

# **ACCREDITATION UNIT**

### **Purpose**

This policy describes the timeline and general rules for accredited conformity assessment bodies (CABs) applying for re-assessment visits.

#### **Authorship**

This publication has been written by JAS-AU staff, and approved by the Accreditation Director.

#### Official language

The text may be translated into other languages as required.

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#### **Further information**

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# 1. Timeline of reassessment process.

| Activity  | Time Frame  | Comment  |  |
|---|---|--|--|
| Submission of application and all necessary documents by the CAB  | Before (12) months from the expiry of accreditation certificate   | Refer to general rules below   |  |
| Application review and resource review by JAS-AU  | Within (1) month from<br>submission of application and<br>all necessary documents   | A new agreement shall be signed between JAS-AU and the accredited CAB; provided that the CAB paid all accreditation fees |  |
|   | Within (1) month after signing the agreement  |  |  |
| Document review by the assessment team  | In case of new/changed certification schemes applied by product certification bodies, evaluation of the scheme shall be performed within (3) weeks before the document review.  | Refer to general rules below   |  |
| In case of nonconformities raised during the document review/scheme evaluation, CAB suggests the appropriate corrective actions using form qf071-24.        | Within one week from receiving the documentation assessment report/scheme evaluation results  | -  |  |
| The designated assessment team assesses the proposed corrective actions submitted by the CAB  | Within one week from receiving<br>them, and shall inform the CAB<br>in writing if any proposed action<br>is inappropriate.  | -  |  |
| CAB rectifies the nonconformities found during the document review/scheme evaluation  | Within (1) month from notifying the CAB of the results of the review  If scheme evaluation is performed, nonconformities resulted from evaluation shall be rectified within (2) months from notifying the CAB of the results of the evaluation. | -  |  |
| Completion of the evaluation of<br>the corrective actions report<br>regarding the document<br>review/scheme evaluation by<br>the designated assessment team | Max. (2) weeks after closing up all non-conformities (by the CAB) detected during the document review/scheme evaluation   | -  |  |

| Submission of new and appropriate corrective actions by the CAB if all non-conformities (raised during the document review) were not closed within the allowed time frame | Within (1) month after receiving the evaluation of corrective actions form regarding the document review nonconformities.   | -   |
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| Planning and conducting the assessment  | Within (6) weeks from accepting the CAB documentation, or before (6) months from the expiry of accreditation certificate  | -   |
| In case of nonconformities raised during the assessment, CAB suggests the appropriate corrective actions using form qf071-24.   | Within one week from the assessment date  | -   |
| The designated assessment team assesses the proposed corrective actions submitted by the CAB  | Within one week from receiving them, and shall inform the CAB in writing if any proposed action is inappropriate.   | -   |
| CAB rectifies the nonconformities found during the assessment   | Within (3) months after conducting the assessment   | -   |
| Completion of the evaluation of<br>the corrective actions report<br>regarding the assessment by the<br>designated assessment team   | Max. (2) weeks after closing up all non-conformities (by the CAB) detected during the assessment  | -   |
| Submission of new and appropriate corrective actions by the CAB if all non-conformities (raised during the assessment) were not closed within the allowed time frame      | Within (1) months after receiving the evaluation of corrective actions form regarding the assessment nonconformities.   | -   |
| Decision on accreditation of the CAB by the accreditation committee   | Within (1) month after sending the documents to the accreditation committee. A justification shall be provided in case the decision is not taken within (1) month | The accreditation decision will be for renewing and extending accreditation in case the CAB applied for both reaccreditation and expansion. |

# 2. General Rules

• The CAB applying for reaccreditation shall submit at least the following:

- a. Application form (qf071-02) identifying scope expansion if applied. The CAB can remove/revise part of accredited scope during the application stage for the next cycle.
- b. Relevant annex for the scope of accreditation (qf071-32). according to JAS-AU's policy JAS-P07 "Documenting and describing the standards of testing and or calibration methods", JAS-G08 "Guidelines for the formulation of the scopes for medical testing laboratories" and ILAC G28: Guideline for the Formulation of Scopes of Accreditation for Inspection Bodies. Certification activities performed and/or managed in multiple countries shall be defined by the CAB according to IAF MD 12.
- c. Questionnaire (qf071-01)
- d. Checklist against the accreditation criteria to which a CAB is applying for, checklist against ISO/IEC 17065 (qf071-21) for product certification bodies, checklist against ISO/IEC17025 for testing and calibration labs Qf071-87, Checklist against ISO/IEC17020 for inspection bodies qf071-93, checklist against ISO 15189 for medical labs (qf071-116), checklist against ISO/IEC 17021-1 for management system certification bodies qf071, checklist against ISO/IEC 17043 for proficiency testing providers qf071-120.
- e. Checklist for evaluation of scheme (qf071-113) for product certification bodies, in case of new or changed scheme
- f. All management system documents in case of transition to a new version of accreditation standard or any revised documents of the management system from the last assessment visit. Copies of the conformity assessment scheme/program/methods, if new or revised.
- g. Proficiency testing and/or interlaboratory comparison records, whenever applicable
- h. Copies of reports/certificates (for each conformity assessment area, if needed)
- Documentation assessment shall be performed by the assessment team in following cases:
  - A Full review shall be done in case of transition to new version of accreditation standard.
  - Partial review is done in case of:
    - a. addition of non-accredited conformity assessment activities (whenever required)
    - b. any major changes in CAB management system documented information, where an email shall be sent to the CAB to provide the assessment team with any revised documents of the management system

- Reassessment includes examination of the whole scope as the initial assessment.
- If the decision on accreditation renewal of the CAB is taken before the expiry date of accreditation certificate, the CAB is consulted regarding the accreditation cycle whether to begin from the date after the certificate end date or the decision date.
- If the decision on the accreditation renewal is not made before the expiry date, a formal letter is issued to the relevant conformity assessment body informing it about the expiry of certificate, the requirements of JAS-AU symbol instructions and the agreement on the use combined JAS-AU symbol and ILAC MRA/IAF MLA mark, if signed with it, regarding the expiry of certificate. The relevant conformity assessment body is requested to provide JAS-AU with evidence on informing affected clients of the expiry of certificate and associated consequences within (10) days of the certificate expiry date. Both the accreditation certificate and scope shall show the expiry status as a watermark on each page. The accreditation directory on JAS-AU website is updated accordingly. A new accreditation certificate and scope is issued on the renewal decision; the cycle starts from the renewal decision date and the expiry period will be stated in the accreditation history on the certificate.
- Failure to comply with the decision will lead to sanctions such as not accepting the application for reaccreditation/terminate the reaccreditation process until the required information is provided.
- JAS-AU will not be held responsible in case the CAB does not abide to the time frames set within this policy and the accreditation certificate expires before the renewal decision is taken.
- In case the conformity assessment body operates in multiple countries, IAF MD 12 shall be applied.