

Hellenic Accreditation System S.A.
Accreditation Regulations

ACCREDITATION REGULATIONS

**Hellenic Accreditation System S.A.
Accreditation Regulations**

ESYD PA

Issue: 02

Revision: 06

Issue Date: 08-01-1997

Revision Date: 08-01-2009

Prepared by: Quality Manager of ESYD

Approved by: Chairman of ESYD

Quality Manager of ESYD

Chairman of ESYD

Hellenic Accreditation System S.A.
Accreditation Regulations

DEFINITIONS

- The term "certification" covers the certification of the compliance of a product, the certification of quality management systems and/or environmental management systems, the environmental verifiers and the personnel certification.
- The term "inspection" is considered to cover the examination of the design of a product, of a service, of a process or of an installation and the determination of its compliance to special requirements or, based on a professional judgment, to general requirements.
- The term "laboratory" is considered to cover the calibration laboratories as well as the test laboratories.
- The terms "applicant bodies" and "accredited bodies" is considered to cover the certification bodies, the inspection bodies and the laboratories

1 GENERAL

- 1.1 The accreditation by ESYD, according to these regulations, is optional.
- 1.2 These regulations are in force concerning the accreditation of laboratories, certification bodies, inspection bodies and environmental verifiers according to criteria and respective guidelines as these are defined in detail in the Document ESYD CRITERIA.

ESYD, according to the legislation in force each time, can undertake the assessment of the technical competence of bodies, activated within the regulatory domain, assessing the compliance to requirements defined by the responsible Official Authorities. In such cases accreditation may be rendered obligatory.

- 1.3 Granting, maintaining, extending and renewing of the accreditation will be towards a body which:
- (a) proves its compliance to these Regulations, to the Accreditation Criteria and furthermore to the Guidelines, as these are defined by ESYD.
 - (b) pays down the corresponding fees

In all cases ESYD requirements are restricted to the fulfillment of the abovementioned accreditation criteria and the compliance to these regulations.

- 1.4 ESYD examines the submitted applications for accreditation in order to define the prerequisites under which they can be satisfied and informs the applicant bodies accordingly.

Hellenic Accreditation System S.A. **Accreditation Regulations**

1.5 All the bodies applying for accreditation are submitted to an initial assessment, in accordance with ESYD rules, in order to enable the ESYD assessors to determine the competence of the certification body, of the inspection body or of the laboratory and their compliance to the criteria against which the acquisition of the accreditation is pursued.

In the case of granting the accreditation, the accredited body is provided with an Accreditation Certificate and an Accompanying Document as well, which determines the scope of accreditation.

1.6 ESYD indicates the way to follow the continuing compliance with the present Regulations and the relevant criteria.

1.7 ESYD specifies the frequency of the surveillance and the reassessment to which the Accredited Body is subjected. The surveillance visits are performed usually in time intervals of 12 months and the reassessment every 4 years, according to the initial date of issue of the accreditation certificate. During the four years validity of the accreditation certificate, three surveillance visits shall be successfully completed and in case of accreditation certificate renewal, the reassessment of the Accredited Body shall be completed. Furthermore, ESYD maintains the right to order for additional or unscheduled surveillance or reassessment visits in time intervals different to those specified. ESYD maintains the right to attend, through its representatives, the visits performed by the applicants or by Accredited Bodies.

1.8 Particularly in the case of a) accident, b) accusation, c) complaint, d) appeal, e) legal requirement or request of a juridical authority, f) any other action that may defame ESYD, ESYD maintains the right to perform unscheduled audit to the Accredited Body, in order to collect evidence for the handling of the above. ESYD should inform the accredited certification body for the performance of the unscheduled audit, at least 24 hours before.

1.9 ESYD specifies the procedures, according to which the applications for accreditation are submitted, and also the prerequisites for granting, maintaining, extending and renewing of the accreditation and the conditions under which the accreditation may be rejected, suspended, withdrawn or reinstated.

1.10 ESYD may suspend or withdraw the accreditation, reduce the scope of accreditation, impose a suspension to the extensions of the scope (in the case of certification bodies) or request for a reassessment, if :

(a) there is any change to some aspect of the status or the operation of the accredited body, affecting its compliance to the present Regulations and the related criteria or affecting its competence or the scope of the operation of the accredited body, or

(b) the Accredited Body does not comply to the requirements of the present Regulations and/or the related criteria specified by ESYD .

