

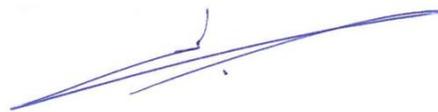
EGAC Guide for Accreditation of Inspection Bodies

PB8I

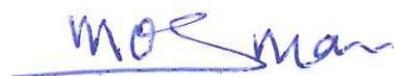
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1. Introduction

The following notes will help organisations seeking accreditation for inspection body to recognised international standards 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 ISO/IEC 17020:2012 and EGAC requirements.

2. Application of Accreditation

To gain accreditation, the IB must be fully conversant, and comply, with the requirements of ISO/IEC 17020:2012, 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;
- **Self-assessment report** for inspection bodies 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 IB 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.
- **Self-assessment report** for inspection bodies quality system implementation.
- IB quality system documents.
- Application fee according to R3G
- IB regulatory documents applicable to the applicant's scope;
- IB documentation - Articles of Association, or equivalent, for review by EGAC.

A preliminary meeting at the EGAC office is recommended for the purposes of clarifying initial questions. Agreement for the operation will be submitted to the applicant to be reviewed and signed.

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

3. Appointment of the assessment team

After the Articles have been approved the applicant shall prepare and submit for initial assessment and review, the documents describing the applicant's quality system including the applicant's quality manual and all associated procedures and documents covering the requirements of the relevant clauses of ISO ISO/IEC17020:2012, This should be done when:

- The applicant is satisfied with the his quality management system.

- The applicant has produced his quality manual and believes that it meets accreditation requirements.

The application will be handled by EGAC IBs accreditation manager, who will study the documentation which the applicant has submitted. EGAC IBs accreditation manager will contact the applicant to inform the composition of the assessment team and to make arrangements for the assessment process to commence.

If the applicant has not sent to EGAC the completed formal application and accompanying the applicant's quality manual within 6 month, the applicant's application will be considered to be neglected.

The assessment will be conducted by as many independent assessors 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 IB 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 IB to any of the nominated assessors will be investigated by EGAC IBs accreditation manager. If EGAC IBs accreditation manager is satisfied with the IB's justification to his objection, he will change this nominated team, other wise he shall inform the IB that his objection is not accepted and EGAC will keep the nominated team. EGAC IBs 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 (according to R5G), he will have to re-apply to EGAC for accreditation and pay a further application fee.

4. 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 and on-site witnessing;
- Where necessary, confirmation of completion of corrective actions to address non conformities raised during the assessment visit;
- EGAC review and decision-making process;
- Granting accreditation to the applicant and issuing a certificate and final scope of accreditation.

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

- The size and location of the applicant organisation;
- The range and complexity of scope;
- The ability of the applicant to correct nonconformities and the consequent number of follow-up meetings required.

It is generally estimated that the minimum would be 10 man days, rising to a maximum of 20 man days. The applicant will be given a quotation for assessment work before assessment takes place.

5. Review of documentation

The applicant will prepare the documentation to be provided for review by the assessment team prior to head office assessment. The documentation required includes as a minimum:

- IB updated documentation (Ex: QM, procedures, WI, last internal audit, last management review, legal entity documentation, Insurance,....)
- Those documents listed in relevant clauses of ISO/IEC 17020:2012;
- Procedures for carrying out competence analysis, in particular for gathering information related to client activities, and the relevant experience and qualifications of personnel;
- Criteria for determining appropriate levels of competence in all relevant areas;
- Procedures and methodologies used for inspection.

EGAC IBs accreditation manager will review these documentation to make a preliminary conformity assessment with the relevant standards, and to gain an understanding of the applicant's organisation and management system.

6. Head Office Assessment

The purpose of the head office assessment is to:

- Determine whether the applicant's documented system meets the relevant standards ;
- 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 support assessor/technical expert, as appropriate. It will cover:

- A presentation by the applicant about his business, organisation, resources, and management systems.
- An assessment of the applicant's management system
- Main clauses of the relevant standards.

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

7. On-Site Assessment of Inspections:

On-site assessment of inspections is the most essential part of the EGAC assessment of IBs to ISO/IEC 17020:2012 and EGAC requirements. This is particularly important when the IB is performing inspections of such nature where the inspector's professional judgment is crucial to the outcome of inspection.

When deciding on the number of on-site assessments of inspections needed the following aspects will be considered by EGAC:

- The fields and types of inspection on the accreditation schedule.
- The IB's procedures for selecting, training, authorizing and monitoring inspectors, having regard to the qualifications and experience required for different fields and types of inspection.
- The internal auditing arrangements of the IB.
- The locations from which inspectors operate.
- Any statutory requirements.
- The extent to which inspectors are required to exercise professional judgment.

