HELLENIC
ACCREDITATION
SYSTEM

APPLICATION FOR REFERENCE MATERIAL PRODUCER ACCREDITATION ACCORDING TO THE STANDARD ELOT EN ISO 17034:2016

Please type or print using CAPITAL LETTERS

Part 1. Producer

1.1 Body details

Name of Organization *: **Year Founded:** **Legal Form:** **(Attach Statutory Documents of the legal entity of the Organization, i.e. Official Gazette, Shareholding)**
Address: **Area Code:** **Tel.:** **FAX:** **Email address:** **VAT:** **Revenue Office:**
Name of person in charge for contacts with ESYD:

***** The complete description of the structure to which the applicant entity belongs is stated, i.e. AUTH / Chemical Engineering Dept. / Organic Chemistry Laboratory

1.2 Name and address of parent organization (if different from entries of table 1.0)

Name: **Address:** **Tel.:** **FAX:**

1.3 Locations of processes related to the production of reference materials for accreditation (table 3.1)

No.	Location, Description	Processes performed in the location	Address and contact details for the location

1.4 Address where the invoice is to be sent (if different from the address of the organization in table 1.0)

Address:
Tel: **FAX:**

1.5 Relevant Information

Is the applicant already accredited according to the standard ISO/IEC 17025?	**Yes (Testing)☐ Yes (Calibration)☐ No ☐**
Does the applicant perform procedures to characterize RMs?	**Yes ☐ No ☐**
Is the process of characterization of RMs assigned to subcontractors?	**Yes ☐ Partially☐ No ☐** **Other (Describe):**
Is the applicant already accredited according to the standard ISO/IEC 17043?	**Yes (Proficiency tests are relevant in any way to the production of RMs fields) ☐** **Yes (in non-relevant fields) ☐ No ☐** **Other (Describe):**

Part 2. Personnel

Please state the name, technical qualifications and relevant experience of the following personnel:

2.1 Technical Manager appointed by the Management regarding technical responsibility

Name	
Technical Qualifications	
Relevant Experience	
Position within the Organization	

2.2 Quality Manager

Name	
Technical Qualifications	
Relevant Experience	
Position within the Organization	

Part 3 Scope of Application:

3.1 Applied Scope of Accreditation (Fill as many lines as needed)

No. Of the material	**Reference Material Type** Reference material or certified reference material	**Type of material/substrate/matrix/ type of reference material or artefact**	**Characterized properties of the Material**	**Characterization Strategy / Approach** **(ISO 17034:2016 7.12)**	**Reference of the RM producer location**
3.1.1					

Part 4 List of required documents for the accreditation as a Producer of (certified) reference materials (C)RM

No.	Document	Attached File Name(s)
4.1.	**Complete** documentation of the management system of the RM-producer granted/applied scope of accreditation (quality management manual, procedures, work instructions, SOPs or other specifications with regard to the applied/accredited reference materials The following instructions / documents must be included: • Contractual arrangements • Production planning and – control • Material processing, - handling and – storage • Data handling (integrity and evaluation) • Metrological traceability of the certified value and its measurement uncertainty (CRM) • Evaluation of homogeneity • Stability evaluation and – monitoring • Characterization of the material • Assignment of property values and their uncertainty (CRM) • Storage and distribution of the RM	
4.2.	List of all quality management documents (including version and/or date of validity)	
4.3.	Most recent management review with contents according to DIN EN ISO/IEC 17034:2016 section 8.6.1	
4.4.	With a variable scope of accreditation: Current list of all offered (C)RM within the scope of accreditation (including the marking of new introduced (C)RM) (**Note: application for a variable scope of accreditations may only be considered if the regulations of ESYD RA are met)**	
4.5.	Evidence of organizational structure, ownership and legal form of the RM-producer (trade register excerpt, list of shareholders, organization chart(s)) If the certification body is part of an organization (within the legal entity or within a larger corporate structure) the ownership structure, the integration within the organization and the relations to other organizational units must be submitted with appropriate information (e. g. with detailed organizational charts and lists of shareholders of all sub-organizations	
4.6.	Coverage of existing liability risks, e.g. evidence of a liability insurance including information about the scope of insurance (liability and financial loss) or information on an equivalent solution (based on 5.3g of ISO 17034:2016)	
4.7.	Current information regarding the number of employees for all activities of the RM-producer broken down according to their function4, working area and the contractual binding to the RM producer	
4.8.	Contracts: • General terms and conditions (if available) • Model contracts with clients and, if applicable, reference to applicable QM documents for the order processing	

