ACCREDITATION REGULATIONS

ESYD RA

Issue: 03
Revision: 05
Issue Date: 08-01-1997
Revision Date: 10-11-2022
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DEFINITIONS

For the purposes of this document the following definitions are referred below:

- The term “body” covers all the conformity assessment bodies including laboratories. Whenever it is used in the text, it refers to the bodies that have submitted application for accreditation and the accredited bodies.
- The term “laboratory” refers to the calibration as well as the testing laboratories (including Clinical Laboratories) and PT Providers.
- The term “certification” refers to product certification, certification of management systems (quality, environmental etc) and persons certification.

1. GENERAL

1.1 The accreditation by ESYD, according to these regulations, is basically voluntary. It becomes mandatory when it is required by national or European legislation (mandatory field). ESYD, according to the current legislation, can undertake the assessment of the technical competence of bodies, which are active in the regulatory sector, assessing the compliance to requirements defined by the responsible Official Authorities.
Accreditation should not be considered to decrease in any way the normal contractual obligations between the accredited body and its Client.
Although accreditation is an indication of the impartiality and the technical competence of a body it does not considered as a proof that the Accredited Body always maintains the certain level of performance for which has been assessed.

1.2 These regulations are in force concerning the accreditation of bodies according to Accreditation Criteria and respective guidelines as these are defined in detail in the Document ESYD CAC.

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 with 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.

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. **Surveillances are scheduled every 18 months and reassessment every 5 years, according to the issue date of the accreditation certificate. In the first accreditation cycle, an additional surveillance is planned, 6 months after the issue date of the accreditation certificate. The planning of reassessment starts 12 months before the expiry 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.**

During the **five-year** period of validity of the accreditation certificate, **two** distinct surveillance visits **(three for the first accreditation cycle)** shall be successfully completed and in case of accreditation certificate renewal, the reassessment of the Accredited Body shall be successfully completed. Furthermore, ESYD maintains the right to order for additional or extraordinary assessment visits in time intervals different to those specified. ESYD maintains the right to attend, through its representatives, on-site inspections/audits performed by applicants or 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 matter that may affect the ability of the body to fulfill requirements for accreditation (e.g., issues of impartiality, misuse of the logo, etc.), g) any other action that may defame ESYD, ESYD maintains the right to perform extraordinary assessment to the Accredited Body, in order to collect evidence for the handling of the above. The extraordinary assessment may be conducted either without any notice or with notification of the body 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 At any point in the application or in initial assessment process, if there is evidence of fraudulent behaviour, if the body intentionally provides false information or conceals

information, ESYD shall reject the application or terminate the assessment process. In this case, the body is required to settle any financial issues that have arisen until this moment.

1.11 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 with the requirements of the present Regulations and/or the related criteria specified by ESYD,

(c) it is found that the Accredited Body acts or is involved in procedures that may harm the reputation of ESYD and / or reliability of Accreditation.

The findings regarding the above, are either included in the report by the Assessment Team or in a recommendation by the Unit if there is no current Assessment Team.

1.12 The Council withdraws the accreditation in case that:

(a) 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 top management and/or managers of the Accredited Body are involved in violations of laws and these acts concern Accreditation

(d) there is evidence of fraudulent behaviour of the Accredited Body or intentionally provides false information or conceals information

(e) there is evidence that the Accredited Body does not comply with the law for conformity assessment issues in its scope of accreditation

The findings regarding the above, are either included in the report by the Assessment Team or in a recommendation by the Unit if there is no Assessment Team in progress.

1.13 (a) All the information that comes to ESYD and its representatives during the accreditation process is considered confidential 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 explicit written approval of the Accredited Body, except if the legislation or authorization by contractual arrangements command differently, in which case the body is informed on the released information concerning it.
Information available in public and information for which body has been informed by ESYD that will be made public is not considered confidential.

(b) Information about the body obtained from sources other than the body (e.g., complainant, regulators) shall be confidential between the body and ESYD. The provider (source) of this information shall be confidential to ESYD and shall not be shared with the body unless agreed by the source.

(c) ESYD, in cases as mentioned to § 1.10-1.12, and when the accreditation is in the mandatory sector i.e., in the cases where accreditation is regulatory requirement (national or European legislation), informs the relevant supervisory governmental authority for the findings, in order to take the appropriate measures when is needed.