1.11 The Council can withdraw the accreditation:

Hellenic Accreditation System S.A.
Accreditation Regulations

(a) if, in the case of an Accredited Body belonging to a physical person, this person declares bankruptcy or agrees a settlement for a part payment of its creditors or

(b) if the Accredited Body, as a Company, is submitted to an obligatory liquidation, (not including the liquidation for reconstruction purposes), or a Liquidator has been appointed for the enterprise or

(c) if the management of the Accredited Body demonstrates negligence, in any way, to comply with the legislation in force.

1.12 All the information that comes to ESYD and its representatives when granting, maintaining and renewing the accreditation are considered as confidential and are kept between the Accredited Body and ESYD. This information is used strictly within ESYD on a basis of “need for information” and in no case, according to the legislation in force, will be revealed, without some explicit written instructions of the Accredited Body, except if the legislation commands differently, in which case the body is informed on the released information concerning it.

1.13 ESYD informs the bodies concerned on the accreditation requirements and provides explanations on specialized subjects or any other additional information related to the accreditation.

1.14 The accreditation certificate is ESYD's property and its use is granted to the body when it is accredited. This granting stops if:

- a) the Accredited Body ceases to operate
- b) its accreditation is suspended or withdrawn.

2 ESTABLISHMENT OF THE RELATED ACCREDITATION CRITERIA

2.1 ESYD has the right to specify the related accreditation criteria, based on which the applicant bodies will be assessed.

2.2 The criteria quoted in the respective standards are taken as a basis for the assessment of the competence of the Laboratories or the Certification Bodies. ESYD may establish additional criteria based on its judgment.

3 PREREQUISITES THAT THE CERTIFICATION BODIES, THE INSPECTION BODIES AND THE CALIBRATION AND TESTING LABORATORIES HAVE TO SATISFY

3.1 **The Accredited Body shall:**

Hellenic Accreditation System S.A.
Accreditation Regulations

(a) comply always with the present Regulations, the related Criteria and the conditions that ESYD establishes concerning the use of ESYD logo, according to Annex A hereto, or related to the reference to the accreditation by ESYD ,

(b) mention that it is accredited concerning those activities which are defined in the accompanying accreditation document only and which are performed in accordance with the present Regulations and the related Criteria that ESYD establishes,

(c) pay down all the owing fees in time, according to what has been decided by ESYD

(d) not use its accreditation in a way defaming ESYD and not proceed to any statement concerning its accreditation that ESYD can reasonably consider as misleading,

(e) interrupt the use of the accreditation and of all the publicity material, containing any reference to this, immediately, in case of suspension or withdrawal of its accreditation (for whatever reason or cause),

(f) return the accreditation certificate in case of withdrawal of the accreditation by ESYD,

(g) make clear in all the contracts with its customers that its accreditation or any of the reports or the certificates do not in any way imply an approval of products or services by ESYD,

(h) assure that:

- no certificate or report or part of them will be used by a customer, neither their use by a customer will be approved, for promotion or advertisement purposes, if the Council judges that such a use is misleading,
- in case that a certificate or a report is partially reproduced by the customer, the written approval of the Accredited Body will be obtained in advance.

(i) assure that any written and fully documented complain by a third party is promptly investigated and is resolved according to the documented policies and procedures for managing the complains to the Accredited Body.

(j) the name of the Body does not create any confusion about its entity and activities

(k) define in its statutes that no consultancy services about accreditation or certification or inspection issues are provided. This is also mandatory for bodies which are part of another body or they use the name of another body or act as its representative.

Hellenic Accreditation System S.A.
Accreditation Regulations

(l) take all the appropriate measures for the participation of authorized persons of national or international organizations and bodies which assess ESYD's assessments of the accredited bodies and their customers.

