



The Rules for IAS -Food & Drug Administration (FDA) -FOOD SAFETY MODERNIZATION ACT (FSMA) Best ISO AR-2-5- REV 10-2025-Dec.-24

1. INTRODUCTION

1.1. Scope

Best-ISO Certification, Co., Ltd. address this document to apply ,obtain and maintain International Accreditation Service, Inc. (IAS), Third-party Certification Bodies program 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 Certification. Best ISO shall comply with the requirements specified in Federal Register Vol.80, No. 228, dated November 27, 2015, 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 and the BEST ISO FDA-FSMA application and this document.

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

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 17000, Conformity assessment – Vocabulary and general principles.

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 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



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Management Systems (FSMS) Certification Bodies (Application from 15 December 2016).

2. DEFINITIONS

Definitions related to conformity assessment are from ISO/IEC 17000, ISO/IEC Guide 2, ISO/IEC 76 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. Others please refer to **AC782: THIRD-PARTY CERTIFICATION BODIES UNDER THE FOOD & DRUG ADMINISTRATION (FDA) FOOD SAFETY MODERNIZATION ACT (FSMA)**

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. Here is IAS

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 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:



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- (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;
- (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.

2.11. Facility 廠址: 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,



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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: **ST1+ST2 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 放棄 :

(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 competence, 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.

2.24. Surveillance (**SV audit**): 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



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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. Best ISO Certification Co. Ltd. is the IAS accreditation CB (MSCB-166) for ISO22000:2018, ISO 9001, ISO14001, ISO27001, ISAO 27701, ISO 13485, ISO45001 and ISO 50001 to apply the FDA FSMA accreditation from a recognized accreditation body-IAS.

3.1.1. Conducting food safety audits

3.1.2. Issuing certifications that 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. **Best ISO demonstrate the** competence and establish conformance with the criteria set in this document and any other documents related to this Program and IAS Policies based on the master list for the documents and the above IAS MSCB-166 certifications

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

3.3.1. Conformance with ISO/IEC 17021-1 in the Quality manual and all documents

3.3.2. Meet the requirements set in these documents. AC782: THIRD-PARTY CERTIFICATION BODIES UNDER THE FOOD & DRUG ADMINISTRATION (FDA) FOOD SAFETY MODERNIZATION ACT (FSMA) with this BEST ISO AR-2-5, AR-2-6, AR-2-7 and all documents

3.3.3. demonstrate that the training and qualifications of its agents used to conduct audits that addressed in these procedure

AR-2-1-Additional Requirements FSMS

AR-2-2-FSMS Auditors Handbook

AR-2-3-HACCP & GMP

AR-2-4-Transition Policy-FSMS-2018

AR-2-5- The Rules for IAS FDA FSMA

AR-2-6 FDA FSMA application

Form 30 Confidential and impartiality -FDA



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3.3.3.1 FDA FSMA qualified Auditor requirement

3.3.3.1.1 ISO/IEC 17024 accredited Certification-Lead auditor for FDA FSMA

- 3.3.3.1.2 If the auditor does not have the certification as 3.3.3.1.1 who needs to be qualified as per the following requirements:
 - a. Minimum 40 hrs training (in total) for the following cases (Each must have minimum 20 hrs, all both need to be conducted)
 - a-1 Preventive Controls (Human and/or Animal food) PCQI or
 - a-2 food safety requirements of the FD&C Act and FDA regulations training
 - a-3 FDA FSMA auditing training and ISO19011 LA training
 - b. Education: 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, plus appropriate experience or additional education,
 - ✧ or demonstration of sufficient knowledge or experience to successfully perform the function required and designated tasks
 - c Working experiences: 2 years full time employees and min one year QA or engineer experience.
 - d. Minimum one FDA FSMA auditing experience

