

**LIST OF APAC ENDORSED NORMATIVE AND APPLICATION DOCUMENTS**

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| **Levels / Schemes** | **ILAC MRA - Schemes** | | | | | | |
| **Testing** | **Calibration** | **Medical** | **Inspection** | **Proficiency Testing Providers** | **Reference Material Producers** | **Biobanking** |
| **Level 1   Generic criteria for an AB** | **ISO/IEC 17011:2017** - Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies | | | | | | |
| **Level 2  Accredited conformity assessment activities** | Testing | Calibration | Medical | Inspection | Proficiency Testing Providers | Reference Material Producers | Biobanking |
| **Level 3   Accreditation Standard** | **ISO/IEC 17025:2017**  General requirements for the competence of testing and calibration laboratories | | **ISO 15189:2012**  Medical laboratories – Requirements for quality and competence | **ISO/IEC 17020:2012**  Conformity assessment - Requirements for the operation of various types of bodies performing inspection | **ISO/IEC 17043:2010**  Conformity assessment - General requirements for proficiency testing | **ISO 17034:2016**  General requirements for the competence of reference material producers | **ISO 20387:2018** Biotechnology - Biobanking - General requirements for biobanking |
| **Level 4 Scope specific criteria** | The WADA International Standard for Laboratories (ISL) | **ISO 15195:2018**  Laboratory medicine – Requirements for reference measurement laboratory | **ISO 22870:2016**  Point-of-care testing (POCT) – Requirements for quality and competence | Not Applicable | | | |
| **Level 5  Scope specific conformity assessment standards** | Accreditation scope | | | | | | |

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| **Levels / Schemes** | **IAF MLA - Schemes** | | | |
| **Certification - Management Systems** | **Certification - Persons** | **Certification - Products, Processes and Services** | **Validation and Verification** |
| **Level 1   Generic criteria for an AB** | **ISO/IEC 17011:2017** - Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies | | | |
| **Level 2  Accredited conformity assessment activities** | Certification - Management Systems | Certification - Persons | Certification - Products, Processes and Services | Validation and Verification |
| **Level 3   Accreditation Standard** | **ISO/IEC 17021-1:2015**  Conformity assessment - Requirements for bodies providing audit and certification of management systems – Part 1: Requirements | **ISO/IEC 17024:2012**  Conformity assessment - General requirements for bodies operating certification of persons | **ISO/IEC 17065:2012** Conformity Assessment - Requirements for bodies certifying product, processes and services | **ISO/IEC 17029:2019**  Conformity assessment — General principles and requirements for validation and verification bodies ISO 14065:2013 Greenhouse gases – Requirements for greenhouse gas validation and verification bodies for use in accreditation and other forms of recognition |
| **Level 4 Scope specific criteria** | * ISO 50003:2014 Energy management system – Requirements for bodies providing audit & certification of energy management systems * ISO 50003:2021Energy management systems — Requirements for bodies providing audit & certification of energy management systems * ISO/IEC 17021-2:2016 — Part 2: Competence requirements for auditing and certification of environmental management systems * ISO/IEC 17021-3:2017 — Part 3: Competence requirements for auditing & certification of quality management systems * ISO/IEC TS 17021-6:2014 — Part 6: Competence requirements for auditing & certification of business continuity management systems * ISO/IEC TS 17021-9:2016 — Part 9: Competence requirements for auditing & certification of anti-bribery management systems * ISO/IEC TS 17021-10:2018 — Part 10: Competence requirements for auditing & certification of occupational health and safety management systems * ISO/IEC 27006:2015 Information technology - Security techniques - Requirements for bodies providing audit & certification of information security management systems * ISO/TS 22003:2013 Food safety management system – Requirements for bodies providing audit & certification of food safety management systems * ISO/TS 22003:2013 FAMI-QS Rules for CBs * ISO/TS 22003:2013 FSSC 22000 Scheme Parts 3 and 4 | * Not Applicable | * GLOBALG.A.P. Integrated Farm Assurance General Regulations | * ISO 14065:2020 General principles and requirements for bodies validating and verifying environmental information * ISO 14064-3:2006 Greenhouse gases — Part 3: Specification with guidance for the validation and verification of greenhouse gas assertions * ISO 14064-3:2019 Greenhouse gases — Part 3: Specification with guidance for the verification and validation of greenhouse gas statements * ISO 14066:2011 Greenhouse gases — Competence requirements for greenhouse gas validation teams and verification teams * ICAO CORSIA Version 1 with ICAO CORSIA Environmental Technical Manual –Volume IV |
| **Level 5  Scope specific conformity assessment standards** | * ISO 9001:2015 Quality management systems – Requirements * ISO 14001:2015 Environmental management systems - Requirements with guidance for use * ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes * ISO 22000:2018 Food safety management systems - Requirements for any organization in the food chain * ISO 22301:2019 Security and resilience - Business continuity management systems – Requirements * ISO 37001:2016 Anti-bribery management systems — Requirements with guidance for use * ISO 45001:2018 Occupational health and safety management systems -- Requirements with guidance for use * ISO 50001:2018 Energy management systems — Requirements with guidance for use * ISO/IEC 27001:2013 Information technology - Security techniques - Information security management systems – Requirements * ISO/IEC 27006:2015 AMD 1:2020 – Information technology – Security techniques – Requirements for bodies providing audit and certification of information security management systems – Amendment 1 * FAMI-QS Certification Scheme Code * FSSC 22000 Certification Scheme Part 2 | * IPC-PL-11-006 IPC Management System Auditors | * GLOBALG.A.P. Integrated Farm Assurance Control Points and Compliance Criteria   Note: Refer to the Global G.A.P website for the latest edition:  http://www.globalgap.org | * ICAO CORSIA SARPs Annex 16 Volume IV |

