

Regulation No. (2) of 2010
Regulating the
Work of Conformity Assessment Entities in the Emirate of Dubai¹

We, Hamdan bin Mohammed bin Rashid Al Maktoum, Crown Prince of Dubai, Chairman of the Executive Council,

After perusal of:

Law No. (3) of 2003 Establishing the Executive Council of the Emirate of Dubai;

Law No. (35) of 2009 Concerning Management of the Public Funds of the Government of Dubai;

Local Order No. (52) of 1990 Concerning the Requirements for Licensing Laboratories Operating in the Emirate of Dubai; and

The Memorandum of Understanding concluded between the Emirates Authority for Standardization and Metrology and the Dubai Municipality on 16 May 2006; and

To ensure quality and reliability of conformity assessment activities in the Emirate of Dubai,

Do hereby issue this Regulation.

Article (1)

This Regulation will be cited as "Regulation No. (2) of 2010 Regulating the Work of Conformity Assessment Entities in the Emirate of Dubai".

Article (2)

The following words and expressions, wherever mentioned in this Regulation, will have the meaning indicated opposite each of them unless the context implies otherwise:

Emirate: The Emirate of Dubai.

DM: The Dubai Municipality.

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¹Every effort has been made to produce an accurate and complete English version of this legislation. However, for the purpose of its interpretation and application, reference must be made to the original Arabic text. In case of conflict, the Arabic text will prevail.

Competent Department:	The Accreditation Department of the DM.
Licensing Authority:	Any of the entities legally authorised to issue Commercial Licences to Conformity Assessment Entities.
Commercial Licence:	The licence issued by a Licensing Authority authorising a Conformity Assessment Entity to conduct commercial activity in the Emirate.
Conformity Assessment Entity:	A public or private legal person that provides testing, inspection, or calibration services; or that grants conformity certificates for products, systems, or persons in accordance with international requirements and standards.
Activity Permit:	A document issued by the Competent Department authorising a Conformity Assessment Entity to conduct its activity in the Emirate, upon verifying that the conditions and requirements adopted by the Competent Department are met.
Registration:	Registering a Conformity Assessment Entity in a special register maintained by the Competent Department, upon verifying that this entity meets the requirements and conditions prescribed by this Regulation.
Accreditation:	Recognition by the Competent Department, upon verifying that a Conformity Assessment Entity meets the prescribed requirements and conditions, that this entity is qualified for and capable of providing its services in accordance with the adopted international standard specifications.
Accreditation Certificate:	A document issued by the Competent Department recognising that a Conformity Assessment Entity is qualified for and capable of providing a service specified in that certificate in accordance with the approved standard specifications.

Article (3)

The DM is the competent official entity having the exclusive authority to register and accredit Conformity Assessment Entities. For this purpose, the Competent Department will have the powers to:

1. issue Activity Permits to Conformity Assessment Entities and register these entities;

2. approve the services provided by Conformity Assessment Entities;
3. oversee the activities of Conformity Assessment Entities and monitor their compliance with this Regulation; with the resolutions and bylaws issued in pursuance hereof; and with the relevant adopted standards;
4. hold the conferences, training courses, and workshops related to its work; and conduct proficiency tests for Conformity Assessment Entities; and
5. create a database of the names and activities of the Conformity Assessment Entities registered with, and accredited by, the Competent Department.

Article (4)

- a. No Person may conduct any of the activities of Conformity Assessment Entities whatsoever, without first obtaining the relevant licence from the Licensing Authority and an Activity Permit from the Competent Department. This does not apply to medical laboratories.
- b. No Conformity Assessment Entity may conduct any activity other than the activity stated in its Activity Permit without first obtaining the relevant approval from the Competent Department.

Article (5)

A Conformity Assessment Entity will be authorised to conduct its activity in the Emirate in accordance with the following procedures:

1. The applicant wishing to operate the Conformity Assessment Entity will submit an application for a Commercial Licence to the competent Licensing Authority in the Emirate, in accordance with the relevant legislation and procedures adopted by that authority.
2. The Licensing Authority will refer the application to the Competent Department to consider its technical aspects and verify that it meets the conditions and requirements adopted in this respect. The implementing bylaw of this Regulation will determine the required documents, data, and information.
3. If the application meets the prescribed conditions and requirements, the Competent Department will issue a no-objection certificate for conducting the relevant activity and will send the same to the Licensing Authority to complete the Commercial Licence issuance procedures.
4. The Conformity Assessment Entity must meet all operational requirements no later than six (6) months from the date on which its Commercial Licence is issued.
5. The Conformity Assessment Entity may not conduct its activity without first meeting all the operational requirements adopted by the Competent Department and obtaining the Activity Permit.

