Accreditation Conditions for Laboratories, Certification Bodies, and Inspection Bodies

Purpose
This document describes the conditions, which have to be fulfilled by accredited CABs including CABs applying for accreditation.

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0. Introduction

Emirates National Accreditations (ENAS) is the authorized body in UAE to accredit conformity assessment bodies (CABs) including calibration and testing laboratories, certification bodies, and inspection bodies. This document gives an overview of the conditions, which an accredited CAB must fulfill. Documents referred to are listed at the end of this document.

Accreditation will be declined to all CABs, which are unable to document that they comply with the accreditation requirements. The accreditation does not replace any other necessary approval. Within the application process ENAS does not consider whether permissions etc. are necessary to perform the work. It is the CAB's own responsibility to make sure that all other necessary permissions are obtained. If permission is necessary, we recommend that these are obtained or clarified before an application for accreditation is sent, (except if the accreditation is a condition for permission).

Further information regarding the accreditation scheme may be found on ESMA’s Website:

[www.esma.gov.ae](http://www.esma.gov.ae)

1. Compliance with requirements.

Accredited CABs shall at all times comply with the requirements for accreditation. The CABs shall adjust to new requirements or alterations in existing requirements within the time limits determined by ENAS. As a supplement to the requirements described in this document, the requirements are specified in the documents listed below:

General requirements:

- ISO/IEC 17025 Conformity assessment – General requirements for the competence of calibration and testing laboratories.
- ISO/IEC 17020 Conformity assessment – General requirements for operation of inspection bodies
- ISO/IEC 17021 Conformity assessment – General requirements for bodies providing audit & certification of management systems.
- ISO IEC 17065 Conformity assessment – General requirements for bodies certifying products, processes & services.
- ISO/IEC 17024 Conformity assessment – General requirements for bodies operation certification of persons
- ENAS Doc. ACG 02 Guidance on the use of ENAS Accredited Symbol
Specific requirements for testing CABs

ACG 04 Requirements for calibration and control of weighing machines for accredited laboratories
ACG 18 Requirements for calibration and control of thermometers for accredited laboratories
ACG 14 Requirement on Method Validation
ACG 08 Requirement on Participation in Proficiency Testing
ACG 12 Requirement on Assuring the Quality of Testing Procedures
ACG 11 Requirement on Traceability of Measurement.

For labs and inspection bodies, ILAC (International Cooperation for Laboratory Accreditation) have prepared guidelines which thoroughly mention the requirements above, where found appropriate. However, for certification bodies guidance documents are provided by IAF.

Accredited CABs must either follow the guidelines set out by ENAS, or otherwise as recommended by ENAS.

2. Application and the application process

2.1 Application.

For Laboratories:
The premises of the lab shall be legally registered and shall meet the local authorities' criteria for registration. It can be applied for accreditation for sampling, testing and calibration in permanent premises and on site, and for interpretation/evaluation of results. However, sampling and result interpretation are mandatory scopes of accreditation for Environmental and geotechnical investigation labs. ENAS at the moment does not allow flexible or multisite accreditation for labs. When applying for accreditation, it is required that the organization (applicant) sends a complete application form with the necessary enclosures, before the handling of the application can be started. ENAS shall have an updated copy of the Quality-manual of the laboratory, appendixes, procedures and also descriptions of relevant education and work experience (CV) and job descriptions for key personnel. If the laboratory is applying for interpretation and evaluation of the results of testing, a description of this shall be enclosed the application, together with the documentation (e.g. regulations) which is the basis of the interpretation and the evaluation. When the handling of the application is finished, all documentation received will be obliterated. The extent of the application shall be described in an own appendix. The laboratory shall for every testing-parameter assign what measure range they want to
issue accredited testing- and/or calibration results in. Regarding the qualitative testing-parameters, the lowest detection-limit shall be given. Once awarded accreditation for a certain scope, the laboratory shall display its scope in legible size, in a place where it can be seen by the customer. If the laboratory does not get sufficient or no samples to maintain competence, the laboratory needs to prove to the assessors through evidences that it has maintained competence in those particular tests.