3.3.3.1.3 Lead auditor

- a Working experiences: At least five years' full-time experience in food or associated industry, including two years' work in quality assurance or food safety functions in food production or manufacturing, retail, inspection, or enforcement, or the equivalent;
- Other formal qualifications (e.g., an advanced degree) as a substitute for a maximum of three years of working experience towards five years of experience.
- b at least one pilot FDA FSMA Witness audit (Due to Covid-19 that could be on line witness) determined by FDA FSMA qualified LA in the first 3 projects, and confirm skills through a witness audit at least once every two years
- c Skills, personal attributes and behaviors of CB auditors and managers should include: that record in the witness reports
 - High ethical standards
 - Objectivity
 - Reasoning skills
 - Interpersonal skills
 - Analytical skills
 - Communication skills
 - Diligence
 - Adaptability



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- Tenacity
- Intuition
- Observational skills

3.3.3.1.4 Trainee auditor (TA): anyone who missed the above 3.3.3.1.1 to 3.3.3.1.3 requirements.

3.3.3.1.5 FSMA auditors annually minimum 8 hours FD&C Act and FDA regulations training.

3.3.3.2 FDA FSMA Program employees of Best ISO

ISO/IEC 17024 accredited Certification internal auditor for FDA FSMA.

Or food safety requirements of the FD&C Act and FDA regulations training: minimum 6 hours FDA FSMA -IAS and BEST ISO training

Note

The mandatory import certification authority that FSMA does not apply to:

- Alcoholic beverages manufactured by foreign facilities. 207

- Meat, poultry and egg products that are subject to U.S. Department of Agriculture oversight at the time of importation

3.3.3.2.1 Initial 6 hours FSMA training and annually minimum 4 hours FD&C Act and FDA regulations training.

4. REQUIRED BASIC INFORMATION

4.1. The following procedures and the contract AR-2-7

M-01-Policy mission

M-02-Quality Manual

AR-2-5 The rules for IAS FDA-FSMA

AR-2-6 The application for IAS FDA FSMA

That address the 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; We keep the all audit reports in the server and files

4.1.2. Conduct onsite audits of an eligible entity as the above reports.

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

4.2. Same as above 4.1 meet the applicable requirements of accreditation under this accreditation program if accredited.



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4.3. Resource

4.3.1. The resources

4.3.1.1. Adequate numbers of employees that see the organization chart in the website.

4.3.1.2. Adequate financial resources that plan to initial public offering (IPO) 2019

4.3.2. The form 12 master list to meet the applicable requirements of this document

4.4. Conflicts of interest

4.4.1. Conflicts of interest

4.4.2. The following procedures written measures to protect against conflicts of interest between the third- party certification body –BEST ISO (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 Best ISO the conflicts of interest

- M-01-Policy mission
- M-02-Quality Manual
- M-03-Independent Certification Board (ICB)
- AR-2-5 The rules for FDA FSMA
- AR-2-6 FDA FSMA
- AR-2-7 contract FDA FSMA

4.5. Monitoring and evaluating

4.5.1 Monitoring and evaluating the performance of its officers, employees, and other agents involved in auditing and certification activities:

4.5.1.1. Identify deficiencies in its auditing and certification program or performance that will public in the end of the yearly and record in the personal files

- The auditing satisfaction rate by office
- The issuing Major rate
- minor NC rate
- complains rate
- witness report
- training record

4.5.1.2. Quickly execute corrective actions. That all corrective action need respond in **30 days and improve in 90 days.**

4.5.2. The procedure P-14 Appeals and P-15 Complaints that announce in the web site and contract that address the appeals and complain processes.

4.6. The procedure I-10 Reporting, I-16 Document Control and P-17 Quality Record address the report and document control and add the following special requirements for the



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FDA FSMA:

4.6.1. Retention time for any hard copy files is **for 4** years. Retention time for electronic copies is **4** years for client application and the following data. Notification requirements are same as above.

4.6.2. The reporting, notification, and records requirements including the following

4.6.2.1 Reporting (electronic **4** years)

- The Contract
- Application form (Attachment A form 1)
- Questionnaire for FDA (Attachment B- Form 2-8)
- Food Safety plans issued by qualified person
- Qualified Internal auditor list
- FSMA - Quality manual
- Evidence in compliance with applicable food safety requirements of the FD&C Act and FDA regulations
- The inspection **reports issued by third party Laboratory that IAF ISO17025 certificated.**
- Previous FDA relative information
- Master list for the qualifier suppliers or suppliers development plan00
- Pervious Management review and internal audit reports
- ISO9001 with HACCP or ISO 22000 with IAF CB logo.

