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Position: Quality Manager	**Position: Director General**
Signature:	**Signature:**

Contents

1. Purpose

The purpose of this document is to describe the full process of accreditation that is applicable to all Conformity Assessment bodies (CABs).

2. Scope

This process document outlines:

- The process and assessment techniques used in the accreditation of testing/calibration and medical laboratories in accordance with ISO/IEC 17025 and ISO 15189
- As a generic process for the accreditation to inspection and certification

3. References

The following documents are referenced:
ISO/IEC 17000, Conformity Assessment – Vocabulary and general principles
ISO/IEC 17011:2017 Conformity Assessment – Requirements for accreditation bodies accrediting conformity assessment bodies;
ILAC and IAF mandatory documents and guidance as applicable
Regulation No. 421/2017
ILAC G26: Guidance for the implementation of a medical laboratory
ILAC P9, ILAC P10, ILAC P14 ILAC P15
Re07.0, “Accreditation Criteria for Conformity Assessment Bodies”.

4. Responsibility and Requirements for Accreditation

It is the responsibility of the director general of EAS and the accreditation director/team leader or responsible persons to implement this document.
The list of all relevant criteria required by CABs to be accredited is provided in EAS Document Re07.0, “Accreditation Criteria for Conformity Assessment Bodies”.

5. Application for Accreditation and Documentation

CABs that believe they comply with all the requirements for accreditation (Re07.0) complete the relevant Accreditation Application Form (F07/01A, B, and C, D) and return it to the EAS office together with the required documentation as detailed in the application form.
To ensure that the application requirements have been fulfilled, accreditation Director or the accreditation team leader or assigned technical personnel will review the application and associated information and documentation for completeness as per F07/18 and will communicate

with the CAB by Acknowledgment Letter. If the submitted documents are not complete the accreditation director /team leader or responsible person will interact with the CAB until they are completed. If there is evidence of fraud or if the CAB provides intentionally false or concealed information at any point, the application or initial assessment shall be rejected or terminated.

6. Resource Review and Quotation

6.1. Resource Review:

The accreditation Director or accreditation team leader will initiate a resource review for allocation of assessment personnel and the required assessment man-days. He or a technical person assigned by him will perform the review by using EAS 's checklist for a resource review (F07/18).
The application shall be accepted once EAS has checked whether the required competencies of assessors or experts to match the requested scope of accreditation in time are available according to **EAS 's list of registered assessors and experts**
The Accreditation director or accreditation team leader will select the assessment team leader, technical assessors and technical experts, if required. The names and organisations of the team members shall be communicated to the applicant CAB to ensure competence, impartiality and no conflict of interest among the CAB and the team members. The CAB shall confirm in writing to EAS the acceptance of the team members, eventually observers or trainees. If the CAB objects to one or more team members it shall inform the accreditation team leader or responsible person in writing together with a justification. If the accreditation team leader or responsible person accepts the reason for rejection, other personnel will be nominated.
If the assessment is accepted or cannot be conducted timely because of unforeseen reasons it shall be communicated to the CAB and a new fitting date will be agreed.
The CAB signs an accreditation agreement with EAS which stipulates legally binding rights and obligations of each party by using form F04/02
Note: Assessor/ technical expert shall not be assigned to the team if related or coming from an organisation from which he/she has resigned and /or has been involved in any activities that may lead to conflict of interest until two years have passed.

6.2. Quotation:

The finance directorate shall affirm the accreditation director/ team leader or responsible person that the CAB has paid before assessment is conducted (F07/26) However, because of government purchasing procedure, governmental CABs can pay accreditation service fee once they receive the accreditation service. Based on this information, the financial directorate shall

issue a quotation for each step of the accreditation process, based on the accreditation fee structure Reg No. 276/2020. Acceptance of the quotation has to be send to EAS by an authorised person of the CAB.

The accreditation director or team leader or responsible person will calculate the man-days based on the number of methods to be assessed, the nature of working methods, number of persons to be witnessed, number of testing or inspection parameters, complexity of the organization, number of branches and other visible conditions, he/she request for the payment to assessors/experts to the finance directorate (F07/16).

7. Review of Documented Information

The accreditation Director of respective department or accreditation desk shall assign the selected assessment team leader and/or technical assessors, when required, to review the CAB's documentation to assess the level of compliance to the relevant accreditation requirement. Team Leader covers the whole system part and Technical assessors review technical part of the requirement using Forms (F07/06 A, B, C, D, E, F, G).Technical Assessor send the completed checklist to Team leader, and then The Team leader compile document review report . The summary of the review will be reported (refer *Document Review Report* F07/15 A, B, C, D, E, F) to the CAB. It will also be indicated whether the CAB can undergo an on-site assessment, a pre-assessment is recommended or that it needs to address non-conformities before further processing.

Note: The assessment team leader may recommend in justified cases that the on-site assessment can start though not all non-conformities found have been closed. This recommendation is to be approved by the accreditation director/team leader or responsible person and to be reported by him in writing to the CAB.

The accreditation cycle begins with the date of the decision by the Director General and last for a maximum of five years (F07/03A to F) shall develop to be followed during onsite assessment. Shorter periods are possible if valid reasons exist (risk based).

8. Preparation for Assessment

8.1 Contractual Agreement with Assessors

On completion of the resource review, the accreditation Director or accreditation team leader or responsible person will request each assessment team member to complete form F07/02, Contractual Activity Agreement, which requires each member to declare his impartiality and freedom of any form of vested interest or conflict of interest.

8.2 Preliminary Visit

A preliminary visit shall be done for CABs

- Which seems to have immature quality management system in document review
- Which has complex premises

To gather information for

- assessment plan
- deciding assessment days

A preliminary onsite visit may be done by EAS's accreditation team leader or assigned responsible person. A preliminary visit should normally not last longer than one day. The costs will be borne by EAS. In case EAS conducts a preliminary visit before the initial assessment, it shall be conducted with the agreement of the conformity assessment body and EAS shall exercise due care to avoid consultancy. EAS shall make the Assessors or any personnel that involved in such activities to sign F07/02 "Contractual activity agreement form" to avoid consultancy during such activities.

8.3 Pre-Assessment

On request of the CAB the assessment team leader, possibly assisted by a technical assessor can do a pre-assessment to gather information about the readiness of the CAB for onsite assessment i.e.:

- Implementation of the quality system.
- existence of adequate records of internal audits and management reviews
- Calibration status of equipment
- Check of number of report/results. At the on-site assessment, at least 10 test reports/results for a medical laboratory, 5 test reports/results for a testing and/or calibration laboratory, 1 inspection report for inspection bodies and 1 certificate for certification bodies (1 product certificate for product certification, 1 system certificate for system certification and 1 personal certificate for personal certification), initial assessment shall be presented.

Note:

- Results can be accepted instead of reports if for acceptable reasons no report form exists

- In case where there is acceptable evidence, the number of reports can be decreased in accordance with the assessment team leader. Reasons for reduction of number of reports can be:
    - high effectiveness of the system;
    - satisfying clearance of findings found during internal audit

The extent and length of the pre-assessment is dependent on the size and complexity of the CAB. It shall normally not exceed more than two days and not more than two assessors. EAS shall make the Assessors or any personnel that involved in such activities to sign F07/02 “Contractual activity agreement form” to avoid consultancy during such activities.

The quotation for the visit will have been included in the formal quotation of the financial department issued to the CAB. A pre-assessment is mandatory if the time between submission of findings as a result of document review by EAS and notification of their clearance has taken more than 6 months.

A list of findings (F07/05) will be provided to the CAB. Such findings are not classified as Major or Minor Non-Conformances or as Observations. The CAB should address all of these findings before the Initial assessment but EAS does not require submission of evidence of clearance before the initial assessment. The pre-assessment team will avoid any form of consultancy.

