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ACCREDITATION CRITERIA AND PROGRAM REQUIREMENTS FOR THIRD-PARTY CERTIFICATION BODIES UNDER THE FOOD & DRUG ADMINISTRATION (FDA) FOOD SAFETY MODERNIZATION ACT (FSMA)

AC782

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PREFACE

The attached accreditation criteria have been issued to provide all interested parties with guidelines on implementing performance features of the applicable standards referenced herein. The criteria were developed and adopted following public hearings conducted by the International Accreditation Service, Inc. (IAS), Accreditation Committee and are effective on the date shown above. All accreditations issued or reissued on or after the effective date must comply with these criteria. If the criteria are an updated version from a previous edition, solid vertical lines (|) in the outer margin within the criteria indicate a technical change or addition from the previous edition. Deletion indicators (→) are provided in the outer margins where a paragraph or item has been deleted if the deletion resulted from a technical change. These criteria may be further revised as the need dictates.

IAS may consider alternate criteria provided the proponent submits substantiating data demonstrating that the alternate criteria are at least equivalent to the attached criteria and otherwise meet applicable accreditation requirements.

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1. INTRODUCTION

1.1. **Scope**: This document sets forth the requirements for obtaining and maintaining International Accreditation Service, Inc. (IAS), Third-party Certification Bodies under the Food & Drug Administration (FDA) Food Safety Modernization Act (FSMA) accreditation and for the qualifying data that must be submitted relating to the scope of accreditation. Third-party Certification Bodies (CBs) seeking accreditation for this accreditation program shall comply with the requirements specified in Federal Register Vol.80, No. 228, dated November 27, 2015, set by FDA; and supplemented by this IAS program requirement, IAS Rules of Procedure for Third-party Certification Body under the Food & Drug Administration (FDA) Food Safety Modernization Act (FSMA), and International Accreditation Forum (IAF) guidance documents on certification or application of Management System Standards.

1.2. **Reference and Normative Documents**: Publications listed below refer to current editions (unless otherwise stated), current editions of related codes published by the International Code Council or codes duly adopted by the relevant jurisdiction.

1.2.1. ISO/IEC 17011, Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies.

1.2.2. ISO/IEC 17021-1, Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements.

1.2.3. ISO/IEC 17065, Conformity assessment – Requirements for bodies certifying products, processes and services.

1.2.4. ISO 19011, Guidelines for auditing management systems.

1.2.5. ISO/IEC Guide 2, Standardization and related activities – General vocabulary.

1.2.6. ISO/IEC Guide 99, International vocabulary of metrology – Basic and general concepts and associated terms (VIM).

1.2.7. IAS Rules of Procedure for Third-party Certification Bodies under the Food & Drug Administration (FDA) Food Safety Modernization Act (FSMA) Accreditation.

1.2.8. IAS Policy on Authorized Signatories.

1.2.9. IAF MD 10:2013 IAF Mandatory Document for Assessment of Certification Body Management of Competence in Accordance with ISO/IEC 17021:2011.

1.2.10. IAF MD 12:2016 Accreditation Assessment of Conformity Assessment Bodies with Activities in Multiple Countries.

1.2.11. IAF MD 16:2015, Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies (Application from 15 December 2016).

1.2.12. ISO/IEC 17000, Conformity assessment – Vocabulary and general principles.

1.2.13. Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications; Final Rule (Federal Register / Vol.80, No.228, November 27, 2015).

2. DEFINITIONS

Definitions related to conformity assessment are from ISO/IEC 17000, ISO/IEC Guide 2, ISO/IEC Guide 99, ISO/IEC 17011 and FDA Final Rule Document for accreditation of Third-party Certification Bodies under the Food & Drug Administration (FDA) Food Safety Modernization Act (FSMA). Some definitions are documented in a way so as to correlate to program requirements for accreditation.

2.1. **Accreditation**: Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

2.2. **Accreditation Body (AB)**: Authoritative body that performs accreditation.

2.3. **Assessment**: Process undertaken by an accreditation body to assess the competence of a CAB, based on particular standard(s) and/or other normative documents and for a defined scope of accreditation.

2.4. **Attestation**: Issue of a statement based on a decision following review that fulfillment of specified requirements has been demonstrated.

2.5. **Audit**: The systematic and functionally independent examination of an eligible entity under this accreditation program by an accredited third-party certification body or by FDA. An audit conducted under this accreditation program is not considered an inspection under section 704 of the FD&C Act.

2.6. **Audit agent**: 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 conducting food safety audits without direct control by the accredited third-party certification body.

2.7. **Conformity Assessment Body (CAB)**: Body that performs conformity assessment services and that can be the object of accreditation.

NOTE: Whenever the word “CAB” is used in the text, it applies to both the “applicant and accredited CABs” unless otherwise specified.

2.8. **Consultative audit**: 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 this accreditation program.

2.9. **Eligible entity (to be audited by an accredited third-party CB)**: 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 this accreditation program conducted by an accredited third-party certification body. Eligible entities include foreign facilities required to be registered under subpart H of the FSMA Final Rule document.

2.10. **Extending Accreditation**: Process of enlarging the scope of accreditation.

2.11. **Facility**: 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.

2.12. **Facility certification**: An attestation, issued 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.

2.13. **Food certification**: An attestation, issued by an accredited third-party certification body, after conducting a regulatory audit and any other activities necessary to establish whether a food (pesticides not included) of an eligible entity complies with the applicable food safety requirements of the FD&C Act and FDA regulations.

2.14. **Food safety audit**: A regulatory 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 this accreditation program.

