



مركز الإمارات العالمي للاعتماد

Emirates International Accreditation Centre

دليل عملية الاعتماد

Guidance for Accreditation Process

EIAC-GD-GEN-004

Signatories	
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Revision history			
Issue no.	Rev. No.	Details	Date
1	0	First Issue for use under EIAC Name	16-03-2021
1	01	Modification in accreditation process: add clause 6 regarding the periodic and re-assessment visits	07-09-2022
1	02	Modified to cover: <ul style="list-style-type: none">The actions taken in case of fraudulent behavior (4.10).The analysis of the extent of the nonconformities under on-site Assessment Clause (4.14 & 4.15)	15-03-2023
1	3	Revised due to the incorporation of the new identity of the Dubai Government	23-07-2024



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1 Scope

This guidance is applicable to the accreditation of all conformity assessment Bodies.

2 Application for accreditation

- 2.1 The Conformity Assessment Body (CAB)/Healthcare Organization (HCO) requesting accreditation shall make application in writing by completing EIAC Application and Agreement of Accreditation available in EIAC website and submitting it electronically along with needed documents to the concern person in EIAC.
- 2.2 The applicant CAB/HCO must specify the scope of accreditation in the Application and Agreement of Accreditation form.
- 2.3 The applicant CAB/HCO shall provide substantiating information and evidence to demonstrate conformity to the latest edition of the Accreditation criteria.
- 2.4 The application process will only be completed once the fee voucher is settled (520AED inside UAE, 620AED for overseas).
- 2.5 The applicant shall receive an acknowledgement of the receipt to his application from EIAC, after assessing the completeness and correctness of the application, within 3 working days.
- 2.6 The applicant shall receive a full review result for his application from EIAC, after assessing its capability to serve for the applied scope, within 5 working days.

3 Resource / Document Review and Self-Assessment

- 3.1 The related Head of Section will nominate a Lead Assessor for the accreditation process.
- 3.2 The related Head of Section will notify the nominated Lead Assessor with the results of the resource review within the same working day and handover to him/ her all the documents submitted by the applicant.
- 3.3 A voucher regarding the document review shall be issued and forwarded to the applicant to be settled before starting the document review process.
- 3.4 The nominated Lead Assessor shall complete the document review and send the result to the applicant within 10 working days.
- 3.5 In case inadequacies were found within the reviewed documents, the applicant shall correct them within 30 working days from receiving the document review result.

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4 On-site Assessment

- 4.1 The Lead Assessor will prepare an Assessment Plan within 10 working days detailing the assessment schedules, defining the responsibilities of the Technical assessors and – where applicable – the Management System Assessor/s or Technical Expert/s.
- 4.2 A voucher for the assessment visit shall be issued and forwarded to the applicant to settle the voucher before the assessment visit date.
- 4.3 The Assessment plan shall be agreed upon with the applicant. CABs/HCO have the right to object to the appointment of the nominated assessment team, including observers, based on solid justification and, in such case, EIAC will accordingly offer an alternative team. In the event that suitable alternative cannot be identified, or when grounds for objections are considered to be unreasonable, EIAC reserves the right to proceed with the previously appointed team.
- 4.4 The assessment visit shall be conducted within the scheduled time specified in the assessment plan; the assessment begins with an Opening Meeting between the assessment team and the representatives of the applicant CAB/HCO. The purpose of the Opening meeting is to introduce the Assessment Team to the applicant CAB/HCO, and vice versa, confirm the purpose of the visit and scope of the assessment, confirm the confidentiality of information by EIAC team and the impartiality of the final outcome of the assessment visit (Lead Assessor's final recommendation) and remind the applicant of what is expected during assessment. The Opening Meeting is to be chaired by the Lead Assessor.
- 4.5 The applicant CAB/HCO is responsible for making all necessary on-site arrangements for the assessment, including the provision to allow the assessment team to examine documentation and access to all areas, records and personnel for the purpose of the assessment.
- 4.6 During the assessment, different team members will assess the implementation of the management system and its effectiveness through assessing the records and the competence of the CAB/HCO. The CAB/HCO must demonstrate that it controls all the activities at all its branches included in the application for accreditation (see part 2 of this document for multi sites).
- 4.7 The Lead Assessor has the right to examine the applicant's management system with the Management Representative and with any appropriate staff to verify that it meets the requirements of the relevant accreditation criteria.
- 4.8 The technical Assessor/s will examine the technical competence of the personnel performing activities sought for accreditation.