For Certification bodies and Inspection Bodies:
The premises of the inspection body and certification body shall be legally registered and shall meet the local authorities' criteria for registration. By applying for accreditation the CAB have to fill in ENAS's application form.

Applicants for accreditation or accredited CABs shall inform ENAS if they are applying for accreditation within the same area, by any other accreditation body, or if their application has been approved or declined by such body. For inspections and certifications multi-site accreditation is allowed especially if decisions are made at one specific office. Inspection bodies shall have available a valid professional indemnity insurance. The certificate will be issued to the address mentioned in the application. The scope will identify locations of issuing certificates.

If an applicant for accreditation started to apply or got its application rejected by any other body as described above, ENAS can request for the reason for this and if necessary request for the relevant assessment report or other relevant information.

If the applicant does not wish to obey these requests, ENAS shall immediately after an accreditation has been approved inform the bodies, (or have refused the application) regarding the decision. This is done to give the bodies a possibility to complain against the decision, if they desire.

Any CB/IBs that want to get accredited should have completed one certification or at least have application in progress in that particular scope for which it has applied. If by surveillance no certificates have been issued, ENAS shall have the right to take a decision on the status of the CB, according to the situation at that time. For IBs they should have conducted inspection with a minimum of one covering the scope. For management system certifications the CB needs to send list of all its customers with scopes issued to ENAS for record. It needs to inform ENAS of its audit plans and update ENAS with its auditors list as and when any changes are made.
2.2 Methods

Preferably standard-methods shall be used. New versions of standard-methods shall be implemented within a year after the publication of them. Modified standard-methods are methods where CABs have done smaller changes/modifying in a standard-method. These changes shall be written in the CABs' own internal testing procedure.

The changes shall be validated and the validation shall document that the results (including the corresponding measurement uncertainty) stays the same in performing according to the standard-method.

The documentation of the validation shall be filed. It shall appear from testing-reports, calibration-certificates, certification reports and inspection reports that the CAB is using a modified standard-method. Simplified reporting shall be granted by the customer.

If another principle of measurement is used and/or a matrix is changed compared to the standard-method, the method shall in any case be defined as an internal-method. Internal-methods based on standard-methods are methods where the CAB has done changes/modifications in the standard-methods, and where the validation data show that the modified method does not give the same result (including the corresponding measurement uncertainty for testing and calibration labs) as when performing according to the standard-method.

The documentation of the validation shall be filed and the modifications from the standard-method shall be described in the CAB's own procedure. A method based on a withdrawn standard-method is defined as an internal method based on the withdrawn standard.

If an earlier version of a standard-method is used longer than one year after it is revised, and this is acceptable for ENAS, the method shall be defined as an internal-method based on the earlier version. All work instructions and checklists shall explain the requirements of the related standards very clearly and in the maximum possible detail.

2.3 Application process.

If ENAS makes use of external assessors during the handling of the application, ENAS shall get approval for the choice of assessor(s) by the applicant. If the applicant wishes to refuse ENAS's proposal for assessor(s) this shall be substantiated, provided the reason is
related to conflict of interest or impartiality. No assessor can be rejected on the basis of cost.

ENAS will evaluate if the reasons for refusing the proposed assessor(s) can be approved. Communication between the CAB and assessors shall during the whole application process be done through the concerned Program manager in ENAS, in case nothing else is declined.

If ENAS shall be able to evaluate the functionality of the applicant's management system, it is a requirement that the system have been implemented before the accreditation is approved. To be able to decide if the accreditation-requirements are fulfilled, an examination of the CAB's management system, assessment of the implementation of the system, control of the participation in – and results from - PT, and observations of the performance of selected tests/calibrations/certification activities/inspection activities and/or sampling.

