

ACCREDITATION PROCESS FOR CERTIFICATION BODIES

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1. The Scheme

- 1.1 The Accreditation Scheme for Management Systems and Product Certification Bodies is the national accreditation scheme of the Accreditation Board For International Standards (ABIS). The said scheme will be referred to as "CB Scheme".
- 1.2 The primary objectives of CB Scheme are to
 - a) Operate the accreditation of certification bodies in accordance to international criteria such as mandatory and guidance documents, requirements for mutual recognition arrangements, and relevant ABIS documents.
 - b) Provide by means of assessment, the assurance that the professional practice by certification bodies, are in accordance to international standards
 - c) Ensure that the accreditation processes are carried out with professionalism and integrity.
 - d) Strengthen and develop accreditation schemes to meet the needs of stakeholders
 - e) Facilitate trade and market access by establishing and maintaining multilateral recognition arrangements with overseas and regional / international accreditation bodies.
- 1.3 The CB Scheme gives formal recognition to certification bodies that have been independently assessed and found to comply with the criteria established by ABIS. Accreditation is granted for the scopes applied, and is not a blanket approval for its total operations
- 1.4 ABIS accredits certification bodies that can demonstrate compliance with the following requirements:

Quality Management System (QMS) Certification bodies

- ISO/IEC 17021 Conformity assessment Requirements for bodies providing audit and certification of management systems
- Mandatory Documents, where applicable
- ABIS CT 04 ABIS Criteria for Certification Bodies (Good Distribution Practice for Medical Devices)
- Certification standards
 - ✓ ISO 9001 (Quality Management Systems Requirements)
 - ✓ ISO 20000 (IT Service Management)
 - ✓ ISO 13485 (Medical Devices Quality Management systems)

Environmental Management System (EMS) Certification bodies

- ISO/IEC 17021 Conformity assessment Requirements for bodies providing audit and certification of management systems
- Mandatory Documents, where applicable
- Certification standard
 - ISO 14001 (Environmental Management Systems Requirements with guidance for use)
- Occupational Safety &Health Management System (OSHAS) Certification bodies
- ISO/IEC Guide 66 General Requirements for Bodies Operating Assessment and
- Certification/Registration of Environmental Management Systems, and the corresponding Guidance (to be replaced by ISO/IEC 17021 wef 1 July 2009 for existing ABIS accredited certification bodies)
- ISO/IEC 17021 Conformity assessment Requirements for bodies providing audit and certification of management systems
- ABIS CT 02 ABIS Criteria for Certification Bodies' Auditors (OSHAS)

Hazard Analysis and Critical Control Point (HACCP) Certification bodies

- ISO/IEC Guide 62 General Requirements for Bodies Operating Assessment and Certification/Registration of Quality Systems, and the corresponding Guidance (to be replaced by ISO/IEC 17021 wef 1 July 2009 for existing ABIS accredited certification bodies)
- ISO/IEC 17021 Conformity assessment Requirements for bodies providing audit and certification of management systems
- ABIS HACCP Document No 1 Requirements for HACCP Auditing Methodology and Criteria for Auditors Certification standard
 - ABIS HACCP Document No 2 (Management of Food Safety Based on HACCP (Hazard Analysis and Critical Control Point) Requirements for a HACCP based Food Management System

Food Safety Management System (FSMS) Certification bodies

- ISO/TS 22003 Food Safety Management Systems Requirements for bodies providing Audit and Certification of Food Safety Management systems
- Certification standard
 - ISO 22000 (Food Safety Management Systems Requirements for any organization in the food chain)

Product Certification bodies

- ISO/IEC Guide 65 General Requirements for Bodies Operating Product Certification Systems and the corresponding Guidance.
- ABIS CT 05 ABIS Criteria for Certification Bodies
- 1.5 This document should be read in conjunction with ABIS 01 Terms and Conditions for Accreditation, ISO/IEC 17021, ISO/IEC Guide 65, and the corresponding mandatory and guidance documents, ISO/TS 22003, and any specific requirements that may be published relating to the CB scheme.

2. Definitions

2.1 Accreditation

Third party attestation (2.8) related to a conformity assessment body (e.g. certification body) conveying formal demonstration of its competence to carry out specific conformity assessment tasks

2.2 **Accreditation Body**

Authoritative body that performs accreditation (e.g. ABIS)

2.3 Accreditation Certificate (Certificate of Accreditation)

A formal document by ABIS to be used by accredited certification bodies to indicate their accredited status.