3.2 Conditions that the Certification / Inspection Bodies have to satisfy

3.2.1 The Certification / Inspection Body shall offer to all its customers quality services consistent with the present Regulations and with the Standard against which it has been accredited. A Certification / Inspection Body is not allowed to offer to its customers certification services, within its accredited scope, which do not comply with the requirements of the present Regulation

3.2.2 The Certification / Inspection Body shall provide to ESYD and its representatives the necessary access and cooperation, in order to enable ESYD to monitor the compliance to the Regulations and the related Criteria. This cooperation shall include:

(a) the provision of a permission to ESYD and its representatives to conduct a detailed inspection of the certificates and of any other files related to the accredited activities,

(b) the provision of a permission to ESYD and its representatives to conduct a detailed inspection of the outcome of the internal audits of the quality system of the Certification / Inspection Body itself,

(c) the provision of help to ESYD and its representatives to investigate the resolution of any appropriately documented complains (written and fully documented), which have been submitted by any third party, concerning the accredited activities of the Certification / Inspection Body,

(d) the provision to ESYD assessment team all the original data (e.g. notes of the auditors) as evidence for the performance of audits.

(e) the provision of information to ESYD regarding the certification or inspections that the CB/IB has performed or will perform.

3.2.3 The holders of certificates bearing the logo of ESYD, which have been granted by accredited Certification / Inspection Bodies, shall allow the access to ESYD assessors in their working areas, in order to conduct an assessment procedure. The accredited Certification / Inspection Bodies are expected to make the necessary arrangements for this purpose with their customers.

3.2.4 The Certification / Inspection Body may use, without any modifications, on documents, brochures or advertisement means the following phrases: "Accredited Certification / Inspection Body registered under the register number" and "registered in the List of the Certification / Inspection Bodies of ESYD under the register number". In case of withdrawal of the accreditation by ESYD, the accreditation body has to cease immediately issuing certificates bearing the logo of ESYD, has to take the necessary measures in order to assure the immediate

Hellenic Accreditation System S.A. Accreditation Regulations

withdrawal of all the related documents, brochures and advertising material and, concerning the existing customers, to act in the way the Council will define.

3.2.5 The laboratories possessing an accredited certification according to ELOT EN ISO 9001 shall not issue certificates or reports on tests and calibrations which bear the logo of ESYD.

3.2.6 The Certification / Inspection Body has to examine whether the requests for certification / inspection have already been submitted to some other certification body and are in progress or a negative answer has been given to it.

Requests that have already submitted to some other body and are in process or a negative answer has been given by it, are permitted to be examined by the Certification / Inspection Body, under the condition that it has informed ESYD on its intention.

3.2.7 The CBs/IBs shall provide to ESYD every year the updated list of the certified by it organizations.

3.2.8 The CBs/IBs shall provide to ESYD every year the list of the consultants who supported the implementation of the management system and the procedures (leading to certification/inspection) of its certified/inspected clients.

3.2.9 The CBs/IBs shall provide to ESYD every year the updated list of auditors/inspectors with the following information: name/ surname/ education/ work experience/ training/ date of evaluation by the CB/IB / technical competence (EA codes, NACE codes, field/type of certification/inspection)/ number of organizations audited/inspected /employment by the CB/IB (mandays).

3.2.10 The CB shall have its own Certification Committee. CBs that do not have Certification Committee shall provide evidence for its appointment and operation until the 1st surveillance of the CB.

3.3 Conditions that the Inspection Bodies have to satisfy

3.3.1 The Inspection Body and its personnel have to be free from any commercial, financial or other pressures or commitments that can influence their technical judgment.

3.3.2 The Inspection Body must not allow to persons or bodies external to the Inspection Body to influence the results of the inspections conducted by the Inspection Body.

3.3.3 The Inspection Body must not participate to any activity that might risk the confidence to the independence of its judgment and its integrity concerning the inspection activities.

3.3.4 The remunerations of the personnel participating to inspection activities must not depend on the number of inspections they perform, neither on the outcomes of these inspections.

3.4 Conditions that the Calibration and Testing Laboratories have to satisfy

Hellenic Accreditation System S.A.
Accreditation Regulations

3.4.1 The Laboratory and its personnel have to be free from any commercial, financial or other pressures or commitments that can influence their technical judgment .

3.4.2 The Laboratory must not allow to persons or bodies outside the Laboratory to influence the results of the inspections conducted by the Laboratory.

3.4.3 The Laboratory must not participate to any activity that might risk the confidence to the independence of its judgment and its integrity concerning the calibration and testing activities.

3.4.4 The remunerations of the personnel participating to calibration and testing activities must not depend on the number of calibrations and tests they perform, neither on the outcomes of these calibrations and tests.

