



**Egyptian Accreditation Council
EGAC**

EGAC Accreditation Process for Person Certification Bodies PB11Ps

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1. INTRODUCTION

The following notes will help organizations seeking accreditation for assessment and certification to recognized international standards and to EGAC requirements to understand the steps involved in EGAC's assessment of their management systems and competence. Before applying formally to EGAC the applicant should be familiar with the requirements of the following documents as appropriate:

- ISO/IEC17011:2017;
- ISO/IEC17024:2012;
- EGAC Requirements;
- IAF Requirements;
- EA Requirements;
- Certification schemes for person which accreditation is sought.

2. Scheme evaluation (National scheme)

- There are 3 cases for certification scheme & scheme owner

1. If CB is the scheme owner: develop and maintain periodically the own scheme with the expert & interested parties.
2. If CB is not the scheme owner: CB has two choices;
 - a. Contractual agreement with scheme owner.
 - b. CB participates in scheme committee.
3. If the C.S. is International standard: the ISO (International Organization for standardization) has the responsibility to maintain and develop the Certification scheme C.S and published it in website.

The certification body shall ensure that the certification scheme is reviewed and validated on an on-going, systematic basis.

- Scheme evaluation (national scheme)

Stage 1: Technical advisory committee review by one or two assessor (assessor ISO 17024 and expert in the field related to scheme) - (Clause 8 and sub clause 9.6.3 & 9.6.5 of ISO/IEC17024:2012, EA1/22:2016).

Stage 2: EGAC technical advisory committee to review the suitability of certification scheme to Egyptian market, needs and to ensure there is no overlapping in this scheme to another law or standard use, on the PRS certification scheme evaluation checklist.

3. Application for accreditation

To gain accreditation, a CB must be fully conversant, and comply, with the requirements of ISO/IEC 17024:2012, relevant ILAC guidance and EGAC regulations.

Applicants will be supplied with an information package containing the following:

- EGAC application form (soft and hard);
- EGAC CAB agreement form;
- Assessment checklist report (self-assessment) for person CBs quality system implementation;
- EGAC fee structure;
- EGAC regulations

- Description of the accreditation scheme (this document);
- Some EGAC publications (as guidance).

Processing of application shall be conducted exactly in accordance with EGAC publications PB1G_Handling of application.

Applicant lab shall submit the following:

- Fully completed EGAC application form (soft and hard)
- Two copies of EGAC CAB agreement to be signed and submitted with the application form.
- Assessment checklist report (self-assessment) for person CBs quality system implementation.
- CB's quality system documents.
- Application fee according to R3G
- CB regulatory documents applicable to the applicant's scope;
- CB's documentation - Articles of Association, or equivalent, for review by EGAC.

A preliminary meeting at EGAC office is recommended for the purposes of clarifying initial questions. Afterwards, the application form is to be completed and signed by a duly authorized applicant representative, and submitted to EGAC together with:

If the applicant CB has not sent the completed application form accompanied with the updated CB quality system, the application will be considered to be lapsed.

If the applicant wishes to be assessed at some later date, it shall have to re-apply to EGAC for accreditation, and pay a further application charges.

In All stages of the accreditation process, only applicant CB staff members are allowed to attend, participate, and/or communicate with EGAC. By CB staff members we mean: CB provider employees who occupy positions in CB organizational structure and its parent organizational structure. These CB staff employees will participate in the activities that match with their job description documented in their management system.

4. Appointment of the assessment team

The applicant's application will be handled by EGAC person CBs accreditation manager, who will study the documentation that has been submitted. EGAC person CBs accreditation manager will contact the applicant to discuss the composition of the assessment team, and to make arrangements for the assessment process to commence.

The assessment will be conducted by as many independent assessment team as the scope of the accreditation requires.

EGAC shall notify the applicant in writing of the names and affiliations of the nominated assessment team. The notification shall seek the approval of the applicant to the nominated team. Objection to any nominated team members shall be in writing, include a detailed justification from the CB to his objection, and shall be lodged with EGAC within seven working days of receipt of the nominations. Failure by the applicant to object to any of the nominated team members shall be considered as acceptance of the team as a whole.