2.4 **Accreditation Criteria:**

Requirements of CB scheme expressed in general terms, which address organisation, human and material resources, operating procedures, certification and quality assurance practices of a certification body, Such requirements are specified in the documents as listed in Clause 1.4 of this document.

2.5 Appeal

Request by the certification body for reconsideration of a decision made by ABIS relating to accreditation

2.6 **Assessment:**

Process undertaken by ABIS to assess the competence of a certification body, based on particular standard(s) and/or guide(s) and/or other normative documents for a defined scope of accreditation

2.7 **Assessor:**

A person assigned by ABIS to perform, alone or as part of an assessment team, an assessment of a certification body

2.8 Attestation

Issue of a statement, based on a decision following review, that fulfillment of specified requirements has been demonstrated

2.9 **Certification:**

Third party attestation (2.8) related to products, processes, systems or persons

2.10 **Certification Body:**

For the purpose of this accreditation, a certification body is an independent impartial body, government or non-government, possessing the necessary competence and reliability to operate a certification system and in which those with an interest in the process of certification are represented without any single interest predominating.

2.11 Complaint

Expression of dissatisfaction, other than appeal, by any person or organizat to ABIS relating to the activities of ABIS or of an accredited certification body, where a response is expected

2.12 Conformity Assessment Body (CAB)

Body that performs conformity assessment services and that can be the object of accreditation (e.g. certification body)

2.13 **Expert:**

A person assigned by ABIS to provide specific knowledge or expertise with respect to the scope of accreditation to be assessed

2.14 Extending Accreditation

Process of enlarging the scope of accreditation

2.15 Management Representative:

A person nominated by a certification body to represent it in all matters relating to accreditation.

2.16 **Nonconformity**

Non-fulfillment of a requirement

2.17 **Reducing Accreditation**

Process of cancelling accreditation for part of the scope of accreditation

2.18 ABIS Accredited Certificate

A certificate includes a statement by the certification body that it is accredited for the scope listed. It bears the accreditation certificate number and the ABIS accreditation mark.

2.19 **Schedule of Accreditation:**

A schedule issued with the Certificate of Accreditation listing the specific scopes for which accreditation has been granted.

2.20 Scope of Accreditation

Specific conformity assessment services for which accreditation is sought or has been granted

2.21 **Surveillance**

Routine examination of a certification body to evaluate its continued compliance with ABIS requirements, normally every twelve month period.

2.22 **Suspending Accreditation**

Process of temporarily making accreditation invalid, in full or for part of the scope of accreditation

2.23 Withdrawing Accreditation

Process of cancelling accreditation in full

3. Organization Structure

3.1 Council Committee for Management Systems and Product

- 3.1.1 The Council Committee for Management Systems and Product (CCMP) is a specialist committee appointed by the ABIS Council. The CCMP is responsible for the formulation of policies, provides guidance and oversees the operation of the Accreditation Schemes for Management Systems and Product Certification Bodies.
- 3.1.2 The CCMP is authorized by the ABIS Council to review, evaluate and approve assessment reports for accreditation of certification bodies through the CCMP Review Committees. The CCMP may also co-opt individuals with relevant technical or management expertise as advisors for the review of assessment reports.
- 3.1.3 The term of office for CCMP members is three years with provision for re-appointment.

3.2 **Project Teams**

- 3.2.1 Project Teams are established for the development of new schemes or for extension of the existing schemes.
- 3.2.2 Project Team members are recommended by the CCMP and approved by the ABIS Council. The basis of appointment will be the members' knowledge and expertise in respective technical field or area. The Project Teams are to recommend criteria for new schemes.
- 3.2.3 The term of office for members of the Project Team is for the duration of the development of the scheme.

3.3 **Assessors / Technical Experts**

- 3.3.1 The CCMP maintains a panel of assessors/technical experts who are appointed from the ranks of government departments, associations & societies, academic and professional institutions, and industry practitioners. The assessors/technical experts are chosen on the basis of their professional knowledge and expertise in a particular scope of accreditation and their ability to examine and evaluate a certification body's standard of management and practices.
- 3.3.2 The assessors/technical experts, upon assignment by the CCMP Chairman, will conduct assessments of applicants and accredited certification bodies based on the criteria established under the CB Scheme.
- 3.3.3 The assessment team submits assessment reports to the CCMP Review Committee for approval, after each assessment on the granting, extension, reduction, renewal, suspension or withdrawal of accreditation.