In the standard of requirements for accreditation bodies there are requirements on the accreditation bodies to be impartial and avoid performing any consultancy towards applicants. If the applicant's cooperation with ENAS demands guidance activities from ENAS, which threaten ENAS's impartiality, ENAS has the right to terminate the application/assessment process.

If during the assessment, it is observed that the conditions, on which the visit was based on, are not fulfilled, the lead assessor can terminate the assessment-visit, e.g. if key personnel are not available as provided, the management system/procedures are not implemented, the CAB shows a lacking willingness to co-operate during the assessment or there are serious nonconformities so that an performance of the assessment-visit is not appropriate.

The management of the organization shall be present at the opening and closing meeting. If the assessment-team fill in non-compliance-forms during the assessment, the applicant shall within the agreed deadline fill in and send all original nonconformity forms to the lead assessor, together with the documentation for the actions performed. A copy of the nonconformity forms, together with the corresponding documentation, shall be sent at the same time directly from the applicant to the lead assessors, which have filled, in the nonconformity forms. Scan copies sent by email are also acceptable.
If requirements given by ENAS are not fulfilled within the time limit, or if the applicant during the next six months after the assessment has not resolved nonconformities, ENAS can dismiss the application without refunding any charges. The applicant is bound to pay all accrued costs. The applicant will get a pre-warning by email to be able to give a statement before the process will be interrupted.

The applicant needs to apply again after such interruption and payment of any pending fee. ENAS shall submit report either by the end of assessment or within the approved time of ENAS procedure.

3. **Proficiency Testing/Interlaboratory Comparisons (ILC)**

ENA S requires that all accredited calibration laboratories participate in interlaboratory comparisons frequently. As a minimum each parameter shall be covered once with acceptable results during a period of renewal, where available anywhere in the world. Calibration laboratories seeking accreditation, shall in agreement with ENAS participate in inter-laboratory comparisons with satisfactory results before accreditation is declined.

Before accreditation is approved the testing laboratories shall, for each parameter, document satisfactory results from interlaboratory comparisons. ENAS requires all accredited testing laboratories shall participate in interlaboratory comparisons frequently for each parameter, and at a frequency in accordance with accepted rules in each testing area. Testing laboratories shall participate in organized ILC programs if these exist for the specific testing area. If organized ILC programs only exist abroad, the laboratories shall either as a main rule participate at least in one of these programs.

ENA S is requesting the laboratories to use ILC organizers that comply with the requirement for ISO/IEC 17043. For testing areas where there do not exist any organized ILC, the laboratories shall perform other actions, which ensure satisfactory control of the test method’s traceability such as comparison with other (accredited) testing laboratories and/or testing of (certified) reference material.
4. Surveillance and renewal; Updating of Quality Manuals and related Documents

To verify that the requirements for accreditations are met, ENAS will perform regular surveillance at the accredited CABs preferably within (12) months after the initial assessment or surveillance assessment.

The accreditation is renewed after three years, with normally two surveillances in between and the reassessment will then be as comprehensive as a first-time assessment. In addition, ENAS shall, when it is needed, accomplish further surveillance activities as e.g. extraordinary visits or claim participation in ILC.

Accredited CABs shall before an ordinary surveillance or renewal visit send in updated versions of relevant documents. The following documentation shall be sent directly to the assessors not later than 4 weeks before a surveillance and renewal visit, if nothing else is agreed on by ENAS.

Lead assessor shall as a minimum receive a copy of the quality manual including Appendixes, an index of other documents and forms in the quality system, a overview of the number of performed accredited tests and/or calibrations last year together with descriptions of relevant education and work experience (CV's) for new key personnel. If possible a copy of reports from internal audits and management's review performed last year, should be sent to the lead assessor. At renewal a description of relevant education and work experience (CV's) and job description for key personnel should be sent in, if relevant.