8.4 Assessment Planning and Sampling

The accreditation Director or accreditation team leader or responsible person or another person assigned by him/her shall plan the initial assessment in order to cover appropriate scope according to sampling procedure P07/03. This includes:

- ❖ Assessment of the quality management system and its use by the staff, using the horizontal check list
- ❖ Assessment of the main premises and side branches if applicable
- ❖ Proof of competence for personnel by assessing the personal records (assessing objective evidence for personnel competence) shall be done according to sampling procedure P07/03
- ❖ Accredited scope activities shall be witnessed according to EAS sampling procedure P07/03
- ❖ For signatories in addition to above competency assessment and witnessing, all shall be interviewed for their understanding of relevant CAB and EAS criteria and record shall be maintained (F07/25).

If the assessment of all branch offices or staff or methods or parameters would require an economically unacceptable effort sampling methods as laid down in P07/03 shall be used

The accreditation director/team leader or responsible person will assure that each team member has a job description so that all needed activities are covered and no confusion will arise during assessment.

The accreditation director/team leader or responsible person shall formally communicate in writing to the CAB details of the assessment team including observers/trainees (their names, parent organization, field of competence), the assessment date, the assessment plan (Form F07/20) and the schedule for the opening and closure meeting (see §5.1).

The CAB shall confirm the team members and arrangements in writing. Further, the Accreditation director/accreditation team leader or responsible person shall plan when and by which means the full scope will be covered and all personnel be witnessed on method for which he is assigned by follow-up activities during the accreditation cycle. The timeline rule (R07.0) gives direction for the time of follow up activities. EAS and the CAB must be aware that the time plan and the methods of follow up activities may be modified according to risks identified during assessment, the maturity of the system or requirements by regulators.

If a reassessment is to be performed, experiences about stability and effectiveness of the system, the risks, performance in PTs etc. have to be considered when planning about methods and frequency of follow-up activities (see §10.2).

8.5 Confirmation of assessment plan

The CAB has the right to object to the proposed plan and date with a valid written justification for the objection without violating the time line rule and submit to the accreditation director/ team leader or responsible personnel. The responsible person will decide on the validity of the objection and reschedule the assessment as per to the agreed time. If the CAB disagrees with the decision then the Appeals Process (Clause 12 of this document) can be followed. If there is an objection to any member of the team the procedure as set out in §5.1 will be followed.

9. Initial On-site Assessment

9.1. Logistic Arrangements

A responsible person assigned by the accreditation director/ team leader shall make all logistic arrangements and communicate them to the team and, as appropriate to the CAB.

The assessment team leader shall collect the necessary documents as per F07/19 that require for the assessment and share with assessment team members.

9.2. Pre-assessment Meeting of the Team

The assessment team leader shall communicate with his/her team prior to the assessment and provide all necessary materials to the technical assessors/experts, clarify and assign roles and responsibilities, emphasize any aspects that may need additional vigilance either due to the nature of the scope, identified risks or due to recently established accreditation requirements.

Note: Any person assigned by EAS to monitor assessors/experts is considered as part of the team and has more authority in the team than the one under monitoring.

9.3. Opening Meeting

The assessment team leader shall chair the opening meeting with management and key personnel at which the agenda items (Form F07/04) shall be discussed. Attendance shall be registered (F06/11B).

The purpose of the meeting will be to:

- Explain the assessment process and the techniques that will be used during the assessment;
- Confirm the scope of activities that will be assessed;
- Check the history of the CAB that requests accreditation shall have sufficient service delivery on the particular scope that enables to assess its competency.
- Confirm, if necessary review the assessment plan;
- Ensure whether the CAB has assigned guider for each assessor and logistic arrangements;
- Clarify any issues or concerns that the CAB may raise before the assessment begins.
- Confirm the team members and the CAB's confirmation that there is no conflict of interest
- Confirm confidentiality for all what has been observed and discussed by the assessment team shall be provided only to EAS and the CAB

9.4. Assessment

The assessment shall be conducted in order to obtain objective evidence that:

- The quality system is implemented, effective, audited by competent internal auditors and operated in such a manner that it meets the accreditation criteria (Specific requirements for certification P07/02 and inspection P07/01 are contained).
- At least one internal audit with clearance of the findings and one management review with a back- log history is available and satisfying

- At least 10 test reports for a medical laboratory, 5 test reports or 5 results (if there is no reporting system for a testing/calibration laboratory),1 for inspection and 1 for certification bodies(1 product, 1 system, 1 personel) have been issued, noting that these numbers are to be applied for each scope. The requirements on the number of reports/results can be modified by EAS according to risks identified during document analysis.

Note: Special considerations may be taken in discussion with EAS for areas of testing/calibration in where there is logic and acceptable evidence to reduce the required number of reports.

- Personnel is continuously trained and competent to perform its tasks
- Corrective and preventive action is taken to correct or re-align the system for continuous improvement; and
- The system and documents are reviewed effectively to ensure that they remain dynamic and self-improving.
- Equipment being adequate for purpose i.e. being calibrated and maintained
- measurements are traceable
- a satisfying policy exists and successful participation in proficiency testing is demonstrated
- The effectiveness of verification/validation protocol within the existing raw data
- The CAB shall be assessed while they are in their normal operation hence; the CAB is expected to operate its normal business in parallel to the assessment.

The assessment team leader shall use the relevant checklists/ Forms (F07/06 A,B,C,D,E,F,G) for each scheme while the technical assessor shall use the Vertical Assessment Forms (F07/07 A,B,C,D,E,F,G) and Witness Form (F07/08 A,B,C,D).The details of the assessment shall be recorded in these forms. Non- conformances/observations shall be transferred without omission and redundancy to Non-conformance, Corrective action and Clearance Report (F07/09). All statements stated by the assessors, clearances submitted from the assessed CAB and evidence that has been attached to support the clearance shall depend on objective evidences and verified by the accreditation advisory committee (F07/11) to give a confidence for the Director General to issues the accreditation certificate.

Note 1: Assessors shall not interfere in the normal routine of the CAB and shall request permission to interview and witness at an appropriate time. However If the CAB is not in a position to do so for whatever reason, then the assessment shall be re-scheduled at the full cost to the CAB.

9.5. Assessors Meeting after Assessment

On completion of assessment, the assessors shall meet to collect and summarize their detailed observations and to arrive at a conclusion, based on the Assessment Report form (Form F07/10). The assessment team leader, seeking advice from the technical assessor(s)/experts shall classify the detailed observations as Major or Minor Non-Conformances or Observations in accordance with the following definitions:

- Observations: A comment on an aspect which, if left unaddressed, could be a source of a non-conformance in the future.
- Minor Non-Conformance: A non-conformance which, in isolation, may not necessarily have a direct impact on the CAB's outcome or results.
- Major Non-Conformance: A non-conformance which could have direct impact on the quality of the CAB's outcomes or results or that leads to system failure such as ineffective or unavailable internal audit, corrective actions, management review, complaint handling and handling of nonconforming work.
- The report shall avoid redundancy about findings found by different assessors and come up with conclusions which will be communicated to the CAB during closing meeting.
- The assessment report in addition to non-conformances shall include a summary of technical competence of the CAB together with a judgement about system compliance, suitability and effectiveness.
- The report shall also be detailed enough regarding method, signatories, scope and parameters as to allow the AAC or other persons to verify conclusions drawn

- The assessment team leader, preferably in full consensus with the team (deviating opinions shall be recorded and brought to attention of the AAC), will recommend an accreditation decision to the AAC based on the following:
  - Where no non-conformances were found, the recommendation will be for accreditation of the full scope of activities as requested by the CAB;
  - Where non-conformances were found which can be cleared within the required timeline, as provided in R07.0 "Timeline Rules of EAS " and which do not constitute a system failure within the Quality System, the recommendation will be for accreditation subject to clearance of findings within the timeline. Evidence of clearance can be assessed by submission of documents to EAS or by re-visit, at costs to the CAB, depending on the nature and severity of the non-conformances;
  - Where non-conformances were found which indicate lack of competence, staff or equipment, a system failure or missing implementation of the system, the

recommendation will be that accreditation is denied, reduced, withdrawn or granted upon fulfilment of conditions which do not influence competence at present.

