Hellenic Accreditation System

ACCREDITATION PROCEDURES

ESYD PA

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Quality Manager of ESYD **Chairman of ESYD**

ACCREDITATION PROCEDURES

1. Submission of Application

1.1 Anyone seeking accreditation submits to ESYD an electronic copy and a hard copy of the following documents:

a) a completed Application Form,
b) the Quality Manual where applicable,
c) the relevant procedures,
d) the necessary legal documents and
e) α copy of the bank deposit receipt showing the payment of application fees.

The applicant may not submit the technical procedures if evidence can prove that these enclose proprietary and confidential information. In that case it is obligatory that the subsequently assigned assessment team shall be acquainted on the procedures during an extra visit at the applicant's premises, debited against the applicant. This procedure is not applicable for technical information described as obligatory in the relevant application forms (e.g. uncertainty budget for calibration laboratories).

1.2 ESYD 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,
d) granting of accreditation will not pose a risk to ESYD reputation,
e) there is no acceptable risk regarding the impartiality of ESYD

1.3.1 In a positive answer, the Director of the relevant Division nominates the assessment team according to the procedure that is described below.

1.3.2 In a negative answer, notifies the applicant and put the reimbursed

application fees at his disposal.

1.3.3 During the reviewing of the documentation if ESYD finds that cannot proceed with the initial assessment of the body according to the foreseen. time limits of the present procedure, then the body is informed accordingly.

1.3.4 In case there is no acceptable risk regarding the impartiality of ESYD the decision to not proceed the accreditation procedure is taken by the BoD of ESYD after recommendation of the National Accreditation Council.

2. Appointment of the Assessment Team

2.1 Following a MU's proposal, the Director of the relevant Division appoints the Lead Assessor and the other Assessors and/or Experts, which will conduct the assessment. The Managing Director may review the nominated assessment teams.

2.2 For Certification/Inspection/Verification Bodies or Environmental Verifiers the Director of the relevant Division 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 team including observers. 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.

2.3 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.

2.4 The applicant is also informed, additionally to the composition of the assessment team, about the following:
a) estimated duration of the Assessment Procedure,
b) required assessment time,
c) accreditation fees and applicant's obligation to pay the 70% of the accreditation fees in cash, three (3) days before the scheduled date of the assessment, at the latest.

2.5 If the applicant does not respond within ten (10) days, this means that there is no objection and the procedure continue, as foreseen.

2.6 In the case that the 70% of the accreditation fees is not paid three (3) days before the scheduled date of the assessment at the latest, the relevant application ceases to be in effect if it is an initial assessment. As for surveillances and reassessments the visit is postponed with simultaneous suspension of the accreditation until the conformity assessment body (CAB) pays the relevant amount.

2.7 In the cases of Certification / Inspection / Validation & Verification Bodies or environmental verifiers, immediately after the notification of the assessment team, the applicant should schedule the witnessed assessment (find available clients). The assessment plan will be finalized during the assessment in the head offices.

2.8 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.

2.9 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 pre-assessment or the main assessment can be prepared, or the applicant is not yet ready for pre-assessment or for main assessment.

2.10 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, with simultaneous notification to the applicant.

3. Pre-assessment (voluntary)

3.1 Pre-assessment is voluntary 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.

3.4 In the cases where a pre-assessment visit is required, this is carried out by the Lead Assessor, lasts up to one (1) day. In any case, it is charged as one (1) Lead Assessor's manday. 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:

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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.

3.5 The maximum time for discharging the possible deficiencies shall not exceed three (3) months, from their notification. This period can be extended to five (5) months, if the nature of deficiencies requires so. If this is not the case, the application ceases to be in effect, with simultaneous notification to the applicant.

3.6 The composition of assessment team is finalised immediately after the completion of the pre-assessment visit.

3.7 In cases of force majeure (e.g. natural catastrophe) the estimated time limits between application for accreditation and pre-assessment, application for accreditation and assessment (when there is no pre-assessment) and pre-assessment and assessment can be extended after decision of the Director of the relevant Accreditation Division. In any case, before the assessment, the applicant shall send to ESYD the changes that may have occurred in the documentation of the quality management system.