2.15. **Foreign cooperative**: An autonomous association of persons, identified as members, who are united through a jointly owned enterprise to aggregate food from member growers or processors that is intended for export to the United States.

2.16. **IAF**: International Accreditation Forum.

2.17. **Key activities**: Auditing activities, audit report generation, policy formulation, process or procedure development, and, as appropriate, contract review, planning conformity assessments (internal audits), reviews, approvals, and decisions on the results of conformity assessments.

2.18. **Multi-site assessment**: Assessment conducted for a multi-site organization.

2.19. **Regulatory audit**: 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.

2.20. **Relinquishment**: (i) With respect to an accreditation body, a decision to cede voluntarily its authority to accredit third-party certification bodies as a recognized accreditation body prior to expiration of its recognition under this accreditation program; and (ii) With respect to a third-party certification body, a decision to cede voluntarily its authority to conduct food safety audits and to issue food and facility certifications to eligible entities as an accredited third-party certification body prior to expiration of its accreditation under this accreditation program.

2.21. **Remote Surveillance Assessment**: A remote assessment tool used to evaluate compliance as part of the IAS ongoing plan of surveillance. Remote surveillance assessments are limited in scope, typically covering a sampling of key requirements. Remote surveillance assessments rely on computer-assisted auditing techniques, including teleconferencing, interactive web-based communications or remote access to management system documentation and records. Remote surveillance assessments do not replace the requirement for initial assessments or periodic onsite reassessments of an accredited organization.

2.22. **Sample**: One or more parts taken from a primary sample.

2.23. **Scope of Accreditation**: Specific conformity assessment services for which accreditation is sought or has been granted.

2.24. **Surveillance**: Set of activities, except reassessment, to monitor the continued fulfillment by accredited CBs of requirements for accreditation.

NOTE: Surveillance includes both surveillance onsite assessments and other surveillance activities, such as the following:

2.24.1. Enquiries from the accreditation body to the CB on aspects concerning the accreditation;

2.24.2. Reviewing the declarations of the CB with respect to what is covered by the accreditation;

2.24.3. Requests to the CB to provide documents and records (e.g., Audit reports, results of internal audits, complaints records, management review records);

2.24.4. Monitoring the performance of the CB (witness audits).

3. ELIGIBILITY

3.1. Any third-party certification body seeking accreditation from a recognized accreditation body for:

3.1.1. Conducting food safety audits; and

3.1.2. Issuing certifications that may be used in satisfying a condition of admissibility of an article of food under section 801(q) of the FD&C Act; or issuing a facility certification for meeting the eligibility requirements for the Voluntary Qualified Importer Program under section 806 of the FD&C Act.

3.2. All applicants seeking accreditation within this program must demonstrate their competence and establish conformance with the criteria set in this document and any other documents related to this Program and IAS Policies.

3.3. Specifically, eligible for accreditation by IAS under this program are the following entities:

3.3.1. A foreign government, agency of a foreign government, foreign cooperative, or any other third party may seek accreditation from IAS to conduct food safety audits and to issue food and facility certifications to eligible entities under this accreditation program. An accredited third-party certification body may use documentation of conformance with ISO/IEC 17021-1 or ISO/IEC 17065:2012, supplemented as necessary, in meeting the applicable requirements of this accreditation program.

3.3.2. A foreign government or an agency of a foreign government is eligible for accreditation if it can demonstrate that its food safety programs, systems, and standards meet the requirements set in this document.

3.3.3. A foreign cooperative or other third party is eligible for accreditation if it can demonstrate that the training and qualifications of its agents used to conduct audits (or, in the case of a third-party certification body that is an individual, such individual) and its internal systems and standards meet the requirements set in this document.

NOTE: The Third-Party Certification rule also provides that the mandatory import certification authority under FSMA does not apply to:

- Alcoholic beverages manufactured by foreign facilities.
- Meat, poultry and egg products that are subject to U.S. Department of Agriculture oversight at the time of importation.

4. REQUIRED BASIC INFORMATION

4.1. A third-party certification body seeking accreditation from IAS must demonstrate that it has the authority (as a governmental entity or as a legal entity with contractual rights) to perform such audits of facilities, their process(es), and food(s) as are necessary to determine compliance

with the applicable food safety requirements of the FD&C Act and FDA regulations, and conformance with applicable industry standards and practices and to issue certifications where appropriate based on a review of the findings of such audits. This includes authority to:

4.1.1. Review any relevant records;

4.1.2. Conduct onsite audits of an eligible entity; and

4.1.3. Suspend or withdraw certification for failure to comply with applicable requirements.

4.2. A third-party certification body seeking accreditation must demonstrate that it is capable of exerting the authority (as a governmental entity or as legal entity with contractual rights) necessary to meet the applicable requirements of accreditation under this accreditation program if accredited.