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

1.15 The accreditation certificate is ESYD's property and its use is granted to the body when it is accredited. The granting stops if:
a) the Accredited Body ceases to operate,
b) its accreditation is withdrawn.
In the cases of suspension, the Accredited Body shall not use the accreditation certificate.

1.16 The financial arrangements between an accredited body and its clients are not in any case under ESYD responsibility.

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 Bodies. ESYD may establish additional criteria based on its judgment.

3. REQUIREMENTS FOR THE ACCREDITED BODIES

3.1 Requirements that the Accredited Bodies shall comply with:

3.1.1 The Accredited Body shall:

(a) comply always with the present Regulations, the related Accreditation Criteria and the conditions and requirements that ESYD establishes concerning the use of ESYD logo, according to the Regulation for the use of National Accreditation Logo (ESYD NAL) and to commit to provide ESYD the relevant documentation of compliance with the above,

(b) cooperate with ESYD whenever necessary in order ESYD to be able to verify compliance with the accreditation requirements,

(c) provide ESYD access to its staff, facilities, equipment, data, documents and records in order ESYD to be able to verify compliance with the accreditation requirements,

(d) arrange on time on-site assessments when requested by ESYD,

(e) include in contracts with its clients that they should commit themselves to provide access to ESYD assessment teams on their premises for the purposes of the assessment, where applicable based on the scope of conformity assessment,

(f) mention that it is accredited concerning those activities which are defined in the Scope of Accreditation only and which are performed in accordance with the present Regulations and the related Criteria that ESYD establishes,

(g) commit to follow the requirements of the Regulation on the Use of the National Accreditation Logo (ESYD NAL),

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

(i) assist ESYD to investigate and resolve any accreditation-related complaint about the body when requested by ESYD,

(j) not use its accreditation in a way harming the reputation of ESYD and not proceed to any statement concerning its accreditation that ESYD or anyone else can reasonably consider as misleading,

(k) 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),

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

(m) 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,

(n) 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 ESYD decides 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.

(o) 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.

(p) assure that the name of the Body does not create any confusion about its activities

(q) define in its statute that no consultancy services are provided in accreditation matters related to its scope of accreditation, concerning its activities as a conformity assessment body and always according to the requirements of the relevant accreditation standard. This is also mandatory for bodies which are either part of another body or they use the name of another body or act as its subsidiary.

(r) to provide to ESYD, access to the staff, the data, the documents and the files of related bodies, parent bodies or other departments within the same company in order ESYD to be able to confirm compliance with the requirements of the relevant accreditation standard for the provision of consultancy services or other services that may impact the relevant impartiality requirements for the conformity assessment activity to be accredited.

(s) take all the appropriate measures for the participation of authorized persons of national, European or international organizations and bodies who evaluate ESYD during the assessments conducted by ESYD to its accredited bodies and their customers.

(t) to offer all its customers quality service consistent with these Regulations and with the standard on which has been accredited.

3.1.2 The certificates / testing reports, irrespective of whether they use ESYD logo for activities which are included in the Scope of Accreditation, are subject to evaluation by the assessment teams of ESYD. The Accredited Body shall not offer to its customers

conformity assessment services within the scope of accreditation which do not meet the requirements of accreditation and is not in accordance with the requirements of this Regulation.

3.2 Requirements that the Certification / Inspection / Validation & Verification Bodies / Environmental Verifiers shall comply with

3.2.1 The Certification / Inspection / Validation & Verification Body / Environmental Verifier 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.

3.2.2 The Accredited Certification / Inspection/ Validation & Verification Bodies/ Environmental Verifiers shall allow the access to ESYD assessors in their working areas, in order to conduct an assessment procedure. The accredited Certification / Inspection/ Validation & Verification Bodies/ Environmental Verifiers are expected to make the necessary arrangements for this purpose with their customers.

3.2.3 The Certification / Inspection/ Validation & Verification Body / Environmental Verifiers may use, without any modifications, on documents, brochures or advertisement means the following phrases: "Accredited Certification / Inspection/ Validation & Verification/ Environmental Verifier Body registered under the register number ....." and "registered in the List of the Certification / Inspection/ Validation & Verification Bodies / Environmental Verifiers of ESYD under the register number .....". In case of withdrawal of the accreditation by ESYD, the accreditation body must cease immediately issuing certificates bearing the accreditation symbol of ESYD, must take the necessary measures in order to assure the immediate withdrawal of all the related documents, brochures and advertising material and, concerning the existing customers, to act in the way ESYD will define.

