

***Hellenic Accreditation System S.A***  
**Accreditation Procedures**

**ACCREDITATION PROCEDURES**

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# **Hellenic Accreditation System S.A**

## **Accreditation Procedures**

### **ACCREDITATION PROCEDURES**

#### **1. Submission of Application**

- 1.1 Anyone seeking accreditation submits to ESYD Unit a completed Application Form (distributed by the Unit), accompanied by the Quality Manual and the relevant procedures in duplicate and pays the application fees.

The applicant may not submit the above-mentioned procedures. In that case the subsequently assigned assessment team shall be acquainted on the procedures during an extra visit at applicant's premises, debited against the applicant.

- 1.2 The Unit examines at first the completeness of the Application Form and the submitted documentation. If there are obvious major deficiencies, the documentation is returned to the applicant for reviewing. If the applicant does not respond within one (1) month from the date the deficiencies were made known, the application ceases to be in effect and it is filed, notifying simultaneously the applicant.

- 1.3 Next, the MU examines whether ESYD is in the position to respond to the submitted application. This can be done when the following requirements are fulfilled:  
a) ESYD has the appropriate technical competence, b) the applicant complies with the requirements set by ESYD Accreditation Rules and Criteria, c) the applicant fulfils the requirements set by the Law and d) granting of accreditation will not pose a risk to ESYD reputation.

1.3.1 In a positive answer, the MU forwards the submitted documentation to the Managing Director, together with a list of available assessors/experts.

1.3.2 In a negative answer, notifies the applicant and put the reimbursed application fees at his disposal.

#### **2. Appointment of the Assessment Team**

- 2.1 Following a MU's proposal, the Managing Director reviews the supporting documents, identifies the points where particular attention should be paid during the assessment, and appoints the Lead Assessor and the other Assessors and/or Experts, which will conduct the assessment.

- 2.2 For Certification/Inspection Bodies or EMAS Verifiers the Managing Director determines also at first after MU's proposal, the type, the number and the audits / inspections which, where necessary, the applicant will perform, and will be witnessed by the assessment team, as well as the composition of the corresponding assessment teams (In general, the number of ESYD assessors corresponds to the number of auditors / inspectors of certification/inspection body). The decision of the Managing Director, about the witnessed assessments, are forwarded to the relevant Technical Committee. In the case when the TC has an objection on this decision concerning the

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number and the type of the witnessed assessments, this objection shall be documented prior to the next TC meeting in order to modify the decision.

- 2.3 The assessment team has to be appointed within forty-five (45) days from the submission of application. The time required for the submission of any additional documentation is not counted in the above interval.
- 2.4 The assigned assessment team is notified to the applicant, who has the right to express any reasonable objections against team's composition; in such a case, the Unit tries to propose an alternative composition, including the employment of a foreign assessor, from an equivalent accreditation body-member of MLA. When an alternative is not possible, ESYD notifies the applicant that it can not proceed to the requested accreditation.
- 2.5 The applicant is also informed, additionally to the composition of the assessment team, about the estimated duration of the Assessment Procedure.
- 2.6 If the applicant does not respond within ten (10) days, the application ceases to be in effect and it is filed, notifying simultaneously the applicant.
- 2.7 After the nomination of the assessment team, the submitted documents, together with the remarks of the Unit are forwarded to the Lead Assessor, and the members of the assessment team are informed on the imminent assessment.
- 2.8 The Lead Assessor reviews the documentation of the applicant, and within ten (10) days submits to the Unit his/her report; which is notified to the applicant, referring to the completeness of the documentation and informs whether a plan for the main assessment can be prepared, or a pre-assessment is required, or the applicant is not yet ready for pre-assessment.
- 2.9 If the applicant does not respond, within one (1) month from the date of notification of any deficiencies, the relevant application ceases to be in effect and it is filed, notifying simultaneously the applicant.

### **3. Pre-assessment**

- 3.1 Pre-assessment is ~~voluntary~~ ~~mandatory~~ and is carried out prior to the assessment, after the confirmation of the applicant. The pre-assessment is proposed for the applicant, in order to avoid problems or delays during the assessment.
- 3.2 The date of pre-assessment is arranged with the applicant in writing.
- 3.3 The pre-assessment, where necessary, shall begin within three months from the submission of application.