6. The Conformity Assessment Entity must, within the six-month time limit, submit to the Competent Department an application for an Activity Permit, failing which, its Commercial Licence will be revoked and it will be subject to the penalties stipulated in this Regulation.
7. The Competent Department will conduct an on-site inspection and audit of the Conformity Assessment Entity. Based on the findings of this audit, the Competent Department may take any of the following actions:
 - a. where all operational requirements are satisfied and all the deficiencies identified by the Competent Department are addressed by the Conformity Assessment Entity, the Activity Permit will be granted to the entity; or
 - b. where any operational requirements are not satisfied or any deficiencies are not addressed within the prescribed time limit, the Activity Permit will not be granted to the Conformity Assessment Entity; and the Licensing Authority will be notified to revoke the Commercial Licence issued to that entity.
8. After it obtains an Activity Permit, the Conformity Assessment Entity will be registered in the approved register maintained by the Competent Department, which records all essential information, including the name and address of the entity, name of its owner, type of the activities it conducts, and services it provides.

Article (6)

An Activity Permit will be valid for a period of one (1) year. The Activity Permit may be renewed for the same period upon the application of the Conformity Assessment Entity. The renewal application must be submitted at least fifteen (15) days prior to the Activity Permit expiry date.

Article (7)

A Conformity Assessment Entity must, during the first year after obtaining the Activity Permit, submit an application for Accreditation as follows:

1. For entities operating in the fields of health, safety, and environmental protection, Accreditation will be mandatory. These entities may not provide services related to such fields unless they obtain Accreditation Certificates. The Competent Department will issue a list of the tests that require mandatory Accreditation.
2. For Conformity Assessment Entities which do not operate in fields related to health, safety, or environmental protection, Accreditation will be mandatory for at least ten percent (10%) of the total tests or services provided by the entity. The number of accredited tests or services may not be less than one (1).
3. Except for the tests and services referred to in paragraphs (1) and (2) of this Article, Accreditation for Conformity Assessment Entities will be optional.

Article (8)

A Conformity Assessment Entity must obtain Accreditation in the mandatory fields and tests referred to in Article (7) of this Regulation within a period not exceeding two (2) years from the date of obtaining its Activity Permit, failing which that permit will be revoked, the entity will be deregistered, and the Licensing Authority will be notified to revoke the Commercial Licence issued to it.

The Competent Department may extend the two-year period referred to in this Article for an additional period not exceeding six (6) months if the Conformity Assessment Entity provides valid technical reasons.

Article (9)

Notwithstanding the provisions of Article (4) of this Regulation, the Competent Department will, in coordination with the competent Government Entities, accredit medical laboratories in accordance with the relevant procedures and requirements adopted by it.

Article (10)

A Conformity Assessment Entity will be accredited pursuant to an Accreditation Certificate issued by the Competent Department for a term of three (3) years, renewable once or several times for the same period. This certificate authorises the accredited entity to use the Accreditation symbol consisting of the logo of the Competent Department and the Accreditation Certificate number.

The implementing bylaw of this Regulation will determine the requirements, conditions, and procedures for obtaining and renewing the Accreditation Certificate; cases warranting suspension and revocation of the Accreditation Certificate; and use of the Accreditation symbol.

Article (11)

A Conformity Assessment Entity may add other activities to those included in its Activity Permit or Accreditation Certificate. The added activities will be subject to the applicable conditions and requirements adopted by the Competent Department.

Article (12)

A registered or accredited Conformity Assessment Entity must:

1. comply with the conditions and requirements for issuance of the Activity Permit and the Accreditation Certificate granted to it, in accordance with the international, regional, and national standard specifications; and abide by the Accreditation scope in the fields in which it is authorised to operate;
2. notify the Competent Department of any changes to its activities, work regulations handbook, or operational processes;

3. participate in the proficiency testing programmes organised by the Competent Department or by the entities recognised by the Competent Department; and
4. provide all necessary support to the employees of the Competent Department conducting audit and assessment of its work and documents and evaluating its procedures.

Article (13)

The activities of registered Conformity Assessment Entities will be subject to audit and assessment; and their Accreditation will be re-assessed from time to time. The Competent Department may take the following action against a Conformity Assessment Entity which fails to comply with certain Accreditation requirements based on the findings of the audit and assessment:

1. suspension of work under the Accreditation granted to the Conformity Assessment Entity and banning it from providing services in the field in which Accreditation is suspended, until the entity takes the required corrective measures within the time limit prescribed by the Competent Department; or
2. revocation of the Accreditation Certificate of the Conformity Assessment Entity, where the entity fails to take the required corrective measures within the time limit prescribed by the Competent Department.

The implementing bylaw of this Regulation will determine the procedures for post-Accreditation follow-up of Conformity Assessment Entities, audit and assessment of their activities, and re-assessment of their performance.

Article (14)

In return for issuing the permits and certificates, and providing other services, under this Regulation and the resolutions issued in pursuance hereof, the DM will charge the fees set out in Schedule (1) attached hereto and approved by Us.