4. Accreditation Process

4.1 Introduction

- 4.1.1 Enquiries regarding CB Scheme can be made at the Accreditation Board for International Boards (ABIS).
- 4.1.2 Certification bodies interested to be accredited may obtain the relevant documents (except ISO/IEC Guides and Standards) and application form from ABIS or download them from ABIS website.
- 4.1.3 The certification body is advised to study in detail the ABIS terms and conditions to ensure that it can substantially meet the accreditation criteria before it lodges an application for accreditation.

4.1.4 The management system of the certification body shall be operational for at least six months before ABIS carries out an assessment of the certification body.

4.2 **Application**

- 4.2.1 All applications shall be made in the form provided by ABIS and be supported with documents containing sufficient information regarding its staff, management system, equipment (where applicable) or other information necessary or requested by ABIS from time to time for the assessment of the certification body.
- 4.2.2 The applicant shall nominate a management representative to liaise with ABIS on all matters relating to accreditation and the applicant shall keep ABIS informed of any change in the representative.
- 4.2.3 The application form is to be returned with the following:
 - a) Quality Manual and the Operation Manual
 - b) Corporate documents such as ACRA or memorandum of articles to prove legal entity of the certification body
 - c) The application fee (non-refundable).
- 4.2.4 Upon receipt of a duly completed application form and satisfactory supporting documents relating to its management system and equipment (where applicable), an acknowledgement letter is sent to the applicant.
- 4.2.5 A quotation for the document review, preliminary assessment (if requested) and Initial assessment, shall be sent to the applicant for agreement.
- 4.2.6 The composition of the assessment team will also be sent to the applicant for agreement.

4.3 **Preliminary Assessment (Optional)**

- 4.3.1 ABIS may arrange for a preliminary assessment at the request of the applicant. If a preliminary assessment is conducted, ABIS will highlight to the applicant on the nonconformities and observations noted and upon full rectification of the nonconformities and observations may recommend the certification body to proceed with the initial assessment.
- 4.3.2 A new quotation for another preliminary assessment will be sent to the applicant if ABIS considers that the corrective actions taken are not satisfactory.

4.4 Initial Assessment

- 4.4.1 The Initial assessment comprises two mandatory components:
 - a) Assessment of the applicant's quality system, including a document review
 - b) Assessment of the applicant's auditors Stage 1 and Stage 2 witnessed assessment (unless it is not applicable to the certification system)
- 4.4.2 This is an on-site evaluation (except document review) of the applicant to determine whether it conforms with the accreditation criteria before accreditation is awarded.
- 4.4.3 After a satisfactory evaluation of the document review, a suitable date for the assessment will be arranged between the assessment team and the applicant. A programme for the assessment will also be drawn up and given to the applicant before the assessment is scheduled to begin. The assessment programme will cover all requirements, including internal audit and management review, of the accreditation criteria as listed in Clause 1.4 of this document.
- 4.4.4 In selecting audits for witnessed assessments, a balanced selection, based on the scopes applied will be made covering the scopes to be accredited.
 - a) Stage 1 Witnessed assessments for QMS, EMS, OSHMS, HACCP, FSMS Certification Bodies (for each scheme) A minimum of 1 initial audit will be witnessed for each scheme.
 - b) Stage 2 Witnessed assessments for QMS, EMS, OSHMS Certification Bodies (for each scheme) The audit witnessed at Stage 1 will also be witnessed at Stage 2.
 - i. Application for more than two scopes (2 digits NACE Code or less) to be accredited
 A minimum of two initial audits or re-certification audits and one surveillance. The surveillance has to cover the critical processes.
 - ii. Application for two scopes or less (2 digits NACE Code or less) to be accreditedA minimum of two initial audits or re-certification audits
 - iii. Application for one scope (4 digit NACE Code) to be accreditedA minimum of 1 initial audit or re-certification audits
 - c) Stage 2 Witnessed assessments for HACCP / FSMS Certification Bodies
 A minimum of 1 initial audit / re-certification audit and one surveillance will be witnessed. The surveillance has to cover the critical processes.
 - d) Witnessed assessments for Product Certification Bodies (where applicable)
 A minimum of two initial audits / re-certification audits shall be covered where an applicant applies for two or less scopes to be accredited. A minimum of two initial audits / re-certification

audits and one surveillance shall be covered where an applicant applies for more than two scopes to be accredited. Where applicable, an adequate number of tests will be witnessed.