4.6.2.2 Notification

- Official letter (without day)
- Attendance sheet with day and signatures (hard and electronic copy)
- CIC (certification information include the FDA legal exclude)
- Form 42 Notice after audit
- Annual auditing notification

4.6.2.3 Record (including the all 4.6.2.1 and 4.6.2.2) plus the following

- Certification
- Appeals
- Complains
- Nonconformities

4.6.2.4 Website Update Requirement

Any revised audit reports, certification updates, or relevant FSMA documents that are required to be publicly accessible shall be uploaded to the official Best ISO website within 5 working days after internal approval.

4.7. Monitoring and evaluating The Best ISO-P-13 and Best ISO-I-11 Assessor Competence addressed the Best ISO auditor's Requirements.



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4.7.1. Addition requirement for the FDA FSMA agents must follow 3.3.3.1 include

4.7.1.1. knowledge and experience :

4.7.1.2. **at least one pilot FDA FSMA Witness audit determined by FDA FSMA qualified LA in the first 3 projects.**

4.7.1.4. All auditor agents and employees sign the (form 30) Confidential and impartiality-FDA FSMA to guarantee that in the past 24 months and the next 12 months, have not/will not provide any kind of consultant service or any personal interest related services to the clients

4.7.1.5. (Form 30 Confidential and impartiality –FDA) The Best ISO 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, Best ISO will follow the requirement and contract review to determine that the audit agent is qualified to conduct such audit under the criteria established in Section 4.7.1 and Form 005 Auditor Application form & Industry Code Application based on the scope and purpose of the audit and the type of facility, its process(es), and food.

4.7.3. Best ISO will not 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. Best ISO will ask the all agent to sign the 4.7.1 agreement and will sue the agent if they cheat the Clients, FDA, IAS and BEST ISO. **To conduct this audit agent that Best ISO design an new A-B-C-A auditing agent contract review from including the wave to process and avoid the auditing agent auditing in 13 months.**

4.8. Audit Planning Requirements

4.8.1. The application procedure AR-2-6 The application of the IAS (FDA)-(FSMA) with the following requirement.

4.8.1.1. Follow the all information from the application form to 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:

- Contract
- Application form (Attachment A form 1)



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- Questionnaire-EH1 for FDA (Attachment B- Form 2-8)
- Food safety plans issued by qualified person
- Internal auditor list
- FSMA - Quality manual
- Evidence in compliance with applicable food safety requirements of the FD&C Act and FDA regulations
- The inspection reports issued by third party Laboratory that IAF ISO17025 certificated.
- Previous FDA relative information
- Master list for the qualifier suppliers or suppliers development plan
- Pervious Management review and internal audit reports
- ISO9001 with HACCP or ISO 22000 with IAF CB logo

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;

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

4.8.3. Best ISO to conduct an audit of the verified customer for the purpose of investigating complaints or responding to the change or prompting the termination of the customer, either short-notice or no announce (without notice). In this case

a) CB shall state and prioritize the verified customer (for example, the documents described in ISO17021 Section 8.5.1) to perform the conditions of the audit;

b) because the client lacks opportunity, for objection to the audit team member, the CB should pay special attention to the assignment of the audit team.

4.9. Authority to Conduct Audits Requirements that all clients sign the contracts

4.9.1. Conduct an unannounced audit in the 30-day operating schedule by the Client, FSMA Audit Agent will communicate with the assigned auditor team and decide the auditing days. Only report to Best ISO when the FSMA Audit Agent on site to conduct this an unannounced audit. The office letter will issue by FSMA Audit Agent without the day.