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- 4.9 The status of CAB's/HCO's compliance with the requirements of the Accreditation Criteria recorded by the Assessment Team members will be reported to the Lead Assessor, for which his final recommendation will be based upon.
- 4.10 At any point in the application or initial assessment process, if there is evidence of fraudulent behavior, if the conformity assessment body intentionally provides false information or if the conformity assessment body conceals information, EIAC shall reject the application or terminate the assessment process.
- 4.11 After the assessors have completed their individual assignments, an assessors meeting shall take place to discuss the followings, prior to conducting the closing meeting:
- Complete technical assessors' reports,
 - Get feedback of each assessor with regards to the competence of the CAB/HCO, and
 - Summarize the assessment findings on the CABs/HCO Corrective Action Report.
- 4.12 The closing meeting is where all assessors present their findings to the CAB's/HCO's management and personnel. The Lead Assessor presents a summary of the results of the assessment and informs the management about the recommendation that will be submitted to EIAC. The Corrective Action report form will be provided to the CAB/HCO that will include all findings, for which the CAB/HCO will have to respond with proposed corrective actions against all findings within 3months.
- Note: For pre-assessment visit, no individual NCR/ OBS shall be raised. Findings will be conveyed to the CAB/HCO during the closing meeting and shall be recorded in the pre-assessment report that will be prepared by the lead assessor and sent to the CAB/HCO within 8 working days.*
- 4.12.1 Factors affecting recommendations for accreditation
- When forming recommendation, Lead Assessor takes into account the number and gravity of individual non-conformities/observations found during the assessment.
 - Where no non-conformities/observations are found, Lead Assessor normally recommends for granting accreditation immediately.
 - Where non-conformities/observations are found, the recommendation will be to grant accreditation after submitting evidences for adequate corrective actions against all the findings raised.
 - Where there is one or more areas within the applied scope having major findings that requires a follow-up/re-witness visit, the recommendation will be only be formed after verifying corrective actions during the follow-up/re-witness.
 - Where there is one or more areas within the applied scope having complete failure, Lead Assessor may recommend accreditation to be reduced accordingly.
 - Where the number of the non-conformities found is such that the Management System fails to meet the requirements of the accreditation criteria, Lead Assessor's recommendation will be that accreditation is refused and the CAB will be advised to discuss future actions with EIAC Management.

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- 4.13 Assessment Team shall individually prepare summary of findings reports and submit them to the lead assessor within 5 working days. Based on these reports, Lead Assessor will prepare the Assessment report and submit it to the CAB/HCO.
- 4.14 The corrective action is mandatory for non-conformity. However, in some situations the verification of implementation will be carried out during future assessment such as when as a corrective action commitment by the CAB is considered enough to close the nonconformity.
- 4.15 Analysis of the extent and cause:
An Extent of Cause Review determines the potential for an issue to exist or to have occurred in other activities, processes, programs, divisions or systems elsewhere in the CAB.
- 4.15.1 The conformity assessment body (CAB) should consider the following factors while conducting the analysis of the extent of the nonconformity;
- Looking for the same/similar issue and conditions in other areas than where originally found
 - Looking for other manifestations of the root cause(s) in other areas
 - What is the magnitude of identified issue (nonconformity).
 - How far-reaching is the impact of nonconformity.
 - Anticipating additional issues based on the identified issue and root cause(s)
 - Reviewing prior implementation/applications of the deficient process, procedure or system to see if earlier deficiencies have gone unnoticed
 - Is there any impact on the final outcome/ client's end.
- 4.15.2 The following actions can be taken to conduct the Extent of Cause Review, as appropriate:
- 4.15.2.1 Scope the Extent of Cause Review by:
- Reviewing the circumstances and conditions that led to the issue.
 - Determining the activities or facilities to which the issue applies
 - Reviewing the root causes identified in the Root Cause Analysis



4.15.2.2 Determine the Extent of Cause Review Methodology, which may include one or more of the following methodologies:

- Precursor/Historical Review: analyze corrective action effectiveness, analyze related assessment findings
- Analyze prior similar issues/occurrence for recurrence.
- Personnel interviews coupled with document reviews.
- Performance measures/metrics
- Observation of similar work activities and processes
- Sampling testing

4.15.2.3 Develop lines of inquiry, gather objective evidence and conduct interviews, as appropriate. Consider:

- Does the same or similar problem exist in other applications, locations or facilities than where originally found?
- Have the same or similar problems occurred prior to this issue?
- Are there other manifestations of the root cause(s)?
- Are there similar or related conditions elsewhere, or can be anticipated based on the identified conditions of this issue?

