



Abu Dhabi Specification

معايير أبوظبي الفنية



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Quality Control in Proficiency testing (PT)
providers.

ضبط الجودة للجهات المزودة لبرامج الجدارة



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Amendment Page

To ensure that each controlled copy of this ADS contains a complete record of amendments, the Amendment Page is updated and issued with each set of revised/new pages of the document. This ADS is a live document which can be amended when necessary. QCC conducts what it takes to make this document available to all and collects all observations on it. QCC prepares for a meeting of the Quality Control Laboratories Working Group to discuss the comments made on the document in order to review and amend it.

<u>Amendment</u>			<u>Discard</u>		<u>Insert</u>	
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About the Abu Dhabi Quality and Conformity Council

The Abu Dhabi Quality and Conformity Council (QCC) was established by law No. 3 of 2009, issued by His Highness Sheikh Khalifa Bin Zayed Al Nahyan, President of the UAE.

QCC is responsible for the development of Abu Dhabi Emirate's Quality Infrastructure, which enables industry and regulators to ensure that products, systems and personnel can be tested and certified to UAE and International Standards.

Products certified by QCC receive the Abu Dhabi Trustmark. The Trustmark is designed to communicate that a product or system conforms to various safety and performance standards that are set by Abu Dhabi regulators.

Foreword

The QCC Working Group for Quality Control in Medical laboratories was formally established in July 2013 with a view to confirming a technical documents for

- Quality Control in testing and calibration laboratories.
- Quality Control in Reference Laboratories.
- Quality Control for Proficiency Testing (Pt) Providers.

That shall improve the quality of services provided by the laboratories in order to preserve public health and safety. These document is prepared in accordance with best international practices and technical documents issued in this regard and specially to meet the needs of the relevant in the Emirate of Abu Dhabi.

1. Scope

This Abu Dhabi Specification (ADS) defines the basic technical requirements for quality control .2 for Proficiency Testing (PT) Providers.

2. Acknowledgements: QCC would like to thank the members of the Working Group listed below. The membership of the QCC Working Group is as follows:

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17	Eng.Jamal Al Hadidi	Abu Dhabi Municipality (ADM)
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19	Dr. Waill AlOmari (Coordinator)	Abu Dhabi Quality and Conformity Council- QCC



QUALITY CONTROL IN PROFICIENCY TESTING (PT) PROVIDERS

3. Terms and definitions

The below terms and definitions - unless indicated otherwise - shall be used for applying these technical standards.

QCC: Abu Dhabi Quality and Conformity Council

Competent Authority: Abu Dhabi Quality and Conformity Council

Accredited Authority: Any authority that provides proficiency testing, accredited by an International Laboratory Accreditation Cooperation (ILAC) accredited organization and is a member of the ILAC Mutual Recognition Arrangement (MRA) in the field of testing, calibration or medical laboratories.

Reference Materials (RM): A material sufficiently stable and homogeneous for a specific set of properties, and is made for measurement or testing of metrological properties.

Reference Standard: A standard used as a calibration base for similar substances. Such standard shall be a series of primary reference standards and secondary reference standards.

National Metrology Institutes: Institutes that develop and maintain national standards based on the definitions of quantities and elements of units as per International System of Units (SI) or other internationally recognized standards. These are the base of series of measurements in a state.

Designated institutes: National Metrology Institutes that have been selected and designated on the basis that they have achieved the highest reference standard(s) in a certain field in a certain state.

4. Responsibility:

Abu Dhabi Quality and Conformity Council shall be the authority responsible for application across the Emirate of Abu Dhabi.

5. Qualification requirements of proficiency testing providers:

5-1 All proficiency testing providers shall fulfil the international standard ISO/IEC 17043

5-2 Calculation of results of participation in proficiency testing.

Proficiency testing providers shall calculate and analyse the results of participation in proficiency testing based on the international standard ISO 13528.

5-3 Measurement units

Based on the Emirates Authority for Standardization and Metrology (ESMA) decision No. (5/1) dated 18/6/2009 regarding the executive regulations for



standard measurements in the state (as amended), results of tests and or calibration shall be in standard measurement units.

5-4 Preservation of results

Proficiency testing providers shall safely preserve the participation results and relevant documents for a minimum period of 5 years.

5-5 Supervision of the performance of proficiency testing providers

- 1- Accredited proficiency testing providers shall provide the QCC with evidence of accreditation.
- 2- Non-accredited proficiency testing providers must prove their efficiency and qualification to competent authorities by meeting the requirements specified.

5-6 Data

Proficiency testing providers shall - upon request - provide the QCC with documents and data to prove efficiency and qualification.

5-7 Subcontracting

- In case a proficiency testing provider conducts works that affect proficiency testing, it shall have to contract an entity that's accredited, or otherwise properly validate its efficiency and qualification. A proficiency testing provider shall be fully responsible for the efficiency and qualification of its contracted non-accredited entities.
- Other entities may be sub-employed in fields specified by international standard ISO 17043.

6. Final provisions

- The QCC and competent authorities shall not be responsible for any errors by proficiency testing providers.
- Cases disputed in terms of interpretation or application, or not provided for herein, shall be referred to the competent technical committee in the Emirate of Abu Dhabi to make appropriate decisions based on international practices and for the best public interest.
- In case application reveals defects or deficiency in this document that might affect public health, the QCC may take appropriate action to remedy such defects for the best public interest.
- These technical standards shall be published in the official newspaper and shall go into effect one year from publishing.



References

- ISO Guide 34 General requirements for the competence of reference material producers
- ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
- ISO Guide 35 Reference material—General and statistical principles for certification
- ISO 15189 Medical laboratories — Particular requirements for quality and competence
- ISO/IEC 17043 Conformity assessment — General requirements for proficiency testing
- OIML V1 International vocabulary of terms in legal metrology (VIML) وترجمته الموافق عليها من قبل المنظمة العربية للتنمية الصناعية والتعدي
- ISO 13528 Statistical methods for use in proficiency testing by interlaboratory comparisons

- قرار مجلس إدارة هيئة الإمارات للمواصفات والمقاييس رقم (1/5) تاريخ 2009/6/18 بشأن اللائحة التنفيذية لتنظيم أعمال المقاييس القانونية في الدولة، صادر بموجب المادة (16) من قرار مجلس الوزراء رقم (31) لسنة (2006) بشأن النظام الوطني للقياس وتعديلاته.