4.3. A third-party certification body seeking accreditation must demonstrate that it has:

4.3.1. The resources necessary to fully implement its certification program, including:

4.3.1.1. Adequate numbers of employees and other agents with 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 issuance of valid and reliable certifications; and

4.3.1.2. Adequate financial resources for its operations; and

4.3.2. The competency and capacity to meet the applicable requirements of this document, if accredited.

4.4. A third-party certification body must demonstrate that it has:

4.4.1. 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; and

4.4.2. The capability to meet the conflict of interest requirements set in this document, if accredited.

4.5. A third-party certification body seeking accreditation must demonstrate that it has:

4.5.1. Implemented a written program for monitoring and evaluating the performance of its officers, employees, and other agents involved in auditing and certification activities, including procedures to:

4.5.1.1. Identify deficiencies in its auditing and certification program or performance; and

4.5.1.2. Quickly execute corrective actions that effectively address any identified deficiencies; and

4.5.2. The capability to meet the quality assurance requirements set in this document, if accredited.

4.6. A third-party certification body seeking accreditation must demonstrate that it:

4.6.1. 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; and

4.6.2. Is capable of meeting the reporting, notification, and records requirements set in this document, if accredited.

4.7. **Third-party Certification Body Audit Agents' Requirements**

4.7.1. An accredited third-party certification body that uses audit agents to conduct food safety audits must ensure that each such audit agent meets the following requirements with respect to the scope of its accreditation under this accreditation program. If the accredited third-party certification body is an individual, that individual is also subject to the following requirements, as applicable:

4.7.1.1. 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;

4.7.1.2. 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 this accreditation program relevant to the audits they will be assigned to perform;

4.7.1.3. Has completed annual food safety training that is relevant to activities conducted under this accreditation program;

4.7.1.4. Is in compliance with the conflict of interest requirements set in this document and has no other conflicts of interest with the eligible entity to be audited that might impair the audit agent's objectivity; and

4.7.1.5. Agrees to notify its accredited third-party 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.

4.7.2. In assigning an audit agent to conduct a food safety audit at a particular eligible entity, an accredited third-party certification body must determine that the audit agent is qualified to conduct such audit under the criteria established in Section 4.7.1 and based on the scope and purpose of the audit and the type of facility, its process(es), and food.

4.7.3. An accredited third-party certification body cannot use an audit agent to conduct a regulatory audit at an eligible entity if such audit agent conducted a consultative audit or regulatory audit for the same eligible entity in the preceding 13 months, except that such limitation may be waived if the accredited third-party certification body demonstrates to FDA, under requirements set in this document, there is insufficient access to audit agents 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. An accredited third-party certification body may submit a request to FDA to waive the requirements mentioned in this section (4.7.3) preventing an audit agent from conducting a regulatory audit of an eligible entity if the audit agent (or, in the case that the third-party certification body is an individual, the third-party certification body) has conducted a food safety audit of such entity during the previous 13 months. The accredited third-party certification body seeking a waiver or waiver extension must demonstrate there is insufficient access to audit agents and any third-party certification bodies that are comprised of an individual in the country or region where the eligible entity is located. Unless FDA notifies a requestor that its waiver request has been approved, an accredited third-party certification body must not use the audit agent to conduct a regulatory audit of such eligible entity until the 13-month limit in has elapsed.

4.8. **Audit Planning Requirements**

Before beginning to conduct a food safety audit under this accreditation program, an accredited third-party certification body must:

4.8.1. Require the eligible entity seeking a food safety audit to:

4.8.1.1. Identify the scope and purpose of the food safety audit, including the facility, process(es), or food to be audited; whether the food safety audit is to be conducted as a consultative or regulatory audit subject to the requirements of this accreditation program, and if a regulatory audit, the type(s) of certification(s) sought; and

4.8.1.2. Provide a 30-day operating schedule for such facility that includes information relevant to the scope and purpose of the audit; and

4.8.2. Determine whether the requested audit is within its scope of accreditation

4.9. **Authority to Conduct Audits Requirements**

In arranging a food safety audit with an eligible entity under this accreditation program, an accredited third-party certification body must ensure it has authority, whether contractual or otherwise, to:

4.9.1. 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;

4.9.2. 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;

4.9.3. When, for a regulatory audit, sampling and analysis is conducted, the accredited third-party certification body must use a laboratory that is accredited in accordance with:

4.9.3.1. ISO/IEC 17025:2005; or

4.9.3.2. 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.

4.9.4. 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 in this document;

4.9.5. Prepare reports of audits conducted under this accreditation program as follows:

4.9.5.1. For consultative audits, prepare reports that contain the elements specified in this document and maintain such records, subject to FDA access in accordance with section 414 of the FD&C Act; and

4.9.5.2. For regulatory audits, prepare reports that contain the elements specified in this report and submit them to FDA and to IAS (where applicable) under the requirements of this document; and

4.9.6. Allow FDA and IAS, to observe any food safety audit conducted under this accreditation program for purposes of evaluating the accredited third-party certification body's performance under the requirements set in this document.

4.10. **Audit Protocol Requirements**

An accredited third-party certification body (or its audit agent, where applicable) must conduct a food safety audit in a manner consistent with the identified scope and purpose of the audit and within the scope of its accreditation.

4.10.1. With the exception of records review, which may be scheduled, the audit must be conducted without announcement during the 30-day timeframe identified under Section 4.8.1.2 and must be focused on determining whether the facility, its process(es), and food are in 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 that are within the scope of the audit.

4.10.2. The audit must include records review prior to the onsite examination; an onsite examination of the facility, its process(es), and the food that results from such process(es); and where appropriate or when required by FDA, environmental or product sampling and analysis. When, for a regulatory audit, sampling and analysis is conducted, the accredited third-party certification body must use a laboratory that is accredited in accordance with paragraph 4.9.3 of this document. The audit may include any other activities necessary to determine 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.

4.10.3. The audit must be sufficiently rigorous to allow the accredited third-party certification body to determine whether the eligible entity is in compliance 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, at the time of the audit; and for a regulatory audit, whether the eligible entity, given its food safety system and practices would be likely to remain in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations for the duration of any certification issued under this accreditation program. An accredited third-party certification body (or its audit agent, where applicable) that identifies a deficiency requiring corrective action may verify the effectiveness of a corrective action once implemented by the eligible entity, but must not recommend or provide input to the eligible entity in identifying, selecting, or implementing the corrective action.