Objections from the CB to any of the nominated team will be investigated by EGAC person CBs accreditation manager. If EGAC person CBs accreditation manager is satisfied

with the CB's justification to his objection, he will change this nominated team, otherwise he shall inform the CB that his objection is not accepted and EGAC will keep the nominated team. EGAC person CBs accreditation manager's decision shall be final.

The applicant will be advised of the fees for full assessment and consecutive assessment visits before the visits take place, and it will be asked to confirm acceptance of these fees.

If the applicant wishes to be assessed at some later date, he will have to re-apply to EGAC for accreditation and pay a further application fee.

5. Assessment Program

The assessment process will consist of the following key stages:

- Review of the applicant's documentation.
- Assessment of the applicant's management systems at head office.
- Witness of examination & evaluation process.
- Where necessary, confirmation of completion of corrective actions to address non conformities raised
- EGAC review and decision-making process.
- Granting accreditation to the applicant and issuing a certificate with a definition of scope for accreditation.

The number of assessor man-days required to complete the accreditation process will depend on various factors including:

- The size of the applicant organization.
- The range and complexity of scope.
- The length of each assessment witnessed, or post assessment audit.
- The ability of the applicant to correct nonconformity and the consequent number of follow-up meetings required.

The applicant will be given a quotation for assessment work before assessment takes place.

6. Documents Review

The applicant will receive from EGAC the documentation (F4WI10Ps) & (F5WI10Ps) to be prepared and provided to EGAC for review by the assessment team prior to head office assessment. The documentation required includes as a minimum:

- Those documents listed in relevant clauses of ISO/IEC 17024:2012
- Procedures for carrying out competence analysis, in particular for gathering information related to client activities, and the relevant experience and qualifications of assessors;
- Criteria for determining appropriate levels of competence in all relevant areas;
- Procedures and methodologies used for assessment.

EGAC assessment team leader will review these documents to make a preliminary assessment of conformity with the relevant standards & IAF guidelines, and to gain an understanding of the applicant's organization and management system.

7. Pre-assessment

If the need for a pre-assessment visit is indicated by the document Review or requested by the CB, EGAC person CBs accreditation manager will make the arrangements for the visit, including a quotation for the fee. EGAC assessors are also permitted to convert the initial assessment visit to a pre-assessment visit when the lead assessor finds major gaps in the certification body quality manual and operating procedures.

A pre-assessment visit is made to the certification body to:

- Discuss observations and non-conformity in documentation;
- Check understanding of the organization structure and delegated powers;
- Confirm the list of locations and activities is complete;
- Agree the scope of accreditation to be assessed;
- Obtain any additional information necessary to develop the assessment plan.

The pre-assessment visit, is normally carried out by the team leader (may be accompanied by EGAC person CBs accreditation manager and/or an expert where appropriate), and is usually completed in one day. The pre-assessment visit allows the team leader to discuss with the CB management the extent to which the CB's quality system, quality manual and operating procedures appear to comply, or not, with the requirement of the relevant standard and the requirements of EGAC, and whether the CB has a stated policy for defined responsibilities and means to implement each of the requirements of the relevant standard. Also to ensure that the CB management fully understands the purpose of a quality system audit and the importance of a periodic review of the quality system to check the effectiveness of the system.

- Any actions that appear to be necessary to comply with the EGAC requirements for accreditation may be suggested.
- The pre-assessment visit is not a full assessment.
- The findings of the pre-assessment visit shall be reported briefly to the CB where they will facilitate the preparations for the initial assessment visit and shall indicate:
 - If a further pre-assessment visit is recommended.
 - Whether plans for initial assessment of the CB can proceed.
 - Specific reasons why plans cannot proceed.
 - A copy of the pre-assessment visit report will be send to the CB.

8. Head office assessment

When the applicant body is ready for the initial assessment from EGAC point of view, EGAC person CBs accreditation manager or his representative will meet with the team leader, assessor/s, and technical experts in an initial meeting for preparation of assessment plan for the initial assessment.

This plan:

- Shall be discussed with the CB.
- Shall indicate the section/activities in the head office to be assessed.
- May specify the applicant's certified companies to be witnessed and by which assessor if possible or this may done later according to the CB audit plan.

The purpose of the head office assessment is to:

- Determine whether the applicant's documented system meets the relevant standards & certification scheme; assess the applicant's head office competence to carry out competence analysis, and to provide and manage the assessment resources;
- Agree the scope area which will be considered.