3.2.4 The Certification / Inspection / Validation & Verification Body/ Environmental Verifier shall examine whether requests for Certification / Inspection / Validation & Verification have already been submitted to another Certification / Inspection / Validation & Verification Body/ Environmental Verifier and are in progress or a negative response has been given to it. Such requests can be undertaken by the Certification / Inspection / Validation & Verification Body / Environmental Verifier as long as it has investigated and recorded in the records the background of the customer.

3.2.5 The Certification / Inspection / Validation & Verification Bodies / Environmental Verifier shall have and provide annually to E.SY.D. the list of companies or the number of companies for each activity that have certified / inspected/ verified, no later than the end of January each year and whenever required by ESYD. Moreover, the Certification / Inspection / Validation & Verification Bodies / Environmental Verifier shall notify all the predicted in the OEF-40.

3.2.6 The Certification / Inspection / Validation & Verification Bodies / Environmental Verifier shall have and provide to ESYD every year the list of auditors/inspectors/verifiers with the following information: name / specialty / technical competence (EA codes, NACE codes, field/type of certification/inspection/verification)/ date of activation and termination of the cooperation, no later than the end of January each year whenever is required by ESYD and in every change.

3.2.7 The Certification / Inspection / Validation & Verification Bodies / Environmental Verifiers shall prepare the final program of the witnessing assessments (availability) until the date of the first day of the assessment.

3.2.8 The technical competence of certification bodies for quality management systems is described in subsections within the sectors defined in the document IAF ID1: 2014 or any other document may replace it (codes IAF / EA). The subsections are defined in the document ESYD SUBSECTIONS.

3.2.9 After successful assessment and decision of the National Accreditation Council, the Scope of Accreditation (SoA) will be offered to the management system certification which will be based on EA sectors. In the SoA is described for each EA code if the scope of accreditation is full or limited and in the case of limited accreditation, they are listed accredited Subsections are listed. The management system certification body, regarding the accredited services which can provide, may:

- Offer without any restriction services explicitly mentioned in the SoA.

- For services not specifically mentioned in the SoA (limited accreditation EA CODE) the certification body shall notify in writing ESYD its intention to provide this service and the subscope it belongs, as well as the measures to be taken in order to meet the requirements of the specific certification, ie. Composition of specific audit team, any additional training or documentation and anything else may needed. ESYD examines the above notice and inform the certification body accordingly within 20 working days.

- For services outside the SoA, the certification body shall submit an application for extension of scope.

3.2.10 The applicant for Certification / Inspection / Validation & Verification Body /Environmental Verifier shall have conducted at least one comprehensive audit / inspection / verification for each field of its requested scope.

3.2.11 In the mandatory sector, where the existence of accreditation is a regulatory requirement for competent authority approval of the activity of a certification or inspection body (for notification and / or licensing), accreditation is granted after successful on-site assessment of a simulated certification / inspection process in the fields requested by ESYD to carry out assessments. Prerequisite for conducting the simulated on-site assessment is that the client of the body under evaluation (manufacturer, producer, company etc.) should have implemented the requirements of

the directive, regulation, harmonized standard or other provision, so that it can be concluded whether the certification / inspection body effectively implements the specific certification system.

3.2.12 In any case, the proposed date of an on-site audit / inspection / verification should be notified by the body to ESYD at least 20 days in advance (1-2 days deviation) otherwise ESYD has the right to consider the audit / inspection / verification as non performed based on the fact that there is no realistic planning of audits / inspections / verifications by the body. Based on proper planning, all the requested on-site assessments should take place within eight months of the date of notification of the assessment team to the body and it is the sole responsibility of the latter to make timely planning. Especially in case of extension, on-site assessments should be carried out within one year of assessment at Head Offices, otherwise ESYD puts the application for extension in record or the assessment in the Head Offices will be repeated.

3.2.13 Finding out that the Body does not have any customer to accredited sector (i.e. IAF Code / subsector / NACE Code / category / product /field) for two consecutive years, results in the withdrawal of accreditation in this sector, based on recommendation of the assessment team. To be accredited again in this sector, the procedure of scope extension is applied.