4.10.4. Audit observations and other data and information from the examination, including information on corrective actions, must be documented and must be used to support the findings contained in the audit report as required by this document and maintained as a record under an appropriate record control procedure that meets the requirements of this document.

4.11. **Food Safety Audit Reporting Requirements**

4.11.1. Consultative audits:

An accredited third-party certification body must prepare a report of a consultative audit not later than 45 days after completing such audit and must provide a copy of such report to the eligible entity and must maintain such report under their control of records procedure requirements, subject to FDA access in accordance with the requirements of section 414 of the FD&C Act. A consultative audit report must include:

4.11.1.1. The identity of the site or location where the consultative audit was conducted, including:

4.11.1.1.1. The name, address and the FDA Establishment Identifier of the facility subject to the consultative audit and a unique facility identifier, if designated by FDA; and

4.11.1.1.2. Where applicable, the FDA registration number assigned to the facility;

4.11.1.2. The identity of the eligible entity, if different from the facility, including the name, address, the FDA Establishment Identifier and unique facility identifier, if designated by FDA, and, where applicable, registration number;

4.11.1.3. The name(s) and telephone number(s) of the person(s) responsible for compliance with the applicable food safety requirements of the FD&C Act and FDA regulations

4.11.1.4. The dates and scope of the consultative audit;

4.11.1.5. The process(es) and food(s) observed during such consultative audit; and

4.11.1.6. Any deficiencies observed that relate to or may influence a determination of compliance with the applicable food safety requirements of the FD&C Act and FDA regulations that require corrective action, the corrective action plan, and the date on which such corrective actions were completed. Such consultative audit report must be maintained as a record and must be made available to FDA in accordance with section 414 of the FD&C Act.

4.11.2. Regulatory audits:

An accredited third-party certification body must, no later than 45 days after completing a regulatory audit, prepare and submit electronically, in English, to FDA and to IAS and must provide to the eligible entity a report of such regulatory audit that includes the following information:

4.11.2.1. The identity of the site or location where the regulatory audit was conducted, including:

4.11.2.1.1. 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

4.11.2.1.2. Where applicable, the FDA registration number assigned to the facility;

4.11.2.2. The identity of the eligible entity, if different from the facility, including the name, address, FDA Establishment Identifier, and unique facility identifier, if designated by FDA, and, where applicable, registration number;

4.11.2.3. The dates and scope of the regulatory audit;

4.11.2.4. The process(es) and food(s) observed during such regulatory audit;

4.11.2.5. The name(s) and telephone number(s) of the person(s) responsible for the facility's compliance with the applicable food safety requirements of the FD&C Act and FDA regulations;

4.11.2.6. Any deficiencies observed during the regulatory audit that present a reasonable probability that the use of or exposure to a violative product:

4.11.2.6.1. Will cause serious adverse health consequences or death to humans and animals; or

4.11.2.6.2. May cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences or death to humans or animals is remote;

4.11.2.7. The corrective action plan for addressing each deficiency identified under Section 4.11.2.6, unless corrective action was implemented immediately and verified onsite by the accredited third-party certification body (or its audit agent, where applicable);

4.11.2.8. Whether any sampling and laboratory analysis (e.g., under a microbiological sampling plan) is performed in or used by the facility; and

4.11.2.9. Whether the eligible entity has made significant changes to the facility, its process(es), or food products during the two (2) years preceding the regulatory audit.

4.11.3. Submission of regulatory audit report:

An accredited third-party certification body must submit a completed regulatory audit report as required by paragraph 4.11.2 of this document, regardless of whether the certification body issued a food or facility certification to the eligible entity.

4.11.4. Notice and appeals of adverse regulatory audit results:

An accredited third-party certification body must notify an eligible entity of a denial of certification and must establish and implement written procedures for receiving and addressing appeals from eligible entities challenging such adverse regulatory audit results and for investigating and deciding on appeals in a fair and meaningful manner. The appeals procedures must provide similar protections to those offered by FDA, including requirements to:

4.11.4.1. Make the appeals procedures publicly available;

4.11.4.2. Use competent persons, who may or may not be external to the accredited third-party certification body, who are free from bias or prejudice and have not participated in the certification decision or be subordinate to a person who has participated in the certification decision, to investigate and decide appeals;

4.11.4.3. Advise the eligible entity of the final decision on its appeal; and

4.11.4.4. Maintain records of the appeal, the final decision, and the basis for such decision.

4.12. **Issuing Food or Facility Certifications Requirements**

4.12.1. Basis for issuance of a food or facility certification:

4.12.1.1. Prior to issuing a food or facility certification to an eligible entity, an accredited third-party certification body (or, where applicable, an audit agent on its behalf) must complete a regulatory audit that meets the requirements of Sections 4.8 –

4.10 and any other activities that may be necessary to determine compliance with the applicable food safety requirements of the FD&C Act and FDA regulations.

4.12.1.2. If, as a result of an observation during a regulatory audit, an eligible entity must implement a corrective action plan to address a deficiency, an accredited third-party certification body may not issue a food or facility certification to such entity until after the accredited third-party certification body verifies that eligible entity has implemented the corrective action plan through methods that reliably verify the corrective action was taken and as a result the identified deficiency is unlikely to recur, except onsite verification is required for corrective actions required to address deficiencies that are the subject of a notification (see clause 4.15).