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 in the Report A-Form 34 and Form 35

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: sign recognized accreditation body agreements with Best ISO and **follow the IAS GUIDELINES FOR FOOD TESTING LABORATORIES August, 2015**

4.9.3.1. IAF ISO/IEC 17025:2005 or

4.9.3.2. Another laboratory accreditation standard that provides at least a similar level of



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assurance in the validity and reliability of sampling methodologies, analytical methodologies, and analytical results. Such as FDA or TFDA laboratory accreditation.

4.9.4. According to the provisions of Section 9.2 "Notification of Serious Public Health Risks" and Section 6.1.4 "Defective Labels" of the FDA's "Description of Accreditation Status in the Certification Body Management Plan of the Accredited Third-Party Certification Program Portal", the audit agent will immediately report to TPP-Best ISO, and Best ISO will report to FDA based on different risk levels. Best ISO will report to FDA situations found during consultations or regulatory audits that may cause or contribute to serious public health risks and follow the provisions of Section 9.2 "Report and Notification Page". If it causes "serious adverse health consequences or death to humans or animals", also known as SAHCODHA. The audit agent will report to TPP in the report, and Best ISO will use the "Defective Label" to notify FDA to take corrective actions and provide evidence.

4.9.5. Prepare reports part A and Part B of audits conducted as the procedures

I-07 Stage 2 report

I-08 Surveillance

I-10 Reporting

4.9.5.1. For consultative audits, follow the procedure I-07 Stage 2 to prepare reports that contain the elements specified in this document and maintain such records, subject to FDA access in accordance with section of the FD&C Act; and

4.9.5.2. For regulatory audits, follow the I-07 Stage 2 report procedure to 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;

4.9.6. Allow FDA and IAS, to observe any food safety audit conducted under this accreditation program for purposes of evaluating the Best ISO CB's performance under the requirements set in this document

4.10. Audit Protocol Requirements:

Head of the FDA FSMA technical committee (TC -FM) according the P-05 Contract Review procedure to with the identified scope and purpose of the audit and within the scope of its accreditation. If any scope change such as the add the scope or the change such as the address or employees that need new contract review and to be the minimum previous ST2 man day audit. In response to an application for expanding the scope of a certification already granted, undertake a review of the application and determine any audit activities necessary to decide whether or not the extension may be granted. This may be conducted in conjunction with an annually surveillance audit. No any discount when add or reduce the scope due to the new quotation for the new certification.

If there is a need for reducing the scope, then the client needs to be informed to remove



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any marketing material stating the old scope, a new certificate is being issued and a new contract review (new calculation of man-days) will be needed for the next audit.

Multi-site need to audit each site and could have maximum 90 % discount for each site if the management system is 100% same, basic will no any discount that will decide by FOM.

4.10.1. 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 and record in the report - part B ;

- an onsite examination of the facility, its process(es), and the food that results from such process(es);
- Where appropriate or when required by FDA, environmental or product sampling and analysis. When, for a regulatory audit, sampling and analysis is conducted, the Best ISO CB must use a laboratory that is accredited in accordance with paragraph 4.9.3.

4.10.2.1 Special requirement

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.

- **HARCP** plans issued by qualified person
- Internal auditor list
- FSMA - Quality manual
- Evidence in compliance with applicable food safety requirements of the FD&C Act and FDA regulations
- The inspection reports issued by third party Laboratory that IAF ISO17025 certificated.
- Previous FDA relative information
- Master list for the qualifier suppliers or suppliers development plan
- Pervious Management review and internal audit reports
- ISO9001 with HACCP or ISO 22000 with IAF CB logo.

4.10.3. Special requirement for the issuing the FDA-FSMA certification

The clients audit result are compliance with the following requirements that could recommend to get the FDA FSMA certification

1) Each parts of the report B must 100% follow the safety requirements of the FD&C Act and



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- 2) after the all corrective action plan and evidence acceptable
- 3) the onsite sampling products test passed (4.9.3) the IAS GUIDELINES FOR FOOD TESTING LABORATORIES August, 2015
- 4) Get the ISO9001 with HACCP or ISO 22000 with IAF CB logo.
After the independent Veto review and approved that will issue the FDA FSMA certification.

