DAkkS
Deutsche
Akkreditierungsstelle

Accreditation of reference material producer

R 17034 | Revision: 1.0 | 13.05.2020

Scope:

This policy sets out requirements for the accreditation procedure for producers of reference materials (RM producers) on the basis of DIN EN ISO/IEC 17011. It specifies, where necessary, the general requirements of DIN EN ISO 17034 for RM producers.

It applies to RM producers with or without their own testing or calibration laboratory.

Additional sectoral rules setting out requirements for the accreditation procedure for RM producers or requirements for RM producers may also apply.

Date of confirmation by the Accreditation Advisory Board: 25.04.2020

Pursuant to Section 2 in conjunction with Section 3 (9) Federal Act on Gender Equality, Section 4 (3) Federal Act on Gender Equality is not directly applicable to DAkkS. In the interest of good readability, the generic masculine is also used for function descriptions in this document, so far as a concrete designation by natural gender is not possible in any meaningful way and natural gender is either unimportant or male and female persons are meant equally.

DAkkS rules and other technical specifications must be easily readable and must therefore contain no slashes, which excludes the use of the internal / and duplicate designations (concerning admissibility, see Section 115 Manual for Drafting Legislation).
Also applicable are the further requirements of DIN 820-2:2012-12 Standardization – Part 2: Presentation of documents (ISO/IEC Directives – Part 2:2011) for the formulation of technical specifications.

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I Requirements for the accreditation procedure

This section specifies the requirements of DIN EN ISO/IEC 17011 for the accreditation of RM producers. The numbering within this section follows the numbering of DIN EN ISO/IEC 17011.

7.1 (DIN EN ISO/IEC 17011) Requirements for accreditation

Subject-specific documents such as DIN EN ISO 6142-1 must be taken into account also if this is indicated for technical reasons or required by law or normative documents.

7.2 (DIN EN ISO/IEC 17011) Application for accreditation

7.2.1 The basis for assessment is the table specified by DAkkS in the annex to the accreditation application specific to RM producers (72 FB 005.36). This must be completed by the RM producer and made available with the application. It provides the basis i. a. for estimating the scope of the assessment. With the documents to be submitted, a further table is requested (72 FB 004.9_A1, Excel list of RM produced), in which RM producers enter which reference materials they have manufactured in which areas since when and how often.

7.4 (DIN EN ISO/IEC 17011) Preparation for the assessment

7.4.1 The assessment team must include at least one technical assessor/expert (FB_{stat}) with practical experience in the area of statistics concerning the production of reference materials (e.g. ISO Guide 35) who, together with the other technical assessors, assesses the statistical procedures for homogeneity and stability assessment and the characterisation of (C)RM.

7.6 (DIN EN ISO/IEC 17011) Assessment

7.6.1 The objective of the assessment is to verify that the (C)RM producer has the competence to produce specific (C)RMs in the areas applied for, and also has sufficient competence and experience to introduce new similar (C)RMs within the areas applied for. During each scheduled assessment, at least one process for a reference material that is produced must be assessed exemplarily for the areas to be assessed. The assessment must include a witness audit of parts of the practical production of a (C)RM.

If different strategies for homogeneity and stability determination and several characterisation strategies are used, it is important to ensure that all approaches used are assessed.

For each process assessed, all production issues, from planning of the (C)RM to dispatch to customers and regular monitoring of the materials used to ensure the stability of the materials, must be addressed. Particular emphasis is given to the planning and production of the materials, their characterisation and the statistical methods used, as well as the assignment of characteristic values and the competence of the personnel involved.

If the RM producer uses subcontractors for specific tasks, the evidence of the competence of the subcontractors and compliance with the relevant requirements of DIN EN ISO 17034 as well as the competence of the RM producer to assess the subcontractors must be assessed.

7.6.3 During the planning of the assessment, at least the following factors must be considered:

- Aspects of the standard which are of equal interest to all assessors must be jointly assessed. With respect to the topics of examination of homogeneity and stability and characterisation of (C)RMs, a joint assessment or agreements between FB and FB_{stat} are essential in order to enable an assessment of whether the (C)RMs are fit for intended use. The scope of the assessment by the technical assessor for statistics (FB_{stat}) depends on the number and complexity of the statistical procedures used and is determined by DAkkS for each individual case;
- On-site witness audits in which parts of the production of the (C)RMs, such as material production, splitting, packaging etc. are observed by the assessor or assessors. If no material is being produced at the time of the assessment, parts of the production process can also be demonstrated;
- Verification of the competence of subcontractors by the RM producer and the associated documentation;
- Contracts with external personnel;
- Procedures for the use of advisory groups and the documentation of their activities;
- Assessment of non-accredited test methods if they are used during the production of reference materials.
  However, an assessment of these requirements within the framework of the production of reference materials is not equivalent to an accreditation as a testing laboratory in accordance with DIN EN ISO/IEC 17025. Documentation of the assessment of the test methods is by means of form 75 FB 002.1_17025-2018, report checklist (sections 6 and 7), form 75 FB 008.1, General record sheet or the relevant subject-specific forms where applicable.