Note: When the assessment team cannot reach a conclusion about the finding the assessment team leader should refer back to the accreditation director/ team leader or responsible person for clarification.

9.6. Closing Meeting:

The assessment team leader shall chair the closing meeting with management and key personnel at which the agenda items (Form F07/04) will be discussed. The purpose of the meeting will be to:

- Acknowledge the cooperation that has been done by the CAB to the assessment team
- repeat the purpose of the assessment; the mode of assessment and the techniques used
- Present the summary report that comprises positive and negative narration of the system
- Explain the significance of major and minor non-conformances and observations
- Provide feedback from each assessor on the areas assessed and the findings raised;
- Provide the conclusion of the assessment with indications of timelines for clearance of non-conformances, where relevant, and submission of evidence of clearance or for the need for re-assessment or re-visit to assess the effectiveness of corrective action;
- Re-confirm the confidentiality about what they have observed and discussed
- Obtain planned actions from the CAB on how they intend to clear the findings(Not Practical) ; and
- Hand over copies of Forms F07/09 and F07/10 to the CAB.
- Explain their right to appeal against the assessment team's recommendation using F07/12 and/or complaints for any dissatisfaction using F07/12A of EAS .
- The assessment team can recommend the reduction of the scope based on assessment outcome

The respective timelines for clearance of non-conformances; the accreditation cycle, re-assessments and granting of accreditation are provided in Timeline Rules of EAS R07.0.

9.7. Accreditation Advisory Committee

9.7.1 Access of Information

EAS shall be responsible for ensuring that all evidence of clearance of non-conformances is received within the required timelines or that a re-visit for assessment of clearances is scheduled (whichever has been stated by the assessment team leader during the Closing meeting). Evidence submitted by mail shall be forwarded to the relevant assessor for sign-off as being effective or not.

The assessment team leader shall submit all assessment documentation to the accreditation Director or accreditation team leader or responsible person in accordance with timeline rule once all findings get cleared by the CAB with all supporting evidences. The accreditation director/team leader or responsible person shall organises all files according to F07/27 and submit to the AAC within a week. The AAC has to submit a recommendation for a Director General within a week.

The CAB File shall remain at EAS as a permanent source of information for client details; planning and scheduling of assessments; records of AAC Decisions and any other related or pertinent information relevant to the status of the CAB.

9.7.2 Objective

The objective of the AAC is to:

- Verify that all requirements and procedures of EAS have been met, i.e.
  - the results of the document review as stated in the Document Review Report
  - the assigned scope of assessment covered by each assessor;
  - which activities or elements of the system were assessed;
  - how were they assessed;
  - what were the observations, comments and findings of each activity or element and the specific details regarding the logic or rationale behind any comment, observation, finding (positive or negative) made by each assessor in his/her notes recorded in the relevant forms.
- Analyse the records of assessment that they are self-explanatory
- verify that the information is complete and consistent as to make a decision on accreditation
- to make recommendations on accreditation decisions
- giving advice to the Director General

9.7.3 Members of the committee

Each AAC shall consist of at least three up to five members:

- The Director General or his deputy will act as Chairperson.
- The other members shall be drawn from EAS's list of assessors/experts. Before being qualified as AAC members they have to be informed about the duties and procedures of the AAC. They shall be registered as potential AAC members. In order to be chosen out of that list, they must be competent in the field for which the CAB seeks accreditation. Assessors/experts who have participated in the assessment of the CAB under consideration shall not be selected to participate in the AAC.

  The AAC may invite the team leaders, assessors or experts for further clarification. The experts need not to be familiar with accreditation or EAS rules but will be asked only for technical opinion or advice without having right in the recommendation or rejection proposal.

9.7.4 Mode of operation

- An AAC is convened on request of the accreditation Director or accreditation team leader or responsible person by the Director General or his deputy within 10 working days according to time line if a decision on accreditation (granting, expanding, reducing, suspending or withdrawing of accreditation) has to be made
- The AAC has an advisory role only. The decision on accreditation or any change of the accreditation status shall be made by Director General.
- According to the decision made, the AAC will check the Accreditation Certificate as proposed by the assigned team leader with all information about competencies, dates etc. as requested in Annex A of this procedure. After obtaining agreement on the contents with the CAB the certificate will be issued in hard copy for the CAB's use and published on the EAS 's website.
- The minutes of the meeting will be logged in the AAC report (Form F07/11) and shall be signed by each member
- Since AAC is an ad-hoc committee, after completing the assigned tasks the committee dissolves automatically.

9.7.5 Decision Pending

Records may be incomplete or needed details may be missing preventing the AAC from making an immediate decision. If clarity cannot be obtained by interview with the invited guests like team

members or experts the AAC may advice to repeat the assessment in full or in part based on the decision of the Director General. A different assessment team will be convened or the previous team will act with at least one additional EAS assessor as observer/s. No additional costs will be imposed to the CAB.

Such a decision taken, the AAC shall advice whether the assessors should be retrained or been removed from the Assessor Register based on the decision of Director General. By considering the frequency of happenings of similar issues, EAS can consider to review its assessor training, Mentoring and monitoring style to re-build the required competency stated in ISO/IEC 17011:2017 Annex A 1.

The accreditation team leader or responsible person prepare the draft accreditation certificate and should be verified by each respective department head using Checklist to Verify Accreditation Certificate F07/28 and then submit the draft certificate and the compiled documents to EAS 's Director General for convening an AAC within 10 working days and the AAC will verify the submitted documents using form F07/11.

When all documents are compiled the accreditation director/ team leader or responsible person will draft an accreditation certificate containing detailed information about competencies of the CAB (see Annex A),

- The name of the accredited conformity assessment body and the name of the legal entity, if different;
- The accredited scheme,
- Issue and expiry date
- Signature with official stamp and attached accreditation scope

The scope of accreditation contains at least the following:

- Accreditation number
- CAB's address
- List of signatory
- The date of coming into effect (date of decision by AAC),
- Issue and expiry date,
- Issue number
- Field of Testing, Sample, Test Method and tested parameters

Note: if flexible scopes have been assessed their definition as submitted for assessment will be listed within the list of accredited standards/methods.

Outcome of the decision shall be communicated to the CAB by the accreditation director/team leader or responsible person.

Before issuing the official certificate the draft shall be sent to the CAB to verify the correctness of the contents then certificate shall be handled to the accredited CAB with orientation in using accreditation symbol.

The accredited CAB certificate with all the detail accredited scope shall be communicated to the public via EAS 's website.

The CAB will present to EAS its templates with the intended use of EAS 's symbol for approval by the accreditation director/ team leader or responsible person.

In case of denial of accreditation the CAB has the right to appeal; EAS will then formulate appeal investigation team as per appeal procedure. If the CAB is interested to reapply for accreditation, EANO shall convene a new assessment team with a new assessment team leader and new assessors/experts.

10 Accreditation Cycle

10.1 Assessment programme

Table1. EAS assessment programme for Laboratories, Inspection, Calibration and Certification Bodies are as follows:

Timeline (Months)	**Cumulative Time for labs (Months)**	**Activity**	**Comment**
0	0	Accreditation	From date of AAC approval
6	6	follow-up visit	Full scope of accreditation to be covered during the four follow-up activities
12	18	follow-up visit	
12	30	follow-up visit	
12	42	follow-up visit	
12	54	Reassessment, if application for continuation is submitted	Full assessment for next cycle Note: for the continuity of the accreditation, re-assessment application shall be submitted at least 6 months ahead of the end of the accreditation cycle.