4.12.1.3. An accredited third-party certification body must consider each observation and the data and other information from a regulatory audit and other activities conducted under Sections 4.8 – 4.10 to determine whether the entity was in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations at the time of the audit and whether the eligible entity, given its food safety system and practices, would be likely to remain in compliance for the duration of any certification issued under this accreditation program.

4.12.1.4. A single regulatory audit may result in issuance of one or more food or facility certifications under this accreditation program, provided that the requirements of issuance are met as to each such certification.

4.12.1.5. Where an accredited third-party certification body uses an audit agent to conduct a regulatory audit of an eligible entity under this accreditation program, the accredited third-party certification body (and not the audit agent) must make the determination whether to issue a food or facility certification based on the results of such regulatory audit.

4.12.2. Issuance of a food or facility certification and submission to FDA.

4.12.2.1. Any food or facility certification issued under this accreditation program must be submitted to FDA electronically and in English. The accredited third-party certification body may issue a food or facility certification under this accreditation program for a term of up to 12 months.

4.12.2.2. A food or facility certification must contain, at a minimum, the following elements:

4.12.2.2.1. The name and address of the accredited third-party certification body and the scope and date of its accreditation under this accreditation program;

4.12.2.2.2. The name, address, FDA Establishment Identifier, and unique facility identifier, if designated by FDA, of the eligible entity to which the food or facility certification was issued;

4.12.2.2.3. The name, address, FDA Establishment Identifier, and unique facility identifier, if designated by FDA, of the facility where the regulatory audit was conducted, if different than the eligible entity;

4.12.2.2.4. The scope and date(s) of the regulatory audit and the certification number;

4.12.2.2.5. The name of the audit agent(s) (where applicable) conducting the regulatory audit; and

4.12.2.2.6. The scope of the food or facility certification, date of issuance, and date of expiration.

4.12.2.3. FDA may refuse to accept any certification for purposes of section 801(q) or 806 of the FD&C Act, if FDA determines that such food or facility certification is not valid or reliable because, for example:

4.12.2.3.1. The certification is offered in support of the admissibility of a food that was not within the scope of the certification;

4.12.2.3.2. The certification was issued by an accredited third-party certification body acting outside the scope of its accreditation under this accreditation program; or

4.12.2.3.3. The certification was issued without reliable demonstration that the requirements of Section 4.12.1.1 were met.

4.13. Frequency of monitoring an eligible entity for which a food or facility certification has been issued.

If an accredited third-party certification body has reason to believe that an eligible entity to which it issued a food or facility certification may no longer be in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, the accredited third-party certification body must conduct any monitoring (including an onsite audit) of such eligible entity necessary to determine whether the entity is in compliance with such requirements. The accredited third-party certification body must immediately notify FDA if it withdraws or suspends a food or facility certification because it determines that the entity is no longer in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations. The accredited third-party certification body must maintain records of such monitoring.

4.14. **Self-assessment Requirements**

4.14.1. An accredited third-party certification body must annually, upon FDA request made for cause, or when required in order to maintain accreditation, conduct a self-assessment that includes evaluation of compliance with document, including:

4.14.1.1. The performance of its officers, employees, or other agents involved in auditing and certification activities, including the performance of audit agents in examining

facilities, process(es), and food using the applicable food safety requirements of the FD&C Act and FDA regulations;

4.14.1.2. The degree of consistency among its officers, employees, or other agents involved in auditing and certification activities, including evaluating whether its audit agents interpreted audit protocols in a consistent manner;

4.14.1.3. The compliance of the accredited third-party certification body and its officers, employees, and other agents involved in auditing and certification activities, with the conflict of interest requirements set in this document;

4.14.1.4. Actions taken in response to the results of any assessments conducted by FDA or, where applicable, IAS; and

4.14.1.5. As requested by FDA, any other aspects of its performance relevant to a determination of whether the accredited third-party certification body is in compliance with these accreditation program requirements.

4.14.2. As a means to assess its performance, the accredited third-party certification body may evaluate the compliance of one or more of eligible entities to which a food or facility certification was issued under this accreditation program.

4.14.3. Based on the assessments and evaluations conducted under paragraphs 4.14.1 and 4.14.2, the accredited third-party certification body must:

4.14.3.1. Identify any deficiencies in complying with the requirements of this accreditation program;

4.14.3.2. Quickly implement corrective action(s) that effectively address the identified deficiencies; and

4.14.3.3. Establish and maintain records of such corrective action(s).

4.14.4. The accredited third-party certification body must prepare a written report of the results of its self-assessment that includes:

4.14.4.1. A description of any corrective action(s) taken under paragraph 4.14.3 of this document;

4.14.4.2. A statement disclosing the extent to which the accredited third-party certification body, and its officers, employees, and other agents involved in auditing and certification activities, complied with the conflict of interest requirements set in this document; and

4.14.4.3. A statement attesting to the extent to which the accredited third-party certification body complied with the applicable requirements of this accreditation program.

4.14.5. An accredited third-party certification body may use a report, supplemented as necessary, on its conformance to ISO/IEC 17021-1 or ISO/IEC 17065 in meeting the requirements of the self-assessment requirements section.

4.15. **Submission of Reports and Notification Requirements**

4.15.1. Reporting results of regulatory audits.

An accredited third-party certification body must submit a regulatory audit report, as described in Section 4.11.2 of this document, electronically, in English, to FDA and to IAS, no later than 45 days after completing such audit.