**International Laboratory Accreditation Cooperation (ILAC) – Application documents** *(*[*https://ilac.org/publications-and-resources/*](https://ilac.org/publications-and-resources/)*)*

#### **» POLICY DOCUMENTS (P SERIES) –** [*https://ilac.org/publications-and-resources/ilac-policy-series/*](https://ilac.org/publications-and-resources/ilac-policy-series/)

* [**ILAC P5:05/2019** ILAC Mutual Recognition Arrangement: Scope and Obligations](https://ilac.org/?ddownload=122554)   
  [**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](https://ilac.org/?ddownload=122335)
* [**ILAC P9:06/2014** ILAC Policy for Participation in Proficiency Testing Activities](https://ilac.org/?ddownload=3259)
* [**ILAC P10:07/2020** ILAC Policy on Metrological Traceability of Measurement Results](https://ilac.org/?ddownload=123220)
* [**ILAC P12:04/2009** Harmonisation of ILAC Work with the Regions](https://ilac.org/?ddownload=842)
* [**ILAC P14:09/2020** ILAC Policy for Measurement Uncertainty in Calibration](https://ilac.org/?ddownload=123348)
* [**ILAC P15:05/2020** Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies](https://ilac.org/?ddownload=123115)

**» ILAC GUIDANCE DOCUMENTS (G SERIES) –** [*https://ilac.org/publications-and-resources/ilac-guidance-series/*](https://ilac.org/publications-and-resources/ilac-guidance-series/)

* [**ILAC G7:04/2021** Accreditation Requirements and Operating Criteria for Horseracing Laboratories](https://ilac.org/?ddownload=123697)
* [**ILAC G8:09/2019** Guidelines on Decision Rules and Statements of Conformity](https://ilac.org/?ddownload=122722)
* [**ILAC G17:01/2021** ILAC Guidelines for Measurement Uncertainty in Testing](https://ilac.org/?ddownload=123528)
* [**ILAC G18:12/2021** Guideline for describing Scopes of Accreditation](https://ilac.org/?ddownload=124300)
* [**ILAC G19:08/2014** Modules in a Forensic Science Process](https://ilac.org/?ddownload=805)
* [**ILAC G21:09/2012** Cross Frontier Accreditation - Principles for Cooperation](https://ilac.org/?ddownload=817) – under revision
* [**ILAC G24:2007** Guidelines for the determination of calibration intervals of measuring instruments](https://ilac.org/?ddownload=818) – *under revision*
* [**ILAC G26:11/2018** Guidance for the Implementation of a Medical Accreditation Scheme](https://ilac.org/?ddownload=819)
* [**ILAC G27:07/2019** Guidance on measurements performed as part of an inspection process](https://ilac.org/?ddownload=122667)
* [**ILAC G28:07/2018** Guideline for the Formulation of Scopes of Accreditation for Inspection Bodies](https://ilac.org/?ddownload=121961).
* [**ILAC G29:06/2020** Guidelines for harmonization of scopes of ISO/IEC 17025 accreditation of WADA anti-doping laboratories](https://ilac.org/?ddownload=123190)

**» ILAC RULES DOCUMENTS (R SERIES) –** [*https://ilac.org/publications-and-resources/ilac-rules-series/*](https://ilac.org/publications-and-resources/ilac-rules-series/)

* [**ILAC R4:10/2016** Use of the ILAC Logo and Tagline](https://ilac.org/?ddownload=120392)
* [**ILAC R7:05/2015** Rules for the Use of the ILAC MRA Mark](https://ilac.org/?ddownload=833)