8. Follow up visits

A recommendation for accreditation cannot be made for the decision-making process until all non conformities have been corrected satisfactorily. This may require follow up visits by the assessment team.

9. Recommendation for accreditation

Once the assessment process is complete and the assessment team is convinced that the applicant organisation conforms with the relevant standards, a report is submitted to EGAC to review by the decision makers (EGAC accreditation committee), who will then decide whether to grant accreditation . Following a decision of granting, the applicant will receive notification from EGAC of accreditation and its schedule of accredited scope.

10. Process for Granting Accreditation

10.1 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.

10.2 Conducting the Technical Committee meeting.

After TC members are appointed, they shall sign a confidentiality and impartiality agreement before their meeting. TC members with EGAC IBs accreditation manager shall review the IB assessment file to verify its harmony with the relevant international standard 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 IB on the specified scope. This shall be recorded on the TC report.

10.3 Conducting the Accreditation Committee (AC) meeting.

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

Meeting papers shall include summary 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. EGAC accreditation director shall attend the meeting to provide any required information about accreditation subjects and to be responsible for the administrative work of the meeting.

10.4 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 IB being discussed, will neither participate nor attend the voting process. The AC can decide granting the accreditation to the IB 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 IB, EGAC shall inform the IB and ask for its representative to receive the accreditation certificate with the approved scope of accreditation.

11. Feedback, complaints and appeals

After receiving the accreditation certificate the accredited IB will be asked to present a feedback report (the IB was received IB Feedback form in the end of the assessment visit) about EGAC's performance during the accreditation process which shall be used for improvement of assessors' performance and/or accreditation process. If the IB has any complaint it can file this complaint at EGAC or by phone. Also, if the AC did not grant the accreditation to the IB, the IB has the right to appeal. If the IB decides to appeal, it can file an appeal at EGAC. Complaints and appeals shall be handled by EGAC's quality department and according to EGAC's procedure (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.

12. POST ACCREDITATION

12.1 EGAC Directory

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

12.2 EGAC consecutive assessment

Following granting of accreditation, labs shall be subject to periodic consecutive assessment visits according to an annual program prepared by EGAC IBs accreditation manager. EGAC will make its program to have a first assessment visit within the last 6 months at the 1st year of accreditation, and a second assessment visit within last 6 months at the 2nd year of accreditation, and a third assessment visit within last 6 months at the 3rd year of accreditation.

In all cases the duration between two sequential assessment visits shall not exceed than 2 years.

If the 1st, 2nd and 3rd assessment showed that the IB needs more frequent visits then EGAC would decide on more 4th un-planned assessment visit.

The consecutive assessment program for all accreditation period will be prepared for each accredited IB by the EGAC IBs accreditation manager, the IB shall be informed.

EGAC sampling procedure will be applied as follow:

12.3 Sampling in assessment of inspection bodies

For Initial/Re-Assessment

No sampling is applied. The initial assessment of HQ and all other locations will be assessed as part of the initial assessment. All scopes applied for, will be subject to an office assessment and technical review.

For Consecutive assessment during [4 years]

Normally, during a single assessment visit, assessors will not be expected to check the whole of the inspection work for which the IB is accredited. However, all the accreditation activities covering all areas of competence and all authorized personnel to do it, shall be assessed during the validity period of the accreditation certificate. Equally not all the quality system needs to be covered at each assessment visit. The assessment team will take into account the

outcomes of the previous audits to be covered. The team leader will normally look at the management review(s), internal audit(s) and compliant records at each assessment visit.

13. Re-assessment and renewal of accreditation

Re-assessment visit will take place on four-yearly intervals. A re-assessment visit will involve a comprehensive re-examination of the IB's quality system and inspection activities and will be similar in format and in detail to the initial assessment.

The IB shall apply for renewal of accreditation at least 9 months before the expiry of its accreditation certificate. Time frames will be as mentioned in EGAC's regulation R5G (Accreditation process timings and response actions).

At each re-assessment, the accredited IB's 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 by (for a recommendation by EGAC technical committee and a decision by the EGAC accreditation committee), 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.

14. Extensions of accredited scope

Accredited organisations 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. EGAC will advise the organisation of the steps required to gain approval for the extension to the accredited scope.

15. THE ROUTE TO ACCREDITATION