Table 2 . EAS assessment programme for new expansion schemes are as follows

Timeline (Months)	Cumulative Time for IBs and CBs (Months)	Activity	Comment
0	0	Accreditation	From date of AAC approval
12	24	follow-up visit	Full scope of accreditation to be covered during the 2 follow-up activities
12	30	Reassessment, if application for continuation is submitted	Full assessment for next cycle Note: for the continuity of the accreditation, re-assessment application shall be submitted at least 6 months ahead of the end of the accreditation cycle.

The tables above are indicative, in all cases the type (on-site visit, document review, PT-performance etc) and the intervals of follow -up activities shall be risk oriented or comply with regulatory demands. When the outcome of the assessment indicated to build trust on the competency of the CAB the team leader may recommend for the elongation by 6 months to be decided by Director General and then modified the programme by responsible person.

10.2 Follow - Up Activities

A part of the team that performed the initial assessment should be allocated for the performance of the follow up activities. In case of unavailability of a team member, a replacement of assessor/expert from the assessor pool can be assigned. EAS take into account when the CAB requests scope extensions. EAS also revise the assessment programme and planning of the assessment while scope extension application received.

Applicable methods for follow-up activities are:

- On-site visits
- Request for and check of documents
- Control of PT results
- Dropping of one-off samples for test/calibration
- Reaction on complaints i.e. by unplanned on-site visit

- Check the previous assessment documents such as previous NC's and corrective actions and its effectiveness
- Remote Assessment(Virtual)
- Off- site Assessment i.e. when it may not be possible or feasible to conduct on-site assessments due to emergency situation like Epidemic, Earth quick, Emergency travel restriction, reasons for affecting safety etc

  The CAB shall completed off site checklist F07/30 and send relevant documents to EAS via electronics or postal method, If there is change from last assessment the CAB should be inform to EAS within 15 days.

Unscheduled assessments shall be performed when there is suspicion of non-compliance i.e. due to a third-party complaint requiring resolution by on-site evaluation. The cost of unscheduled assessment shall be borne by EAS if the complaint has been unjustified.

The team size for follow up activities shall be appropriate for the scope to be assessed. However, the team should have at least a team leader and a technical Assessor. If the CAB has only 3 staff or less, the technical assessor can be left out if the team leader is technically competent or a technical assessor alone will undertake also the obligations of a team leader.

The documentation with the findings of the follow up activity shall be submitted to the Director General for decision whether accreditation can be continued. The AAC may be involved when Director General needs advice. EAS accreditation director/team leader or responsible person shall notify CABs in writing of the decision for continuation of accreditation.

10.3 Renewal of Accreditation

Accredited CABs must apply for renewal of their accreditation at least six months in advance to expiry date and EAS shall schedule timely the reassessment in communication with the CAB. The accreditation director/ team leader or responsible person shall initiate a new resource review as per Clause 5.1 of this process and will compose an assessment team. Preferably, new team members should be selected for each reassessment. This especially applies to the assessment team leader.

The process of assessment and approval will be the same as for initial application as per § 7, 8 and 9 of this document.

Based on a positive decision from the AAC, EAS would continue its follow -up activities within the new accreditation cycle from the date of that decision. The frequency and methods of these activities will be based on the experiences gained with this CAB and the identified risks but within the limits as given by ISO/IEC 17011 or regulatory requirements. If the CAB didn't reapply and

completed within the last 6 months before certificate expiry date, the CAB withdraws immediately after the expiry date even the CAB is on process to reapply and on document review by assessors of EAS. EAS immediately download the certificate of CABs from its website.

10.4 Extension of Scope

An accredited CAB may apply at any time for extension of its scope by filling in the relevant Accreditation Application Form (F07/01 A, B, C, D).

If the CAB requests the extension scope to be assessed in conjunction with the next EAS assessment visit, it should apply at least 3 months prior to the scheduled visit. The application can be submitted also in a shorter time if resources at EAS are available.

The rules and procedures for assessment and the accreditation decision are the same as for an initial assessment.

Note: The time for clearance of non- conformities within the scope extension and identified during a follow-up activity is only two months. If the assessment for scope extension is done independently of a follow-up activity the time for clearance may be extended to three months based on acceptable reasons.

Where accreditation is granted for the extended/reduced scope, a revised Accreditation certificate with extended scope of accreditation is issued to the CAB and published on the website.

The effective date of the modified scope is stated in the certificate. The date of expiry of the revised certificate shall be the same as the original certificate.

The previous assessment Program of follow up activities shall be revised to include the extension scope.

11 Reducing, Suspending and Withdrawing Accreditation

11.1 Voluntary reduction/suspension: A CAB may apply for reduction/suspension to EAS in writing with valid reasons. If the reasons are accepted by the accreditation Director or accreditation team leader, EAS will reduce/suspend according to the application within three working days and will inform the CAB in writing. If the scope is reduced it cannot be re-instated but can reapply.

CABs in voluntary suspension may apply in writing to EAS for permission for a continuation of the voluntary suspension, but not longer than 6 months in total. Exceeding this duration will result in withdrawal of accreditation. For reinstatement within this 6 months period the CAB shall demonstrate i.e. by an assessment or document submission that the reasons for suspension have been removed.

Enforced reduction or suspension: The accreditation team leader or responsible person shall inform the CAB in writing that they will be suspended or parts of the scope will be reduced and shall detail the reasons for suspension/ reduction. The letter shall inform about the maximum length of the suspension (6 months without possibility of extension of the period) and about fees that are payable during such a period of suspension in writing. If the scope is reduced it cannot be re-instated.

12 Withdrawal of Accreditation

12.1 Accreditation may be withdrawn on application of an accredited CAB on whatever reason. In this case the CAB shall inform its customers and notify EAS about this in writing within 30 days.

12.2 Withdrawal of accreditation by EAS shall be authorized by Director General when withdrawal issue comes from the accreditation team leader or responsible person. The Director General may convene by the AAC for consultation when required.

12.3 Reasons for withdrawal of accreditation are the same as for suspension but they cannot be rectified in the time line as given in EAS 's rules. EAS shall communicate before withdrawal with the CAB as to find a better solution than withdrawal Reasons for Reduction, Suspension or Withdrawal of Accreditation

The following reasons are applicable:

- Due to non-compliance with requirements
- Decision of Director General based on recommendation of the assessment team
- Because of a complaint, but first the complaint has to be handled according to Procedure for Handling of Complaints P07.12
- For exceeding the Corrective Action Timeframe
- loss of an EAS approved technical signatory

  Note: In the case of loss of an EAS approved technical signatory for a specific scope, the CAB shall not issue any certificates for that scope by using EAS symbol unless a new technical signatory is in place and approved by EAS .

  If the organization have only 1 signatory that covers its full scope, the organization shall notify EAS, and go into voluntary suspension. The CAB shall remain suspended until EAS has verified the competence of any new proposed technical signatory for the relevant accredited scope.
- Because of non-payment of fees

Note: An accredited facility will be suspended for non-payment of fees on the recommendation of the Finance and Supply Service Head to the accreditation assessment director/ team leader. If an accredited facility pay all outstanding amounts within the six month immediately after the suspension they shall be re-instated.

- If accredited facilities fail to settle all outstanding amounts during the suspension period of six months, their accreditation will be withdrawn. An application for accreditation with all associated costs has to be submitted to EAS to be accredited again. The CAB shall be treated as a new organization.
- Due to Change of Physical Location

  Note: CABs that are due to change physical location or are due to lose EAS approved signatories are required to notify EAS at least four weeks prior to any changes. A change in physical location may mean a change from one room to another or from one building to another. The organization shall analyse the impact of the change in location and shall prove its ability to further obtain valid results.
- Failure to notify EAS within the stated period will result in a penalty of 25% of the follow up fee and possibly re-assessment by EAS.
- In the case of change of location, instruments or key persons the organization will be required to go into suspension until they are able to verify their capability in line with their scope of accreditation. Records must contain evidence of acceptable comparative data from before and after the move. In addition, records of the checking of environmental conditions must be available.
- Failure of an organization to comply with the terms of the Accreditation Agreement.

