	<b>List of required documents for the accreditation as a Producer of (certified) reference materials (C)RM according to DIN EN ISO 17034</b>		LI-EU_RM_EN	
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Required documents shall preferably be submitted electronically, in the way that the numbering can directly be assigned to the relevant documents. For submission the Deutsche Akkreditierungsstelle GmbH (DAkkS) provides a **structured zip-folder** where the required documents should be stored electronically and resend to the DAkkS. In individual cases it may be necessary to submit documents in hard copy.

All documents/evidences must be submitted<sup>1</sup> immediately after request<sup>2</sup>. By sending the documents the CAB ensures DAkkS the completeness of the submitted documents. If necessary, further documents may be required by DAkkS manager or the assigned assessor.


Documents must be submitted in German or English language.

No.	Document
1.	<p><b>Complete</b> 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)</p> <p>The following instructions / documents must be included:</p> <ul style="list-style-type: none"> <li>• Contractual arrangements</li> <li>• Production planning and - control</li> <li>• Material processing, - handling and - storage</li> <li>• Data handling (integrity and evaluation)</li> <li>• Metrological traceability of the certified value and its measurement uncertainty (CRM)</li> <li>• Evaluation of homogeneity</li> <li>• Stability evaluation and - monitoring</li> <li>• Charakterization of the material</li> <li>• Assignment of property values and their uncertainty (CRM)</li> <li>• Storage and distribution of the RM</li> </ul>
2.	List of all quality management documents (including version and/or date of validity)
3.	Most recent management review with contents according to DIN EN ISO/IEC 17034 section 8.6.1
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)
5.	<p>Evidence of organisational structure, ownership and legal form of the RM-producer (trade register excerpt, list of shareholders, organisation chart(s))</p> <p><i>If the certification body is part of an organisation (within the legal entity or within a larger corporate structure) the ownership structure, the integration within the organisation and the relations to other organisational units must be submitted with appropriate information (e. g. with detailed organisational charts and lists of shareholders of all sub-organisations)</i></p>
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

<sup>1</sup> The planning of the assessment for initial accreditation or extension of the RM-producer takes place immediately after confirmation of the application. The documents are requested with this confirmation and must be submitted immediately. If no documents are submitted, the application will be rejected.

Documents for surveillance and reassessment must be submitted immediately upon request.

<sup>2</sup> To submit documents incomplete or late can be punished as an administrative offence according to § 12 AkkStellG (Accreditation Body Act).

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No.	Document
7.	Current information regarding the number of employees <sup>3</sup> for all activities of the RM-producer broken down according to their function <sup>4</sup> , working area <sup>5</sup> and the contractual binding <sup>6</sup> to the RM-producer
8.	Contracts: <ul style="list-style-type: none"> <li>• General terms and conditions (if available)</li> <li>• Model contracts with clients and, if applicable, reference to applicable QM documents for the order processing</li> <li>• Model contracts with external employees</li> <li>• Model contracts with sub-contractors</li> </ul>
9.	Evidence of the obligation of the laboratories top management regarding the impartiality according to DIN EN ISO/17034 section 4.2.2 d)
10.	Up to date analysis of risks regarding the impartiality including the analysis of related bodies and presentation of the management of impartiality according to DIN EN ISO 17034 section 4.2.2
11.	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
12.	List of reference materials produced in the last three years (Entry in the attached Excel file LI-EU_RM_A1_EN)
13.	Copy of one reference material certificate (CRM) or product information sheet (RM) for each of the applicant/accredited areas
14.	<b>Documents relating to subcontracting<sup>7</sup> (if applicable):</b> <ul style="list-style-type: none"> <li>• Documented procedure on subcontracting, including criteria for the involvement of subcontractors for all tasks subcontracted in the production of RM</li> <li>• List of subcontractors including subcontracted tasks, if applicable, structured according to the fields RM are produced</li> <li>• Evidences of competences for the operations performed by subcontractors (e.g. copies of an accreditation certificate with annex, audit reports or similar evidences)</li> </ul>
15.	Spatial plan indicating the areas relevant for RM production
16.	List of equipment used for producing RM (without measuring instruments) with in-house registration (including rented equipment, if applicable)  <b>Information necessary:</b> Inventory number, location, usage, indication of the equipment/type of equipment/item, manufacturer
17.	Filled Partial Assessment Report/Checklist DIN EN ISO 17034  <i>The template to be filled in is included in the zip-folder. Document will be submitted to DAkkS electronically (Word-document).</i>

