design, Operations, Assessment, and Accreditation of Food Import and Export Inspection and Certification Systems.

Appendix B

Cross-Walk: ISO/IEC 17021:2011 and ISO/IEC 17065:2012

ISO/IEC 17021:2011		ISO/IEC 17065:2012	
4	Principles	4.5, 4.6 and Annex A	
5	General requirements		
5.1	Legal and contractual matters	4.1	Legal and contractual matters
			4.1.2a
5.2	Management of impartiality	4.2	Management of impartiality
			4.2.1 4.2.6 4.2.7 [a]
5.3	Liability and financing	4.3	Liability and financing
			4.4.1 to 4.4.3 [a]
6	Structural requirements	5	Structural requirements
6.1	Organizational structure and top management	5.1	Organizational structure and top management
			5.1.1 [a] 5.1.3 bullets f) and g) [a]
6.2	Committee for safeguarding impartiality	5.2	Mechanism for safeguarding impartiality
			5.2.1 [a] 5.2.3 [a]
7	Resource requirements	6	Resource requirements

ISO/IEC 17021:2011		ISO/IEC 17065:2012	
7.1	Competence of management and personnel	6.1	Certification body personnel
			6.1.2.2 bullets f) to h) [a]
7.2	Personnel involved in the certification activities	6.1	Certification body personnel
7.3	Use of individual external auditors and external technical experts	6.2	Resource for evaluation
			6.1.3 bullet c) [a] 6.2.1 [a] 6.2.2.1 to 6.2.2.3 [a] 6.2.2.4 bullets d) to f) [a]
7.4	Personnel records	6.1	Certification body personnel
7.5	Outsourcing	6.2	Resources for evaluation
8	Information requirements	4.6	Publicly available information
			4.6 bullet b) [a]
8.1	Publicly accessible information	4.6	Publicly available information
8.2	Certification documents	7.7	Certification documentation
8.3	Directory of certified clients	7.8	Directory of certified products
8.4	Reference to certification and use of marks		
			4.1.3 Use of license, certification and marks of conformity ~~a~~
8.5	Confidentiality	4.5	Confidentiality

ISO/IEC 17021:2011		ISO/IEC 17065:2012	
8.6	Information exchange between a certification body and its clients	4.6	Publicly available information
9	Process requirements	7	Process requirements
9.1	General requirements	7.1	General
			7.1.1 to 7.1.3 [a] 7.3.2 [a]
9.2	Initial audit and certification	7.4	Evaluation
			7.4.4 to 7.4.5 [a] 7.4.7 to 7.4.8 [a] 7.6.3 to 7.6.5 [a] 7.7.2 [a] 7.7.3 bullets a) to c) [a]
9.3	Surveillance activities	7.9	Surveillance
			7.9.1 to 7.9.4 [a] 7.10.3 [a]
9.4	Recertification	N/A	
9.5	Special audits	N/A	
9.6	Suspending, withdrawing or reducing the scope of certification	7.11	Termination, reduction, suspension or withdrawal of certification
			7.11.2 to 7.11.6 [a]
9.7	Appeals	7.13	Complaints and appeals
9.8	Complaints	7.13	Complaints and appeals

ISO/IEC 17021:2011		ISO/IEC 17065:2012	
			7.13.6 [a] 7.13.9 [a]
9.9	Records of applicants and clients	7.12	Records
			7.12.1 [a] 7.12.3 [a]
10	Management system requirements for certification bodies	8	Management system requirements
10.1	Options		
10.2	Option 1: Management system requirements in accordance with ISO 9001	8.1	Option B
10.3	Option 2: General management system requirements	8.2-8.8	Option A
			8.2.4 to 8.2.5 [a] 8.5.1.2 [a] 8.6.3 [a]
[a] Additional text of ISO/IEC 17065, not contained in ISO/IEC 17021			