Note: There may not be a need to assess an applicant's test facilities and the competency of its test personnel if the applicant has been accredited for the same scope under the Accreditation Board For International Standards (ABIS). The same principle will apply to routine surveillance, reassessment and extension of scope.

- 4.4.5 All assessments shall be conducted by assessor(s) appointed by the CCMP Chairman. Appropriate technical experts may be co-opted by the CCMP Chairman to give technical advice to the assessors.
- 4.4.6 The applicant shall make available personnel such as management representative, key technical staff and auditors of the applicant for interview during the assessment.
- 4.4.7 The assessment shall take place at the premises of the applicant and on a representative sample of witnessed assessments as recommended by the assessment team.
- 4.4.8 The applicant shall be informed on the assessment findings which include comments on competence and conformity. During the assessment, nonconformities and observations may be raised. The management representative should ensure that the nonconformities and observations raised are fully understood and acknowledged.
- 4.4.9 The applicant will be given one month to respond, in writing, to the minor nonconformities and observations from the date of closing meeting. Once the applicant has taken the necessary corrective actions, the assessment team shall review the corrective actions and if it considers necessary, conduct a verification visit to verify the actions taken, and shall submit an assessment report to the CCMP Review Committee within a reasonable time frame. When there are major nonconformities, the time frame shall be extended to three months, and a re-assessment may be conducted.
- 4.4.10 The CCMP Review Committee comprises appropriate members from the CCMP.
- 4.4.11 Appropriate technical experts may be co-opted by the CCMP Review Committee in its evaluation of the assessment reports.

4.5 **Award of Accreditation**

4.5.1 The CCMP grants accreditation to the applicant upon being satisfied that the certification body meets the criteria for accreditation.

- 4.5.2 All decisions of the CCMP on the granting of accreditation, extension, reduction, renewal, or suspension or withdrawal of the same shall, unless expressly provided herein, be final and not called into question by the certification body.
- 4.5.3 A Certificate of Accreditation shall be issued to the accredited certification body together with a Schedule giving the details of its scope of accreditation.
 - A certification body may request for additional certificates and an administrative fee of \$100/-(excluding GST) per additional certificate shall be charged. GST will not be charged for overseas certification bodies. The Certificate of Accreditation is valid for a period of four years with provision for renewal on expiry.
- 4.5.4 The accredited certification body shall pay to ABIS an annual certificate fee and a levy based on the number of accredited certificates issued, and other assessment and administrative fees as determined by ABIS from time to time. 4.5.5 All accredited certification bodies will be listed in a Directory published by ABIS and in the ABIS website.

4.6 Routine Surveillance and Reassessment

4.6.1 ABIS shall conduct surveillance assessments on accredited certification bodies to ensure that standards of practice complying with the criteria are maintained. The first surveillance is usually conducted six months after the award of accreditation and thereafter once annually. For newly established certification bodies, the surveillance is conducted twice a year for the first two years. The approval of the CCMP review committee is not needed for continuation of accreditation.

Note: A newly established certification body is one that has recently been established and has limited records to demonstrate that its quality system meets all requirements of the accreditation criteria.

- 4.6.2 A reassessment which includes a document review and comprises a full assessment shall be conducted prior to the expiry of the Certificate of Accreditation. The Certificate shall be renewed on the condition that the accredited certification body has been found to have maintained the necessary standard of practice during the validity of the Certificate and is capable of maintaining the standard established.
- 4.6.3 The certification body has to inform the Council in writing within one month of the proposed actions on the minor non-conformities and observations, and complete the corrective actions within three months from the date of closing meeting, and the corrective actions have been verified to be satisfactory. A verification visit may be conducted to verify the actions taken. When there are major nonconformities, the certification body has to take corrective actions on the major nonconformities, and inform the Council in writing within one month from the date of closing

