



RULES OF PROCEDURE FOR ACCREDITATION THIRD-PARTY CERTIFICATION BODIES UNDER THE FOOD & DRUG ADMINISTRATION (FDA) FOOD SAFETY MODERNIZATION ACT (FSMA)

1.0 PURPOSE AND SCOPE

The purpose of these rules is to establish procedures governing accreditation of Third-Party Certification Bodies under the Food & Drug Administration (FDA) Food Safety Modernization Act (FSMA) by International Accreditation Service, Inc. (IAS). The Third-Party CB must demonstrate its competence for the respective discipline(s) and the technical categories or sectors for which accreditation is sought, in accordance with FDA and IAS requirements.

IAS accreditation does not make any representation nor should it be construed as making representation regarding attributes not specifically addressed by the accreditation. Accreditation also does not constitute an endorsement or recommendation for use of a particular third-party certification body, or of the services offered by a third-party certification body. Accreditation attests to compliance by the Third-party CB to the IAS program requirements for third-party certification bodies under the Food & Drug Administration (FDA) Food Safety Modernization Act (FSMA). Accreditation is no longer valid upon revocation, suspension, or cancellation of the accreditation.

2.1 APPLICATION

2.2 General

Applications for accreditation of Third-party CBs shall be filed on forms provided for that purpose. Applications will not be accepted unless they are fully executed in the manner required by IAS. An application is required for each Third-party Certification Body seeking accreditation.

2.3 Fees

2.3.1 Initial Application

2.3.1.1 **To receive a fee quotation for accreditation, please email GetAQuote@iasonline.org or call 866.427.4422. For international calls, +1 562.364.8201.**

2.3.1.2 Each initial application shall be accompanied by the basic new application fee as provided in your quotation.

2.3.1.3 The basic fee covers one sector/cluster of certification discipline, as applicable and as provided in your quotation. Additional fields of certification disciplines require a supplementary charge as provided in your quotation. Normally an "additional field of certification discipline" involves distinct expertise (e.g. Chemistry, Veterinary etc.) as described in the IAS Program Requirements for third-party certification bodies under the

Food & Drug Administration (FDA) Food Safety Modernization Act (FSMA).

2.3.1.4 The filing fees include issuance of the accreditation certificate.

2.3.1.5 Each initial accreditation is valid for a one-year period from the accreditation date.

2.3.1.6 Fees are charged to reinstate expired or canceled accreditation.

2.3.2 Renewing Accreditation

2.3.2.1 An application to renew accreditation must be filed at least 15 days prior to the expiration date if continued accreditation is desired and shall be accompanied by the applicable fee. Applications to renew accreditation may be for a one-, two- or three-year period.

2.3.2.2 Accreditation is subject to cancellation if an application to renew accreditation is not completed by the renewal date.

2.3.3 Fee Modifications: Any modifications to the fees must be reviewed and approved by the IAS president or his/her designee.

2.3.4 Cancellation: Initial request applications held for more than 180 days, without the applicant's having fulfilled IAS requirements for accreditation, are subject to cancellation unless such term is extended by the IAS president or his/her designee.

2.3.5 Nonrefundable: All IAS fees are nonrefundable.

2.3.6 Taxes and charges: All sales, use, excise, value-added and similar taxes and charges are the responsibility of the applicant, and the applicant agrees to reimburse IAS for any such taxes and charges imposed on IAS with respect to services provided by IAS.

3.1 DATA

3.2 The following items and data shall be submitted with the application: Electronic submission is preferred.

3.2.1 Documentation addressing each item in the applicable IAS program requirements in a management system manual which must be signed and currently dated by a responsible officer of the applicant, verifying that the information provided is true and correct.

3.2.2 An itemized list of the certification disciplines for which accreditation is sought.



3.2.3 A descriptive list of subcontractors used (if applicable) along with information regarding the certification processes that are subcontracted.

3.2.4 A list of approved auditors along with the respective sectors/clusters under which they are approved.

3.3 IAS may at any time, in addition to the data submitted above, require other information regarding the operation of the CB and the outcome of its services.