<sup>3</sup> Regardless of the extent of employment, each employee counts.

<sup>4</sup> e. g. technical employees, managing employees, etc. depending on their function of the RM-producer.


<sup>5</sup> Depending on the organisation of the working areas of the RM-producer.

<sup>6</sup> Permanent employees (internal) and further employees bound by contract (external).

<sup>7</sup> Where appropriate, according to the annex to the application.

No.	Document
18.	<p><b>Normative documents within the scope of accreditation</b></p> <p>Submission of a copy of all certificate-relevant technical standards or standards for the activities of the RM-producer within the scope of accreditation, as far as DAkkS does not determine a different regulation.</p> <p>All standards, documents equivalent to standards, in-house methods etc., which form the basis for the production of (certified) reference materials within the scope of accreditation and contain requirements for the performance of activities within the scope of accreditation shall be submitted<sup>8</sup>. <i>(The provision is permitted license-free according to § 45 Copyright Act (§45 Urheberrechtsgesetz (UrhG))</i></p> <p><i>These documents will be send separately from the other listed documents in a separate zip-folder. The identification of the normative documents is part of the respective file name. If the normative documents within the scope of accreditation have already been submitted by the RM-producer, only the normative documents concerning changes of the scope shall be submitted.</i></p>

<sup>8</sup> Publicly freely accessible documents that are subject to the accreditation scope do not have to be submitted.

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**Additional required documents in case of using a non-accredited internal testing laboratory, or of non-accredited testing, calibration or examination procedures used for characterization of the material and, if applicable, determination of the assigned values.**

Nr.	Unterlagen
19.	List of applied testing-, calibration- and examination procedures in the framework of RM-production
20.	List of RM used for the procedures mentioned in No. 19
21.	Current list for participation in proficiency testing, like ring- and interlaboratory comparisons as well as EQAS <sup>9</sup> according to published DAkkS-rules (only submit the lists, no participants lists of individual proficiency testing)
22.	<p>Metrological traceability: List of equipment with in-house registration (including used rental equipment, used working standards as well as equipment/facilities which are not under permanent control of the CAB).</p> <p><b>Necessary information:</b> Inventory-No., location, measurand (of which an evidence of the metrological traceability must be available), name of the equipment/type of equipment/object, producer, calibration-/functional checks interval, identification/name of the evidence(s) regarding metrological traceability, <b>type of measurement traceability (regarding 71 SD 0 005_e).</b></p> <p><i>Optional specifications: Testing standard, serial number, responsible person for the equipment, and others</i></p>
23.	Spatial plan with information on testing -, calibration -, examination areas including information about the use of mobile facilities for the testing -, calibration - and examination activities
24.	<p><b>In the case of testing and calibration procedures:</b> Filled Partial Assessment Report/Checklist DIN EN ISO/IEC 17043 <u>clause 6 and clause 7 filled in</u> The template to be filled in is included in the zip-folder (document shall be provided electronically (word file) to DAkkS)</p> <p><b>In the case of medical examination procedures:</b> Filled Partial Assessment Report/Checklist DIN EN ISO 15189 <u>clause 4.1 and clause 5 filled in</u> The template to be filled in is included in the zip folder (document shall be provided electronically (word file) to DAkkS)</p>

<sup>9</sup> External Quality Assessment Schemes.