حكومة دبي
GOVERNMENT OF DUBAI

مركز الإمارات العالمي للاعتماد
Emirates International Accreditation Centre

مركز الامارات العالمي للاعتماد

Emirates International Accreditation Centre

المتطلبات العامة لإنشاء وتوسيع أنظمة الاعتماد

Establishing & Extending Accreditation Schemes

EIAC-RQ-GEN-004

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Revision history			
Issue no.	**Rev. No.**	**Details**	**Date**
1	0	First Issue as General Requirement	02-03-2021
1	01	Revised due to the incorporation of the new identity of the Dubai Government	05-07-2024
1	02	Revised to include the requirement for preparing the application and guidance documents for Healthcare Providers (point 3.5)	19-02-2025

Contents

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1 Objectives

This requirement details the EIAC activities relevant to schemes selection, development, adoption, extension and discontinuation, when necessary. It also gives details on how EIAC is documenting the rules and processes for its accreditation schemes referring to the relevant International Standards and/or other normative documents.

This requirement was established with reference to the EIAC internal procedure 'Establishing & Extending Accreditation Schemes'

2 Determining Suitability of Conformity Assessment Schemes for Accreditation Purposes

2.1 EIAC uses the general requirements for accreditation of conformity assessment bodies and healthcare providers set out in the relevant International Standards and/or other normative documents for the operation of conformity assessment bodies and healthcare providers, e.g. ISO/IEC 17000 series of standards, ISQua Guidelines, as accreditation criteria for its main accreditation programs:

- Accreditation of testing labs: ISO/IEC 17025.
- Accreditation of calibration labs: ISO/IEC 17025.
- Accreditation of sampling labs: ISO/IEC 17025.
- Accreditation of medical labs: ISO 15189.
- Accreditation of Inspection bodies: ISO/IEC 17020.
- Accreditation of proficiency testing providers ISO/IEC 17043.
- Accreditation of biobanking: ISO 20387.
- Accreditation of Management Systems Certification Bodies: ISO/IEC 17021-1.
- Accreditation of Product Certification Bodies: ISO/IEC 17065.
- Accreditation of Persons Certification Bodies: ISO/IEC 17024.
- Accreditation of Reference Materials producers ISO/IEC 17034.
- Accreditation of Validation and Verification Bodies ISO/IEC 17029.
- CABs-developed schemes (subject to EIAC review and acceptance for suitability and feasibility).

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- Healthcare providers' standard schemes as per ISQua Guidelines (subject to EIAC review and acceptance for suitability and feasibility).

2.2 Conformity assessment bodies may develop their own conformity assessment schemes or use existing normative documents for developing their schemes, such as for example ISO/IEC 17067 for product certification and ISO/TS 22003 and ISO 22000 for Food Safety Management System. Such schemes are acceptable by EIAC and considered suitable for the purpose of accreditation.

2.2.1 EIAC will determine the suitability of any conformity assessment scheme for accreditation purposes before using it, by verifying the scheme based on the following criteria:

- The scheme falls under any of the international standards mentioned in the previous point for the main accreditation program and doesn't contradict the existing international standard requirements
- The scheme contains sufficient information to enable the decision on conformity to be made in line with the corresponding ISO/IEC 17000x
- The scheme has taken into consideration applicable national legislation within its scope
- Whether other interested parties/ stakeholders were consulted in the preparation/review of the scheme.

EIAC may considers the regional reference publication EA-1/22 A: 2016 EA "Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Body Members" also as a guidance document for determining the suitability of the conformity assessment schemes.

2.2.2 If the conformity assessment scheme is considered not suitable for the purpose of accreditation, the CAB will be informed in writing at the application stage with the justified reasons

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3 Developing/ Extending of Accreditation Schemes

3.1 EIAC is developing or extending existing schemes in any of the following cases, as minimum:

- EIAC is requested directly by any of the interested parties such as CABs, regulators, consumers, etc. or other interested parties to develop or adopt a certain scheme,
- There is a need to develop or extend EIAC activities to new fields, reacting to certain market demand/regulations,
- Reacting to new global requirement,
- An internal decision by EIAC due to receiving several applications in particular field(s).
- An industry specific accreditation scheme exists but not suitable for accreditation purpose and there are new applications to EIAC within its scope.

3.2 The situation will be analyzed with a study of the existing resources, i.e. competence of staff & technical assessors in order to evaluate the suitability for launching the new scheme

3.3 The development or extension will be decided to take place if the following conditions were met:

- Mandatory by laws or regulations where the scheme deliver their objectives.
- Development/Extension is feasible; in other words
- The demands from applicant CABs or healthcare providers will recover the cost of establishing and running the new scheme after an accreditation cycle is passed.
- Technical expertise within the field are accessible (technical assessors, committee members & staff).