#### **» JOINT ILAC / IAF DOCUMENTS (A SERIES) –** *https://ilac.org/publications-and-resources/joint-ilac-iaf-series/*

* [**IAF/ILAC A1:03/2020** IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements and Procedures for Evaluation of a Regional Group](https://ilac.org/?ddownload=847)    
  [IAF/ILAC-A1/A2: Addendum 01/2021 - IAF/ILAC Approach to Remote Peer Evaluations of Regions and Single Accreditation Bodies during the COVID-19 Pandemic](https://ilac.org/?ddownload=123559)
* [**IAF/ILAC A2:01/2018** IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements and Procedures for Evaluation of a Single Accreditation Body](https://ilac.org/?ddownload=861)

[IAF/ILAC-A1/A2: Addendum 01/2021 - IAF/ILAC Approach to Remote Peer Evaluations of Regions and Single Accreditation Bodies during the COVID-19 Pandemic](https://ilac.org/?ddownload=123559)

* [**IAF/ILAC A3:03/2020** IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Template report for the peer evaluation of an Accreditation Body based on ISO/IEC 17011:2017](https://ilac.org/?ddownload=849)

#### **» ILAC GA RESOLUTIONS –** *https://ilac.org/publications-and-resources/ga-resolutions/*

**International Accreditation Forum (IAF) – Application documents** [*https://iaf.nu/en/iaf-documents-categories/*](https://iaf.nu/en/iaf-documents-categories/)

#### **» Policy Documents (PL Series) –** *https://iaf.nu/en/iaf-documents/?cat\_id=5*

* **[IAF PL 8:2016](https://iaf.nu/en/iaf-documents/?cat_id=5)** [Rules for the Use of the IAF Logo](https://iaf.nu/en/iaf-documents/?cat_id=5)
* **[IAF PL 9:2019](https://iaf.nu/en/iaf-documents/?cat_id=5)** [General Principles for the Use of the IAF CERTSEARCH Mark](https://iaf.nu/en/iaf-documents/?cat_id=5)

**» MLA Documents (ML Series) –** *https://iaf.nu/en/iaf-documents/?cat\_id=6*

* **IAF ML 1:2016** Guidance for the Exchange of Documentation among MLA Signatories for the Assessment of Conformity Assessment Bodies
* **IAF ML 2:2016** General Principles on the Use of the IAF MLA Mark
* **IAF ML 3:2012** Guidance for responding to Inquiries on Multilateral Recognition Arrangement (MLA) Signatory Equivalence and on the acceptance of certification documents
* **IAF ML 4:2016** Policies and Procedures for an MLA on the Level of Single Accreditation Bodies and on the Level of Regional Accreditation Groups

#### **» Mandatory Documents (MD Series)** **–** [*https://iaf.nu/en/iaf-documents/?cat\_id=7*](https://iaf.nu/en/iaf-documents/?cat_id=7)

* **IAF MD 1:2018** IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization
* **IAF MD 2:2017** IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems
* **IAF MD 4:2022** 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 6:2014** Application of ISO 14065:2013
* **IAF MD 7:2010** Harmonisation of Sanctions
* **IAF MD 8:2020** Application of ISO/IEC 17011:2017 in the Field of Medical Device Quality Management Systems (ISO 13485)
* **[IAF MD 9:2017](https://iaf.nu/en/iaf-documents/?cat_id=7)** [Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)](https://iaf.nu/en/iaf-documents/?cat_id=7) *[[SUPERSEDED BY IAF MD 9:2022]](https://iaf.nu/en/iaf-documents/?cat_id=7)*
* **IAF MD 9:2022** Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)
* **IAF MD11:2013 IAF** Mandatory Document for Application of ISO/IEC 17021 for Audits of Integrated Management Systems (IMS)
* **[IAF MD12:2016](https://iaf.nu/en/iaf-documents/?cat_id=7)** [Accreditation Assessment of Conformity Assessment Bodies with Activities in Multiple Countries](https://iaf.nu/en/iaf-documents/?cat_id=7)
* **[IAF MD13:2020](https://iaf.nu/en/iaf-documents/?cat_id=7)** [Knowledge Requirements for Accreditation Body Personnel for Information Security Management Systems (ISO/IEC 27001)](https://iaf.nu/en/iaf-documents/?cat_id=7)
* **[IAF MD14:2014](https://iaf.nu/en/iaf-documents/?cat_id=7)** [Application of ISO/IEC 17011 in Greenhouse Gas Validation and Verification (ISO 14065:2013)](https://iaf.nu/en/iaf-documents/?cat_id=7)
* **IAF MD15:2014** IAF Mandatory Document for the Collection of Data to Provide Indicators of Management System Certification Bodies' Performance
* **IAF MD16:2015** Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies
* **[IAF MD17:2019](https://iaf.nu/en/iaf-documents/?cat_id=7)** [Witnessing Activities for the Accreditation of Management Systems Certification Bodies](https://iaf.nu/en/iaf-documents/?cat_id=7)
* **IAF MD20:2016** Generic Competence for AB Assessors: Application to ISO/IEC 17011
* **[IAF MD21:2022](https://iaf.nu/en/iaf-documents/?cat_id=7)** [Requirements for the Migration to ISO 45001:2018 from OHSAS 18001:2007](https://iaf.nu/en/iaf-documents/?cat_id=7)
* **IAF MD22:2019** Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS)
* **[IAF MD23:2018](https://iaf.nu/en/iaf-documents/?cat_id=7)** [Control of Entities Operating on Behalf of Accredited Management Systems Certification Bodies](https://iaf.nu/en/iaf-documents/?cat_id=7)