3.8 In the case where the time between the pre-assessment and assessment is more than twelve (12) months, the applicant is informed for possible necessity of repetition of the pre-assessment.

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 inform the Unit that notifies the assessment plan to the applicant, in writing.

4.3 The applicant shall respond in writing if accepts the plan of assessment. If the applicant does not respond before the date of the arranged assessment, this means that there is no objection, and the procedure continues as it is foreseen.

5. Commencement of the assessment

5.1 An observer 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 communicates 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. Laboratories / PT Providers Assessment

6.1 Following the Introductory Meeting, an examination of the laboratory's quality system / PT provider and an assessment of on-going work will be conducted, in order to verify by observation, that the work carried out by the laboratory / PT Provider 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 / PT Provider, 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 finding.

7. Assessment of a Certification / Inspection / Validation & Verification Body / Environmental Verifier

7.1 Following the Introductory Meeting the assessment starts in the premises of the applicant. During the 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 finding shall be countersigned by the applicant's representative.

7.2 The assessment of Certification / Inspection / Validation & Verification Bodies / Environmental Verifiers shall always include witnessed assessments.

7.3 The Lead Assessor in cooperation with the assessment team will inform the applicant for the audits that is interested in attending and shall finalize the program of the witnessed assessments, taking into account the relevant nomination by ESYD and the record of the auditors / inspectors for each technical field on sampling. The date of the witnessed assessments shall be agreed at least twenty (20) working days before the assessment with probability of divergence one (1) or two (2) days. The Lead Assessor gives to the applicant the relevant form to complete it and send it back to ESYD.

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. The performance of all auditors / inspectors individually and as a team is evaluated.

7.6 The non-conformities observed are recorded in specific forms and shall be countersigned by the applicant's auditors / inspectors, which means that they accept that the findings are documented and to propose relevant corrective actions.

8. Assessment completion

8.1 The assessment of the applicant is finalised with an Intermediate Meeting after the completion of the assessment in the head offices. During this Intermediate Meeting, the Lead Assessor presents a summary of the findings and the body representative responds for their acceptance.

8.2 After the completion of the witnessed assessments, a Closing Meeting is held, if necessary, at the body's premises in order for the Lead Assessor to finalize the proposed Scope of Accreditation and to inform the representative of the body about his recommendation and for the findings of the assessment. The body within fifteen (15) days of the closing meeting shall respond to the findings providing a root cause analysis and proposal for corrective actions to resolve the non conformities which may have identified and the timetable for their implementation. The implementation of corrective actions should include an analysis of the extent and causes of nonconformities by the body. Within fifteen (15) working days of the Intermediate Meeting, the Lead Assessor on behalf of the assessment team responds to the acceptance of the proposed corrective actions and implementation timetable and determines which of them requires either (a) on-site assessment; (b) submission of documentation and objective evidence of the corrective actions within a period of 1-3 months (c) accepts the implementation timetable and defines the need or not to submit the body a progress report until their examination at the next assessment of the body; (d) accepts immediate corrective actions.
At the same time, the Lead Assessor forwards his/her recommendation to the Unit with notification to the assessed body including all the relevant assessment forms and information for the acceptance of the corrective actions implementation plan not later than 1 month after the Closing Meeting. In the cases where witnessed assessments have not been performed, the Intermediate Meeting is considered as the Closing Meeting.

8.3 For the corrective actions of cases (a) and (b) of 8.2 the maximum time provided for the discharge of any possible non-conformities cannot exceed three (3) months, after issuing them. This period can be extended to five (5) months, if the nature of corrective actions requires so. In an opposite case the applicant shall submit a new application for accreditation, as appropriate.

9. Examination by the Accreditation Manager

9.1 Within fifteen (15) days of the receipt of the corrective actions, the Lead Assessor shall, either the non-conformities are fully closed or are closed based on the implementation of corrective actions according to the timetable accepted, send his/her final recommendation to the Unit together with the proposed Scope of Accreditation.