3.4.5 When the products are tested by bodies (e.g. manufacturers) that participated in their design, their production or their sale, measures shall be taken for a clear discrimination of the various responsibilities and an appropriate statement shall be done.

3.4.6 The Laboratory shall offer to its Customer or his Representative a reasonable cooperation in order to enable him to monitor the performance of the Laboratory regarding the respective contract. This cooperation shall include :

(a) conducting any reasonable calibrations or tests for inspection purposes, in order to enable the customer to verify the competence of the Laboratory on calibrating and testing.

(b) providing access to the Customer, or his representatives, to the respective areas in the Laboratory, where calibrations and tests for the specific Customer are conducted, in order to physically attend the performance of these calibrations and tests (under the condition of respecting the requirements on the confidentiality concerning the work conducted for other customers).

(c) the preparation, the packaging and the delivery of items to be calibrated, test specimens, samples or other items that the Customer needs for calibration purposes.

3.4.7 The Laboratory has to provide to ESYD and its representatives the appropriate reasonable facilitation and the appropriate cooperation, required in order to enable ESYD to monitor its compliance to the present Regulations and the related competence Criteria. This cooperation shall include:

(a) providing access to ESYD and its representatives to the respective areas in the Laboratory, where calibrations and tests are conducted, in order to physically attend their performance,

(b) conducting any reasonable calibrations or tests for inspection purposes, in order to enable ESYD to verify the competence of the Laboratory on calibrating and testing,

Hellenic Accreditation System S.A.
Accreditation Regulations

(c) the preparation, the packaging and the delivery of items to be calibrated, test specimens, samples or other items that ESYD needs for calibration purposes,

(d) providing a permission to ESYD and its representatives to conduct a detailed inspection of the calibration certificates, the test certificates and other files related to the accredited activities,

(e) providing a permission to ESYD and its representatives to conduct a detailed inspection of the outcomes of the internal quality system audits, of the measurement audits and of the competence tests of the Laboratory itself,

(f) providing help to ESYD and its representatives in order to investigate the resolution of any appropriately documented complains (written and fully documented), which have been submitted by any third party, concerning the accredited calibrations or tests of the Laboratory,

3.4.8 The Laboratory has to provide to all its clients services with consistent quality according to these regulations and to the standard that the laboratory is accredited. A laboratory is not allowed to provide its clients, testing and calibration services, in the frame of its accreditation that are not in accordance with the requirements of Accreditation Criteria.

3.5 Additional conditions for accreditation granting to Certification / Inspection Bodies

3.5.1 The technical competence of the certification bodies for quality management systems is distinguished in separate subsections, within the sections identified in the Guideline EA-07/01 (EA sections). These subsections are identified in the ESYD Document SUBSECTIONS.

3.5.2 The candidate certification body for quality management systems to be accredited shall have concluded a full audit at least in one enterprise for each one subsection in its scope.

3.5.3 An official Scope of Accreditation (SA) will be offered to the certification body, following a successful assessment and a respective decision of the Council, based on the EA sectors. In the Scope of Accreditation, for every EA sector a description (full or limited) is included in order to describe the extent of the accreditation and in the cases where the extent is limited the accredited Subsections are included. The certification body, concerning the provision of accredited services, may:

- Provide under no constraint the services that are explicitly quoted in the SA.
- For services not quoted explicitly but included in the SA, in case of limited scope, the certification body will acknowledge in writing to ESYD its intention to provide the particular service and the measures it is also going to take in order to respond to the requirements of the particular certification, that is the formation of a specified auditing

Hellenic Accreditation System S.A.

Accreditation Regulations

team, any complementary training and whatever else it is advisable. ESYD examines the above acknowledgement and informs the body accordingly within 20 working days.

