International Management Accreditation Board
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General Rules For Accreditation Of Conformity Assessment Bodies

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Area of application

This rule describes the general accreditation procedures. It primarily serves to provide information for applicants about the procedure of accreditation. It contains requirements to conformity assessment bodies and to the accreditation procedure. It applies for all accreditation activities and is binding on all organizations and persons involved in the process of accreditation. Additional general or sectorial requirements can be defined in further subordinate documents.

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1. General information

The International Management Accreditation Board (herein referred as IMAB) has entered into accreditation procedure during year 2001. This document should inform prospective applicants in detail about the general requirements for the accreditation as a conformity assessment body and the process of accreditation by IMAB. The requirements defined by this document apply as general rules for all respective applicants.

2. Requirements for accreditation

Classified as conformity assessment bodies (CAB) are laboratories, certification and inspection bodies, service providers of proficiency testing schemes, reference materials producers as well as validation and verification bodies. In principle, an accreditation is possible if the general requirements of accreditation according to respective normative requirements, are fulfilled. The normative requirements for the particular conformity assessment bodies are set out in …

- DIN EN ISO/IEC 17025 for testing and calibration laboratories
- DIN EN ISO 15189 for medical laboratories
- DIN EN ISO/IEC 17020 for inspection bodies
- DIN EN 45011 for certification bodies for products
- DIN EN ISO/IEC 17021 for certification bodies for management systems
- DIN EN ISO/IEC 17024 for certification bodies for persons
- DIN EN ISO/IEC 17043 for providers of proficiency testing schemes
- DIN EN ISO/IEC 17025 in connection with ISO Guide 34 for reference materials producers
- DIN EN ISO 14065 for validation and verification bodies for greenhouse gases.

Further requirements - particularly requirements of legal regulations and accreditation criteria for individual departments are defined in sectorial rules. They apply in addition.

3. Procedure of the accreditation process

3.1. Application procedure

3.1.1. Request and expert talk

On its website IMAB provides information about the process of accreditation, the requirements of accreditation and the specific requirements for certain scopes of accreditation. If requested by the CAB a free expert talk up to two hours in one of the IMAB offices or a charged expert talk at the CAB can be hold. Content of the expert talk could be for example -

- Information about content, procedure and budget of the accreditation process;
- Clarification of the scope of the intended accreditation;
- Information about specific accreditation criteria for the intended accreditation;
- Rights and obligations of the customer and IMAB after accreditation has been granted.

3.1.2. Application for accreditation

Application forms and all corresponding forms are provided on IMAB website or will be provided to the applicant on request. The application must contain the complete intended scope of accreditation and signed with a legally binding signature by an authorized representative of the CAB. Changes of the application are possible and have to be signed in a legally binding way like the application. Changes of the applied scope during the assessment on-site are only possible after agreement with the office of IMAB. All applications will be registered within IMAB by the central application processing, formally tested and forwarded to the responsible department(s) for a technical review. The case number is determined by the central application processing. If more departments are concerned, a leading department will be determined by IMAB central application processing. The confirmation of the receipt and the completeness of the application will be handled by the leading department. In the confirmatory letter the name of a contact person is given. Normally this contact person is the customer manager for all accreditations of this customer. If an application is made incomplete, is incorrect or unclear, IMAB works towards a correction or supplement of the application.

3.1.3. Submission of necessary documents

After application, the applicant has to submit the documents, which are necessary for preparing the assessment. For every CAB type (testing laboratories, inspection bodies, etc.) the necessary documents are listed, the corresponding forms are available on the website of IMAB and also will be sent by the customer manager on request. The submission of the necessary documents should normally be done electronically. The submitted documents should enable an explicit allocation to the documents listed in the appropriate corresponding form.

3.2. Assessment process

3.2.1. Preparation of the assessment

IMAB checks the submitted documents for completeness and plausibility. The assessment team together determines the assessment extent (including the monitoring of the conformity assessment activities on site as witness audit). IMAB makes use of the available technical expertise of other authorities for the purposes of assessment. Assessments and surveillance are commissioned to be undertaken by the technical expert. The CAB will be informed about the designated assessors and the organizations they belongs to. The CAB can raise a written objection against particular assessors within two weeks after the notification of the assessors, stating a reason. The decision about the consideration of the raised objection will be made by IMAB.

After the assessment team has been finally determined, the assessors will be assigned by IMAB. The relevant documents of the CAB will be sent to the members of the assessment team. The assessors are entitled to demand additional documents from the CAB. The demand of those documents will be notified and finally committed to IMAB. If the document check does not result to an objection the proposed date for the assessment is considered as confirmed. If the document check by the assessment team reveals deviations, which in principle preclude from an accreditation, the CAB will be informed by the customer manager and requested to submit revised documents. An assessment on site only takes place after another document check does not result in any deviations, which preclude from an accreditation.

The current framework and cooperation agreements and the agreed process description for performing the assessment and surveillance activities apply here.