3.3 Requirements that Calibration/Testing Laboratories and PT Providers shall comply with

3.3.1 The Laboratory / PT Provider 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 Laboratory / PT Provider must not allow to persons or bodies outside the Laboratory / PT Provider to influence the results of the inspections conducted by the Laboratory / PT Provider.

3.3.3 The Laboratory / PT Provider 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.

3.3.4 The remunerations of the personnel participating to calibration / testing or PT Provider activities must not depend on the number of calibrations / tests or PT Provider schemes they perform, neither on the outcomes of these calibrations / tests or PT Provider Schemes.

3.3.5 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.

3.3.6 The Laboratory / PT Provider shall offer to its Customer or his Representative a reasonable cooperation in order to enable him to monitor the performance of the

Laboratory / PT Provider regarding the respective contract. This cooperation shall include:

(a) conducting any reasonable calibrations/tests or PT Schemes for inspection purposes, in order to enable the customer to verify the competence of the Laboratory / PT Provider on calibration / testing / PT performance.

(b) providing access to the Customer, or his representatives, to the respective areas in the Laboratory, PT Provider where calibrations, tests, PT Schemes for the specific Customer are conducted, in order to physically attend the performance of these calibrations / tests / PT Schemes (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 verification purposes.

3.3.7 The Laboratory / PT Provider 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 / PT Provider, where calibrations, tests and PT Schemes are conducted in order to physically attend their performance,

(b) conducting any reasonable calibrations / tests / PT schemes for inspection purposes, in order to enable ESYD to verify the competence of the Laboratory on calibration and testing / PT performance,

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

(d) 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 / PT Provider itself,

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

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

3.4 Actions in case of violation of the requirements for the accreditation

3.4.1 In case that an accredited body does not satisfy some of the conditions of paragraphs 3.1 to 3.3 or 4.1 to 4.3 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 inform 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,

The suspension duration can not exceed the 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 or

- Withdraw the accreditation granted in part or in whole.

3.4.2 In order to lift the suspension of the accreditation, it shall be well documented that the reasons for the suspension of accreditation have been eliminated.

3.4.3 When it is established according to ESYD procedures that the activity of an Accredited Body does not fulfil the requirements of the Standards and the ESYD Regulations and this puts in danger the reliability of accreditation, the Managing Director of ESYD 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 to decide the suspension or the withdrawal of the accreditation, implementing the normal decision making procedure. In any case ESYD can make public the above actions.

In cases of suspension / withdrawal, ESYD is obliged to notify this intention to the Body.

4. CHANGE NOTIFICATION

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

4.2 The Accredited Body shall notify in writing immediately ESYD and in 15 days at the latest on any change on:

(a) its legal, commercial or organizational structure and its ownership status,

(b) its organization, top management and the critical staff, e.g. changes concerning BoD, Quality Manager, Director of Certification, Technical Director,

(c) the policy or the procedures,

(d) its facilities and location. Particularly in the case of relocation of the laboratory, the laboratory is obliged to inform ESYD in writing, of the exact date of closure of the existing facilities, in order to put the accreditation certificate on suspension until the successful on-site assessment of the new facilities by ESYD. Please note that the suspension period can not exceed six (6) months,

(e) the personnel, the equipment, the facilities, or other assets, related to its accredited activities,

(f) the persons with signature authorization,

(g) the scope of accreditation,

(h) any change that may affect the body's ability to comply with the accreditation requirements.

ESYD reviews the changes made and informs the Body of the actions that may be necessary to undertake in order to continue to be accredited.

4.3 The Certification / Inspection / Validation & Verification Body / Environmental Verifier is obliged to notify ESYD in advance on any chances concerning its inspectors / auditors / verifiers, in those cases where the respective accreditation has been granted based on the competence and the availability of the inspector / auditor / verifier under replacement. All other replacements of inspectors / auditors / verifiers will be assessed by ESYD during the regular surveillance of the body.

4.4 ESYD will inform in due time, through its website or by e-mail 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, for the body to adapt its procedures as necessary.

4.5 The views of the interested parties, concerning any imminent changes, are expressed to ESYD, through their representatives participating in the National Accreditation Council.

4.6 The Accredited Body may resign from its accreditation after notifying ESYD, with written notification. In this case, the body is obliged to settle any financial issues that have arisen.