- meeting. A re-assessment may be conducted. Upon approval by the CCMP review committee, a revised Certificate will be issued to the certification bodies to reflect the change in the expiry date.
- 4.6.4 The certification bodies may request for an extension or reduction in the scope of accreditation for consideration during the surveillance and reassessment. For extension of scope, the certification bodies shall write formally to ABIS at least one month before the date of During these consideration of scope will be assessed, if needed. Upon approval by the CCMP review committee, a revised Schedule will be issued to the certification bodies to reflect any changes in

4.6.5 Witnessed assessments shall be conducted as part of the routine surveillance and reassessment unless it is not applicable to the certification system. At least one Stage 1 initial certification audit will be witnessed for each scheme per cycle. The audit witnessed at Stage 1 will normally be witnessed at Stage 2.

Please refer to Annex 1 on the number of witnessed assessments required.

4.6.6 If the certification body's certified client does not allow ABIS to witness the audit, the certification of the client may be withdrawn. ABIS will also inform all its accredited certification bodies of the withdrawal. If the client chooses to seek certification from another certification body, ABIS will inform the new certification body that it wishes to witness the audit. This would only be applicable for ABIS accredited certification that is mandatory.

4.7 **Non-routine Assessment**

the scope of accreditation.

- 4.7.1 Non-routine assessments will include visits made to consider requests for extension in the scope of accreditation, or to investigate complaints made against the accredited certification bodies on areas within the scope of accreditation, if these could not be conducted during the surveillance visits.
- 4.7.2 Unannounced assessments are conducted for special reasons such as to investigate a complaint against a certification body. ABIS reserves the right to conduct unannounced visits when the need arises.
- 4.7.3 ABIS may conduct non-routine assessment for reinstatement of accreditation for a certification body whose accreditation has been suspended or inoperative due to various reasons such as change of premises.

4.8 Suspension and Withdrawal of Accreditation

- 4.8.1 A suspension or withdrawal may be made against an accredited certification body for any or all scopes included in the scope of accreditation for such period as the CCMP may determine if it is satisfied that the certification body has:
 - a) Not maintained a standard of practice complying with the accreditation criteria;
 - b) Violated the terms and conditions for the accreditation stipulated in ABIS 01;
 - c) Failed to provide reasonable facilities for the assessors to discharge their duties;
 - d) Failed to rectify the nonconformities within the agreed time frame;
 - e) Failed to submit the corrective actions within the agreed time frame without valid reason; or
 - f) Failed to pay all necessary fees levied by ABIS from time to time.
- 4.8.2 Where any failure to comply with any criteria of accreditation is, in the opinion of the CCMP, of a temporary nature and rectification will not be immediate, ABIS may retain accreditation on a suspended basis for any or all of its accredited scopes.
- 4.8.3 ABIS shall withdraw the accreditation when departures from the accreditation criteria, which lead to suspension of accreditation, are not rectified within the stipulated time frame which is normally one year.
- 4.8.4 ABIS shall inform the accredited certification body in writing of the suspension or withdrawal and the reasons for the suspension or withdrawal. The certification body shall have the right to appeal to the ABIS Council.
- 4.8.5 No accreditation shall be suspended or withdrawn unless ABIS has:
 - a) Served at least two weeks' written notice to the accredited certification body, stating the grounds for the suspension or withdrawal; and
 - b) Considered any written appeal from the accredited certification body received during these two weeks.
- 4.8.6 During the two weeks' notice, the status of accreditation of the certification body is considered to be in temporary suspension and no accredited certificate shall be issued.
- 4.8.7 If a written appeal has been received, the ABIS Council shall convene an Appeal Committee chaired by a ABIS Council member and comprising of members not involved in the evaluation of the certification body to consider the explanations given, and if the accredited certification body so wishes, shall provide an opportunity for the accredited certification body to be heard as soon as possible. Where necessary, appropriate technical experts may be co- opted to assist in hearing the appeal.