The CAB can request a charged one-day preliminary visit at the applicant by an assessor. Emphasis of the preliminary visit is:

- evaluation of the personnel, equipment-wise and accommodation requirements for the accreditation;
- evaluation of the suitability of the available quality management system; the documentary check;
- the reconciliation of the scope of the accreditation;
- a mutual exchange of information and the clarification of open questions concerning the process of accreditation.

3.2.2. On-site assessment

Before the assessment, an assessment plan will be created for the course of the assessment and will be coordinated with the CAB. The assessment plan should be available for the CAB at least one week before the assessment. For certification and inspection bodies the on-site assessment also involves additional witness audits, beside the assessment of the office location, in which the activity of the CAB will be monitored at one or more client in the particular areas applied for accreditation.

The assessment starts with an opening meeting, in which, among other things, the purpose, the applicable criteria and the assessment plan will be explained. In the course of the assessment a review of processes described in the documentation of the CAB in their practical implementation and a rating with regard to the accreditation criteria.

The aim of the assessment is the determination of the competence of the CAB to carry out the applied conformity assessment activities and the conformity with all requirements laid down in the accreditation rules. The accreditation team shall be granted access to all premises, records and documents relevant to the accreditation, including personnel records, unless legislation states otherwise. The assessors are committed to the confidential use of all data they got access to while performing their task for IMAB. The accreditation team shall be provided all aid and support necessary for their task, as long as it is required for the assessment. The assessment of the CAB takes place at their office and the places where testing, inspection and/or certification work is carried out. The CAB has to ensure that on-site assessments by the assessors of IMAB at clients and, where necessary, sub-contractors (e.g. laboratories) can be carried out. The assessment ends with a final meeting of the assessment team with the representatives of the CAB. In this meeting the assessment team presents the assessment results, documents the detected deviation and informs about the further steps to be taken in the proceeding. As far as possible the required corrective actions will be defined on-site by the CAB and documented in the non-conformity reports. The fundamental suitability of the defined measures will be confirmed by the signature of the particular assessor in the non-conformity report. If necessary the CAB will be given the necessary time for a root cause analysis and the setting of appropriate corrective actions, for which a period of two weeks is considered appropriate. The deadlines for fulfilling the corrective actions should be defined in the particular deviation report. After the first accreditation the deviations should be eliminated within a maximum period of four months. For re-accreditations, surveillance and extensions there is a deadline of two months, as far no other period was set by the assessor. A shortening of the period shall be justified in the individual case. An extension of the period requires the approval of IMAB. In individual cases non critical non-conformities can be converted into conditions. Follow up-assessment on-site can be determined due to the assessment results. All proofs of elimination of non-conformities have to be submitted to IMAB afterwards.

3.2.3. After the on-site assessment

The assessment reports will be sent immediately to the CAB after receipt and examination at IMAB office. The CAB will be given the opportunity to comment on the reports after receiving them. A period of two weeks is considered appropriate.

The CAB sends the proofs of performed corrective actions to the particular assessors. The assessors confirm by signature on the deviation report the implementation of corrective actions that meet the given requirements. The assessors can demand improvements on the submitted corrective actions to the CAB. Costs for the necessary increased assessment expenditure will be charged to the CAB's account. The increased assessment expenditure has to be explained to IMAB by the assessor. If the given period of time for implementation of the corrective actions cannot be adhered or the documentation of the CAB is so much defective that the corrective actions cannot be approved by the assessors a follow up assessment can be required. Non critical non-conformities can lead to scheduled conditions.

3.3. Accreditation process

3.3.1. Decision on accreditation

The accreditation committee is an organ of IMAB and consists of all members that can be involved in decisions about an accreditation. Members of the accreditation committee are persons with technical expertise, which are appointed for this purpose by IMAB management. It is determined for each member for which departments it can be included in the accreditation decisions. IMAB ensures confidential handling with information about the specific accreditation process by the members. The objectivity, impartiality and independence of the accreditation decision are guaranteed. For each department, which is concerned in a specific accreditation process, an accreditation committee of the above mentioned members will be formed. Based on the recommendations of the assessment team the accreditation committee decides in internal relationship on the accreditation for this department.

A precondition for forming an accreditation committee is that all corrective actions on the part of the CAB have to be carried out, conditions for all non critical non-conformities have been suggested and the documentation of the process, including the recommendation on accreditation of the assessment team, is completely available. Normally a period of 4 weeks is intended for the decision making process in the AkA.

3.3.2. Notification of accreditation, accreditation certificate and annex to the certificate

The accreditation is granted in form of a notification according to the specifications. The accreditation is usually granted for 3 years or 5 years depending upon commercial contracts. With a positive notification the applicant receives an accreditation certificate including the annex, from which the accreditation scope is apparent in detail. If applied for, the authorization to use the accreditation symbol is included in the notification of accreditation. Conditions that might be connected with the positive decision are specified in the notification of accreditation. With granting of accreditation the CAB will be listed in the database of accredited bodies on the website of IMAB. This list is maintained by IMAB and shows the current scope of CABs accredited by IMAB. If the accreditation is not or only partially granted, the CAB receives a notification with an explanatory statement. Objections within the meaning of article 7.10 of DIN EN ISO/IEC 17011 against (partially) negative notifications of accreditation will be treated accordingly.

