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Position: Quality Manager	Position: Director General
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Contents

1 Purpose

The purpose of this document is to set accreditation criteria (requirement) for conformity assessment bodies to be accredited by the Ethiopian Accreditation Service (EAS).

2 Scope

This document specifies the requirements that a *conformity assessment body* shall meet if it is to be accredited by the Ethiopian Accreditation Service (EAS) as competent in the performance of specified activities. Additional, and more specific, criteria may be established for certain fields of conformity assessment and these criteria will be published by EAS as Guidance documents where relevant.

3 References

The following documents are referenced:

ISO/IEC 17011:2017, Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies;

ISO/IEC 17020:2012, General criteria for the operation of various types of bodies performing inspection;

ISO/IEC 17021, Conformity assessment – Requirements for bodies providing audit and certification of management systems;

SO/IEC 17025:2017General requirements for the competence of testing and calibration laboratories;

SO 15189:2012 Medical laboratories – Requirements for quality and competence;

ISO/IEC 17024:2012 General Requirements for Bodies Operating Certification of persons,

ISO/IEC17065:2012 General Requirements for Bodies Operating Product Certification Systems

ILAC P8:03/2019 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Conformity Assessment Bodies

ILAC-R7:05/2015 Rules for the Use of the ILAC MRA Mark

4 Responsibility

It is the responsibility of the accreditation directorate and the respective accreditation team to implement these requirements effectively.

5 Criteria

5.1 Criteria for Certification Bodies

The Certification Bodies seeking accreditation shall comply with the following requirements:

- IAF MD 1:2018 IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization
- The certification body should implement the system at least for 3 months and 1 test results must be released
- The Certification body should submit the Quality Policy Manual and their supporting procedures to EAS
- The certification body should conduct Internal Audit and take Corrective Action at the time of Application and submit their evidence
- Rules for the use of the ILAC and/or AFRAC MRA Mark and the IAF MLA Mark document No. R04.2
- IAF ID 3: 2011 Informative Document for Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified organizations when required
- IAF ID 4:2020 Market Surveillance Visits to Certified Organizations

i. Criteria for Management System Certification Bodies

In addition to criteria specified in 3.1 the Certification Bodies seeking accreditation for Management System Certification shall comply with the following requirements:

- ISO/IEC 17021, Conformity assessment – Requirements for bodies providing audit and certification of management systems
- IAF MD 4:2018 IAF Mandatory Document for the use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes
- IAF MD 5:2019 Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems
- IAF MD 2:2017 IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems

- IAF MD 10:2013 IAF Mandatory Document For Assessment of Certification Body Management of Competence in Accordance with ISO/IEC 17021:2011
- IAF MD 11:2013 IAF Mandatory Document for Application of ISO/IEC 17021 for Audits of Integrated Management Systems (IMS)

ii. Criteria for Product Certification Bodies

In addition to criteria specified in 3.1 the Product Certification Bodies seeking accreditation for Product Certification shall comply with the following requirement:

- ISO/IEC 17065:2012 General requirements for bodies operating product certification systems
- ISO/IEC 17067:2013 Conformity assessment -- Fundamentals of product certification and guidelines for product certification schemes
- IAF MD 2:2017 IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems

iii. Criteria for Person Certification Bodies

In addition to criteria specified in 3.1 the Certification Bodies seeking accreditation for person Certification shall comply with the following requirements:

- ISO/IEC 17024:2012 General Requirements for Bodies operating Certification of persons
- IAF MD 2:2017 IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems

5.2 Criteria for Inspection Bodies

The Inspection Body seeking accreditation shall comply with the following requirements:

- ISO/IEC 17020:2012 General criteria for the operation of various types of bodies performing inspection
- ILAC P15:05/2020 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies
- IAF MD 1:2018 IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization
- IAF MD 7:2010 IAF Mandatory Document for Harmonization of Sanctions to be applied to Conformity Assessment Bodies
- The Inspection body should implement the system at least for 3 months and 1 inspection report must be released

- The Inspection Body should submit the Quality Policy Manual and their supporting procedures to EAS
- The laboratory should conduct Internal Audit and take Corrective Action at the time of Application and submit their evidence
- Rules for the use of the ILAC and/or AFRAC MRA Mark and the IAF MLA Mark document No. R04.2

Inspection Body which is laboratory based shall comply with the following requirements:

- ILAC-P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities
- ILAC P10:07/2020 ILAC Policy on Metrological Traceability of Measurement Results
- Policy on the Traceability of Measurement Results document no.PM 10/01.

5.3 Criteria for Testing and Calibration Laboratories

The laboratories seeking accreditation shall comply with the following requirements:

- ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
- ILAC-P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities
- ILAC P10:01/2013 ILAC Policy on the Traceability of Measurement Results
- Policy on the Traceability of Measurement Results document no. PM 10/01
- The laboratory should implement the system at least for 3 months and 5 test report/test result must be released in order to have sufficient data for sampling
- The laboratory should submit the Quality Policy Manual and their supporting procedures to EAS
- The laboratory should conduct Internal Audit and take Corrective Action at the time of Application and submit their evidence
- The laboratory should submit Method validation and/or verification Procedure including Validation and/or verification data
- Five years PT plan and/or ILC should be submitted and approved by EAS
- ILAC-G8:03/2009 Guidelines on the Reporting of Compliance with Specification
- ILAC-G24 Guidelines for the determination of calibration intervals of measuring instruments
- ILAC-P14:01/2013 ILAC Policy for Uncertainty in Calibration
- Rules for the use of the ILAC and/or AFRAC MRA Mark and the IAF MLA Mark document No. R04.2