4.15.2.4 Analyse the data gathered to identify whether the issue conditions and causes applies to other areas within the CAB. Consider whether the existence of similar conditions and causes elsewhere in the CAB:

- heightens the issue severity.
- requires refining the root and/or contributing causes.
- identifies deeper systemic issues that may warrant management's attention and resolution

4.15.2.5 Document the results of the Extent of Cause Review in the Assessment Findings and Corrective Actions Report, Example 1: It was noted that, the technician who was performing the microbiological testing of tap water was not authorized by the laboratory to conduct this test.

Analysis of the extent of the nonconformity:

The conformity assessment body (CAB) should consider the following factors while conducting the analysis of the extent of the nonconformity;

- This was only one such case or there were few more unauthorized technicians.
- This was only limited to tap water testing or there are unauthorized technicians for other testing as well.
- Is there any impact on the clients' end?
- Is there a need to crosscheck the work already performed (already conducted tests) by the unauthorized technician.
- Is there a need to recall the test report(s)?

Example 2: The laboratory technician was found using obsolete form to record the test results.

Analysis of the extent of the nonconformity:

The conformity assessment body (CAB) should consider the following factors while conducting the analysis of the extent of the nonconformity;

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- This was only one such case or there were few more obsolete forms in use.
- This was only limited to this particular technician or few/all other technicians were using obsolete forms in the same section of lab.
- What about other sections of lab. Are there any obsolete forms in use?
- Is there any impact on the Test Report?
- Is there any impact on the clients' end?
- Is there a need to recall the test report(s)?

4.16 After the scheduled time, CAB/HCO shall submit proposed corrective action report to the Lead Assessor.

4.17 Upon receipt of corrective actions and their evidences (where applicable), Lead Assessor will distribute the corresponding Corrective Actions along with their evidences to the concerned assessor.

4.18 The Assessors shall evaluate the appropriateness and effectiveness of the submitted corrective action and record their comments on the Corrective Action Report:

- Once a corrective action is deemed inappropriate, the assessment team will reject the proposed corrective action and require the CAB/HCO to propose another corrective action. The Lead Assessor and the CAB/HCO shall agree on the implementation date of the corrective action.
- If the succeeding submitted corrective actions still do not guarantee an effective rectification of the observed non-conformities, the Lead Assessor reserves the right to reject the proposed corrective action and proceed with the preparation of the Summary of Findings which will be submitted to Head of Section for further consideration along with the all related documents. An appropriate recommendation shall be made based on the seriousness of the observed non-conformities.
- If a follow-up visit is required, the assessor shall update the Corrective Action Report and the CAB/HCO shall be informed of the schedule of the visit. The follow up visit shall follow the processes as defined in point 10 of this document

4.19 A follow up visit is to be conducted within the scheduled time to verify the effective implementation of a proposed corrective action.

4.20 The follow up visit will limit its activity to the identified areas where non-conformities/observations raised during the assessment. No further non-conformities/observations will be raised, other than verifying and closing the previous non-conformities/observations raised.



- 4.21 During the follow up visit, if the previous non-conformities/observations raised were found unsatisfying, the Assessment Team reserves the right to proceed with the Summary of Findings report. An appropriate recommendation shall be given based on the result of the Follow-up visit.
- 4.22 After the evaluation of the submitted corrective action, Lead Assessor shall prepare Summary of Findings Report and submit it to Head of Section who shall review the assessment records and make his/her decision regarding the recommendation of Assessment.

5 Decision on accreditation

- 5.1 The lead assessor will select the relevant task force to review the recommendation for accreditation and other supporting documents and presents its recommendation whether to grant accreditation to an applicant CAB/HCO or not within 1 month. The lead assessor will update the assessment report with the task force's recommendation and submit it to the Head of Section. Noted that any task force member having direct/indirect interest with the CAB/HCO in question shall not take part in task force proceedings.
- 5.2 The Head of Section will review the assessment package within 5 working days. Based on the review, he/ she makes a decision as per the recommendation or at his/ her own discretion,
- 5.3 The final approval will be done by Department Director who will update the Decision Making Report with the final decision within 3 working days.
- 5.4 The applicant is notified in writing of the individual accreditation decision.
- 5.5 An applicant can object to an individual accreditation decision within 30 calendar days of the date of dispatch of this decision. The procedure for appeal must be observed in this case.