  Note: CABs involved in certification and inspection will not be subject to suspension because of change in physical location unless the accredited facility is supported by an in -house laboratory**.**

12.4 Consequences of Suspension or Withdrawal of Accreditation

An accredited CAB shall, withdrawal of EAS accreditation, immediately cease to issue certificates and any other materials displaying the EAS accreditation symbol or containing references to EAS accreditation. In the case of partial reduction of scope, reports shall clearly identify the scopes for which accreditation can still be claimed. Failure to comply with this requirement is a fraudulent and can result in prosecution.

Once accreditation suspended the CAB's details (adjusted scope, duration etc.) shall be displayed at the EAS website and withdrawn display for three months and certefication will be lifted out from the website.

12.4 Re-instatement of Suspended CABs

- Once an organization has satisfactorily addressed the issues that resulted in suspension of accreditation, accreditation may be re-instated on recommendation by the accreditation director/ team leader. A positive recommendation is required prior to re-instatement of accreditation based on an assessment or other evidence that the reasons for suspension have been rectified satisfyingly. All costs will be on account of the CAB.
- Prior to re-instatement the assessment team leader shall notify the finance department of the re-instatement in order to ensure that all outstanding fees have been paid.
- Notification of re-instatement of accreditation will be sent to the CAB, detailing the scope to the CAB's. The new scope will be published on EAS's web site.

  Note: Re-instatement after withdrawal of accreditation is not possible. To continue with accreditation the CAB shall re-apply and the entire process will be followed as for a new application. The previous accreditation number will be obsolete and a new EAS accreditation number will be issued.

13. Appeals

A CAB may appeal using the appeal registration form 07/12 "Request from a CAB for reconsideration of any adverse decision made by the accreditation body related to its desired accreditation status". An appeal against a decision or an action by EAS staff will be managed by a committee chaired by Director General. An Appeals Committee will consist of the Director General and two assessors/experts appointed by Director General from the EAS assessors' pool being qualified for the relevant scope and not involved in the case under investigation. If needed, i.e. an appeal is not related to technical issues, the appeals committee will be composed out of at least two members of the concerned department of EAS.

An appeal against an AAC decision shall go to the Chairperson of the Accreditation Council. He shall appoint an appeals committee of at least three members from EAS's pool of assessors/experts being competent and independent as to maintain impartiality. The committee secretary shall not give vote regarding the decision of the appeal committee. The Director General will provide for relevant documents and witnessing to support the decision.

- The appeal shall be registered in Form F07/12.
- The committee shall investigate the appeal by reviewing all available facts.
- The committee may seek clarification from relevant parties who may have knowledge about the matter contained in the appeal.
- The committee shall formulate a conclusion and recommendation to EAS for corrective action, where appropriate.
- In case of a valid appeal, action taken by EAS may involve improvement followed by monitoring and alerting staff against future recurrence and, in extreme cases, removal of the assessor or Accreditation Advisory Committee member(s) from future duties.
- The outcome of the investigation shall be transmitted to the appellant within 30 days from the date of receipt of the appeal.
- If the appellant object to a decision of the appeals committee or an action where the Director General is involved, the appeal shall be forwarded to the chairperson of the Accreditation Council for review and consideration by council members. The decision of the Council will be based at least on the available objective evidence that was considered by the Appeals Committee and/or on additional facts if the Director General is involved. The decision of the Council is final. The appellant will be informed accordingly.
- A brief summary of the nature of the appeal, outcome of the investigation and action taken shall be added to the personnel file of the relevant EAS assessors and AAC members, if appropriate.

Complaints by the CAB shall be handled according to Procedure for Handling of Complaints P07/12.

14. Advisory Technical Committee

EAS has access to necessary assessors/experts for advising on technical matters related to accreditation activities by its pool of assessors/experts. Staff from various bodies (such as conformity assessment bodies, customers of EAS accredited CABs, industries, professional associations, regulatory bodies), EAS's assessor pool, EAS's staff and individuals are contained in this list.

An Ad-hoc technical committee will be assigned using this pool by the accreditation director/ team leader or responsible person when required for advising EAS on matters related to specific scopes (existing and extension of accreditation service, development and adoption of guidance or documents, technical criteria or requirements, procedures etc.)

The Director General shall approve the established ad-hoc committee. The chair person will be either an accreditation director/team leader or responsible person or EAS's Quality Manager. This ad-hoc committee dissolves after completion of its task and reports to the director general. The selection of the members of the committee shall consider the following conditions:

- Competence in the specific fields
- Inclusion of interested parties if the required competence is there
- maintenance of impartiality and confidentiality

EAS shall provide awareness training to the TC members on the accreditation policy and process before commencing the work.

15. Change in the scope of EAS

15.1 Extension of Accreditation Activities

The need for accreditation of new conformity assessment areas may arise according to the development of the country, on request of interested parties or CAB's needs. Once a new area is identified, EAS shall evaluate the need for providing accreditation, determine whether it can be included under an existing scope, analyse the availability of resources, evaluate the need for guidance documents and determine the requirements for accreditation with respect to the client needs.

"EAS should follow the international documents where available and if needed nationally accepted standards and also adopt as criteria documents any guidance documents issued by the International Accreditation Forum / International Laboratory Accreditation Cooperation.

The Ad-hoc technical committee shall be composed from EAS expert / assessor pool and expert/s of the potential client who brings the request of the extension scope. The technical committee will have three to seven members and based on the availability of relevant experts from the client who brings the request one upto three members can participant in the technical committee. However, if the initiation of the extension scope is from EAS , then all the technical committee members can be from EAS assessors and expert/s who has the knowledge on the area. When there is opportunity to access out of the office an exprienced expert/s on that particular scope, EAS can directly used thier experties without estabilishing an Ad-hoc committee . The technical committee members shall get approval from Director General to commence the work. The accreditation dirctor/ team or responsible person has the knowledge on the area can be the chair of the committee . Once the necessary document is developed, it will be communicated to interested parties for their comment. For a regulated inspection and certification EAS executes the accreditation with bilateral discussion with the regulatory.

After the acceptance of the extended scope, EAS prepares suitably technically qualified assessors by training based on the extension scheme requirements. EAS will inform customers about the new scheme through its website and accreditation events.

15.2 Reduction of Accreditation Activities

There may be the case that EAS considers to reduce its scope of activities due to lack of customers, assessors/experts, financial issues or lack of competence. In such a case EAS will ask for advice

- The regulators/authorities
- A technical committee
- CABs possibly accredited in this scope
- Its legal department

If the decision is made by the Director General to reduce the scope at a time to be fixed, EAS will inform customers about the reduction through its website and accreditation events.

The accreditation of CABs in this scope is valid until the time of a regular on-site follow-up activity. If no evidence is given for an earlier withdrawal, EAS will extend the period up to the expiry date of the accreditation certificate.

16 Proficiency Testing

It is the policy of EAS that all applicant laboratories and inspection bodies (IB) supported by a testing laboratory, shall demonstrate evidence of satisfactory participation in Proficiency Testing (PT) schemes and have a realistic ongoing participation plan in place in all fields for which it intends to be accredited (see PT policy of EAS).

A five years participation plan shall be presented and evaluated by the technical assessor with regard to suitability of the scheme (list of parameters, methods, equipment used, materials tested or artefacts, type of testing) for the different scopes and adequacy of frequency of participation.