<table>
<tr><td></td><td>• Model contracts with external employees
• Model contracts with sub-contractors</td><td></td></tr>
<tr><td>4.9.</td><td>Up to date analysis of risks regarding theimpartiality including the analysis of related bodies and presentation of the management of impartiality according to DIN EN ISO 17034:2016 section 4.2.2</td><td></td></tr>
<tr><td>4.10</td><td>Explanation on used IT-systems and their function and a description of interfaces between those IT-systems as well as to external databases/archive systems including the process of release of those systems</td><td></td></tr>
<tr><td>4.11</td><td>List of reference materials produced in the last three years (follow the structure of table 3.1)</td><td></td></tr>
<tr><td>4.12.</td><td>Copy of one reference material certificate (CRM) or product information sheet (RM) for each of the applicant/accredited areas of table 3.1 and, if present, for the materials of table 4.11</td><td></td></tr>
<tr><td>4.13</td><td>Documents relating to subcontracting (if applicable):
• Documented procedure on subcontracting, including criteria for the involvement of subcontractors for all tasks subcontracted in the production of RM
• List of subcontractors including subcontracted tasks, if applicable, structured according to the fields RM are produced (as shown below)
<table>
<tr><th>No.</th><th>Subcontractor Name</th><th>Activities performed by the subcontractor</th><th>Relevance to the RM (table 3.1)</th><th>Subcontractor’s Accreditation/third-party recognition</th></tr>
</table>
• Evidences of competencies for the operations performed by subcontractors (e.g. copies of an accreditation certificate with annex, audit reports or similar evidences).</td><td></td></tr>
<tr><td>4.14</td><td>Spatial plan indicating the areas relevant for RM production</td><td></td></tr>
<tr><td>4.15.</td><td>List of equipment used for producing RM (without measuring instruments) with in-house registration (including rented equipment, if applicable)
Information necessary: Inventory number, location, usage, indication of the equipment/type of equipment/item, manufacturer</td><td></td></tr>
<tr><td>4.16</td><td>List of applied testing/calibration and examination methods in the production of the RMs.</td><td></td></tr>
<tr><td>4.17</td><td>RM list for the methods referenced in 4.16</td><td></td></tr>
<tr><td>4.18</td><td>Participation list in external quality assessment programs, interlaboratory comparisons regarding the methods referenced in 4.16</td><td></td></tr>
<tr><td>4.19</td><td>Information regarding the fulfillment of the ISO/IEC 17025 regulations (paragraphs 4-7) or ISO 15189 (p. 4-7) regarding the methods referenced in 4.16 (e.g. questionnaires, reports, accreditation certificates etc.)</td><td></td></tr>
</table>

4.20	Declaration of possible internal calibration procedures and relevant information (as shown below)	

No.	Parameter/equipment	Reporting Standard	Procedure	Details on the metric process supported by the calibration

Part 5. Conformity with the Accreditation Standard ELOT EN ISO 17034:2016 and ESYD Regulations RA

Do you consider that your laboratory fulfils the Accreditation Standard ELOT EN ISO 17034:2016 and ESYD Regulations RA?

Yes ☐ No ☐

If not, which points are in non-agreement and when do you anticipate correcting the non-conformity?

Points of non-conformity	Corrective action (date)

Part 6 Declaration (Law 1589/86)

6.1 The producer is applying for accreditation to ESYD for:

(please check appropriate boxes)

Initial Assessment ☐

Extension of an existing Accreditation official Field ☐

6.2 I accept the performance of a pre-assessment according to ESYD PA YES NO

6.3 After accreditation, the laboratory is bound to continue fulfilling the requirements of ESYD which are stated in detail in the documents ELOT EN ISO 17034:2016 and ESYD RA as well as in any other specified publication.

6.4 I understand the way the accreditation system functions.

6.5 I declare that the information presented in this document is correct.

6.6 I shall provide the assessment team with any necessary information and shall facilitate the conduct of the assessment.

6.7 I undertake the payment of all fees to ESYD, in accordance with the policy of ESYD regarding accreditation fees, regardless of the granting or not of accreditation and declare that we will pay in due time the surveillance fees for maintaining the accreditation status.

6.8 I enclose the application fees.

Legal Representative's Signature _____ Date _____