FM 001 - Application from an Accreditation Body to Join the IAAC MLA

1. **This is an application for:**

Initial recognition for the IAAC MLA

Extension of the scope of the IAAC MLA

together with the next re-evaluation

separate from the next reevaluation

Date (month and year) when you prefer to have the peer evaluation\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Tick the scope of the MLA being applied for:**

Calibration Laboratory - ISO/IEC 17025 (Cal)

Laboratory medicine - ISO 15195 (Med Lab)

Testing Laboratory

ISO/IEC 17025 (Test)

International Standard for Laboratories (ISL) – WADA

ISO 15189 - Medical/Clinical Laboratories (Med)

Point-of-care testing - ISO 22870 (POCT)

Biobanking - ISO 20387 (Bio)

Proficiency Testing - ISO/IEC 17043 (PTP)

Reference Materials Producers - ISO 17034 (RMP)

Inspection - ISO/IEC 17020 (INSP)

Management Systems Certification - ISO/IEC 17021-1 (MS)

Quality Management Systems Certification – ISO 9001 (QMS)

Environmental Management Systems Certification - ISO 14001 (EMS)

Food Safety Management Systems Certification - ISO 22000 (FSMS)

Food Safety System Certification (FSSC 22000)

Information Security Management Systems Certification – ISO/IEC 27001 (ISMS)

Medical Devices Management Systems Certification Bodies – ISO 13485 (MDMS)

Energy Management systems - ISO 50001 (EnMS)

Occupational Health and Safety Management Systems - ISO 45001 (OH&SMS)

Anti-Bribery Management Systems - ISO 37001 (ABMS)

Product Certification - ISO/IEC 17065 (Product)

Global G.A.P - GLOBAL G.A.P. IFA Control Points and Compliance Criteria

Certification of persons - ISO/IEC 17024 (Persons)

International Personnel Certification Association – IPC-PL-11-006 (IPC)

Validation and Verification of Green House Gases - ISO 14065 (GHG)

Validation and Verification – ISO/IEC 17029 (V/V)

**3. Name and Address of Accreditation Body (Applicant):**

|  |  |
| --- | --- |
| **3a. Head Office street address:** | **3b. Head Office postal address:** |

**4. Do you have offices other than Head Office?**

If yes, inform below the addresses of all other offices or attach a list of them.

**5. Economy. (If the applicant conducts accreditation in more than one economy, list all of them and the number of accredited CABs):**

**6. If the applicant is a member of a region other than IAAC, please inform the name of the region, whether you are already recognized or are applying for recognition by that region for this scope.**

**7. Name and position of Applicant contact person:**

**8. Telephone (including international access):**

**9. E-mail address:**

**10. Legal status of Applicant (see ISO/IEC 17011 clause 4.1):**

**11. History of the Applicant (Foundation date, operational period, pertinent historical background).**

**12. Applicant’s relationship to government, if any:**

1. **Describe the relationship between the applicant organization and any related organizations in relation to safeguarding impartiality (see ISO/IEC 17011 section 4.4 and clause 5.3):**

**14. Describe the basis of the applicant’s authority for accreditation, whether derived through government or otherwise (see ISO/IEC 17011 clause 5.5)**

**15. In case the applicant is a signatory of ILAC, IAF or a Regional Group’s Arrangement, please identify the scope of that MLA, the date of signature, the date of the last evaluation, and the date of the last decision for granting or maintaining the Arrangement. Please indicate whether you wish IAAC to take the last evaluation report into account in the peer evaluation process (see MD 002 Annex 2).**

**16. Please answer the following questions for each scope of the MLA being applied for:**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Cal** | **Test** | **Med** | **PTP** | **RMP** | **Insp** | **Prod** | **Pers** |
| 1. How long has the accreditation program been in operation? |  |  |  |  |  |  |  |  |
| 1. Accreditation criteria used (include a reference to the relevant standard or guide and the year of issue) |  |  |  |  |  |  |  |  |
| 1. Number of Staff including management staff and assessment personnel. |  |  |  |  |  |  |  |  |
| 1. Number of accreditations granted in each field (attach a list of the names of the accredited bodies in each field or a link to the database on the internet, if any) |  |  |  |  |  |  |  |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **WADA** | **POCT** | **QMS** | **EMS** | **FSMS** | **FSSC 22000** | **ISMS** | **MDMS** | **EnMS** | **OH&SMS** | **ABMS** | **Global GAP** | **IPC** | **GHG** | **V/V** |
| 1. How long has the accreditation program been in operation? |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Accreditation criteria used (include a reference to the relevant standard or guide and the year of issue) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Number of Staff including management staff and assessment personnel. |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 1. Number of accreditations granted in each field (attach a list of the names of the accredited bodies in each field or a link to the database on the internet, if any) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**17. Please list all other operational field(s) of accreditation that the AB offers that are not part of this application or the AB’s current IAAC recognition. For each, include information of the criteria used with appropriate reference to the relevant standard or guide and year of issue, or a summary description of the normative document used.**

**18. Documentation to be submitted:**

Initial recognition for the IAAC MLA: Include in your application package one (1) copy via electronic means of each of the documents listed below.

