مجلس أبـــوظبـي للـجـودة والـمـطابـــقـة
ABU DHABI QUALITY & CONFORMITY COUNCIL

Abu Dhabi Specification

معايير أبوظبي الفنية

ADS 10-2014

م أ ف 10- 2014

Quality Control in Reference laboratories

ضبط الجودة في المختبرات المرجعية

هاتف ٦٦٦٦ ٤٠٦ ٢ ٩٧١+ | فاكس ٦٦٧٧ ٤٠٦ ٢ ٩٧١+ | ص.ب. ٨٥٣ أبوظبي، الإمارات العربية المتحدة
Tel +971 2 406 6666 | Fax +971 2 406 6677 | P.O. Box 853 Abu Dhabi, United Arab Emirates | www.qcc.abudhabi.ae

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.

Amendment			Discard		Insert	
No	Date	*Sections Changed	Page(s)	Issue no	Page(s)	Issue no
		Document launched	-	-	9	1

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 in reference laboratories. It includes all reference laboratories in Abu Dhabi Emirate for medical and non-medical like (soil, food, environment, chemistry, water,…..) .2

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:

	Name	Entity
1	Dr. Laila Abdel Wareth (chair)	*Abu* Dhabi Health Services Company. (SEHA)
2	Dr.Eman Alzaabi	*Abu* Dhabi Health Services Company (SEHA)
3	Dr. Issam Ateig	*Abu* Dhabi Health Services Company (SEHA)
4	Dr. Fatima ALQahwagi	Health Authority - Abu Dhabi (HAAD)
5	Hala Abdulrahman	Health Authority - Abu Dhabi (HAAD)
6	Eng. Mekhled Alzaben	Emirates Authority For standardization and Metrology (ESMA)
7	Eng. Oraib ALDmour	Emirates Authority For standardization and Metrology (ESMA)
8	*Dr. Reem El Bahtimi*	*National Reference Laboratory* (NRL)
9	Dr. Riyad Shareef	Central Testing Laboratories (CTL)- QCC
10	Eng. Waleed Rusheidat	Intertek Company
11	Dr. Rehab Al Ameri	Abu Dhabi Quality and Conformity Council- QCC
12	Eng. Osama Melhem	Abu Dhabi Quality and Conformity Council- QCC
13	Eng. Husain Al Bazzi	Abu Dhabi Quality and Conformity Council- QCC
14	Eng.Hasan Siraji	Abu Dhabi General Services (Musanada)
15	Salama AlDhahiri	Abu Dhabi Quality and Conformity Council- QCC-CTL
16	Maha AlMarzouqi	Abu Dhabi Quality and Conformity Council- QCC-CTL
17	Eng.Jamal Al Hadidi	Abu Dhabi Municipality (ADM)
18	Anoop Mony	Alhoty Laboratories.
19	Dr. Waill AlOmari (Coordinator)	Abu Dhabi Quality and Conformity Council- QCC

QUALITY CONTROL IN REFERENCE LABORATORIES

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

Reference Laboratory: A laboratory designated by the QCC to perform certain tests using reference measurement procedures.

Note: the term (referral lab) is used in the field of medical labs to denote labs sub-employed by other medical labs to perform certain tests. This document does not apply to such labs.

Performing a reference measurement: a fully verified procedure that's proven to give measurement results with an uncertainty value that is appropriate for potential application.

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.

Identification Number: Unique number specified by the QCC for a reference laboratory.

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. Mandatory Requirements:

1- A reference lab shall have all legal permits necessary for practicing in the Emirate.
2- Materials necessary for work shall always be available in a reference lab.
3- A reference lab shall be accredited by an authority approved by the QCC for the required field. The QCC may appoint a non-accredited lab, provided the lab submits evidence of efficiency and qualification in the required field.
4- A reference lab shall meet all requirements stated in the international standard ISO/IEC 17025, requirements stated below under A & B and stated in items 4 & 5 of international standard ISO 15195 relevant to reference medical labs. These requirements apply to all reference labs, regardless of accreditation:

A- Management system requirements as per item 4 of international standard ISO 15195, includes:
   1- Organization and management : as per item 4.1
   2- Quality control system : as per item 4.2
   3- Workers in the laboratory : as per item 4.3
   4- Measurement records and documents : as per item 4.4
   5- Contracting : as per item 4.5

B- Technical requirements, as per item 5, includes:
   1- Working areas and climate conditions : as per item 5.1
   2- Accepting and handing samples : as per item 5.2
   3- Equipment and devices : as per item 5.3
   4- Reference materials : as per item 5.4
   5- Reference measurement procedures : as per item 5.5
   6- Metrological sequence and measurement uncertainty : as per item 5.6
   7- Quality assurance : as per item 5.7
   8- Reporting results : as per item 5.8

5- A reference lab shall meet all other requirements that are specific to their operational jurisdiction; especially those related to data protection, materials transferring and handling as well as waste disposal.