4.15.2. Reporting results of accredited third-party certification body self-assessments.

An accredited third-party certification body must submit the report of its annual self-assessment required by Section 4.14.1 electronically and in English to IAS, within 45 days of the anniversary date of its accreditation under this accreditation program. For an accredited third-party certification body subject to an FDA request for cause, or in the case where a self-assessment was requested due to any concerns raised with its accreditation status, the report of its self-assessment must be submitted to FDA electronically, in English, within 60 days of the FDA request, denial of renewal, revocation, or relinquishment of recognition of the accreditation body that granted its accreditation. Such report must include an up-to-date list of any audit agents it uses to conduct audits under this accreditation program.

4.15.3. Notification to FDA of a serious risk to public health.

An accredited third-party certification body must immediately notify FDA electronically, in English, if during a regulatory or consultative audit, any of its audit agents or the accredited third-party certification body itself discovers a condition that could cause or contribute to a serious risk to the public health, providing the following information:

4.15.3.1. The name, physical address, and unique facility identifier, if designated by FDA, of the eligible entity subject to the audit, and, where applicable, the registration number;

4.15.3.2. The name, physical address, and unique facility identifier, if designated by FDA, of the facility where the condition was discovered (if different from that of the eligible entity) and, where applicable, the registration number assigned to the facility; and

4.15.3.3. The condition for which notification is submitted.

4.15.4. Immediate notification to FDA of withdrawal or suspension of a food or facility certification.

4.15.5. An accredited third-party certification body must notify FDA electronically, in English, immediately upon withdrawing or suspending any food or facility certification of an eligible entity and the basis for such action.

4.15.6. Notification to IAS or an eligible entity.

4.15.6.1. After notifying FDA under paragraph 4.15.3 and 4.15.4, an accredited third-party certification body must immediately notify the eligible entity of such condition and must immediately thereafter notify IAS, except for third-party certification bodies

directly accredited by FDA. Where feasible and reliable, the accredited third-party certification body may contemporaneously notify IAS and/or the eligible entity when notifying FDA.

4.15.6.2. An accredited third-party certification body must notify IAS electronically, in English, within 30 days after making any significant change that would affect the manner in which it complies with the requirements of this accreditation program and must include with such notification the following information:

4.15.6.2.1. A description of the change; and

4.15.6.2.2. An explanation for the purpose of the change.

4.16. **Conflict of Interest Requirements**

4.16.1. An accredited third-party certification body must implement 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, including the following:

4.16.1.1. Ensuring that the accredited third-party certification body and its officers, employees, or other agents involved in auditing and certification activities do not own, operate, have a financial interest in, manage, or otherwise control an eligible entity to be certified, or any affiliate, parent, or subsidiary of the entity;

4.16.1.2. Ensuring that the accredited 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;

4.16.1.3. Ensuring that an audit agent of the accredited third-party certification body does not own, operate, have a financial interest in, manage, or otherwise control 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; and

4.16.1.4. Prohibiting an accredited third-party certification body's officer, employee, or other agent involved in auditing and certification activities from accepting any money, gift, gratuity, or other item of value from the eligible entity to be audited or certified under this accreditation program.

4.16.1.5. The items specified in Section 4.16.1.4 do not include:

4.16.1.5.1. Money representing payment of fees for auditing and certification services and reimbursement of direct costs associated with an onsite audit by the third-party certification body; or

4.16.1.5.2. Lunch of de minimis value provided during the course of an audit and on the premises where the audit is conducted, if necessary to facilitate the efficient conduct of the audit.

4.16.2. An accredited third-party certification body may accept the payment of fees for auditing and certification services and the reimbursement of direct costs associated with an audit of an eligible entity only after the date on which the report of such audit was completed or the date a food or facility certification was issued, whichever is later. Such payment is not considered a conflict of interest for purposes of Section 4.16.1.

4.16.3. The financial interests of the spouses and children younger than 18 years of age of accredited third-party certification body's officers, employees, and other agents involved in auditing and certification activities will be considered the financial interests of such officers, employees, and other agents involved in auditing and certification activities.

4.16.4. An accredited third-party certification body must maintain on its website an up-to-date list of the eligible entities to which it has issued food or facility certifications under this accreditation program. For each such eligible entity, the website also must identify the duration and scope of the food or facility certification and date(s) on which the eligible entity paid the accredited third-party certification body any fee or reimbursement associated with such audit or certification.

4.17. **Record Keeping Requirements**

4.17.1. A third-party certification body that has been accredited must maintain electronically for four (4) years records created during its period of accreditation (including documents and data) that document compliance with these accreditation program requirements, including:

4.17.1.1. Any audit report and other documents resulting from a consultative audit conducted under this accreditation program, including the audit agent's observations, correspondence with the eligible entity, verification of any corrective action(s) taken to address deficiencies identified during the audit;

4.17.1.2. Any request for a regulatory audit from an eligible entity;

4.17.1.3. Any audit report and other documents resulting from a regulatory audit conducted under this accreditation program, including the audit agent's observations, correspondence with the eligible entity, verification of any corrective action(s) taken to address deficiencies identified during the audit, and, when sampling and analysis is conducted, laboratory testing records and results from a laboratory that is accredited in accordance with Section 4.9.3, and documentation demonstrating such laboratory is accredited in accordance with Section 4.9.3;

4.17.1.4. Any notification submitted by an audit agent to the accredited third-party certification body in accordance with Section 4.7.1.5;

4.17.1.5. Any challenge to an adverse regulatory audit decision and the disposition of the challenge;

4.17.1.6. Any monitoring it conducted of an eligible entity to which food or facility certification was issued;

4.17.1.7. Its self-assessments and corrective actions taken to address any deficiencies identified during a self-assessment; and

4.17.1.8. Significant changes to its auditing or certification program that might affect compliance with this accreditation program.