- For services not included in the Scope of Accreditation, the certification body will apply for an extension of the Scope .
- 3.5.4 The candidate product certification/inspection body for accreditation should have conducted at least one concluded respective certification/inspection in every certification/inspection object.
- 3.5.5 In cases, where the accreditation is a prerequisite by law for the authorization of a CB/IB, it is permitted to grant the accreditation after the successful evaluation of a witnessed assessment carried out in simulated conditions, in the fields that is requested by ESYD to be performed witnessed assessments. Prerequisite for the conduction of the witnessed assessment in simulated condition is that the manufacturer who is under assessment shall supply the requirement of the relevant directive or the relevant harmonized standard or other relevant provision in order to be possible to be concluded if the inspection or certification body apply the specific certification system in practice.
- 3.5.6 In any case, the proposed date for the performance of the witnessed certification/inspection shall be notified to ESYD by the CB/IC, at least one month in advance.
- 3.5.7 The evidence that an accredited CB/IB does not have a client for a specific scope of accreditation for two consecutive years leads to the suspension of the accreditation for this specific scope.

In the case where the suspended accreditation was initially granted after assessment and witnessed assessment, the accreditation can be reinstated when the CB/IB notifies ESYD for a client to the specific scope and it's ability to perform an audit.

On the contrary, when the suspended accreditation was initially granted without a witnessed assessment, the reinstatement of the accreditation will be made after a successful witnessed assessment.

For the QMS Certification Bodies (ISO 9001) the absence of a client for two consecutive years will suspend the recognition of it's technical competence on the specific Subsection. The accreditation will remain to the relevant EA sector in the case when another sub-scope additionally to that suspended is included.

3.6 Actions in case of violation of the prerequisites for the accreditation

- 3.6.1 In case that an accredited body does not satisfy some of the conditions of paragraphs 3.1 to 3.5 or 5.2 or 5.3 or the conditions for the use of the National Accreditation Logo specified in the Regulation for the Use of the National Accreditation Logo (ESYD NAL), ESYD can decide to warn in writing the body for the violation and give a deadline for its removal and for the implementation of the necessary corrective actions and/or
- Proceed to a reproach against the body in writing and/or
 - Suspend for a specified period the accreditation granted, or
 - Suspend the accreditation granted, until the removal is done and so is the implementation of the corrective actions.

Hellenic Accreditation System S.A.

Accreditation Regulations

- The above actions will be carried out by ESYD within six months. After the period of six months the accreditation is withdrawn in the case where the causes of the suspension have not been eliminated.
- 3.6.2 When it is established according to ESYD procedures that the activity of an Accredited Body does not fulfill the requirements of the Standards and the ESYD Regulations and this puts in danger the reliability of accreditation, the Managing Director can forbid the issuance of tests/certificates with ESYD logo for all or part of the scope of Accreditation, until the ESYD assessment establishes that the danger is no longer present or reversely that there are reasons for the BOD to decide the suspension or the withdrawal of the accreditation.
In any case ESYD can publicize its above actions.

4 THE MEANING OF THE ACCREDITATION

4.1 The accreditation must not be considered in any way that it reduces the usual contractual obligations between the Accredited Body and its Customer. Even though the accreditation constitutes an indication of the integrity and the competence of a Certification Body, an Inspection Body or a Laboratory, it cannot be considered that it constitutes a guarantee on behalf of ESYD that the Accredited Body always maintains a specified level of performance.

4.2 The accreditation itself does not give the right to a certain Laboratory to approve some product (the accreditation may constitute an important factor allowing the approval and certification authorities to decide on whether they are going to use a certain laboratory, in relation to their own activities, or if they are going to entrust the approval and certification duties to a certain laboratory).

4.3 The Certification Bodies shall take every measure necessary to preclude any supplier, certified by them, from creating in any way an impression that he possesses a product certification, when he is certified to the standard ELOT EN ISO 9001 only.

4.4 The financial arrangements between a Certified Body and its customers do not fall into the responsibility and the control of ESYD in any way.

5 CHANGE NOTIFICATION

5.1 The Certified Body shall notify ESYD immediately on any changes affecting its compliance with the present Regulation and the related Accreditation Criteria or affecting in some other way the competence or the scope of accreditation of the Certified Body.

5.2 The Accredited Body shall notify immediately ESYD on any change on:

- (a) its legal, its commercial or its organizational structure,

Hellenic Accreditation System S.A.
Accreditation Regulations

- (b) its organization and its management, e.g. changes concerning personnel possessing vital managerial positions,
- (c) the policy or the procedures,
- (d) the building (built facilities),
- (e) the personnel, the equipment, the facilities, the surrounding area or other assets, related to its accredited activities,
- (f) the person with a signature authorization,
- (g) the compliance with the requirements of ESYD ,
- (h) the proprietary status quo of the Body.