Technical Assessor/expert shall as a minimum receive the scope of accreditation, technical procedures, an overview of performed accredited tests and/or calibrations the previous year along with the relevant previous assessment report. Results of ILC performance since last visit will be evaluated during the visit. Any new technical personnel inducted will be interviewed for their competence on the related accreditation standard and their CVs examined and authorizations checked. In addition, at renewal a copy of the technical procedures including appendixes for technical personnel is required.

Regarding substantial changes in e.g. the quality system, or by renewal of accreditation, the CAB shall fill in and send a checklist to ENAS so that all gaps can be traced easily.
During the assessment, the CAB's key personnel shall the whole time be available for the assessment team. The management of the organization shall be present at the closing meeting.

If the assessment team gives any nonconformity during a surveillance or renewal, the descriptions in section 2.3 in this document, (regarding nonconformity forms together with documentation) must be followed.

Requirements for new appliers, as given in section 2 in this document, are also valid for already accredited CABs.

5. Application for Extension.
Accredited CABs can any time apply for extension of the accreditation. When applying for an extension the CAB needs to send a completely-filled application form together with the necessary appendixes, before the handling of the application can start. If the application for extension includes accreditation for interpretation/evaluation of the results, this shall be stated in the application form and be described in an appendix to the applications.

If the application of extension is sent ENAS not later than 2 months before an ordinary surveillance or renewal, the application for extension will normally be treated during the planned visit. In such cases fully documentation for evaluation of the application (procedures of methods and other relevant documents, results of ILC etc.) shall be sent ENAS within 4 weeks before the date of the planned visit.

The CAB has a duty to arrange and give ENAS the necessary access to their premises and to all relevant documentation as and when required by ENAS. For mandatory scope of accreditation unannounced visits will be made which will vary from CAB to CAB.

_Necessary access_ means access, which is necessary to be able to verify accordance to the requirements in the relevant requirement-standard.
Relevant documentation means documentation, which gives support in the evaluation according to relevant requirement-standards. Including is documents, concerning the work done by the CAB. Relevant documentation shall on request be available for ENAS as soon as possible.

During the assessment, the CAB has a duty to adjust their normal activities so that the assessment team can perform an efficient assessment.

ENAS informs the organization about the visit in suitable time, but when it is required ENAS’s assessment team shall be given access without the CAB being informed in advance.

Documentation and premises shall be accessible for staff employed in ENAS as well as the assessors/experts, which is engaged by ENAS and accepted by the CAB.

7. General Information Obligation
Accredited CABs shall at all times keep ENAS informed regarding changes in the organization which may influence the organization's ability to comply with the terms of accreditation. The organization shall inform ENAS immediately if there are changes in:
   a) Legal status, ownership, name, E-mail address, phone, fax no, etc.
   b) The organization, management and key personnel, i.e., quality manager in charge, the responsible for validation, the responsible for interpretation (for accreditation, which includes interpretation and evaluation of results).
   c) The management system if significant for the compliance with the terms of accreditation
   d) For labs, essential calibration and testing facilities, such as equipment, instruments and laboratory premises (e.g. moving of the laboratory), and other essential resources. ENAS shall approve such changes before they are effectuated.
   e) Substantial changes in national and international standard-methods which is used by the CAB in tests/calibrations, or other substantial changes in methods.

8. Use of the ENAS Accredited Symbol, and reference to the accreditation.
Accredited CABs are requested to use ENAS’s symbol. Use of ENAS’s symbol and reference to accreditation shall be in accordance with ENAS’s requirements of ACG 02.
The CABs shall have rules for how they refer to the accreditation in advertising materials and in other connections.

9. Accreditation Fees
Applicants and accredited CABs are obliged to pay fees in accordance with the existing document regarding fees for the services performed by Emirates National Accreditations. The fee structure is available on website [Error! Hyperlink reference not valid.]