4.10.3.1 Auditing finding and result

Best ISO define and use the Costco and VDA auditing rate methods to check each items of (The safety requirements of the FD&C Act and FDA regulations) in the Reports B. The following is the result for recommends

- 1) **Each parts of the report B must 100% follow the safety requirements of the FD&C Act and FDA regulations** that could recommend to get the FDA FSMA certification after the corrective closed and products test passed (4.9.3)
- 2) One part of (The safety requirements of the FD&C Act and FDA regulations) that 60 % to 99.9999% that cloud accept to improve and must have on site closed and minimum charge 4 Hr. and one report fee.
- 3) Any part of the report Part B (The safety requirements of the FD&C Act and FDA regulations) under 60% will fail the auditing and case the full **Stage1 plus Stage 2** audit.

The above special requirement could be sufficiently rigorous 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 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.

5) For consultative audits

Could introduce the above system and include conformance with applicable industry standards and practices;

6) Corrective action closed

Best ISO define the following Finding that identifies a deficiency requiring

- The audit team shall identify and report any nonconformity (form 8- NC management) use the form and its supporting audit evidence to the client. When nonconformities are identified, the audit team shall classify each nonconformity as either major or minor according to the definitions
- Major, any part of the report Part B(The safety requirements of the FD&C Act and FDA regulations) under 80%.
- Minor, any nonconformity that did not follow the FD&C Act and FDA regulations
- The audit team shall not recommend to the client specific solutions to address the



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identified nonconformities.

- In case of conformity, opportunities for improvement may be identified 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. Report A and Report B for all 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. Reporting

Food Safety Audit Reporting Requirements

4.11.1. Consultative audits

auditor must prepare a report Part A (form 34) 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

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

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



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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

Best ISO CB 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, :

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;

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 violation product

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

4.11.2.6.2. May cause temporary or medically reversible adverse health consequence 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 Best ISO CB (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;

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



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BEST ISO 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

Best ISO will notify an eligible entity of a denial of certification and must establish and implement written procedures (P-14 Appeals and P-15 Complaints Issue) and the contract 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. The FDA appeals procedures and process and From 8 that public in the web site bestiso.vip

4.11.4.2. Procedure M-03-ICB- addressed that BEST ISO using the competent persons, who may or may not be external to the Best ISO CB, 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

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, Best ISO (or, where applicable, an audit agent on its behalf) must complete a regulatory audit with report Part A and Part B 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.

The clients' audit result is compliance with the following requirements that could recommend to get the FDA FSMA certification

1) Each parts of the report B must 100% follow the safety requirements of the FD&C Act and FDA regulations.

2) after the all corrective action plan and evidence acceptable

3) the onsite sampling products test passed (4.9.3)

4) Get the ISO9001 with HACCP or ISO 22000 with IAF CB logo.

4.12.1.2.

If, as a result of an finding (MAJOR or minor) during a regulatory audit, an eligible entity must implement a corrective action plan to address a deficiency and evidence to Best ISO,. The



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MAJOR need From 8-NC management and minor could use the form 35- section 3. Best ISO may not issue a food or facility certification to such entity until after the Best ISO 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).

If happen the on site closed the NC that same as 4.10.3

4.12.1.2.1 Major: One or more of the following:

- The absence of or total breakdown of a system to meet an FDA FSMA requirement and the safety requirements of the FD&C Act and FDA regulations.
- Any finding that would result in the probable shipment of nonconforming products.

4.12.1.2.2 Minor: A failure to comply with the safety requirements of the FD&C Act and FDA regulations that, based on judgment and experience is not likely to result in the failure of the quality management system or reduce its ability to ensure controlled processes or products usability.

4.12.1.3.

The lead auditor of Best ISO need to review NC first, and the veto will review and 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 Best ISO uses an audit agent to conduct a regulatory audit of an eligible entity under this accreditation program, the Best ISO certification (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. Best ISO may issue a food or facility certification under this accreditation program for a term of up to 12 months.