In the absence of PT schemes, inter-laboratory comparisons or other means as indicated in EAS ’s PT-policy document may be agreed as substitute. The laboratory has to justify the use these means and to prove that the used method is adequate. The CAB will continue to explore the availability of PT schemes.

The team will evaluate the outcome of conducted PT schemes.

The team will confirm that the CAB has a policy how to react on poor PT-results and has to be convinced that the root cause analysis taken by the CAB is appropriate and will lead in future to proper results. By the result of the next PT the CAB will give evidence of the successful removal

of the reasons for failure. The result shall be immediately submitted to accreditation director/ team leader or responsible person.

Links to PT providers are available on the EAS website to assist easy search/communication with them.

17 Traceability

EAS has traceability policy PM 10/01 to be followed and comply by the CABs for their measurement traceability. All measuring equipments that have significant impact on the measurement uncertainty reflected in the outcome result shall be traceable to the primary measuring unit.

The assessment team shall have to decide whether the methods chosen to obtain traceability are appropriate and will document the results in the traceability check list F07/24. When the team is not satisfied with the ways chosen, the given uncertainties do not relate with the uncertainties in the traceability chain that cannot be corrected by the CAB, and then the affected scope shall not accredit.

18 Records of CABs

All records related to the accreditation of a CAB including email and/or letter correspondence, assessment records, AAC Reports, and copies of accreditation certificates shall be kept in the CAB File and shall be maintained in accordance to Records Control Procedure P9.4.

The following records relate to this procedure:

- F07/01A,B,C,D: Applications for Accreditation
- F07/02 Contractual Activity Agreement
- F07/03 A,B,C,D,E, F, Assessment Programme
- F07/05 Pre-Assessment Findings
- F07/06A,B,C,D,E,F,G: Assessment Checklists
- F07/07A,B,C,D,E,F,G: Vertical Assessment Records
- F07/08A,B,C Activity Witnessing Record
- F07/09: Non-conformance, Corrective Action and Clearance report
- F07/10: Assessment Report
- F07/11: Accreditation Approvals Committee Report
- F07/12: Appeal Registration

- F07/13: Attendance Register
- F07/14: Proficiency Testing Links
- F07/15: Document Review Report
- F07/16: Fee Quotation
- F07/17: Declaration of Confidentiality
- F07/18: Checklist for Completeness of Application and Resource Review.
- F07/19: Assessment Pack Contents Registration and Verification
- F07/20: Assessment Plan
- F07/25 Requirements of Nominated Representative and Technical Signatories Checklist Form

Annex A: Accreditation Certificate and Scope of Accreditation

Accreditation Certificate

Name of Facility:

Addis Ababa

Ethiopia

Facility Accreditation Number: T000x

Is accredited by the Ethiopian Accreditation Service (EAS) to perform tests in accordance with the attached Scope of Accreditation in the field of _____

The facility is accredited in accordance with the requirements of ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories. The accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system. While this certificate remains valid, the Accredited Facility named above is authorized to use a combined ILAC-EAS accreditation mark/symbol to issue test reports and/or certificates.

Effective Date:

Certificate Expire:

_____

Meseret Tessema

Director General

Ethiopian Accreditation Service

Scope of Accreditation

Facility Accreditation Number:

Permanent Address of Laboratory Name of the Lab: Location: Postal Address:	Management Signatories: Nominated Representative: Technical Signatories:

Telephone No: Fax No: Email: Website:	Original date of Accreditation: Issue No: Date of issue: Expiry date:

Field of Testing	Sample	Test Method	Type of tests

_____

Meseret Tessema

Director General

Ethiopian Accreditation Service

Ethiopian Accreditation Service

Accreditation Certificate

Name of Facility:

Addis Ababa

Ethiopia

Facility Accreditation No: CAL000x

Is accredited by the Ethiopian Accreditation Service (EAS) to perform calibration in accordance with the attached Scope of Accreditation in the field of _____

The facility is accredited in accordance with the requirements of ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories. The accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system. While this certificate remains valid, the Accredited Facility named above is authorized to use EAS accreditation symbol to issue test reports and/or certificates.

Effective Date:

Certificate Expire

_____

Meseret Tessema

Director General

Ethiopian Accredidation Service

Scope of Accreditation

Facility Accreditation number:

Permanent Address of Laboratory:	Management Signatories:

Name of the lab: Location: Postal Address: Telephone No: Fax No: Email: Website			Nominated Representative: Technical Signatories: Original Date of Accreditation: Issue No: Date of issue: Expiry date:		
S.No	Measured quantity /Calibration item	Range	Measurement conditions/ procedure	Calibration and measurement capability (*)	Remarks

_____

Meseret Tessema

Director General

Ethiopian Accreditation Service

ETHIOPIAN ACCREDITATION SERVICE

Ethiopian Accreditation Service

Accreditation Certificate

Name of Facility:

Addis Ababa

Ethiopia

Facility Accreditation No: M000x

is accredited by the Ethiopian Accreditation Service (EAS) to perform tests in accordance with the attached Scope of Accreditation in the field of **Medical testing**

The facility is accredited in accordance with the requirements of ISO/IEC 15189:2012, General requirements for the competence of Medical laboratories. The accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system. While this certificate remains valid, the Accredited Facility named above is authorized to use the Combined ILAC-EAS accreditation mark/symbol to issue test reports and/or certificates.

Effective Date:

Certificate Expires:

_____

Meseret Tessema

Director General

Ethiopian Accreditation Service

Scope of Accreditation:

Facility Accreditation Number:

Permanent Address of Laboratory: Name of the Lab: Location: Postal Address:	Management Signatories: Nominated Representative: Technical Signatories:

Telephone No: Fax No: Email: Website:			Original date of Accreditation: Issue No: Date of issue: Expiry date:
Field of Testing	Type of Sample	Type of Test	Test Method

_____

Meseret Tessema

Director General

Ethiopian Accredidation Service

ETHIOPIAN ACCREDITATION SERVICE

Ethiopian Accreditation Service

Accreditation Certificate

Name of Facility: XXX

Addis Ababa

Ethiopia

Facility Accreditation No: IB000x

Is accredited by the Ethiopian Accreditation Service (EAS) to perform inspection in accordance with the attached Scope of Accreditation in the field of _____

The facility is accredited in accordance with the requirements of ISO/IEC 17020:2012, General requirements for the competence of Inspection bodies. The accreditation demonstrates technical competence for a defined scope and the operation of an inspection body's quality management system. While this certificate remains valid, the Accredited Facility named above is authorized to use the combined ILAC-EAS accreditation mark/symbol to issue inspection reports and/or certificates.

Effective Date:

Certificate Expires:

_____

Meseret Tessema

Director General

Ethiopian Accredidation Service

Scope of Accreditation

Type of Inspection Body:

Facility Accreditation number:

Permanent Address of Inspection Body: Name of the IB: Location:	Management Signatories: Nominated Representative: Technical Signatories:

Postal Address: Telephone No: Fax No: Email: Website:			Original Date of Accreditation: Issue No: Date of issue: Expiry date:
Field of Inspection	Item Inspected	Type and range of inspection	Inspection scheme or Regulation code

_____

Meseret Tessema
Director General
Ethiopian Accreditation Service

Ethiopian Accreditation Service

Accreditation Certificate

Facility: XXXXXXXX

Addis Ababa

Ethiopia

Facility Accreditation No: CMS000x

Is accredited by the Ethiopian Accreditation Service (EAS) to perform certification in accordance with the attached Scope of Accreditation in the field of _____

The facility is accredited in accordance with the requirements of ISO/IEC 17021-1:2015/ISO/IEC 17021-2:2017/ISO/IEC17021-3:2017 requirements for the competence of bodies providing audit and certification of management systems. The accreditation demonstrates technical competence for a defined scope and the operation of a management system certification body's quality management system. While this certificate remains valid, the Accredited Facility named above is authorized to use the relevant IAF-EAS accreditation Mark/symbol to issue certification reports and/or certificates.