7.7 (DIN EN ISO/IEC 17011) Accreditation decision-making

7.7.3 (i) For the decision-making process, the Accreditation Committee requires the following additional documents:

- The completed Excel table (72 FB 004.9_A1, Excel list of RM produced);
- A completed form 75 FB 008.38a for each production of an RM assessed and the on-site witness audit, and
- a completed Form 75 FB 008.38b for each statistical procedure assessed, and
- a completed form 75 FB 008.38c for each subcontractor assessed respectively.

7.8 (DIN EN ISO/IEC 17011) Accreditation information

7.8.3 f) The scope of accreditation is presented in tabular form (see Annex 1).

The contents of this table are based on:

- The scope of accreditation requested,
- the experience of the (C)RM producer in the areas in which accreditation is sought, as derived from the submitted Excel table (72 FB 004.9_A1, Excel list of RM produced) and
- the competence determined during the on-site assessment.

Depending on the level of experience in the production of (C)RMs, either individual selected (C)RMs or areas which may include several different (C)RMs can be accredited. If the RM producer has produced only a small number of (C)RMs to date, or if the assessment shows that there is little experience or limited competence in some areas, only the production of specific (C)RMs is accredited. Where extensive experience and adequate competence is available, areas can be defined using more or less general matrix/product specifications or the specification of a product group. Instead of individual reference materials, reference material groups can be defined. In these areas, the RM producer may then produce other (C)RMs within the framework of accreditation without leaving the scope of accreditation. Further information and examples can be found in Annex 1 to this document.

This assumes that the specified characterisation strategies in these areas are retained and that the test, calibration and analysis methods used for the new reference materials added, including sample pretreatment, are not fundamentally different from those used in the accredited area. If however this is not the case, this (C)RM is outside the scope of the accreditation.

RM producers accredited with variable scope must maintain an up-to-date list of the reference materials produced in the accredited area (content: product/matrix /object of analysis, relevant characteristics including measuring range (in the case of quantitative characteristics) and characterisation method used, and must provide it to their customers and DAkkS upon request. This list is referenced in the annex to the accreditation certificate as follows:

“The reference material producer maintains an up-to-date list of reference materials/certified reference materials in the accredited area.”

II Specification of requirements of DIN EN ISO 17034

This section specifies the requirements of DIN EN ISO 17034 in greater detail. The numbering within this section follows the numbering of DIN EN ISO 17034

6.1 (DIN EN ISO 17034) Personnel

6.1.3 The level of competence must be sufficient to supervise external personnel, assess the competence of subcontractors, independently plan the production of (C)RM and professionally assess and define the reference values and, where applicable, their measurement uncertainties. This requires relevant knowledge of the material for the selection and assessment of the candidate RM (such as its homogeneity and stability), its intended use (including test, calibration and analysis methods) and experience with the methods used for characterisation.

If external personnel are used, they must be contractually bound (permanently or project-based). The contracts must contain at least the following:

- Description of the activity commissioned (area and type of activity);
- Duration of the activity commissioned;
- Arrangements for the protection of confidentiality and impartiality;
- Integration into the quality system and commitment to adhere to it;
- Arrangements concerning training and the required competence.

6.2 (DIN EN ISO 17034) Subcontracting

6.2.3 For each (C)RM, it must be clear which activities are subcontracted.

6.2.5 For test and calibration services, the requirements can be fulfilled as follows:

- Accreditation in accordance with DIN EN ISO/IEC 17025 or, in the case of medical examinations, an accreditation in accordance with DIN EN ISO 15189 or, in certain cases, DIN EN ISO 15195 in conjunction with DIN EN ISO/IEC 17025 for methods used as part of the production process. Membership of the CIPM MRA and participation in key comparisons are considered valid as proof;
- Alternatively, the RM producer can use an on-site audit carried out by a competent auditor and documented in writing to provide evidence that the relevant requirements of the applicable standards in the 17000 series or DIN EN ISO 15189 as well as other applicable requirements are fulfilled for the subcontracted work. Competent and comprehensive conduct of the audit must be clearly evident from the audit records.
  These audits must be conducted regularly;
- Documented assessments on the basis of experience with work carried out in the past, successful participation in proficiency testing, results of testing of other comparable materials. See also section 7.12.4 b of DIN EN ISO 17034.