Extension of the scope of the IAAC MLA: Submit this FM 001 application form. Once an evaluation team has been appointed, documents as indicated in the table below must be provided to the evaluation team in accordance with the IAAC procedures and the agreed upon schedule for the MLA scope extension evaluation.

| **Documentation** | **Required for extensions?** |
| --- | --- |
| The AB’s self-evaluation according to the IAF/ILAC A3; this self-evaluation. Note: this document shall not be protected, as the evaluation team will need to use it to prepare the evaluation report. | Yes |
| Form IAAC FM 003 providing a cross-reference table between each clause, sub-clause or specific requirement of ISO/IEC 17011, IAAC MD 002 section 2 and IAAC, ILAC and IAF mandatory documents and the documentation of the applicant. Note: this document shall not be protected, as the evaluation team will need to use it to prepare the document review report. | Yes, for the following parts of ISO/IEC 17011:  4.6, 6 and, 7 as applicable to the scope of extension |
| All documents referred to in FM 003. | Yes, for the following parts of ISO/IEC 17011:  4.6, 6 and 7 as applicable to the scope of extension |
| The AB’s quality manual | Yes |
| Master list of AB’s documents. | Yes |
| Documentary evidence of legal identity (see ISO/IEC 17011 clause 4.1). | No |
| All accreditation criteria and associated generally applicable criteria that the applicant publishes. (The accreditation criteria used shall normally be the latest version of the standard or guide applicable to the field of accreditation. In cases when IAAC, ILAC and/or IAF have agreed to a transition period for the implementation of a new version of a standard or guide, the applicant shall also include any policy and or procedure for the implementation of the new version.) | Yes, for the scope of extension |
| A copy of the directory or other listings providing the name and scope of accreditation of each accredited CAB, or reference to the website where this information may be found. | Yes |
| Any other documentation that describes the mechanics of operation of the accreditation system, including annual reports, questionnaires, newsletters, guidance documents, etc.; | No |
| Copies of the most recent internal audit and management review reports. | Yes, when they include the new scopes |
| Reports on any recent evaluations carried out by other relevant organizations, if applicable. | No |
| In case the applicant is a signatory of ILAC, IAF or a Regional Group Arrangement and wishes IAAC to take that recognition into account in the peer evaluation process (see MD 002 Annex 2), please provide the complete Final Report of the last evaluation or reevaluation, information on closure of all findings and the decision made by ILAC, IAF or the Regional Group. | Yes |
| Name of the AB’s peer evaluator qualified by IAAC for each scope. If not, include the FM 006 peer evaluator application for each scope. | Yes |
| For certification bodies, list of foreign critical locations of accredited CBs. | Yes |
| For laboratories and inspection bodies | |
| * summary listing of all proficiency testing activity over the past five years, in which accredited and applicant laboratories/inspection bodies have participated; | Yes |
| For laboratories |  |
| * the policy on the implementation and use of proficiency testing; | Yes |
| * operational procedures covering proficiency testing including criteria for statistical evaluation and corrective action procedures; | Yes |
| * the policy for metrological traceability; | Yes |
| * information about the available sources of metrological traceability and the calibration and measurementcapabilities (CMC) available from these sources (see ILAC P10 and ILAC P14); | Yes |
| * a list of recent international comparisons in which the economy’s national metrology institute (NMI) or designated institutes have been involved (e.g., BIPM or regional metrology organization) or, when applicable, reference to the NMI’s calibration and measurement capabilities as published on the BIPM website; | Yes, for extensions for testing and calibration |
| For calibration laboratories | |
| * the requirement document(s) for the estimation and reporting of measurement uncertainty and expression of the laboratory’s calibration and measurement capabilities (CMC) on it scope of accreditation (see ILAC P14). | Yes |
| For proficiency testing providers | |
| * when the accreditation body organizes non-commercial proficiency testing programs aimed at covering the needs of accredited laboratories, the document describing the AB's role in these programs and how the AB ensures its impartiality (see ILAC P13). | Yes |
| For Green House Gases Verification/Validation Bodies: | |
| * scoping of the program for verification/validation | Yes |
| * information on the use of specific schemes | Yes |

**19. Other information related to the integrity of accreditation activity (e.g. other activities of the applicant body, mutual recognition agreements, relationships with other bodies, subcontracting).**

**20. Please complete the Declaration on the following page.**

Please send your completed, signed and dated application, along with all requested documents to the IAAC MLA Secretary.

**Declaration**

As an Accreditation Body Member of IAAC, the Applicant, duly represented by the undersigned:

* Accepts the IAAC evaluation procedures for Accreditation Bodies defined in MD 002;
* Accepts the respective MLA requirements and agrees with the terms of the IAAC MLA;
* Confirms that the operations of the Applicant comply with ISO/IEC 17011:2017 or further versions thereof;
* Confirms that the accreditation criteria it uses are the most up to date version of the standard or guide applicable to the field of accreditation and that it is in line with any transition period approved by IAAC, ILAC and or/IAF for the implementation of IAAC MLA relevant normative document specified in PR 025;
* Submits the completed Application
* Agrees to supply all appropriate documentation requested by the lead evaluator and the evaluation team to carry out the initial evaluation and the agreed upon extension of MLA recognition.
* Agrees and understands that if appropriate documentation is not supplied to the lead evaluator and the evaluation team in a timely manner, the evaluation could be canceled and subject to further action by the IAAC MLA Group, as per MD 002;
* Applies to join the Multilateral Recognition Arrangement.

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Name and title of an authorized executive

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Date Signature