4.17.2. An accredited third-party certification body must make the records of a consultative audit required by Section 4.17.1.1 available to FDA in accordance with section 414 of the FD&C Act.

4.17.3. An accredited third-party certification body must make the records required by Sections 4.17.1.2 through 4.17.1.8 available for inspection and copying promptly upon written request of an authorized FDA officer or employee at the place of business of the accredited third-party certification body or at a reasonably accessible location. If such records are requested by FDA electronically, the records must be submitted electronically not later than 10 business days after the date of the request. Additionally, if the records are maintained in a language other than English, an accredited third-party certification body must electronically submit an English translation within a reasonable time.

5. ADDITIONAL INFORMATION (AS APPLICABLE)

5.1. Procedures for Accreditation

5.1.1. A third-party certification body seeking accreditation must submit its request for accreditation.

5.1.2. IAS will examine the application and inform the applicant about any deficiencies detected. IAS will review the application submitted and may deny moving forward the accreditation process (or renewal) by providing a written response to the applicant stating the reasons for denial.

5.2. Assessment Process

5.2.1. Assessment process starts at the time of application acceptance by IAS and payment of the application fees by the applicant CB.

5.2.2. The applicant needs to send a copy of its Quality Manual in English language for an initial review of CB's documentation.

5.2.3. An assessment agenda will be then sent to encompass two assessment activities:

5.2.3.1. Assessment of the documentation and records of the CB (office assessment);

5.2.3.2. Assessment of the CB's competence to conduct food safety audits that includes an assessment of the auditors' skills and knowledge through witnessing a food safety audit for one of the eligible entities within the scope of accreditation.

5.2.4. For witnessing of the applied scope, the number of witness audits to be demonstrated depends on the extent of the scope of accreditation sought. The number of demonstrations needed will be determined by IAS following any IAF guideline/mandatory documents.

5.2.5. At all times during the assessment process, i.e., during the assessment or upon request, the applicant or accredited CB shall provide IAS with unrestricted access to documents pertaining to its auditing and reporting process, in particular, records of complaints, disputes and any related corrective actions undertaken.

5.2.6. A preliminary visit is optional and must be requested by the applicant CB. A preliminary visit is for the purpose to better understand the accreditation process and to clarify expectations of IAS and the requirements of the criteria documents. A preliminary report will be provided, however this shall not reduce the number of assessment days or assessors required for the initial assessment.

5.2.7. Where required and when appropriate conditions prevail (e.g., scope extensions, relocation of premises, follow-up assessments, etc.), IAS may consider a combination of remote assessments, and/or onsite witness visits. IAS' decision to grant a remote assessment is final when this option is requested by the CB. Remote assessments are not intended to replace the need for periodic onsite surveillance and reassessments of an accredited organization.

5.2.8. After the initial year of accreditation, the CB is subject to an onsite surveillance visit. The surveillance visit shall be completed approximately 12 months from the date of the initial granting of accreditation. As determined by IAS, a demonstration of the CB's competence for the accredited scope may also be completed during the surveillance assessment by IAS. This may also be replaced by a remote assessment depending on the size of the scope and the sampling performed at the initial assessment.

5.2.9. IAS will conduct a full reassessment of the CB at a minimum of once every two years commencing from the date of the surveillance assessment. Reassessment entails a full verification of the CB's scope of accreditation for continued compliance with IAS accreditation requirements. This will include both quality management system assessment and a number of witness audits that will provide confidence that the CB is consistently conducting food safety audits in a competent, professional and ethical manner.

5.2.10. For initial assessment of a CB with multiple premises where key activities are conducted, assessment shall be made to all premises.

For surveillance assessment and reassessment where the CB works from various premises, IAS requires all premises where one or more key activities are performed to be assessed within one accreditation cycle.

5.3. **Period of Accreditation**

IAS may grant accreditation to a third-party certification body under this accreditation program for a period not to exceed four (4) years.

5.4. **Reassessment Process**

5.4.1. A third-party certification body that has been accredited by IAS and wants to be reaccredited must file a new application asking for renewal.

5.4.2. An applicant whose renewal application was denied by IAS must notify FDA electronically, in English, within 10 business days of the date of issuance of a denial of accreditation or denial of the renewal application, of the name and contact information of the custodian who will maintain the records required and make them available to FDA. The contact information for the custodian must include, at a minimum, an email address and the physical address where the records will be located. FDA will provide notice on the website of the date of issuance of a denial of renewal of accreditation of a third-party certification body that had previous been accredited. A food or facility certification issued by an accredited third-party certification body prior to issuance of the denial of its renewal application will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP (voluntary qualified importer program).

5.5. **Monitoring of Third-party CBs by FDA**

FDA will periodically evaluate the performance of each accredited third-party certification body to determine whether the accredited third-party certification body continues to comply with the applicable requirements of this accreditation program, and whether there are deficiencies in the performance of the accredited third-party certification body that, if not corrected, would warrant withdrawal of its accreditation. For a third-party certification body accredited by IAS, FDA will evaluate an accredited third-party certification body not later than three (3) years after the date of accreditation for a 4-year term of accreditation, or by no later than the mid-term point for

accreditation granted for less than four (4) years. FDA may conduct additional performance assessments of an accredited third-party certification body at any time. In evaluating the performance of an accredited third-party certification body, FDA may review any one or more of the following:

5.5.1. Regulatory audit reports and food and facility certifications;

5.5.2. The accredited third-party certification body's self-assessments;

5.5.3. Reports of assessments by IAS;

5.5.4. Documents and other information relevant to a determination of the accredited third-party certification body's compliance with the applicable requirements of this accreditation program; and

5.5.5. Information obtained by FDA, including during inspections, audits, onsite observations, or investigations, of one or more eligible entities to which a food or facility certification was issued by such accredited third-party certification body.