For the in-company transfer of work covered by DIN EN ISO 17034, the internal contractor must be included in the RM producer's quality system. Otherwise, the same rules as for subcontractors apply.

7.2 (DIN EN ISO 17034) Production planning

7.2.4 The measures taken to demonstrate that information can be transferred from previous batches to new batches must be documented in the production plan for the new batch.

7.3 (DIN EN ISO 17034) Production control

7.3 The written confirmation may only be issued by personnel authorised for this purpose.

7.12 (DIN EN ISO 17034) Characterisation

7.12.4 Where characterisation analyses for the production of certified reference materials (CRMs) make use of other reference materials for the purpose of metrological traceability, it is necessary to ensure that only CRMs are used for this purpose.

7.14 (DIN EN ISO 17034) RM documents and labels

7.14.1 The so called product information sheet for non-certified RM required by the standard can also be named differently. However, it must be ensured that it is easy for the customer to see whether a document is for a CRM or RM. Further requirements for the content of RM documents from other specific standards must be taken into account.

7.15 (DIN EN ISO 17034) Distribution service

7.15.4 The requirement is met when the RM producer passes this information on to its direct customers or to its authorised sellers. For customers not reached via these distribution channels, this information must be made available on the producer's web pages.

7.16 (DIN EN ISO 17034) Control of quality and technical records

7.16.3 When determining the retention periods, the dispatch date of the last (C)RM sold for the batch and the period of validity to be indicated in the RM documents must be taken into account.

References

JCGM 100 2008	Evaluation of measurement data — Guide to the expression of uncertainty in measurement
EA-4/02 2013-10	Evaluation of the Uncertainty of Measurement in Calibration

Annex 1 to 7.8 (DIN EN ISO/IEC 17011) Accreditation information (informative)

Examples of the presentation of the certificate annex with explanations:

The table columns (as per 72 FB 005.36) Product, Property, Range and Characterisation method describe the scope of accreditation and are obligatory, as is the Location column, if the RM producer operates at multiple locations.
The following examples are designed to illustrate how the choice of terminology can make the accredited area of RM producers more or less variable.

Example of a scope of accreditation without possible variations within the accreditation.

Product	Property	Range	Characterisation method	Type (RM/CRM)*	Location
Drinking water	Lead, cadmium, nickel	0.1 – 100 µg/l	Method-based measurand using a network of competent laboratories	CRM	

*) RM = Reference material; CRM = Certified reference material

In this case, the accreditation is valid for the production of CRMs of lead, cadmium and nickel in drinking water with certified contents of 0.1 – 100 µg/l.

Example of a scope of accreditation with possible variations for the products within the accreditation.

Product	Property	Range	Characterisation method	Type (RM/CRM)*	Location
Water	Lead, cadmium, nickel	0.1 – 100 µg/l	Method-based measurand using a network of competent laboratories	CRM	

*) RM = Reference material; CRM = Certified reference material

An accreditation for CRMs for lead, cadmium, nickel in all waters from ultrapure water to sea water and waste water is hereby granted.

The product “water” can be limited for example to natural water, fresh water, industrial water and waste water, raw and drinking water.

Example of a scope of accreditation with possible variations for the attributes of the (C)RM within the accreditation.

Product	Property	Range	Characterisation method	Type (RM/CRM)*	Location
Drinking water	Metals	0.001 – 95 % m/m	Method-based measurand using a network of competent laboratories	CRM	

*) RM = Reference material; CRM = Certified reference material

The accredited area covers CRMs for all metals in the periodic table in drinking water.

The attribute “metals” can be limited for example to heavy metals, trace metals, alkali metals and alkaline earth metals or “metals in accordance with TrinkwV”.

Optionally, possible variations for products and properties can also be granted together.

The key factors in the differentiation of the areas are the competence and experience, proven in the assessment, of the RM producer with the products, their properties and their use in the areas to be accredited. This also includes in-depth knowledge of the test, calibration and analysis methods used.