4.1 PROCESSING

Upon receipt by IAS of applicable fees, applications will be processed to their completion, which will be one of the following:

4.2 Accreditation upon determination by the IAS that based on review of evidence submitted and on-site assessments, the applicant possesses the expertise, facilities and independence to properly act as a third-party certification body under the Food & Drug Administration (FDA) Food Safety Modernization Act (FSMA) for the specific sectors/clusters requested in the application.

4.3 Disapproval for lack of evidence that justifies accreditation as described in Item 4.1 above.

An accreditation certificate shall be issued by IAS for each application accredited.

5.1 ASSESSMENTS

5.2 Initial Assessment: Prior to accreditation, for initial application, on-site assessments will be conducted by the IAS to evaluate expertise and equipment in the area of certification for which accreditation is being sought. For Initial Assessments, all critical locations, which are covered by the scope of accreditation of the certification body, are visited and assessed.

5.3 Surveillance Assessment after Initial Year of Accreditation: All accredited third-party certification bodies are subject to an onsite surveillance assessment at the end of the initial year of accreditation. Should there is a request for scope expansion or a need for onsite verification of the effective implementation of the system (e.g. formal end user complaints, big number of findings in the initial assessment, e.t.c.), Surveillance assessment duration can increase. Surveillance assessment typically includes a witness assessment of the audit process of the CB in one of the eligible entities for certification.

5.4 Reassessment: A full on-site reassessment is required at the end of every two-year term commencing from the date of initial accreditation. Supplementary on-site reassessments may be conducted to investigate formal complaints or other changes in a CB's status that may affect the ability of the CB to fulfill IAS requirements for accreditation.

5.5 Transfer of Accreditation: Certification Bodies currently accredited by an IAF MLA-recognized accreditation body may seek to transfer accreditation to IAS. In this case, CBs must provide the following:

5.5.1 A complete copy of the most recent assessment report from your current accreditation body.

5.5.2 Corrective actions for any deficiencies noted in the assessment report, including acknowledgement of acceptance of the corrective actions by the previous accreditation body. If the applicant and the accreditation body differ on the corrective actions or deficiencies, IAS will review them and make a decision as to status.

5.5.3 A copy of the current accreditation certificate issued by the previous accreditation body.

6.1 EXPENSE REIMBURSEMENT

6.2 All expenses, including but not limited to travel and staff time, related to the assessments noted under Section 5 are reimbursable to IAS by the applicant.

6.3 When IAS performs witnesses audits, or investigates formal complaints, related to IAS CB accreditation, all expenses including but not limited to travel and staff time are reimbursable to IAS by the Certification Body.

7.1 MAINTENANCE OF ACCREDITATION

7.2 Third-party Certification Bodies accredited under these rules shall notify IAS in writing within thirty days concerning the following:

7.1.1 Change in CB name.

7.1 Change in CB ownership.

7.1.3 Change in CB address.

7.1.4 Changes in scope, policies or procedures that might affect the agency's accreditation.

7.1.5 Changes in principal officers or key personnel.

7.2 The Certification Body agrees to permit unannounced assessments of its office and certified facilities by the IAS for cause.

8.0 RIGHT TO APPEAL DECISIONS INVOLVING ISSUANCE OF ACCREDITATION OR DENIAL OF THE APPLICATION

The applicant seeking issuance of an IAS accreditation for third-party certification body under the Food & Drug Administration (FDA) Food Safety Modernization Act (FSMA) may appeal a written decision of IAS involving the cancellation of the application or the issuance of or refusal to issue the accreditation for which the applicant has submitted an application. This appeal right shall apply to applicants for initial accreditation and applicants seeking renewal of an existing accreditation. Only the affected applicant may appeal the decision of IAS regarding the



subject application.

Procedures for appeals of denial of accreditation shall be in accordance with the Rules of Procedure for Appeals Concerning International Accreditation Service, Inc., Actions.

9.0 PROPRIETARY DATA

Data in any accreditation file or application are considered proprietary to the applicant. The data may be disclosed by IAS only upon the written consent of the applicant or pursuant to subpoena issued by a court or other governmental agency of competent jurisdiction.