The head office assessment takes place after the review of documentation, and is carried out by the team leader and a assessor, as appropriate. It will cover:

- A presentation by the applicant about his business, organization, resources, management systems, and plans for these;
- An assessment of the applicant's management system;
- Key clauses of the relevant standard/IAF/EU Guidelines.

The assessment team needs to be assured that the applicant has the essential competence to undertake certification and/or verification work. Non conformities will be raised as appropriate. The assessment team will explain those non-conformities that must be corrected before EGAC will undertake to witness assessments.

The head office assessment starts with an opening meeting. The EGAC team leader shall chair the opening meeting. This opening meeting sets the scene, and its purpose is to ensure that the CB management and staff understand what is going to happen during the assessment. It may be appropriate for the team leader to request that a representative from the CB presents a brief overview of the CB's operations. The assessment team shall sign confidentiality and impartiality agreement before starting the assessment.

EGAC assessors shall seek objective evidence of the implementation of the certification body's policies and procedures the assessment shall be conducted generally in accordance with (ISO 19011: 2018).

The assessment will contain a revision of auditing records, contracts, process assessment, interviews, validation and assessment of performance measures. Particular emphasis will be placed on the critical areas identified during the desk top review.

Time will be allowed each day for a review of the documented procedures and instructions for the areas to be audited including any changes made since the desk top review.

Should the EGAC assessors identify non-conformities with the relevant criteria then they shall record them. The extent and direction of the EGAC assessors' questions should be such that the CB representative clearly understands where procedures and practice do not meet the assessment criteria.

Team leader shall chair the closing meeting and present the non-conformities and requests that a representative from the CB accepts and signs each form. The CB shall then be presented with a copy of the non-conformity reports.

Team leader shall then ask for confirmation from the CB that details of root cause analysis and the proposed corrective actions with the date of completion will be provided to EGAC office for review, just after receiving the assessment report from EGAC.

EGAC assessment team shall discuss the audits and surveillances, which it wishes to witness, according to the examination process.

Where possible a date shall be determined for the final closing meeting.

9. Witnessed examination/evaluation process.

The purpose of witnessed assessment is for the applicant to demonstrate his competence and his ability of assessment according to the ISO/IEC 17024:2012 and IAF & EU mandatory documents/guidance and EGAC requirements.

Variations to this requirement will depend on the scope proposed for accreditation.

All scopes applied for, will be subject to an office assessment and technical review during the complete accreditation cycle. The minimum and maximum number of witnessed scopes during initial assessment will be according to EGAC's sampling procedure. Special measures may be taken in case of complaints about the CB's performance.

Upon receipt of the information about the audited organization the team leader shall confirm the arrangements for the witnessed assessment to the CB.

At the CB's opening meeting with its client, EGAC team leader should request the opportunity to thank the client for permitting EGAC attendance, give an assurance of confidentiality and briefly describe the EGAC role. The EGAC team leader should also advise that the EGAC assessment team will necessarily make extensive notes.

EGAC assessors shall play a silent role in the audit, and shall exercise great care to avoid influencing the audit in any way.

EGAC assessment team shall monitor all the activities performed by the CB auditors/evaluators/examiners and will record their observations.

At the end of each day's audit activity EGAC assessors will also attend any private discussions between the auditors (evaluators/examiners) concerning the progress of the audit.

EGAC assessors will discuss, in private, the on-going performance of the auditors /evaluators/examiners. The team performance of the auditors/evaluators/examiners shall be assessed, as well as their individual performance.

After the closing meeting, EGAC assessors will discuss, in private with the auditors (evaluators/examiners), their findings with regard to the auditors (evaluators /examiners)' performance during the audit.

One copy of each non-conformity report (if any) may be given to the lead auditor of the CB at the meeting.

The CB's evaluators/examiners shall be requested to acknowledge the factual basis of the non-conformity, and to sign the appropriate section of the form before they leave the audited organization if possible. If not, this may be carried out on later day before the assessment closing meeting.

The CB's evaluators/examiners are not required, at this stage, to propose corrective actions or to estimate a timescale for completion. Those points will be dealt with at the closing meeting of EGAC's assessment.