5.4 Criteria for Medical Laboratories Accreditation

The Medical laboratories seeking accreditation shall comply with the following requirements:

- The Medical Laboratory should complies and fulfilled the regulatory requirement and a registered legal entity, if the medical laboratory is governmental or part of governmental organization it is considered as legally recognized where as the private medical laboratories shall renew their license on annual bases this indicates the fulfilment of requirement.
- ISO 15189 Medical laboratories — Requirements for quality and competence
- ILAC-P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities
- ILAC P10:01/2013 ILAC Policy on the Traceability of Measurement Results
- Policy on the Traceability of Measurement Results document no.PM 10/01.
- ILAC-G26:07/2012 -Guidance for the Implementation of a Medical Laboratory Accreditation System
- The laboratory should implement the system at least for 3 months and 10 test report/result must be released in order to have sufficient data for sampling
- The Medical laboratory should submit the Quality Policy Manual and their supporting procedures to EAS
- The Medical laboratory should conduct Internal Audit and take Corrective Action at the time of Application and submit their evidence
- The laboratory should submit Method validation and/or verification Procedure including Validation and/or verification data
- Five years PT plan and/or ILC should be submitted and approved by EAS

6 Records

- All applicant/accredited CABs records

Revision No.	Date approved	Revision History
1	2015-10-30	In the reference ISO 15189, Medical laboratories – Requirements for quality and competence; ISO/IEC 17024, General Requirements for Bodies Operating Certification of persons, ISO/IEC17065, General Requirements for Bodies Operating Product Certification Systems,ILAC-P8:12/2012 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories and Inspection Bodies and ILAC-R7:05/2015 Rules for the Use of the ILAC MRA Mark are added. Under certification the following points were added : • The Certification Body should submit the Quality Policy Manual and their supporting procedures to EAS • The laboratory should conduct Internal Audit and take Corrective Action at the time of Application and submit their evidence • Rules for the use of the ILAC and/or AFRAC MRA Mark and the IAF MLA Mark document No. R08.3/02 • IAF ID 3: 2011 Informative Document for Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified organizations when required • IAF ID 4:2012 Market Follow up Visits to Certified Organization when required • ISO/IEC Guide 65;1996 was revised by ISO/IEC 17065:2012 Under the Inspection body the following points were added. • ISO/IEC 17020 General criteria for the operation of various types of bodies performing inspection

		• ILAC-P15:06/2014 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies • IAF MD 1:2007 Mandatory Document For Certifications Of multiple Sites Based On Sampling • IAF MD 7:2010 IAF Mandatory Document for Harmonization of Sanctions to be applied to Conformity Assessment Bodies • The Inspection body should implement the system at least for 3 months and 1 inspection report must be released • The Inspection Body should submit the Quality Policy Manual and their supporting procedures to EAS • The laboratory should conduct Internal Audit and take Corrective Action at the time of Application and submit their evidence • Rules for the use of the ILAC and/or AFRAC MRA Mark and the IAF MLA Mark document No. R08.3/02 Inspection Body which is laboratory based shall comply with the following requirements: • ILAC-P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities • ILAC P10:01/2013 ILAC Policy on the Traceability of Measurement Results • Policy on the Traceability of Measurement Results document no.PM 8.2/A
1.1	2018-10-17	Criteria for testing, calibration and Medical Laboratories were separated and explained clearly under 3.3 and 3.4
1.2	2021-05-17	This document was revised because of the new ISO/IEC 17011:2017 • Separate purpose and scope

		• References updated from ILAC-P8:12/2012 ILAC P8:03/2019 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Conformity Assessment Bodies • Remove no specific references that was mentioned previously:- ILAC Docs: www.ilac.org IAF Docs: www.iaf.nu EAS Docs: www.EAS -eth.org AFRAC Docs: www. • Remove IAF MD 3:2008 IAF Mandatory Document for Advanced Follow up and Recertification Procedures from clause 5.1 Criteria for Certification Bodies • Removed out dated IAF ID 4:2012 Market surveillance Visits to Certified Organization when required and replace IAF ID 4:2020 Market Surveillance Visits to Certified Organizations under clause 5.1 • Remove IAF MD 5:2015 IAF Mandatory Document Determination of Audit Time of Quality and Environmental Management System and replaced by IAF MD 5:2019 Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems and removed IAF MD 18:2015 Application of ISO /IEC 17021:2011 in the Service Management Sector (ISO/IEC 20000-1) Under item i. Criteria for Management System Certification Bodies • Removed ILAC-P15:06/2014 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies ILAC P15:05/2020 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies, ILAC P10:01/2013 ILAC Policy on the Traceability of Measurement Results and replaced by ILAC

1.3	2022-05-09	P10:07/2020 ILAC Policy on Metrological Traceability of Measurement Results • from clause 5.2 Criteria for Inspection Bodies The document is revised due to the name Ethiopian National Accreditation Office (ENAO) change to Ethiopian Accreditation Service (EAS) and new logo developed.
1.4	2023-02-07	• 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.