Proprietary data may also be disclosed to an IAS Accreditation Committee member; a staff member of IAS or an authorized representative of IAS having a legitimate interest therein; any duly identified representative of any Third party Certification Body, or like person or organization who initially prepared the data, or a duly authorized representative thereof stated to be an employee or principal thereof having a legitimate interest therein. Governmental regulatory bodies may be granted access in the interest of public safety or preservation of property as it relates to enforcement of laws/regulations upon receipt of an official written request.

For this accreditation program, third-party certification body files can also be disclosed to US FDA according to FDA Final Rules under the Food & Drug Administration (FDA) Food Safety Modernization Act (FSMA)

From time to time, IAS records and files are audited by national and international bodies on a random basis to establish conformance with international accreditation and conformity assessment standards. It is understood that, by executing an accreditation application, CBs grant IAS the authority to allow such access.

10.0 ACCREDITATION DOCUMENTS AND LISTINGS

A certificate of accreditation shall be issued and maintained current for each accredited third party certification body upon satisfactory completion of the accreditation requirements. For each accredited CB, a listing shall be posted on the IAS website. Accreditation actions will also be noted on the IAS website.

11.0 INDEMNIFICATION

All applications for an IAS accreditation shall contain such indemnifications and like provisions running in favor of IAS, its parent corporation, ICC, the directors, officers, agents and employees of both such entities as the Board of Directors of IAS shall from time to time require.

12.1 USAGE OF THE IAS NAME OR SYMBOL BY ACCREDITED CERTIFICATION BODIES

12.2 An accredited third party certification body can

make reference to its IAS accreditation in certificates, in its general literature and promotional materials, and in business solicitations, under the following provisions:

12.2.1 The CB may not reference its accredited status in any way that indicates or implies accreditation in areas outside the actual scope of the specific IAS accreditation; or that indicates or implies IAS endorsement of any particular product, material or service.

12.2.2 When the IAS name and/or the registered symbol are used on the CB's letterhead or in other general literature or promotional materials, it shall be accompanied by the word "ACCREDITED." The symbol must also include the name of the accredited program, e.g., "Food & Drug Administration (FDA) Food Safety Modernization Act (FSMA)". When the IAS name or symbol is printed on letterhead and/or other CB stationery, such stationery may not be used for work proposals or quotations if none of the work is within the CB's current scope of accreditation with IAS.

12.2.3 The IAS symbol is to be used on IAS-endorsed certificates. The IAS symbol may not be changed in any way, although it may be enlarged or reduced.

12.2.4 When the IAS name and/or symbol is used on a business solicitation, such as a work proposal or quotation, the CB must attach to the solicitation a copy of its current IAS certificate of accreditation, so as to make clear the CB's scope of accreditation.

12.2.5 The IAS symbol displayed on the CB's IAS-endorsed certificates must include the name of the accredited program, e.g., "Food & Drug Administration (FDA) Food Safety Modernization Act (FSMA)" provided the certificates relate to audits performed within the CB's IAS-approved scope of accreditation. Whenever the IAS symbol is used on a certificate covering multiple disciplines/sectors, some of which are within the CB's scope of accreditation and some of which are outside the scope, the CB must clearly identify whatever portion of the certification scope is not covered by IAS accreditation.

12.3 It is the CB's responsibility to not misrepresent its accreditation status in any way, and to secure IAS approval in advance whenever there is a question about the CB's intended use of the IAS name and/or symbol.

13.1 REVOCATION/MODIFICATION/SUSPENSION/ CANCELLATION OF THE ACCREDITATION WITH RIGHT TO APPEAL

13.2 Any accreditation is subject to revocation, modification, suspension or cancellation upon occurrence of any of the following:

13.2.1 Failure by the CAB to comply with the current or updated Rules of Procedure.

13.2.2 Failure to comply with the current or updated



program requirements

13.2.3 Failure to comply with any condition to the issuance of the accreditation.

13.2.4 Any misstatement, whether intentionally or unintentionally made, in the application or any data or documentation submitted in support thereof.

13.2.5 Failure to comply with any provision contained in the application.

13.2.6 Failure to comply with any terms of the management system documentation on which the IAS accreditation was based referred to in Section 3 of these Rules of Procedure.