In the event that significant problems are encountered which may prevent the progress of the overall assessment, then EGAC's team leader shall seek guidance from EGAC person CBs accreditation manager to determine the way forward.

10. Final closing meeting

When all witnessed assessments have been completed, EGAC's team leader in consultation with EGAC's person CBs accreditation manager shall arrange to hold a final closing meeting with the CB. EGAC team leader shall chair the final closing meeting. The purpose of the final meeting is to enable EGAC team leader to present the CB management with a brief summary of the overall assessment.

11. Post assessment

EGAC shall provide the CB, within two weeks of the witnessed assessment, with the assessment report. The report will include the non-conformities, observations and a recommendation regarding accreditation. On receipt of evidence of corrective action for any outstanding non-conformities, EGAC person CBs accreditation manager shall consult with the team leader/assessor/s who will confirm within two weeks, whether the nonconformities have been satisfactorily discharged.

When a follow-up visit is required, the assessors shall return to look specifically at the clearance of the nonconformities. If an assessor observes a new potential nonconformity during the visit, the assessor should bring the matter to the attention of management and report this, in writing, to EGAC.

A recommendation for accreditation cannot be made in the decision-making process until all corrective actions have been completed satisfactorily. This may require follow up visits by the assessment team.

Once the assessment process is completed and the assessment team ensures that the applicant CB organization conforms to the relevant standard/ IAF Guidelines, a report is submitted to the decision makers, who will then decide whether to make a recommendation for accreditation.

12. The process for granting accreditation

12.1 Appointing the members of the Technical Committee (TC)

TC is formed for each applicant according to its specific discipline or scope. Each TC shall consist of at least two members All these members shall be not involved in the assessment process in any way. EGAC has TC members covering the main disciplines and sectors within which it operates, who are drawn from experts in the field as appropriate.

12.2 Conducting the Technical Committee (TC) meeting.

After the TC members are appointed, they shall sign confidentiality and impartiality agreement before their meeting. TC members with EGAC person CBs accreditation manager shall review the CAB assessment file to verify its harmony with ISO/IEC

17024:2012 and EGAC requirements. The assessment file shall include the proposed scope of accreditation assessed, the assessment report, the resolution of all nonconformities and the recommendation of the assessment team. The decision of the TC is taken by consensus. The TC may decide that further actions or information are required. When satisfied, the TC shall recommend the accreditation of the CAB on the specified scope. This shall be recorded on the TC Report.

12.3 Conducting the Accreditation Committee (AC) meeting.

EGAC AC is headed by EGAC executive director. It has 7 members representing the stakeholders. In case that the TC recommends the accreditation of the CB, the AC meeting shall be invited to meet by EGAC executive director. The AC shall meet as needed typically every month.

Meeting papers shall include assessment reports for the assessment activities and the TC reports. The AC may invite to the attendance of its meeting whoever it sees fit for help with experience in the field of accreditation activities without having a vote to be counted in the proceedings. When setting up a meeting, the AC members shall be required to sign a confidentiality and impartiality agreement.

12.4 Decision making and granting accreditation

The AC meeting shall be considered legal if more than 50% of its members attend resolutions shall be based on the majority of votes of the attending members, with EGAC executive director vote as casting vote. Members involved with the CB being discussed, will neither participate nor attend the voting process. The AC can decide granting the accreditation to the CB directly or require further actions to be taken or information to be provided. This shall be recorded on the AC minutes of meeting. In case that the AC decides granting the accreditation to the CB, EGAC shall inform the CB and ask for its representative to receive the accreditation certificate with the approved scope of accreditation.

13. Feedback, complaints and appeals

After receiving the accreditation certificate the accredited body will be asked to fill a feedback report about EGAC's performance during the accreditation process which shall be used for improvement of assessors' performance and/or accreditation process. If the CB has any complaint it can file this complaint at EGAC or by phone. Also, if the AC did not grant the accreditation to the CB, the CB has the right to appeal. If the CB decides to appeal, it can fill an appeal at EGAC. Complaints and appeals shall be handled by EGAC's quality department and according to EGAC's publication (PB3G - Guidelines for dealing with complain and appeal) which is available on demand. A neutral Appeal committee shall be appointed to resolve this appeal according to the mentioned procedure.

14. POST ACCREDITATION

EGAC publishes a directory of accredited certification CBs, which contains details of the accredited scope of each accredited organization. The directory, which is updated regularly, is published on EGAC's website.