9.2 The Director of the relevant Division appoints the Accreditation Manager for the specific issue. The Accreditation Manager* is **either** a member of the relevant Division, trained in the specific accreditation standard, with at least three (3) years working experience in ESYD as Accreditation Manager **or LA of ESYD in the specific accreditation standard in the last three years**. In any case, he/she should not have participated in the specific assessment team.

9.3 The Accreditation Manager examines the submitted information and the recommendation of the Lead Assessor, and either:

9.3.1 Approves Lead Assessor's recommendation, forms the proposed Scope of Accreditation, and forwards his recommendation to the National Accreditation Council, or

9.3.2 Refuses Lead Assessor's recommendation and decides that further corrective actions shall be performed and 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 Accreditation Manager in collaboration with the relevant Director examines the subject and proposes as appropriate.

9.4 In specific cases, the Accreditation Manager in collaboration with the Director has the potentiality / possibility to either consult a technical/s expert/s on the specific issue or/and to establish a special working group comprising of the Heads of the relevant Division in order to evaluate / examine the specific assessment.

9.5 When necessary, an additional assessment visit is conducted.

9.6 The MU calculates the total time spent for the assessment.

For the accreditation Standards ISO 15189 and ISO/IEC 17043, in case the Accreditation Manager, who is a member of the staff, has participated in the specific assessment team and there is no other member available who meets the requirements of ESYD PA § 9.2, as Accreditation Manager may be appointed an ESYD Lead Assessor in the specific standard if he /she has participated in at least 30 assessments during the last three years.

10. Accreditation Granting

10.1 The National Accreditation Council at its meeting examines the recommendation of the Accreditation Manager and further recommends to the Board of Directors the granting of accreditation.

10.2 ESYD Board of Directors decides on granting accreditation.

10.3 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 his debt and returns mandatory the document ESYD DEIP properly filled.

10.4 The Certificate of Accreditation, valid for five years, as well as the Scope of Accreditation, is issued by ESYD after signed by the Managing Director of ESYD.

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 Surveillances are scheduled every 18 months according to the issue date of the accreditation certificate, except for the first surveillance after the initial assessment of the body which is planned 6 months after the issue date of the accreditation certificate. In cases where there is a specific requirement from the accreditation scheme, the plan of surveillances/reassessments of the scheme, is applied. In any case, the time between two assessments cannot exceed 24 months. In specific cases, the Unit can decide for the performance of an extraordinary assessment.

11.3 The surveillance takes place according to the accreditation programme prepared by the relevant Division. Adherence to schedule is under the responsibility of the Unit.

11.4 The surveillance follows the same procedure as the above described for the initial assessment, with the following modifications:

11.4.1 In the cases where during surveillance there is no modification of the scope of Accreditation or when the modification is related only to the updating of the scope of Accreditation based on new editions of standards, a review by an Accreditation Manager is not required. Maintenance of accreditation is completed with a recommendation from the assessment team.

11.5 During the surveillance visit, the assessment team is not expected to examine the whole Scope of Accreditation of the accredited body. The surveillance planning is prepared in a way in order to ensure that between the initial assessment and the re-assessment are examined all elements of the assessment criteria at least once as well as the full scope of accreditation of the accredited body.

At each surveillance visit shall be assessed at least the following elements:

- Internal audit and periodic review
- Complaints against the body
- Previously identified non-conformities
- The proper use of ESYD accreditation symbol by the accredited body

11.6 If, during a surveillance visit, non-conformities are found, the procedure described in paragraphs 8.2 and 8.3 is followed but the deadline for their closing is 45 days after the Final Meeting and it is possible until they are closed, suspension or withdrawal of accreditation or part of the Scope of Accreditation.

The Lead Assessor is responsible for monitoring the compliance with the time limits for the closing of the non-conformities and for the compliance with the respective response times of the assessment team in the correspondence with the body.

11.7 If during the surveillance visit, very important non-conformities or deficiencies are found, the Lead Assessor shall send immediately recommendation for suspension or withdrawal for a part or the whole Scope of Accreditation of the accredited body.