Article (15)

Without prejudice to any stricter penalty stipulated in any other regulation, a person who commits a violation of any of the provisions of this Regulation and its implementing bylaw will be punished by the fine prescribed for that violation in Schedule (2) attached hereto and approved by Us.

Upon repetition of any of the violations set forth in the above-mentioned schedule within one (1) year from the date of the previous violation, the amount of the fine will be doubled. A fine must not exceed one hundred thousand Dirhams (AED 100,000.00).

In addition to the penalty of a fine, the Competent Department may, in coordination with the concerned entities, take one or more of the following measures against a violating entity:

1. temporary suspension of the Activity Permit until the relevant requirements are fulfilled;
2. temporary suspension of the Accreditation Certificate;
3. revocation of the Activity Permit and the Accreditation Certificate, and deregistration of the violating entity; and/or
4. revocation of the Commercial Licence.

Article (16)

The employees of the Competent Department nominated by a resolution of the Director General of the DM will have the capacity of law enforcement officers to record the acts committed in breach of the provisions of this Regulation, its implementing bylaw, and the resolutions issued in pursuance hereof.

Article (17)

The DM will not be liable to third parties for any damage they may suffer as a result of a registered or accredited Conformity Assessment Entity conducting its activities or providing its services. The concerned entity will be solely liable to remedy such damage.

Article (18)

The DM may seek assistance from local Government departments and public authorities and corporations in the Emirate, including police personnel. Upon request, these entities must provide prompt support to the DM.

Article (19)

The fees and fines collected pursuant to this Regulation will be paid to the Public Treasury of the Emirate.

Article (20)

A Conformity Assessment Entity may submit a written appeal to the Director General of the DM against any of the decisions or measures taken against it by the Competent Department within thirty (30) days of being notified of the contested decision or measure.

Submitted appeals will be considered by a committee formed pursuant to a resolution of the Director General of the DM for this purpose. The decisions issued by the committee in respect of appeals will be final.

Article (21)

All Conformity Assessment Entities operating in the Emirate by the effective date of this Regulation must comply with the provisions of this Regulation within one (1) year from the date on which it comes into force.

Article (22)

The Director General of the DM will issue the bylaws and resolutions required for the implementation of this Regulation.

Article (23)

Any provision in any other local legislation will be repealed to the extent that it contradicts the provisions of this Regulation.

Article (24)

This Regulation will be published in the Official Gazette and will come into force on the day on which it is published.

Hamdan bin Mohammed bin Rashid Al Maktoum

Crown Prince of Dubai

Chairman of the Executive Council

Issued in Dubai on 15 July 2010

Corresponding to 3 Shaban 1431 A.H.

Schedule (1)

Fees for Services Provided by the Competent Department

SN	Description	Fee (in Dirhams)
1.	No-objection Certificate	500.00
2.	Activity Permit	4,000.00
3.	Activity Permit Renewal	500.00
4.	Application for Accreditation	500.00
5.	Review of Accreditation Documents	3,500.00
6.	Initial Assessment	2,500.00
7.	Accreditation Assessment	AED 6,500.00 per day per assessor
8.	Issuing an Accreditation Certificate and approving an Accreditation field	1,200.00
9.	Using the Accreditation symbol	5,000.00
10.	Training	AED 100.00 per day per trainee
11.	Proficiency Testing Programme	Fee is calculated based on the actual cost of the programme. The fee must not be less than AED 500.00 or more than AED 2,000.00.
12.	Reinstatement of a temporarily suspended Accreditation	1,200.00

*An additional fee of one hundred Dirhams (AED 100.00) will be charged for each service provided by the Competent Department to a Conformity Assessment Entity existing outside of the Emirate.

Schedule (2)
Violations and Fines

SN	Violation	Fine (in Dirhams)
1.	Conducting the Conformity Assessment Entity activity without an Activity Permit	30,000.00
2.	Conducting an activity that is not stated in the Activity Permit	10,000.00
3.	Failure by a Conformity Assessment Entity to apply for an Activity Permit within the prescribed time limit	10,000.00
4.	Failure by a Conformity Assessment Entity to apply for Accreditation of activities where the Accreditation is mandatory	30,000.00
5.	Failure by a Conformity Assessment Entity to participate in any of the proficiency testing programmes prescribed for the activities it is accredited to conduct	3,000.00
6.	Failure by a Conformity Assessment Entity to participate in any of the proficiency testing programmes prescribed for the activities it is not accredited to conduct	1,000.00
7.	Non-compliance with the terms and requirements of the Activity Permit or Accreditation Certificate	15,000.00
8.	Failure to notify the Competent Department of any change to the Conformity Assessment Entity's activities, or to the work regulations or operational processes adopted by it	5,000.00
9.	Obstructing the work of the Competent Department's inspectors	5,000.00