3.4 After deciding to launch the scheme based on its suitability, the present competence and resources will be analysed and the needs will be identified. Such needs include but not limited to:

- Required application and guidance documents for both the EIAC and the CABs or healthcare providers.
- Required human/ personnel resources, their qualifications and definition of the needed training.
- Required technical experts and assessors.
- Required accreditation decision Maker for new accreditation schemes

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3.5 The required application and guidance documents are prepared as per below:

- International, regional or national reference application/ guidance documents shall be used for the preparation/ adopting of EIAC application or guidance documents. These are downloaded from the websites of ARAC, ILAC, IAF, APAC, EA, IAAC or other internationally recognized regional accreditation bodies that are signatories to ILAC MRA/ IAF MLA.
- Additionally, documents from national accreditation bodies may be used provided that these ABs are signatories to the ILAC MRA/ IAF MLA.
- For healthcare providers, the recent ISQua Guidelines to be implemented.
- For healthcare providers, the latest ISQua Guidelines to be implemented and as per Annex A for the EIAC Accreditation Standard development process.

3.6 Makes available all needed resources for introducing the new activity.

3.7 With the help of identified technical experts, EIAC will document the rules and processes for its accreditation schemes referring to the relevant International Standards and/or other normative documents following its internal Procedure.

3.8 Views of interested parties will be taken by involving the EIAC Technical and Advisory Committee members and circulating the draft scheme documents to interested parties for comments according to EIAC internal Procedure.

3.9 If there was no regional or international guidance, application or normative documents available, EIAC will develop the needed documents using its technical and advisory committee members or experts possessing the necessary competence and with participation of appropriate interested parties, according to EIAC internal Procedure.

These documents shall not contradict or exclude any of the requirements included in the relevant international standards and/or other normative documents.

3.10 The implementation of the new documents will be subject to transition arrangements, which will be communicated by email to all interested parties and also published on EIAC website

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4 Discontinuing an Accreditation Scheme

4.1 Before EIAC decides to discontinue an accreditation scheme in part or in full, the views of interested parties will be sought by circulating the proposal for discontinuation with justification

4.2 The contractual duties with CABs accredited under the scheme, which is subject to discontinuation, will be identified and discussed with each CAB for alternatives.

4.3 The discontinuation of the scheme will be subject to transition arrangements, which will be communicated by email to all interested parties and also published on EIAC website.

4.4 External communication regarding the discontinuation will all be through the website and regular EIAC circulars.

4.5 All information regarding the discontinued scheme(s) will be published by EIAC on its website and maintained for the duration of the transitional arrangements.

5 References & Related Documents

5.1 Document Control Procedure: EIAC-PR-001.

5.2 ISO/IEC 17011: Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies.

5.3 EA-1/22 A-AB: EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Body Members.

5.4 ISQua Guidelines and Principles for the Development of Health and Social Care Standards.

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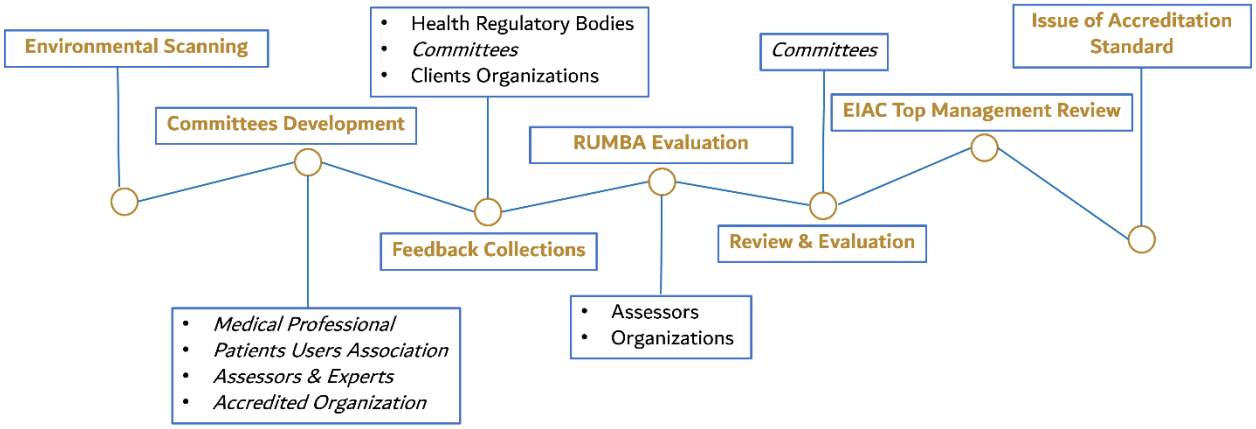
Annex A

EIAC Accreditation Standard for Healthcare Providers

Development Process



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