13.2.7 Any other grounds considered as adequate cause in the judgment of IAS.

13.3 The revocation, modification, suspension or cancellation of accreditation may only be appealed by the holder of the accreditation.

13.4 Procedures for appeals of revocation, modification, suspension or cancellation of accreditation shall be in accordance with the Rules of Procedure for Appeals Concerning International Accreditation Service, Inc., Actions. The IAS president or his/her designee, or the Board of Directors, as the case may be, may shorten any

of the time periods set forth in the Rules of Procedure for Appeals Concerning International Accreditation Service, Inc., Actions, if such action is deemed necessary, in their discretion, in the interest of public safety and welfare.

14.1 REVOCATION/MODIFICATION/SUSPENSION/CANCELLATION WITHOUT RIGHT TO APPEAL

Notwithstanding anything in these rules to the contrary, any initial application, or accreditation may be revoked, modified, suspended or cancelled by the IAS president or his/her designee for any of the following reasons with no right of appeal:

14.2 Failure to pay required fees to IAS within thirty days from the date of the mailing by IAS of written demand for payment.

14.3 Failure to perform any certification or to furnish any material or data relating to CB accreditation required by IAS within the specified time limit, unless extended by the IAS president or his/her designee.

14.4 Failure to respond and resolve IAS Corrective Action Requests or Concerns resulting from an IAS assessment report in the allotted time, unless extended by the IAS president or his/her designee.

14.5 Failure to permit or submit to an on-site or witness assessment as set forth in Section 5.0.

14.6 Failure to furnish information and/or submit to a

surveillance assessment as required in Section 5.2 of these rules within the specified time limit.

15.1 RESULTS OF REVOCATION/MODIFICATION/SUSPENSION/CANCELLATION

15.2 Upon the occurrence of any of the events set forth in Section 14.1 or Section 15.0, IAS, by the decision of its president or his/her designee, may choose any of the following actions:

15.2.1 Revocation of the accreditation.

15.2.2 Modification of the accreditation, on such terms as determined by the IAS president or his/her designee.

15.2.3 Suspension of the accreditation for such period on such terms as determined by the IAS president or his/her designee.

15.2.4 Cancellation of the accreditation.

15.3 The decisions of the IAS president or his/her designee with respect to any of the actions set forth in Section 16.1 may become effective immediately if deemed necessary, in the interest of public safety and welfare, may be stayed pending an appeal pursuant to the Rules of Procedure for Appeals Concerning International Accreditation Service, Inc., Actions, or may be otherwise stayed on such terms and conditions as determined by the president or his/her designee.

15.4 Upon revocation or cancellation of the accreditation or during any period of suspension, unless this provision is specifically modified by the terms of the suspension, the accredited CB shall discontinue all use of the IAS symbol. Upon revocation or cancellation of accreditation, the CB shall return any certificate of accreditation to IAS. The CB shall also immediately discontinue any references to IAS accreditation on any certificates, or promotional material.

15.5 IAS shall have the right to immediately notify governmental jurisdictions, FDA and any other interested parties of any improper and unauthorized reference to the continuation of the accreditation, when in the sole judgment of IAS, as determined by its president or his/her designee, such notification is necessary in the interest of public safety or welfare.

15.6 Upon the determination by IAS that cause exists for any of the actions specified in Section 16.1 above, with respect to the accreditation, IAS shall deliver to the CB a written statement, signed by the IAS president or his/her designee, setting forth the factual basis for such action. This written statement shall include a specific reference to the cause for the action which is set forth in the Rules of Procedure. This statement shall be delivered to the CB by certified or registered United States mail, with postage prepaid, to the most current address of the CB contained in the records of IAS.



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16.1 CBs OPERATING UNDER SPECIAL JURISDICTIONAL/GOVERNMENTAL REGULATIONS

16.2 Regulatory entities in certain economies may place specific compliance requirements on CBs operating within their jurisdiction. If an applicant CB intends to seek acceptance of its certificates by these entities, they must agree to comply with the additional assessment requirements, including more frequent on-site assessments.

16.3 By executing the IAS application for third party certification body accreditation, the CB agrees to furnish all needed documentation, pay the required fees, perform additional audits, or otherwise fully comply with the requirements of the regulatory entities from whom they are seeking approval. ■