6- A reference lab shall meet any other requirements the QCC might approve in the future.

7- The QCC may appoint foreign reference labs in certain fields if no domestic reference labs are able to meet the requirements of this document.

6. Tasks

6-1 Mandatory tasks:

6-1-1 Providing reference measurement procedures that are up to date and sufficient to meet the requirements expected by the Emirate in the field of appointment.

6-1-2 Assessment and validation of measurement procedures commonly used in other peer labs, as well as the reference materials provided by other companies for the scope of work of reference labs.

6-1-3 Advising legislative and supervisor authorities on the uncertainty tolerance in tests whose results affect the community health and safety.

6-1-4 Conducting tests that require high precision, or support other labs in case inconsistent results are obtained.

6-1-5 Ongoing participation in proficiency testing and continuous benchmarking with other reference labs, foreign or domestic.

6-1-6 All services and operations provided by a reference lab shall be based on best international standards and practices.

6-1-7 A reference lab - either independently or in cooperation with competent authorities - shall periodically take samples of its work, analyse them and submit reports or early warnings to relevant authorities; especially in cases suspected to affect the community health or safety. This shall enable such authorities to take timely corrective and preventive actions.

6-1-8 A reference lab shall promptly notify the QCC about any changes that might negatively affect its efficiency and qualification in its reference lab field.

6-2 Optional tasks:

6-2-1 Providing or manufacturing reference materials, as per the relevant international standards, to meet the needs of labs operating in the Emirate.

6-2-2 Conducting efficiency and qualification tests for labs operating in the Emirate.

6-2-3 Holding workshops and training sessions for lab workers to transfer knowledge, apply new work procedures, unify or update current work procedures.

6-2-4 A reference lab shall pioneer research and generate publications locally, regionally and internationally.

7. For certificates issued by labs in their accredited fields, only those agreed by the QCC can use the label “reference lab” - coupled with the lab identification number - as specified by the QCC.

8. Methodology of validation of reference lab efficiency and qualification

The efficiency and qualification of a reference lab is validated by accreditation certificates, extent of commitment to assigned tasks and the results of proficiency testing with other international reference labs.

9. Awarding, expansion of scope, suspension, withdrawal and termination of reference laboratories accreditation:

9-1 Awarding of accreditation:

- Labs wishing to be accredited by the QCC as reference labs in a certain field shall submit an application to the QCC supported with all required documents.
- In case a lab meets all mandatory requirements, the QCC shall issue an accreditation decision for a certain field.
- A lab’s application that goes 6 months without meeting mandatory requirements shall be cancelled.
- The QCC shall specify an identification number for the reference lab.

9-2 Expansion of accreditation scope:

A reference lab that wishes to expand its fields of accreditation must submit a written application to the QCC, which will be processed as a new application by the QCC.

9-3 Suspension of accreditation:

A reference lab accreditation may be suspended totally, or in part, in one of the following cases:

1- Major case of inconsistency in assessment conducted by an entity approved by the QCC.
2- Inability to resolve inconsistency issues within the specified period.
3- Not providing the QCC with documents requested for assessment within the specified period.

9-4 Withdrawal of accreditation:

A reference lab has the right to request withdrawal of their accreditation - needless of justification - provided the QCC is notified at least 6 months before the withdrawal date.

9-5 Termination of accreditation:

A reference lab accreditation may be terminated in one of the following cases:

1- Reference lab can no longer prove its capability as the best national lab in its accreditation field.
2- Inability to meet the mandatory requirements of this document.
3- Inability to resolve inconsistency issues within the specified period.
4- Use of the “reference lab” label and identification number for tests irrelevant to the accreditation field.
5- Recurring cases of inconsistency.
6- In case accreditation was totally suspended, and the lab failed to take corrective action during the suspension period.

10. 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

- ISO17025:2005 General requirements for the competence of testing and calibration laboratories
- ISO 15195:2003 Laboratory medicine –– Requirements for reference measurement laboratories
- ISO Guide 34 General requirements for the competence of reference material producers
- ISO/IEC 17043 Conformity assessment –General requirements for proficiency testing