11.8 During the surveillance visits of the certification / inspection / verification bodies or environmental verifiers, there shall be appropriate and prompt planning of the audits of the accredited body to its clients, so that the witnessed assessments to be finalized in a period of eight (8) months at the maximum, starting from the notification of the assessment team to the body. The above is sole responsibility of the accredited body. For this reason, the planning of the witnessed assessments shall be done during the

assessment in the premises of the accredited body. The exact date of the witnessed assessments shall be agreed at least twenty (20) working days before their conduction with possible deviation one (1) or two (2) days. Otherwise ESYD has the right to consider the specific witnessed assessment as it was not done, since the planning which was done by the accredited body was not realistic. If a witnessed assessment is not conducted because of force majeure either for the auditor / inspector or for the client of the accredited body or even for the member of ESYD assessment team during an eight (8) month period, then it can be transferred to the next surveillance visit to the accredited body. If the transferred witnessed assessment will not also be conducted in the next surveillance visit or in the case where there is no cooperation between the accredited body and its client in a specific field / code, then withdrawal of the specific scope/codes according to the provisions of Accreditation Regulations (RA), is decided. If a witnessed assessment is not conducted within a period of eight (8) months because of reasons attributed to the accredited body, except the above-mentioned case, or when there is a systematic deviation then paragraph 1.11 of Accreditation Regulations (ESYD RA), is applied.

11.9 Findings that are referred to paragraphs 1.10 – 1.12 of Accreditation Regulations (ESYD RA) are written down either in a report by the assessment team or in a recommendation of the responsible MU, if there is not any current assessment team.

12. Extension of the Scope of Accreditation

12.1 For the extension of the Scope of Accreditation, including the addition of new specialised staff, the accredited body shall submit an application, the necessary documentation and settles up the corresponding fees.

12.2 For the extension of the Scope of Accreditation, the same procedure is followed as in the case of initial accreditation. Moreover, it is possible that the assessment will be conducted by one assessor only.

12.3 The accredited body can submit application for extension of the Scope of Accreditation any time during the assessment cycle. In the cases that at the time of submission of the application for extension, a surveillance visit is in progress, it is recommended the assessment of extension to be included in the surveillance visit of the accredited body. If this is not the case, the assessment for the extension of the Scope of Accreditation will be conducted separately.

12.4 In the cases that an accredited body applies for extension of the Scope of Accreditation in a technical field which is similar to the Scope of Accreditation that the body already has and as for the applied extension, the same technical competence is required, concerning the involved staff and equipment, and the only difference is the implementation of a procedure, it is possible, after decision of the Accreditation Manager, a supplementary assessment to be conducted. In this case, the submitted documentation is reviewed by the Lead Assessor or by the technical assessor who then forwards his recommendation to the Accreditation Manager, without the conduction of on-site assessment in the accredited body's premises or of witnessed assessment.

13. Reassessment of Accredited bodies

13.1 Accredited bodies are subject to re-assessment once every five years. The planning of reassessment starts 12 months before the expiry date of the accreditation certificate. In any case, the time between two assessments cannot exceed 24 months. Reassessment follows the same procedure as the initial assessment. Concerning the witnessed assessment, the provisions of § 11.7 of this document apply.

13.2 If during a re-assessment visit non-conformities are found, the procedure described in paragraphs 8.2 and 8.3 is followed but the deadline for their closing is 45 days after the Final Meeting. Suspension or withdrawal of accreditation is possible until their closing.

13.3 In the case where, the validity of the accreditation certificate expires the corresponding file ceases to be in effect and a new application for accreditation shall be submitted.

14. Re-granting of Accreditation Certificate

In the case that due to special circumstances and only if ESYD is responsible for the delay, the assessment visit (head offices / laboratory installations) has been carried out within the period in which the Accreditation Certificate was valid and the assessment of the body is successfully completed within six months from the date of expiration of the Certificate, the same Accreditation Certificate may be re-granted.

The issue date of the Accreditation Certificate will be the date of the final accreditation decision and the expiration date will be five years or a multiple of five years from the initial issue date of the Certificate.

15. Accreditation Cycle

The accreditation cycle of ESYD is defined at 5 years. Initiation of the accreditation cycle is defined as the issue date of the accreditation certificate.