3.4. Surveillance procedure

For the maintenance of the accreditation regular surveillance measures should be performed during the accreditation period. The defined surveillance intervals are oriented on the requirements of DIN EN ISO/IEC 17011. Monitoring measures can be among others:

- On-site assessments at the CAB;
- Documentary checks;
- Witness audits and witness tests.

For on-site assessments the following intervals apply:

The first surveillance take place not later than 12 month after accreditation has been granted. All further surveillance assessments for laboratories, inspection bodies, providers of proficiency testing schemes and reference materials producers generally take place in an interval of 18 month. For certification bodies, validation and verification bodies all further surveillance assessments generally take place in an interval of 12 months. In addition the following principles apply:

- In the sum of surveillances between two reassessments (e.g. between the assessment for the initial accreditation and reassessment) the entire scope of accreditation including the Quality Management system have to be assessed on-site;
- For an accreditation of a CAB with several locations the sum of surveillances between two reassessments the entire scope of accreditation including the Quality Management System have to be assessed on-site on every location;
- Additional specifications of the standard-setting bodies (e.g. for product certification bodies) about scope and frequency of monitoring activities are considered, when they deviate from the above mentioned monitoring activities;

- In justified cases the monitoring intervals can be shortened. This can happen due to a recommendation of an assessor, an Accreditation Committee decision or a decision by IMAB;
- Need specific surveillances are possible only if justified in exceptional cases in correct manner.

The preparation, realization and post processing of surveillance activities will be carried out according to the procedure described in 3.2. After completion of the procedure the CAB receives a confirmation of the maintenance of accreditation from the customer manager, unless the surveillance activities lead to a restriction of the scope of accreditation. In those cases an AkA will be formed. By completion of the procedure the CAB will be informed about the date of the next regular assessment.

3.5. Extension and re-accreditation

3.5.1. Extension of accreditation

An extension occurs only upon request. Extensions can be occurred in line with a regular surveillance assessment or at a different time. An application for an extension in line with a regular surveillance assessment should be available for IMAB at least eight weeks before the scheduled assessment. In justified exceptional cases extensions and changes of the scope can be requested during the assessment when the assessor is, with regard to his expertise, in a position to realize such an extension and IMAB confirms this. In justified exceptional cases a decision on the basis of a document check is possible.

3.5.2. Re-accreditation

In due time before the expiry of an accreditation, the CAB will be informed about this circumstance and the possibility of a re-accreditation will be offered. The maximum permitted time interval of 60 months between two reassessments must be maintained. The re-accreditation requires a renewed application of the CAB. The procedure of re-accreditation complies with the process described in 3.1 to 3.3.

4. Revocation and repealing accreditation and suspending, withdrawing or reducing

Suspending : Process of temporarily making accreditation invalid, in full or for part of the scope of accreditation
Withdrawing : Process of cancelling accreditation in full
Reducing : Process of cancelling accreditation for part of the scope of accreditation

In administrative law the facts of withdrawing or reducing of an accreditation granted by IMAB are implemented through a (partial) revocation or a repealing (in the case of illegality) of the notification of accreditation. In this section the revocation of a notification of accreditation is synonymously used as the withdrawing or reducing of accreditation. The suspending of accreditation occurs as a provisional measure not as a revocation, but as a measure of its own kind by notification. For IMAB accreditations, the terms of DIN EN ISO/IEC 17011 apply.

The revocation of a notification of accreditation can be effected completely or partially by request of the CAB, due to the results of surveillance or other circumstances. Reasons for a revocation of notification of accreditation by IMAB can be:

- Loss of significant requirements of accreditation (e. g. personnel, accommodation, equipment);
- Repeated or serious breach of the rules of accreditation;
- Willful deceit of the accreditation body by submission of false or incomplete information, which are important for the assessment of the CAB;
- Non-conformance with granted conditions even after an extension of time limit.

Revocation of a notification of accreditation occurred after a decision of the Accreditation Committee. In case that a CAB applies itself for suspending, withdrawing or reducing a decision of the Accreditation Committee is not necessary. The entry in the database of accredited CABs will be adjusted or deleted. Issued certificates including annex have to be sent back on demand. Authorities that granted a permission, designation or notification due to an accreditation will be informed about the revocation, suspending or withdrawing. The accreditation expires through expiry of the accreditation period, a waiver declaration or when the activity covered by the accreditation is definitely discontinued. Determining and abdication have to be notified immediately. The reinstatement of accreditation only occurs after decision of the Accreditation Committee and requires an on-site-assessment as a rule. The repealing of an accreditation can occur, when it subsequently becomes aware that the requirements of Section 2 were not fulfilled at the time of accreditation and thus the accreditation is illegitimate. Objections within the meaning of Section 7.10 of DIN EN ISO/IEC 17011 against notifications of revocation, withdrawing or suspending are treated as objections in the meaning.