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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 BEST ISO (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;

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

4.12.2.3. The contract AR-2-7 address that 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 Best ISO CB acting outside the scope of its accreditation under this accreditation program;

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 Best ISO 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, Best ISO could follow the procedure (P-11 Special Visit) to conduct any monitoring (including an onsite audit) of such eligible entity necessary to determine whether the entity is in compliance with such requirements. Best ISO will 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. Best ISO will maintain records of such monitoring as the report A and B.

4.14. Self-assessment Requirements

4.14.1. Best ISO have internal audit and management review procedure annually, upon



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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 Best ISO 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 Best ISO CB is in compliance with these accreditation program requirements.
- 4.14.2. As a means to assess its performance, the Best ISO CB 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 Best ISO CB 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;
 - 4.14.3.3. Establish and maintain records of such corrective action(s).
- 4.14.4. The Best ISO CB 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 Best ISO CB, and its officers, employees, and other agents involved in auditing and certification activities, complied with the conflict of interest requirements set in this document;



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4.14.4.3. A statement attesting to the extent to which the Best ISO CB complied with the applicable requirements of this accreditation program.

4.14.5. Best ISO CB 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

Best ISO CB 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. Self-assessments

Reporting results of Best ISO CB self-assessments. Best ISO CB 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 Best ISO CB 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. (4.9.4.)

Best ISO CB must immediately notify FDA electronically, in English, if during a regulatory or consultative audit, any of its audit agents or the Best ISO CB 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;

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.

4.15.4.1 Withdrawal and suspension that addressed in the procedure Best ISO-P-12, however the special requirement as following



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Certificate Suspension

4.15.4.1.1 Certification by Best ISO may be temporarily suspended for a variety of reasons including:-

- a) voluntary cessation (by the client) of the operation of the clients certificated Management system, for whatever reason, e.g move of premises, staff shortages etc,
- b) the Management system adopted by the client has persistently or seriously failed to meet the certification criteria, and has shown itself to be incapable of being effective,
- c) the client has not permitted Best ISO to conduct surveillance/re-assessment activities when such activities are required; or
- d) when no visit to the Head Office of the client has taken place within 12 months of the previous visit. Note: Should follow the decision made by the **Veto** if unavoidable circumstances have occurred.

4.15.4.1.2 Reports of overdue visits and other requests to suspend a client' s registration are reviewed by the **Veto**, and a decision made regarding their suspension. In cases of persistent breach by the client of regulations relating to registration or prolonged delays to the performance of visits the client may be considered for immediate withdrawal (see 9.0 below)

4.15.4.1.3 Once a suspension decision has been ratified, the client is advised of their suspension by the **FM**, using official letter as appropriate.

4.15.4.1.4 Under such a suspension, Best ISO will advise the client that they must not make any claims to the effect that their system is certificated.

4.15.4.1.5 Best ISO may also place notice on its website that the clients certification is in suspension, and take any additional actions it feels appropriate to advise other interested parties.

The **FOM** will amend the clients certification notes with the details/history of the suspension. On a monthly basis Best ISO will review the status of each client which is in a state of suspension, to ensure that the period of suspension has not exceeded its maximum period (ie 60 days).

4.15.4.1.6 A reminder letter is sent by the **FM** on at a least a monthly basis, to reiterate to the client their continued suspended status. Should the maximum suspension period be approached, the



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client will also be advised and when exceeded withdrawal of certification will commence.

4.15.4.2 Certificate Withdrawal

4.15.4.2.1 Certificates of Registration are withdrawn by Best ISO when the registered company fails to comply with the Regulations relating to Registration.

4.15.4.2.2 Reasons for withdrawing certification are documented, Withdrawal of a certificate due to Best ISO's failure to conduct a continual assessment visit within the timeframe carries with it the potential for a high degree of customer dissatisfaction and must be dealt with accordingly. Correspondence must be modified to show where it is Best ISO's fault.

4.15.4.2.3 Prior to making a recommendation to withdraw certification, the **FOM** shall report to ICB (Best ISO- The Independent Certification Board). Details of the reason for withdrawal and evidence of appropriate authorization shall be recorded in the notes by FOM.

The decision to recommend the withdrawal of certification shall then be communicated **to the ICB**, in writing by special delivery.