10. Sanction when failing to comply with the conditions
If the accredited CAB fails to comply with the requirements for accreditation, ENAS can put in effect one or more of the following sanctions, depending on how serious the non-compliances are:

   a) Instructions of corrective actions (non-compliances)
   b) Suspend the accreditation or parts of it
   c) Withdraw the accreditation or parts of it

ENAS shall evaluate which sanctions to be used. When it is necessary to do withdrawals, instructions of corrective actions and/or suspension shall be used first if ENAS finds that appropriate. The sanctions can be described as following:

I) Instructions of corrective actions (nonconformities).
ENAS can require that the CAB correct the nonconformities within a specified date. If the CAB wishes to keep the accreditation, it must prove that the non-compliance is satisfactory corrected within the time limit.

The instructions may include withdrawal of accredited calibration certificates and test reports. ENAS may also decide that an extraordinary visit to the CAB is required to check that the corrections are satisfactory implemented.

II) Suspension:
If the nonconformity is not corrected within the agreed time, or if the nonconformity is substantial, the accreditation – or part of it- can be suspended for a limited time. A suspension is a blocking of the CAB’s accredited activity because of serious deficiency in fulfilling the requirements set by ENAS. Examples of serious deficiencies are:
a) No traceability to standards of measurement.
b) Unacceptable results from interlaboratory comparisons (ILC) or qualified tests.
c) Unsatisfactory competence because of changes in personnel/changes in the qualifications of key personnel.
d) Lacking of performance of satisfactory corrections within the time limit.
e) Big mistakes by performance of tests/calibrations, which show serious errors in the management system.
f) Misuse of the accreditation, or if the accreditation is not much used.

Changes of the CAB’s premises, regarding moving/rebuilding will normally lead to suspension. The same can in some cases be the result of changes in the organization.

A CAB can ask to be suspended on voluntary base. An argument for this voluntary suspension can be i.e. that the CAB itself register that the requirements for accreditation is not fulfilled, or by moving to new premises.

- When the accreditation or parts of this is suspended, the CAB shall not offer or perform accredited services for the suspended activities as long as the suspension lasts.
- Accredited calibration-certificates/test reports shall not be issued within the area, which is included in the suspension.
- Suspensions are time limited to 2 months, but ENAS may prolong for practical reasons such as purchase or installation of an equipment etc.

The accreditation can be re-established by ENAS if the conditions which caused the suspension are improved in a satisfactory way within the time limit. In most of the cases this would be done by physical verification of the site. However, in certain cases where documentary evidence is sufficient, physical verification may not be needed. This would be decided by the concerned in charge either alone or if needed in consultation with the recommendations of the lead/technical assessor to lift suspension without a visit.

III) Withdrawal of accreditation:

If the CAB does not want to or is unable to correct the nonconformities, within the time limit, or the nonconformity is so serious that the CAB no longer has the necessary qualifications to carry out accredited conformity assessment tasks, the accredited scope
or parts of the scope shall be withdrawn. In this case, the CAB's accreditation is terminated by the withdrawal. By termination of the accreditation the CAB is required to return the accreditation certificate and the accreditation document to ENAS.

If parts of the accreditation are withdrawn the CAB shall hand over to ENAS accreditation documents for destruction or alteration. The CAB shall no longer offer to carry out accredited services within the areas withdrawn.

If the accreditation is fully or partially withdrawn the CAB shall, in writing, inform clients concerned about the consequences. A copy of this information shall be sent to ENAS.

In the case of withdrawal or suspension, paid fees will not be refunded. The CAB has a duty to pay all incurred costs. During a period of suspension the regular fees shall be paid as normal.

Before a decision to suspend or withdraw accreditation can be made, the CAB must be given a notice and the possibility of a hearing, except in certain cases, where immediate suspension is needed due to unsatisfactory performance.

Appeals on decisions concerning sanctions can be made.