ESYD examines the changes that were born and notifies the Body on the actions, which potentially have to be undertaken, in order to continue the accreditation initially granted.

5.3 The body is obliged to notify ESYD in advance on any changes concerning its auditors, in those cases where the respective accreditation has been granted based on the competence and the availability of the auditor under replacement. All other replacements of auditors will be inspected by ESYD during the regular supervision of the body.

5.4 ESYD will inform in due time, through the Internet or by e-mail or by fax or by a registered letter the Accredited Bodies on any changes to be made to the present Regulations, the related Criteria and the other requirements that ESYD stipulates and an appropriate time limit will be given, that ESYD considers as reasonable, for the body to adapt its procedures as necessary. When these adaptations will be concluded, the Accredited Body will inform ESYD accordingly.

5.5 The attitudes of the interested parties, concerning any imminent changes, are expressed to ESYD, through their representatives participating in ESYD and/or the Technical Committees of ESYD.

5.6 The Accredited Body may relinquish the accreditation after notifying ESYD, one month in advance (or some other period that might be agreed with ESYD), with a related written notification.

6 APPEALS

If a complaint about a decision by ESYD to refuse, suspend or withdraw an accreditation or that an accreditation has been granted on questionable grounds is not resolved to the satisfaction of

Hellenic Accreditation System S.A. **Accreditation Regulations**

the complainant, then, the appellant may appeal, either to ESYD or to the Ministry of Development, as following:

A) An interested party may appeal to the Minister for Development, within a month after the decision will be communicated to him. The appeal is presented to the relevant Department of the General Secretariat for the Industry of the Minister for Development.

The Minister for Development decides on the appeals taking the opinion of a three-member committee, which is created following a ministerial decision. Members of this committee are appointed one senior officer of the General Secretariat for the Industry of the Minister for Development, one representative of the Technical Chamber of Greece and one representative either of the Association of the Greek Laboratories or the Association of the Greek Certification Bodies.

The Managing Director will appoint a MU to support the proceedings of the Appeal Panel and provide the Appeal Panel with documentation relevant to the appeal. . The Members of the Appeal Panel shall sign the same confidentiality statement as signed by all members of ESYD.

The decision shall be issued within two months since the appeal has been raised. The exertion of the appeal does not sustain the implementation of the decision.

B) An appeal against a decision of ESYD may be submitted to ESYD. The appeal is received by the Managing Director who summons the Committee of Appeals in which chairs. The Committee consists of:

- a representative of the Association of Accredited Labs or Accredited Cerification/inspection Bodies (depending on the case of a Lab or a Body)
- a Lead Assessor of ESYD, different than the one who carried out the assessment in the specific Body/Lab, appointed by ESYD
- an Expert, having documented the appropriate technical experience from the relative Chamber or Ministry, appointed by the relevant Chamber of Ministry
- a legal advisor or attorney, appointed by ESYD

The Committee

- examines initially the validity of the appeal
- checks for any discrepancies from the requirements set by the Standards and ESYD
- makes a final decision on the appeal which is notified to the appellant.

The appeals, the minutes of the Committee and any consecutive actions are kept in records.

In both cases of appeals, the Unit will proceed to the actions deriving from the Appeal Panel report.

After the resolution of an appeal the Chairman of the BoD shall consider, in consultation with the BoD, the underlying issue of whether a particular Appeal or series of Appeals calls into question the validity of specific ESYD or Council policies and/or procedures

All persons should remember when handling an appeal that questions of legal liability and responsibility may be raised. ESYD procedures do not address such issues and therefore staff

Hellenic Accreditation System S.A.
Accreditation Regulations

should be aware that correspondence and decisions made in the course of investigating an appeal may be used in a legal context during or subsequent to the investigation of the appeal.

7 COMPLAINS

7.1 Any complains against ESYD or its operation shall be addressed to the Chairman of the Council in writing.

**8 CONDITIONS FOR THE USE OF THE NATIONAL
ACCREDITATION LOGO BY ACCREDITED BODIES**

8.1. The conditions for the use of the National Accreditation Logo by Accredited Bodies are described in the Regulation for the Use of the National Accreditation Logo (ESYD NAL).