Effective Date:

Certificate Expires:

_____

Mr. Meseret Tessema

Director General

Ethiopian Accredidation Service

Scope of accreditation

Facility Accreditation Number:

Permanent Address of Certification Body	Management Signatories:
Name of the CB: Location Postal Address: Tel: Fax: Email: Website:	 Nominated Representative: Original date of Accreditation Issue No: Date of issue: Expiry date:

XXXXX Complies with the accreditation criteria for Certification Bodies as laid dawn in ISO/IEC 17021 and ISO/IEC TS 17021-3 / ISO/IEC17021-2 and is authorized to certify organizations to ISO 9001 QMS/ ISO 14001 EMS/18001 OHSAS in the following sectors.

Technical cluster	Critical code	IAF code	Description

_____

Mrs. Meseret Tessema

Director General

Ethiopian Accredidation Service

ETHIOPIAN ACCREDITATION SERVICE

Ethiopian Accredidation Service

Accreditation Certificate

Facility: XXXXXXXX

Addis Ababa

Ethiopia

Facility Accreditation No: CPe000x

is accredited by the Ethiopian Accreditaion Service (EAS) to perform Personnel certification in accordance with the attached Scope of Accreditation in the field of certification of persons_____

The facility is accredited in accordance with the requirements of ISO/IEC 17024:2012/ General requirements for bodies operating certification of persons. The accreditation demonstrates technical competence for a defined scope and the operation of a certification body's quality management system. While this certificate remains valid, the Accredited Facility named above is authorized to use the relevant EAS accreditation symbol to issue certification reports and/or certificates.

Effective Date:

Certificate Expires:

_____

Mrs. Meseret Tessema

Director General

Ethiopian Accredidation Service

Scope of accreditation

Facility Accreditation Number:

Permanent Address of Certification Body Name of CB: Location: Postal Address: Tel: Fax: Email: Website:	Management Signatories: Nominated Representative: Original date of Accreditation: Issue No: Date of issue: Expiry date:

XXXXX Complies with the accreditation criteria for Certification Body as laid dawn in ISO/IEC17024:2012 Conformity assessment — General requirements for bodies operating certification of persons is authorized to provide Personal Certification for the following schemes :

Personnel Certified	**Standard**

_____

Meseret Tessema

Director General

Ethiopian Accredidation Service

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ETHIOPIAN ACCREDITATION SERVICE

Ethiopian Accredidation Service

Accreditation Certificate

Facility: XXXXXXXX

Addis Ababa

Ethiopia

Facility Accreditation No: CPr000x

is accredited by the Ethiopian Accreditaion Service (EAS) to perform product certification in accordance with the attached Scope of Accreditation in the field of product certification

The facility is accredited in accordance with the requirements of ISO/IEC 17065:2012 requirements for bodies certifying products, processes, and services. The accreditation demonstrates technical competence for a defined scope and the operation of a certification body's quality management system. While this certificate remains valid, the Accredited Facility

named above is authorized to use the relevant EAS accreditation symbol to issue certification reports and/or certificates.

Effective Date:

Certificate Expires:

_____

Mr. Meseret Tessema

Director General

Ethiopian Accredidation Service

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ETHIOPIAN ACCREDITATION SERVICE

Scope of accreditation

Facility Accreditation Number:

Permanent Address of Certification Body Name of CB: Location: Postal Address: Tel: Fax: Email: Website:	Management Signatories: Nominated Representative: Original date of Accreditation: Issue No: Date of issue: Expiry date:
XXXXX Certification Scheme, Complies with the accreditation criteria for Certification Bodies as laid dawn in ISO/IEC 17065:2012,Conformity assessment - Requirements for bodies certifying	

products, processes and service is authorized to provide Product Certification for the following:

Product	Certification Scheme	Standard /Regulation	

_____

Meseret Tessema
Director General
Ethiopian Accredidation Service

Annex B Revision History

Revision No.	Date approved	Revision History
1	2011-08-24	Inclusion of: cover page; correction of section numbering errors; amendment of Appeals Process for Council involvement in final appeal; inclusion of the Appeal Registration form F07/12& GD07/3; and definitions of NCs and observation.
2	2012-10-08	Amend 5.1 to indicate that EAS shall issue a quotation rather than a specific designation in EAS ; Inclusion of the requirement for 6 months and 100 tests in clauses 9 and 10; Amend Clause 11 to indicate that the DG or delegated deputy shall chair the AAC; that the EAS hair shall not have participated in the

		assessment; and that assessors or experts shall be used for AAC participation, wherever possible. Inclusion of Clause 13: Application for Extension of Scope of Accreditation. Amend Clause 16 to remove “intra-laboratory” from second bullet and to include reference to EAS PT policy and F07/14. Amend Clause 17 to update references to EAS documents. Amend Annex A to update Scope format.
3	2013-06-01	Amend 5.1 to reference Reg 275/2012. Remove reference to laboratories and replace with CABs in 10.3 and 11.0. Remove reference to Test/calibrations and replace with Scope in 13.2. Clause 12.2 is updated to allow for the Director General rather than the AAC to decide on the outcome of Follow Up assessments. Remove reference to “intra-laboratory” and leave as “inter-laboratory” in first paragraph of 16. Update and correct Annex.
4	2013-12-27	Clause 2 Inclusion of Regulation No 279/2012 Council of Ministers Regulation to establish Ethiopian Accreditaion Service Clause 4 revised to address who revised the application and why the application revised Clause 5 was revised to indicate that the accreditation director make resource review in an interactive communicative manner with relevant team and the Finance and Supply Service Head shall reaffirm the Accreditation Director for charging the CAB as per F07/16. EAS establishment regulation no. changed to Reg No 275/2012). And also to include in the clause that Assessor/ technical expertise shall not be assigned to the conformity assessment body from which he/she resigned and /or involved in any activities that may lead to conflict of interest until two years. Clause 6 revised to indicate that Whenever the Team Leader needs an

impute from the technical assessor/s the Team Leader can have a direct contact with the technical assessor/s for their assistance on the document review of the technical part

Clause 8.2 revised to indicate that the details communication of CABs shall include the parent CAB of assessors.

Clause 9 revised to indicate that sufficient

historical data required for pre-assessment is (at least 4 months from the start of system implementation (i.e. from the beginning of the project to establish the system) with at least 50 test results that can be assessed for calibration and testing laboratories, 1 inspection report for inspection bodies and 1 certificates for the certification bodies) and to remove the last two bulletin from the purpose of per-assessment.

Clause 10 revised to include assessment sampling procedure, logistics arrangements and to indicate sufficient historical data required for accreditation is with at least 50 test results that can be assessed for calibration and testing laboratories, 1 inspection report for inspection bodies and 1 certificate for the certification bodies.

Clause 11 revised to indicate that if Accreditation is refused by AAC and the assessment will need to be repeated, it will be assessed by other Assessment team or the previous team with at least one additional EAS internal or external assessor as observer/s.

Clause 12 revised to indicate that the reassessment may be extended to 18 months from the last surveillance based on the recommendation of surveillance assessment team, in the absence of one or more assessment team members other assessor can be substituted and new team members should be selected for each reassessment especially applies to the lead Assessor.

Clause 13 revised to include the procedures of reduction scope of accreditation in this clause.