4.15.4.2.4 If a satisfactory response is not received within 14 days of the date of recorded dispatch, then the FM concludes the withdrawal of Certificate **report to FOM**.

4.15.4.2.5 If a formal appeal is made, then procedure Best ISO-P-14 Appeals, is invoked. Records of all appeal, the final decision, and the basis for such decision are maintained **by FOM** and sent to ICB for reviewing.

4.15.5. Best ISO CB 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, Best ISO 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 Best ISO CB may contemporaneously notify IAS and/or the eligible entity when notifying FDA.

4.15.6.2.

Best ISO CB must notify IAS electronically, in English, within 30 days after making any



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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;

4.15.6.2.2 An explanation for the purpose of the change.

4.16. Conflict of Interest Requirements

4.16.1.

Best ISO CB must implement a written program to protect against conflicts of interest between the Best ISO CB (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 Best ISO CB, including the following:

4.16.1.1.

Ensuring that the Best ISO CB 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 Best ISO CB 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 Best ISO CB 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;

4.16.1.4.

Prohibiting Best ISO CB'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

4.16.1.5.2.

Lunch of minimis value provided during the course of an audit and on the premises where



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the audit is conducted, if necessary to facilitate the efficient conduct of the audit

4.16.2.

Best ISO CB 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 Best ISO CB'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.

Best ISO CB 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 Best ISO CB any fee or reimbursement associated with such audit or certification.

4.17. Record Keeping Requirements

4.17.1.

BEST ISO that has been accredited must maintain electronically for 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



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4.9.3;

4.17.1.4. Any notification submitted by an audit agent to the Best ISO in accordance with Section 4.6.2

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;

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

4.17.2. Best ISO CB 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.

Best ISO CB 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 Best ISO CB 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, Best ISO CB must electronically submit an English translation within a reasonable time.

5. ADDITIONAL INFORMATION (AS APPLICABLE)

5.1. Procedures for Accreditation that for IAS

5.1.1. BEST ISO seeking IAS CB.

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



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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

5.3. Period of Accreditation

IAS may grant accreditation to BEST ISO under this accreditation program for a period not to exceed four (4) years.

5.4.1. BEST ISO 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 BEST ISO that had previously been accredited. A food or facility certification issued by Best ISO CB 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 Best ISO CB to determine whether the Best ISO CB continues to comply with the applicable requirements of this accreditation program, and whether there are deficiencies in the performance of the Best ISO CB that, if not corrected, would warrant withdrawal of its accreditation. For BEST ISO accredited by IAS, FDA will evaluate Best ISO CB 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 Best ISO CB at any time. In evaluating the performance of Best ISO CB, 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 Best ISO CB's self-assessments

5.5.3. Reports of assessments by IAS



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5.5.4. Documents and other information relevant to a determination of the Best ISO 's compliance with the applicable requirements of this accreditation program;

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 Best ISO CB. FDA may conduct its evaluation of Best ISO CB through a site visit to Best ISO CB'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 Best ISO performance during a food safety audit of an eligible entity, or through document review.

5.6. Scope Extension Requests

Best ISO 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.

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 5.7.1.1, 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;

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

5.7.1.5.1. FDA will notify a Best ISO 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 Best ISO 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 Best ISO 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



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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 Best ISO 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.



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Document History

Status of Guidance	Timing of Current Version	Type of Revisions	Description of Changes
Draft	Jan. 2016	Rev 1	First version
Final	Jun. 2016	Rev 2	IAS IA Audit Finding
Final	Nov. 2021	Rev 3	IAS SV Audit Finding
Final	Apr. 2022	Rev 4	IAS finding 3.3.3.1 Lead auditor requirement
Final	27.Apr.2022	Rev 5	IAS CAR
Final	1.Jan. 2023	Rev 6	2023 internal finding
Final	06-July-2023	Rev 7	AB IAS 2023 finding
Final	1-Jan-2025	Rev 8	AB-IAS finding
Final	6-Jun-2025	Rev 9	FDA finding change the 4.9.4
Final	24, Dec. 2025	Rev 10	FDA finding change