- 4.8.8 If no appeal has been received by the ABIS Council against the notice of suspension or withdrawal, or if in the opinion of the ABIS Council the explanations submitted are not satisfactory, ABIS shall, on the expiry of the notice, suspend or withdraw the accreditation and inform the certification body in writing. Relevant stakeholders will be informed of the suspension or withdrawal. The suspension or withdrawal will also be uploaded in the ABIS website.
- 4.8.9 Any accredited certification body may voluntarily withdraw its accreditation by giving two weeks written notice to ABIS.
- 4.8.10 A certification body whose accreditation has been voluntarily withdrawn, withdrawn by ABIS or suspended shall not issue ABIS accredited certificates or represent or imply in any way to any party that its accreditation under ABIS is operative.
- 4.8.11 A certification body whose accreditation has been withdrawn shall return the Certificate of Accreditation and all other appropriate documents to ABIS immediately.

4.9 Reinstatement of Accreditation

4.9.1 A certification body whose accreditation has been suspended in part or in full may have its accreditation reinstated subject to a re-assessment. The certification body shall satisfy all the criteria of a formal assessment and the award of accreditation as per clauses 4.4 and 4.5.

4.10 **Re-application**

- 4.10.1 A certification body whose accreditation has been withdrawn by ABIS may re-apply one year after its withdrawal date and shall be considered as a fresh applicant.
- 4.10.2 A certification body that has withdrawn its accreditation may re-apply and shall be considered as a fresh applicant.

4.11 Prohibition of Issue of Certificates to Accreditation Standards

4.11.1 A certification body cannot issue certificates based on accreditation standards such as ISO/IEC 17025. If a certification body provides such certification, ABIS shall initiate its process of suspension of accreditation. Further decisions shall be based on the actions taken by the certification body.

Note: It is accepted that a certification body may have to assess subcontractors to confirm that they meet the certification body's requirements which may include accreditation standards e.g. ISO/IEC 17025.

Documentation issued to subcontractors as a result of a successful assessment should clearly state that this is only for the purpose of the subcontract and is not certification or accreditation in accordance with ISO/IEC 17011.

5. Branch Offices

- 5.1 An accredited certification body shall seek approval from ABIS if it wishes to set up a branch office to conduct certification covered in the scope of accreditation. The certification body shall not issue ABIS accredited certificates unless accreditation has been extended to cover the work performed in the branch office.
- 5.2 If an accredited accreditation body wishes to seek accreditation for its branch office, it shall apply formally to ABIS to request for an extension of the accreditation to the branch office.
- 5.3 ABIS may consider on a case to case basis the accreditation of overseas branch if it meets the following:
 - The HQ overseas and controls the management system and its implementation in the branch office; and
 - The branch offices must operate to the same management system and procedures as the HQ.

6. Safety

- 6.1 Safe working conditions are essential to good certification practice and management. The certification body shall observe all necessary safety precautions to ensure that its certification activities are performed in a safe working environment.
- ABIS will not arrange for on-site assessment if it considers the certification body premises to be unsafe.
- 6.3 It is the certification body's responsibility to comply with relevant health and safety requirements.

Annex 1

WITNESSED ASSESSMENTS

Stage 1 audit

At least one Stage 1 certification audit will be witnessed for each cycle, for each scheme, unless the certification body has not conducted any stage 1 audit during the cycle.

Stage 2 audit

The audit witnessed at Stage 1 will normally be witnessed at Stage 2.

The selection of witnessed assessments, during an accreditation cycle

(1st surveillance to re-certification) shall be based on Table 1.

Table 1 - No of witnessed audits (Stage 2) for each scheme

		No of Certificates Issued				
	1 to 50	51 to 150	151 to 300	301 to 500	More than 500	
	Management System (for Each Scheme)					
No of witnessed audits	1 initial audit /re-certification audit and 1 surveillance	2 initial audits /re-certification audit and 1 surveillance	3 initial audits /re-certification audit and 1 surveillance	3 initial audits /re-certification audit and 1 surveillance	4 initial audits /re-certification on audits	
f wit	Product (for certification systems with factory inspection)					
No oN	1 initial audit /re-certification audit and 1 surveillance	2 initial audits /re-certification audit and 1 surveillance	3 initial audits /re-certification audit and 1 surveillance	3 initial audits /re-certification audit and 1 surveillance	4 initial audits /re-certification audits	

Notes

- a. Witnessing of audits will be conducted on critical scopes, wherever possible
- b. 50% of the initial audits / re-certification audits can be replaced by surveillance which has to cover all critical processes
- c. Two surveillance are considered as 1 initial / re-certification audit
- d. The number of certificates issued is based on the last submission by the certification body for the annual billing of the accreditation fees