6 Periodic and Re-assessment visits

- 6.1 The Case Manager in coordination with the Team Leader will prepare the accreditation program for accreditation cycle (which begins at /after the date of the accreditation decision for granting the accreditation or at the reaccreditation decision) for each CAB detailing the assessment visits of each CAB's activities during the accreditation cycle. The program shall be approved by the related Head of section.
- 6.2 The EIAC's accreditation cycle is three years from the date of accreditation decision or reaccreditation decision. In any case, it shall not be longer than five years.



- 6.3 The program will ensure that a representative sample of the scope of accreditation at the relevant locations is assessed, considering previous cycle performance of CAB, risks and covering the requirements of relevant scheme/ accreditation criteria.
- 6.4 A sample of the scope of accreditation shall be assessed at least every two years as per Sampling work instruction.
- 6.5 Based on the accreditation program; the accredited CAB shall be subject to an announced/ unannounced periodic visit that will carry out at least once per year. Additional special visits may carry out at the discretion of EIAC and as the need arises.
- 6.6 The Department's Director is entitled to extend the time between consecutive on-site assessments based on the maturity of the CAB and the history of accreditation. In any way, the time between consecutive on-site assessments shall not exceed two years.
- 6.7 The re-assessment visit shall be conducted before the end of the validity of the accreditation certificate, covering the whole scope during the accreditation cycle in order to renew the accreditation certificate. Formal application is not required in case of re-assessment.
- 6.8 In cases where the CAB requested an extension in accreditation scope; a formal application for extension of accreditation scope shall be received 2 months prior to the planned assessment.
- 6.9 Same initial assessment procedure is also applicable for the periodic assessment, extension of accreditation scope and re-assessment visits. In case of any change in the assessment team, the CAB shall be notified to get its acceptance

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7 Multi Sites:

7.1 Initial Submission:

7.1.1 **Application** shall be submitted by the site(s) (preferably the site manager) applying for accreditation (or, vice versa, as long as the dependency of liability is assured). Fee is 520 AED/ Application.

7.1.2 One **Document review**/ application (same management system used by all sites). Fee 3,520 AED

Note: *The CAB/HCO may either have separate management systems for each site, or one management system that will control all sites (however formed, as long as implementation deemed reliable and sustainable).*

7.2 **Initial assessment:** All Multi-sites shall be assessed at the time of initial assessment. Chargeable based on the number of man days/ site.

7.3 **Reporting:** a separate report will be issued for each site /visit.

7.4 **Follow up/ Re witness** visit: will be conducted for individual site, if recommended by lead assessor. Chargeable based on the number of man days/ site.

7.5 **Decision of section Head:** Separate decisions based on the closure of the findings for each report/ site

7.6 Certificate:

- For Lab/HCO: A separate certificate will be issued to individual site with different initial accreditation date and different scope; charges applicable 1,200 AED for each branch
- For CB: One certificate will be issued for the multi sites; charges applicable 1,200 AED with specifying the site(s) in the scope

7.7 EIAC Symbol:

- For LAB/HCO: Charges applicable is 5,000 AED/site/scope for 3 years;
- For CB: Charges applicable for all sites is 5,000 AED/scope for 3 years; no charges for the added site(s) in future.



7.8 **Extension the branches:**

7.8.1 Document review will not be required for the added siteⁱ.

7.8.2 Management system assessment will be required for each siteⁱⁱ.

7.8.3 Extension of scope:

- For Laboratory/HCO: extension of scope might be carried during the nearest surveillance/ re-assessment visit for the related site, or an extension of scope visit will be conducted to the related site. Chargeable based on the number of man days/ site.
- For CB: Extension of scopes will cover all sites. Chargeable based on the number of man days/ visit

7.9 **Suspension or Withdrawal Decision:**

In case of suspension or withdrawal,

- For Lab/HCO: In case of suspension or withdrawal due to system failure found in any of the given sites, the related certificate will be affected only. EIAC will have to verify the management system status of other locations (i.e. records) by separate visits.
- For CB: In case of suspension or withdrawal due to system failure found in any of the given sites, the whole sites will be affected.

7.10 **Scope to be covered during on site visit:**

Based on "EIAC 70 02 WI3 Sampling of Assessment Scope"

ⁱ As long as the accredited site can provide the added site with the current management system against which accreditation was provided

ⁱⁱ EIAC may decide not to assess the management system once again for the added site if the management system was controlled from one location. In this case, EIAC may only verify the accessibility to the management system from the new site and the implementation of the management system within that site (i.e. records).