15. Consecutive Assessment Visit

EGAC assessment visit will take place annually to reflect the range of activity of the accredited CB.

It will normally cover a review of the records associated with assessment activity to determine continued conformity of the organization's management system. Witnessed assessments or post-assessment audits will also be programmed.

The first consecutive assessment visit shall take place **within the last 6 months at the 1st year of accreditation** after the date that initial accreditation was granted; the month of this visit will be assigned as the profile month of the CB. Thereafter all periodic visits will occur periodically at or around the profile month for the CB.

Where there has been an extended period between initial assessment and grant of accreditation, the time between grant and first consecutive assessment may be shortened.

EGAC shall inform the accredited CB at least three months before the annual date of accreditation for conducting the assessment visit and the CB shall confirm its readiness within 15 days.

The purpose of assessment visit is to:

- Confirm the accredited CB's continued conformity with relevant criteria, and,
- Confirm that a CB is operating within its accredited scope and in accordance with EGAC Conditions

Performance, size and complexity of the organization will be key considerations. The anticipated minimum would be annual visits to head office, one witnessed assessment per year, and each "critical elements" location will be visited at least once during the validity period of the accreditation certificate. One witnessed assessment will be conducted for each scope during the accreditation cycle. A judgment will be made on the level of sampling possible for consecutive assessment cycles according to the sampling procedure.

Any revisions to the documented system will be reviewed during these visits. Where the changes are extensive additional time may need to be scheduled.

16. Sampling in assessment of certification bodies

16.1 For Initial Assessment

The initial assessment of head office (HO) and all other locations undertaking any of the critical elements will be assessed as part of the initial assessment. All scopes applied for, will be subject to an office assessment and technical review.

EGAC will cover the scope for each applicant CB through the use of the following mechanisms that are available, including:

- Office assessment activities
- Witnessing activities:

Where an organization operates from a number of offices, witness assessments will be selected from a cross section of locations. It will not be necessary to witness the range of scopes per office.

16.2 For consecutive assessment during [4 years]

Each critical location will be visited at least once during the validity period of the accreditation certificate. This visit will include a witnessed assessment where appropriate.

A witnessed assessment will be carried out in each scope area.

The minimum number of witnessed assessments is 1 per year.

16.3 For re-assessment

The re-assessment of HO and all other locations undertaking any of the critical elements will be assessed as part of the re-assessment. All scopes applied for, will be subject to an office assessment and technical review.

17. Re-assessment and renewal of accreditation

Re-assessment visit will take place in four-year intervals. A re-assessment visit will involve a comprehensive re-examination of the CB's quality management system. Assessment activities will be similar in format and in detail to the initial assessment.

The CB must apply for renewal of accreditation at least six months before the expiry of the validity of accreditation. If the CB doesn't apply for renewal of accreditation, three months before the expiry of accreditation it shall be presumed that the CB is no longer interested in accreditation and the accreditation status of the CB shall expire on the validity date mentioned in the certificate. Time frame will be as mentioned in EGAC's regulation R5G.

At each re-assessment, the accredited CB current schedule of accreditation shall be considered in advance of the visit. Following the re-assessment visit, which will follow the same general procedure as the initial assessment, and the receipt of evidence of clearance of nonconformities, the report and recommendations will be considered, (for a recommendation by the TC and a decision by the EGAC AC), for re-accreditation for a further four year period. A new certificate of accreditation is issued on the renewal; however the certificate number remains the same.

17. Extensions to accredited scope

Accredited CB may be able to extend the scope of their operation into activities beyond those covered by their accredited scope. Extensions to scope require formal application using the form provided by EGAC, and will be dealt with on a case by case basis. The application will need to be accompanied by documentary evidence of competence in relation to the relevant industrial and technical activities.

When an accredited CB applies for an extension of its schedule of accreditation, including the addition of new specified staff, it may be combined with the assessment visit of an imminent scheduled visit, or an extra visit is arranged in the normal way. It is helpful in visit planning if the application for extension of scope is submitted to EGAC at least three months before the next scheduled visit.



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If the extension is assessed during a scheduled visit it shall not be allowed to reduce the effectiveness and coverage of the assessment/re-assessment visits.