FDA may conduct its evaluation of an accredited third-party certification body through a site visit to an accredited third-party certification body's headquarters (or other location that manages audit agents conducting food safety audits under this accreditation program, if different than its headquarters), through onsite observation of an accredited third-party certification body's performance during a food safety audit of an eligible entity, or through document review.

5.6. **Scope Extension Requests**

An IAS-accredited third-party certification body may request extension of their scope of accreditation at any time during the effective term of accreditation by submitting a written request identifying the discipline/scopes to be added.

The length of time to process a request for extension of the scope is dependent on submittal of the information requested above, and the scheduling of the assessments. All expenses and costs related to scope extensions are the responsibility of the Certification Body as per the client's IAS quotation.

5.7. **Withdrawal of Accreditation or Voluntary Relinquishment of Accreditation**

5.7.1. Withdrawal

5.7.1.1. Mandatory withdrawal. FDA will withdraw accreditation from a third party certification body:

5.7.1.1.1. Except as provided in Section 5.7.1.2, if the food or facility certified under this accreditation program is linked to an outbreak of foodborne illness or chemical or physical hazard that has a reasonable probability of causing serious adverse health consequences or death in humans or animals;

5.7.1.1.2. Following an evaluation and finding by FDA that the third-party certification body no longer complies with the applicable requirements of this accreditation program; or

5.7.1.1.3. Following its refusal to allow FDA to access records or to conduct an audit, assessment, or investigation necessary to ensure continued compliance with this accreditation program.

5.7.1.2. Exception. FDA may waive mandatory withdrawal under Section 5.7.1.1, if FDA:

5.7.1.2.1. Conducts an investigation of the material facts related to the outbreak of human or animal illness;

5.7.1.2.2. Reviews the relevant audit records and the actions taken by the accredited third-party certification body in support of its decision to certify; and

5.7.1.2.3. Determines that the accredited third-party certification body satisfied the requirements for issuance of certification under this accreditation program.

5.7.1.3. Discretionary withdrawal. FDA may withdraw accreditation, in whole or in part, from a third-party certification body when such third-party certification body is accredited by an accreditation body for which recognition is revoked, if FDA determines there is good cause for withdrawal, including:

5.7.1.3.1. Demonstrated bias or lack of objectivity when conducting activities under this accreditation program; or

5.7.1.3.2. Performance that calls into question the validity or reliability of its food safety audits or certifications.

5.7.1.4. Records access. FDA may request records of the accredited third-party certification body and where applicable, may request records from IAS, when considering withdrawal under Sections 5.7.1.1.1, 5.7.1.1.2 or 5.7.1.3.

5.7.1.5. Notice to the third-party certification body of withdrawal of accreditation.

5.7.1.5.1. FDA will notify a third-party certification body of the withdrawal of its accreditation through issuance of a withdrawal that will state the grounds for withdrawal, the procedures for requesting a regulatory hearing on the withdrawal, and the procedures for requesting reaccreditation

5.7.1.5.2. Within 10 business days of the date of issuance of the withdrawal, the third-party certification body must notify FDA electronically, in English, of the name of the custodian who will maintain records, and provide contact information for the custodian, which will at least include an email address and the street address where the records will be located.

5.7.1.6. Effect of withdrawal of accreditation on eligible entities. A food or facility certification issued by a third-party certification body prior to withdrawal will remain in effect until the certification terminates by expiration. If FDA has reason to believe

that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP (voluntary qualified importer program).

5.7.2. Voluntary relinquishment of accreditation

5.7.2.1. Notice to FDA of intent to relinquish or not to renew accreditation. A third-party certification body must notify FDA electronically, in English, at least 60 days before voluntarily relinquishing accreditation or before allowing accreditation to expire without seeking renewal. The certification body must provide the name and contact information of the custodian who will maintain the records required after the date of relinquishment or the date accreditation expires, as applicable, and make them available to FDA. The contact information for the custodian must include, at a minimum, an email address and the physical address where the records will be located.

5.7.2.2. Notice to IAS and eligible entities of intent to relinquish or not to renew accreditation. No later than 15 business days after notifying FDA under Section 5.7.2.1, the certification body must notify IAS and any eligible entity with current certifications that it intends to relinquish accreditation or to allow its accreditation to expire, specifying the date on which relinquishment or expiration will occur. IAS will maintain records of such notification.

5.7.2.3. Effect of voluntary relinquishment or expiration of accreditation on food or facility certifications issued to eligible entities. A food or facility certification issued by a third-party certification body prior to relinquishment or expiration of its accreditation will remain in effect until the certification expires. If FDA has reason to believe that a certification issued for purposes of section 801(q) or 806 of the FD&C Act is not valid or reliable, FDA may refuse to consider the certification in determining the admissibility of the article of food for which the certification was offered or in determining the importer's eligibility for participation in VQIP.

5.7.2.4. Public notice of voluntary relinquishment or expiration of accreditation. FDA will provide notice on the website of the voluntary relinquishment or expiration of accreditation of a certification body under this accreditation program.

6. LINKS TO ADDITIONAL REFERENCES

Not in use at this time.