#### **[IAF MD24:2021](https://iaf.nu/en/iaf-documents/?cat_id=7)** [Transition Requirements for ISO 50003:2021](https://iaf.nu/en/iaf-documents/?cat_id=7)

* **[IAF MD25:2022](https://iaf.nu/en/iaf-documents/?cat_id=7)** [Criteria for Evaluation of Conformity Assessment Schemes](https://iaf.nu/en/iaf-documents/?cat_id=7)

#### **» Informative Documents (ID Series) –** [*https://iaf.nu/en/iaf-documents/?cat\_id=10*](https://iaf.nu/en/iaf-documents/?cat_id=10)

* **IAF ID 1:2020** IAF Informative Document for QMS and EMS Scopes of Accreditation
* **IAF ID 3:2011** Informative Document for Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations
* **IAF ID 4:2020** Market Surveillance Visits to Certified Organizations
* **IAF ID12:2015** Principles on Remote Assessment
* **IAF ID13:2017** IAF Medical Device Nomenclature (IAF MDN) Including Medical Device Risk Classifications
* **IAF ID14:2022** Guidance on the Determination of Audit Time for Integrated Audit of Multi-Site Management Systems

**» IAF GA Resolutions –** [*https://iaf.nu/en/iaf-documents/resolutions/*](https://iaf.nu/en/iaf-documents/resolutions/)

**APAC MRA requirements for an accreditation body (AB)**

APAC MRA-002 APAC Mutual Recognition Arrangement

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| **Schemes / Levels** | **ILAC MRA - Schemes** | | | | | | | | | | **IAF MLA - Schemes** | | | |
| **Level 1   Generic criteria for an AB** | ISO/IEC 17011 - Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies | | | | | | | | | | | | | |
| **Level 2  Accredited conformity assessment activities** | Testing | Calibration | | Medical | | Inspection | | Proficiency Testing Providers | Reference Material Producers | Biobanking | Certification - Management Systems | Certification - Persons | Certification - Products, Processes and Services | Validation and Verification |
| **Level 3   Accreditation Standard** | **ISO/IEC 17025:2017** | | | **ISO 15189:2012** | | **ISO/IEC 17020:2012** | | **ISO/IEC 17043:2010** | **ISO 17034:2016** | **ISO 20387:2018** | **ISO/IEC 17021-1:2015** | **ISO/IEC 17024:2012** | **ISO/IEC 17065:2012** | **ISO/IEC 17029:2019**  **ISO 14065:2013** |
| **Level 4 Scope specific criteria** | The WADA International Standard for Laboratories (ISL) | | ISO 15195:2018 | | ISO 22870:2016 | | Not Applicable | | | | ISO 50003:2014 / ISO 50003:2021 ISO/IEC 17021-2:2016  ISO/IEC 17021-3:2017  ISO/IEC TS 17021-6:2014  ISO/IEC TS 17021-9:2016  ISO/IEC TS 17021-10: ISO/IEC 27006:2015  ISO/TS 22003:2013  ISO/TS 22003:2013 FAMI-QS Rules ISO/TS 22003:2013 FSSC 22000 Scheme | Not Applicable | GLOBALG.A.P. Integrated Farm Assurance General Regulations | ISO 14065:2020  ISO 14064-3:2006  ISO 14064-3:2019  ISO 14066:2011 ICAO CORSIA Version 1 with ICAO CORSIA Environmental Technical Manual –Volume IV |
| **Level 5  Scope specific conformity assessment standards** | Accreditation scope | | | | | | | | | | ISO 9001:2015 QMS  ISO 14001:2015 EMS  ISO 13485:2016 MDQMS  ISO 22000:2018 FSMS  ISO 22301:2019 BCMS  ISO 37001:2016 ABMS  ISO 45001:2018 OHSMS  ISO 50001:2018 EnMS  ISO/IEC 27001:2013 ISMS  FAMI-QS Certification Scheme Code FSSC 22000 Certification Scheme Part 2 | IPC-PL-11-006 IPC Management System Auditors | GLOBALG.A.P. Integrated Farm Assurance Control Points and Compliance Criteria:  http://www.globalgap.org | ICAO CORSIA SARPs Annex 16 Volume IV |