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- 3.4 In the cases where a pre-assessment visit is required, this is carried out by the Lead Assessor, possibly in co-operation with a staff member of the Unit, and normally lasts one day. The results of the pre-assessment visit are recorded in a report, which is notified to the applicant. Depending on the findings of pre-assessment it can be judged that:
- 3.4.1 A plan for assessment can be prepared, after the applicant implements any corrective actions that might have been raised as a result of the pre-assessment visit;
  - 3.4.2 A further pre-assessment visit is required;
  - ~~3.4.3 Serious deficiencies prevent the continuation of pre-assessment.~~
- ~~3.5~~ The maximum time for discharging the possible deficiencies shall not exceed three (3) months, from their notification. This time period can be extended to five (5) months, if the nature of deficiencies requires so. ~~In an opposite case, the applicant shall submit a new application for accreditation, as appropriate.~~
- 3.6 The composition of assessment team is finalised immediately after the completion of the pre-assessment visit.

#### **4. Elaboration of the assessment visit plan**

- 4.1 For the preparation of the assessment team the applicant is asked to provide copies of any in-house methods or procedures. In case the applicant refuses to provide the above methods, the assessment team shall be acquainted on the methods during an extra visit at applicant's premises, arranged between the applicant and the Unit. This visit is debited against the applicant.
- 4.2 The Lead Assessor shall prepare the plan of the assessment visit in applicant's premises and in conjunction with the Unit will estimate the required time for the conduct of the assessment.
- 4.3 In the cases of Certification/Inspection Bodies or EMAS Verifiers, the time required for the observation of witnessed assessments, will be also estimated.
- 4.4 The above estimated time comprises the basis for calculating the applicant's economic obligations for the conduct of assessment.
- 4.5 The Unit notifies in writing the applicant on the plan of assessment and on his budgeted economic obligations.
- 4.6 The applicant shall accept in writing the plan of assessment and shall pay in advance the seventy per cent (70%) of his budgeted economic obligations.
- 4.7 If the applicant does not respond before the arranged date of the assessment, the application ceases to be in effect and is filed, notifying simultaneously the applicant.

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### **5. Commencement of the assessment**

- 5.1 The relevant staff MU may be present in the assessments of the applicant.
- 5.2. The assessment visit begins with an Introductory Meeting, which takes place in the premises of the applicant, in which the assessment team and representatives of the applicant participate. The purpose of the Introductory Meeting is to clarify any possible difficulties, to confirm the purpose of the assessment and to become explicit what is expected by the applicant during the assessment.
- 5.3. The assessment team communicate exclusively with the personnel of the laboratory/body involved in the quality system. Any consultant on the QMS of the applicant or the organization being audited during a witnessed assessment may be present during the assessment/audit provided that remains a silent observer.

### **6. Laboratory assessment**

- 6.1 Following the Introductory Meeting, an examination of the laboratory's quality system and an audit of on-going work will be conducted, in order to verify by observation, that the work carried out by the laboratory meets the accreditation criteria and standards and the documented quality system of the laboratory. During the assessment every assessor/expert is accompanied by an authorised member of the laboratory, which does the laboratory manager assign for this purpose.
- 6.2 Assessors/experts shall evaluate the competence of the laboratory, the suitability of the methods used and of the equipment involved, including their state of calibration and maintenance. They will establish the traceability of the measurements to national or international standards, especially for those that have serious influence on the precision or validity of the calibration and testing. The assessors/experts will also evaluate the competence of the laboratory staff, especially those who perform calibration and testing procedures, and the effectiveness of the quality system, so as to verify that there are no mistakes or failures in recording, analysing and reporting of the results.
- 6.3 The observations made will be based on objective evidence, and will be recorded and verified before assessors/experts leave the area under assessment. Assessors/experts have to make detailed observations and to record their findings in specific forms. The accompanying laboratory representative shall countersign each observation.

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### **7. Assessment of a Certification/Inspection Body or an EMAS Verifier**

- 7.1 Following the Introductory Meeting the assessment starts in the premises of the applicant. During assessment, the Assessors/experts examine the quality system, seek for objective evidence for the implementation of policies and procedures and record the observations in specific forms. Each observation shall be countersigned by the applicant' representative.
- 7.2 The assessment of Certification/Inspection Bodies and EMAS verifiers shall always include witnessed assessments.
- 7.3 During the Head Quarters assessment, the plan of the witnessed assessments shall be prepared by the Lead Assessor, in co-operation with the Unit, according to the provisions of paragraph 4, and the guidance of the Technical Committee.
- 7.4 The applicant shall accept the plan in writing.
- 7.5 The assessment team witnesses the audits / inspections avoiding at any way to influence them. The assessment team witnesses any activity that auditors / inspectors of the body perform and record the observations in specific forms.
- 7.6 The performance of all auditors / inspectors individually and as a team is evaluated.
- 7.7 The non-compliances observed are recorded in specific forms and shall be countersigned by the applicant's auditors / inspectors
- 7.8 During the above audits / inspections, where necessary, the applicant shall propose and implement corrective actions.