11. Transferring of accreditation.

In cases where by purchase, merger, and changes of name etc. where accredited CABs wish to transfer an accreditation from one organization to another. Transfer implies that an assigned accreditation is transferred from one organization to another. The accreditation-number will normally be kept. Conditions for approval of transmission are as follows:

a) The system of performance of the accredited tests/calibrations shall not in principal be changed, and the changes shall not be in conflict with the accreditation conditions.

b) The changes do not lead to weakening of the quality of the work or the integrity of the organization.

c) The changes have no influence on fulfillment of the requirements of
accreditation. d) The transferring of accreditation does not mislead the market.

e) The organization obliges the responsibility towards customers and ENAS.
   (This implies that it at any time in the transmission process there have to be a clearly defined legal body which is responsible towards customers and ENAS).

f) The changes are not in conflict with UAE’s laws.

If transmission is requested the accredited CAB needs to send an application by letter for transmission of the accreditation. The application must include:

g) Complete description of the background of the application.

h) Clear and precise description of new legal status, when it is relevant.

i) Description of possible changes in the quality system.

j) Company-attestation

k) Binding statement from the new owner/management that they will fulfill the requirements for accreditation.

l) Binding statement from the new owner/management that possible relevant responsibility is taken over from the one the accreditation was transmitted from (e.g. abidance of offers which are already contracted make for delivery of accredited services).

m) Plan for updating of the quality manual, procedures, catalogues, and other affected documents (e.g. change of name).

n) Information regarding updating of necessary contract of employments, agreement with subcontractors etc. when relevant.

In accordance with the conditions of transmission, ENAS will decide whether verifications must be done at the location of the applicant or transmission can be declined on behalf of the received documentations.

In the cases where changes lead to a new accreditation certificate and accreditation document, the CAB which is accredited has a duty to return the earlier edition of these to ENAS when the transmission is declined.

12. Notice to relinquish/ dissolution

An accredited organization may terminate its accreditation, without any argument, with two-months notice. The notice must be in writing. In special cases, this period
might be shortened.

If the organization is dissolved, it has a duty to immediately inform ENAS, which will withdraw the accreditation at once. The requirements, which are described in section 10 in this document regarding withdrawing are valid. The same requirements are valid if the CAB for different reasons needs to reduce the accreditation size.

ENAS shall not be held responsible for a CAB’s obligations to its clients.

14. The Right to Appeal against Decisions made by ENAS.
Any appeal against ENAS's decisions must be presented to ENAS and submitted to BOD Chair within 3 weeks after the CAB receives ENAS’s decision. ENAS shall perform the necessary investigations and may annul or alter the decision, or reject the appeal if the terms to deal with it do not exist. If the decision is not altered, ENAS shall send all documents concerning the matter to the Appeal Committee selected by the Board of Directors Chair. The Appeal Committee makes a decision to either reject or accept the appeals and inform the Director of National Accreditation Department for their decision.

The CABs have at any time an opportunity to appeal ENAS’s activities, such as interpretation of the requirements for accreditation. Appeals shall be in writing. During the handling of appeals deadlines for closing of possible nonconformity be postponed.

15. References

(1) ISO/IEC 17025— Conformity Assessment -- General requirements for calibration- and testing laboratories competence.
(2) ISO 17020 Conformity Assessment -- General requirements for operating of inspection bodies
(3) ISO 17021 Conformity Assessment -- General requirements for operating of certification bodies
(4) ISO/IEC 17065 Conformity Assessment -- General requirements for operating of product certification bodies
(5) ISO/IEC 17011 Conformity Assessment -- General requirements for operation of accreditation bodies.
(6) ACG 02 Guidelines on the use of ENAS-accredited symbol by conformity assessment bodies.

(7) ACG 04 Requirements for calibration and control of weights for accredited laboratories

(8) ACG Requirements for calibration and control of thermometer for accredited laboratories

(9) ISO/IEC 17043 Requirements for proficiency testing

Documents published by ENAS are available on Internet: www.esma.ae
Documents published by ILAC are available on Internet: www.ilac.org/
Documents published by IAF are available on Internet: www.iaf.nu/
Documents published by ARAC are available on Internet: www.arac-accreditation.org/