Clause 14 revised to indicate that the Finance and Supply Service Head should report to the Accreditation Director to make the suspension effectively in case of Suspension for Non-payment of Fees, CABs involved in certification and inspection will not subject to suspension because of change in physical location unless the

		accredited facility is supported by in house laboratory, and Enforced withdrawal of accreditation shall be authorized by the chair of AAC only or call all of the AAC members, based on objective evidence and a suitable recommendation from the assessment Lead assessor/Team Leader or the Accreditation Director. Clause 15 was revised to indicate any appeals against to the AAC decision and activities Director General involved shall go to accreditation council Clause 16 procedures for advisory technical committee and clause 17 procedures for Extension of EAS accreditation activities were included. Clause 19 was revised to remove F07/04: Opening and closing meeting agendas, GD07/01: Accreditation criteria for conformity assessment bodies, GD07/02: Accreditation Fees, GD07/03-α: Guidance on scopes, R07/01: Timeline Rules of EAS from records Annex A was revised to include Accreditation Certificate Format
5	2015-05-20	Clause 2 was revised to include the following references ILAC/IAF A2: Requirements and Procedures for Evaluation of a Single Accreditation Body, ILAC-P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities, IAF/ILAC-A5:11/2013 IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Application of ISO/IEC 17011:2004 Clause 3 was revised to include responsibility for implementation of the document. Clause 4 was revised to give responsibility of reviewing application completeness to respective team. Clause 5.1 was revised to give responsibility of resource review to respective team. Clause 5.2. was revised to make more clear communication between Finance & supply and accreditation directorate in case of fee quotation for accreditation Clause 6 was revised to give responsibility of assigning assessment team for respective team. Clause 8. was revised to make more clear communication conducted with CABs by Accreditation director and respective team leader

		Clause 9 was revised to reduce the minimum test conducted b y laboratory for per-assessment to 25. Clause 10.4 was revised to reduce the minimum test conducted b y laboratory for initial assessment to 25. Clause 12.2 was revised to give responsibility of for planning of Follow Up assessment to respective team. And also to include that For small scope CABs for which full assessment is conducted, /100% of the facility assessed based the recommendations of assessment team and approved by Director General the next assessment can extended to 18 months Clause 13.1 was revised to include reduction of scope in the title Clause 13.2 was revised to make clear how document review, assessment and decision on accreditation were conducted and also the time for the clearance of non-conformities in case of scope extension Clause 15 was revised to make clear the appeal seen the committee established by the accreditation council and Director general. Clause 18 was revised to make clear arrangements that can substitute PT in case of un availability or uneconomical to participate in PT Clause 19 was revised to include the following records:- • F07/16: Fee quotation • F07/17: declaration of confidentiality • F07/18: checklist for completeness of application and resource review. • F07/19: registration and verification • F07/20: Assessment Plan

6	2015-10-20	• Clause 5.1 added signing of accreditation agreement before document review. • Clause 6 added needs to make preliminary visit before initial. • Clause 9 and 10.4 number of reports required after implementation changed • Clause 10.6 added involvement of technical expert in NC classification as needed, NC classification criteria redefined and assessment reporting contents more elaborated. • Clause 11.4. AAC voting replaced by AAC decision and members role changed to advising DG • Clause 12.3. Reassessment application time line set and its extent defined • Clause 18. PT policy and ongoing PT plan requirements have been revised to explicitly define implementation and to include elements of ILAC P9 • Certificate formats for different certification bodies accreditation set to be unique separate table describing assessment cycle plan was added separate table describing assessment cycle plan was added to specify for inspection and certification The Accreditation process was revised because of the new standard ISO/IEC 17011:2017 Clause 14.1 includes the interested parties will be engaged Clause 7.4 accreditation cycle programme, Clause 9(d) Verify draft accreditation certificate by second person and 10.2 EAS notifies CABS in writing of the decision for continuation of accreditation made by the director. The CAB shall be informed using **F07/29.**
1.7	2018-10-16	Clause 10.2 Added Off- site Assessment i.e. when it may not be possible or feasible to conduct on-site assessments due to emergency situation like Epidemic, Earth quick, Emergency travel restriction, reasons for affecting safety etc
1.8	2019/06/06	

		Clause 7.4 align with sampling procedure P07/03
1.9	2019/07/01	Assessment Cycle plan for Inspection Accreditation changed from 2 and ½ years to 4 years ½ months Accreditation Calibration Certificate template changed Separate purpose and scope Remove ILAC Docs: www.ilac.org, IAF Docs: www.iaf.nu and EAS Docs: www.EAS -eth.org from reference list and added specific reference ILAC G26: Guidance for the implementation of a medical laboratory ILAC P9, ILAC P10, ILAC P14 ILAC P15 Re07.0, "Accreditation Criteria for Conformity Assessment Bodies".
2	2020/04/14	Documentation for completeness as per F07/18 and will communicate with the CAB by Acknowledgment Letter Accreditation Director included as per new structure on each activities
2.2	2020/12/18	Clause 6.2.accreditation fee structure Reg No. 276/2020 Clause 8.2 In case EAS conducts a preliminary visit before the initial assessment, it shall be conducted with the agreement of the conformity assessment body and EAS shall exercise due care to avoid consultancy Clause 8.3 Pre assessment- it shall normally not exceed more than two days and not more than two assessors. EAS shall make the Assessors or any personnel that involved in such activities to sign F07/02 "Contractual activity agreement form" to avoid consultancy during such activities **8.5 Remove Objections to Team Members and replaced by Confirmation of assessment plan** • Clause 9.6 added Present the summary report that comprises positive and negative narration of the system • Acknowledge the cooperation that has been done by the CAB to the assessment team • Explain their right to appeal against the assessment team's recommendation using F07/12 and/or complaints for any

dissatisfaction using F07/12A of EAS.

Under item 9.7.1 change the submission of information to access of information and remove this sentence. And replaced by The assessment team leader shall submit all assessment documentation to the accreditation Director or accreditation team leader or responsible person in accordance with timeline rule once all findings get cleared by the CAB with all supporting evidences. The accreditation director/team leader or responsible person shall organises all files according to F07/27 and submit to the AAC within a week. The AAC has to submit a recommendation for a Director General within a week.

9.7.2 purpose replaced by objective

- 9.7.5. Added The name of the accredited conformity assessment body and the name of the legal entity, if different;
- The accredited scheme,
- Issue and expiry date
- Signature with official stamp and attached accreditation scope

The scope of accreditation contains at least the following:

- Accreditation number
- CAB's address
- List of signatory
- The date of coming into effect (date of decision by AAC),
- Issue and expiry date,
- Issue number
- Field of Testing, Sample, Test Method and tested parameters

Included Before issuing the official certificate the draft shall be sent to the CAB to verify the correctness of the contents then certificate shall be handled to the accredited CAB with orientation in using accreditation symbol.

In case of denial of accreditation the CAB has the right to appeal; EAS will then formulate appeal investigation team as per appeal procedure. If the CAB is interested to reapply for accreditation, EANO shall

		convene a new assessment team with a new assessment team leader and new assessors/experts. Table 2 Remove 6 month follow up for Calibration and Certefication and added The tables above are indicative, in all cases the type (on-site visit, document review, PT-performance etc) and the intervals of follow -up activities shall be risk oriented or comply with regulatory demands. When the outcome of the assessment indicated to build trust on the competency of the CAB the team leader may recommend for the elongation by 6 months to be decided by Director General and then modified the programme by Accreditation director/team leader or responsible person. Annex A front page of accreditation certification for Testing and inspection added the Accredited Facility named above is authorized to use a combined ILAC-EAS accreditation mark/symbol to issue test reports and/or certificates. Second page of calibration certificate scope edited

S.No	Measured quantity /Calibration item	Range	Calibration and Measurement Capability (±)	Calib meth Refe Stan Equi

The document is revised due to the name Ethiopian Accredidation Service (EAS) change to Ethiopian Accreditation Service (EAS) and new logo developed. Under Item No. 10.2 added Remote Assessment(Virtual)

12.4. included withdrawn display for three months

2.3	2022-05-09	• Correction done on page 1 that, this document was prepared by Meseret Tessema replaced by Zewdu Ayele (new quality manager). • Former director general was resigned and replaced by Mrs. Meseret Tessema.
2.4	2023-02-07	