### **8. Assessment completion**

- 8.1 The assessment is finalised with a Final Meeting in applicant's premises. During the Final Meeting the Lead Assessor presents a summary of the findings and the applicant representative shall propose corrective actions for the discharge of any non-compliance that may have been raised during assessment, and a time schedule for their implementation.
- 8.2 In cases of Certification/Inspection Bodies and EMAS Verifiers the Final Meeting takes place after the completion of the witnessed assessments and after a significant progress in the implementation of corrective actions has been made.
- 8.3 The maximum time provided for the discharge of any possible non-compliances cannot exceed three (3) months, after issuing the schedule for their discharge. This period can be extended to five (5) months, if the nature of corrective actions requires

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so. In an opposite case the applicant shall submit a new application for accreditation, as appropriate.

### **9. Examination by the Technical Committee**

- 9.1 Within ten (10) days after the Final Meeting, the Lead Assessor prepares his/her recommendation, which is then forwarded by the Unit and is notified to the applicant.
- 9.2 After the implementation of any corrective actions and submission of documented evidences to the Lead Assessor he/she prepares within fifteen (15) days, in the case when the corrective actions are totally accepted, his/her final recommendation and forward it to the Unit. Also, the proposed Scope of Accreditation is submitted.
- 9.3 The MU forwards the documentation provided by the Lead Assessor to the relevant Technical Committee.
- 9.4 The Technical Committee examines the submitted information and the recommendation of the Lead Assessor, and either:
  - 9.4.1 Approves Lead Assessor's recommendation, forms the proposed Scope of Accreditation, and next the recommendation together with the corresponding documentation is forwarded by the Unit to the National Accreditation Council, or
  - 9.4.2 Refuses Lead Assessor's recommendation and decides that further corrective actions shall be performed. The Unit then notifies the Lead Assessor and the applicant the reason for these further corrective actions and asks for their implementation. In case of any dispute between the body and the Lead Assessor concerning the characterization and the correctness of non-compliances, the Technical Committee in collaboration with the Unit examines the subject and propose as appropriate.
- 9.5 When necessary an additional assessment visit is conducted.
- 9.6 The Lead Assessor in collaboration with the Unit calculates the total time spent for the assessment and the time required for the yearly surveillance.

### **10. Accreditation Granting**

- 10.1 The National Accreditation Council examines the recommendation of the relevant Technical Committee and, in case all the requirements for accreditation are satisfied, recommends accreditation granting. The BoD finally decides after the Council's recommendation the accreditation granting.

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- 10.2 ESYD's decision, the rest of economic obligations of the applicant and the corresponding expenses for surveillance and maintenance are notified to the applicant, who shall accept them in writing, settles up his debt and returns mandatory the document ESYD PQ8-E1 properly filled.
- 10.3 The Certificate of Accreditation, valid for four years, and the Scope of Accreditation, signed by the authorised persons, is issued by the Unit.

### **11. Surveillance of Accredited Bodies**

- 11.1 The purpose of surveillance of accredited bodies is to ascertain that they continue to comply with ESYD requirements.
- 11.2 The surveillance takes place once per year..
- 11.3 The surveillance takes place according to a time schedule prepared by the Unit and approved by the Managing Director. Adherence to the schedule is under the responsibility of the Unit.
- 11.4 The surveillance follows the same procedure as the above described for the initial assessment.
- 11.5 If, during a surveillance visit, non-compliances are found, a period of one month is provided for their discharge. Suspension or withdrawal of accreditation is possible until their discharge.

### **12. Extension of the Schedule of Accreditation**

- 12.1 For the extension of the Scope of Accreditation, including the addition of new specialised staff, the laboratory shall submit an application, the necessary documentation and settles up the corresponding fees.
- 12.2 The Unit forwards the application to the Lead Assessor/Assessors/Experts who, where possible, has conducted the initial assessment. After reviewing the submitted documentation they recommend to the relevant Technical Committee, if a new assessment is required, or if the official schedule of accreditation can be extended without any further assessment.

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- 12.3 The Committee approves the recommendation of the Lead Assessor and follows the same procedure as that described for the initial assessment.
- 12.4 A similar procedure is followed in the cases of extension of accreditation for Certification/Inspection Bodies or EMAS Verifiers.

**13. Re-assessment of Accredited bodies**

- 13.1 Accredited bodies or persons are subject to re-assessment once every four years. Re-assessment follows the same procedure as the initial assessment.
- 13.2 If during a re-assessment visit non-compliance is found, a period of one month is provided for its discharge. Suspension or withdrawal of accreditation is possible until their discharge.
- 13.3 In the case where, during the reassessment the valid period of the Certificate of Accreditation is exceeded, this period can be extended, after a documented proposal of the relevant MU and a decision of the National Accreditation Council, until the completion of the reassessment according to ESYD Accreditation Procedures.