

## Accreditation of reference material producers

Specific Accreditation Protocol: This is a brief description of the accreditation service for conformity assessment of a specific activity. It should be read in conjunction with the RvA Policy Rules (RvA-BR002).

### 1. Normative documents

#### 1.1 Accreditation criteria, guidelines and explanatory documents

**Criteria:**

- ISO Guide 34, General requirements for the competence of reference material producers, 2009

**Guidelines and explanatory documents:**

- ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories, 2005
- ISO Guide 30:1992, Terms and definitions used in connection with reference materials
- ISO Guide 31:2000, Reference materials-Contents of certificate and labels
- ISO Guide 35: 2006, Reference materials- General and statistical principles for certification
- ISO/IEC 17000:2004, Conformity assessment - Vocabulary and general principles
- ISO 10012:2003, Measurement management systems - Fundamentals and vocabulary
- International vocabulary of metrology – Basic and general concepts and associated terms (VIM):2008, also issued as ISO Guide 99: 2007.
- Evaluation of measurement data — Guide to the expression of uncertainty in measurement (GUM): 2008
- EA-4/02, Expression of the Uncertainty of Measurement in Calibration, 1999
- RvA-T001, Application of the terms 'Own method', 'Conforming to' and 'Equivalent to'
- RvA-T002, Explanatory document on microbiology
- RvA-T018, Acceptable traceability
- RvA-T022, Eerstelijnscontrole
- RvA-T025, Scope of testing laboratories
- RvA-T030, Interlaboratory comparisons
- RvA-T034, Accreditation of Reference Material Producers

### 1.2 Documents for Conformity Assessment

The reference material producer shall identify normative documents for applied calibration and/or testing methods

### 2. Description of the scope of accreditation

The scope of accreditation, which is annexed to the accreditation certificate, is defined as follows:

Nr. or Category	Matrix / Artefact	Property Value(s) / Identity / Characterisation Ranges	Characterisation Procedure/ Technique And specific technical Standards
	General description of the reference material as a carrier of the certified property value(s)	Specification of property values and certified ranges	Generally by the methods described in ISO Guide 35

Detailed information and examples are given in RvA-T034.

### 3. Assessments

The assessment strategy depends on the requested scope of accreditation. In section 3.1 departures or special cases derived from the general RvA policy rules are given.

#### 3.1 Documentation

<i>Documents to be made available prior to the assessment</i>	<i>Pre - assessment</i>	<i>Initial or re-assessment</i>	<i>Surveillance</i>	<i>Scope extension<sup>1)</sup></i>
- Evidence of legal entity (abstract from registration Chamber of Commerce and regulations)	√	√		
- Quality manual and procedures addressing the requirements of the accreditation standard	√	√	√	√
- Technical procedure and working instructions		√	√	√
- Cross reference tables between management system documents and requirements from the accreditation standard	√	√	√	√
- A reference material certificate template	√	√		√
- Validation reports (analytical methods and certification methods)		√	√	√
- Reports from internal audits and management review		√		√

#### 3.2 Assessment process

<i>Assessment method</i>	<i>Initial or reassessment</i>	<i>Surveillance</i>	<i>Scope extension<sup>1)</sup></i>
Document review	√	√	√
Office assessment	√	Annually	√
On site-witnessing	√	Annually	√

1) Based upon the requested scope extension (in RvA-F105), the RvA will determine the assessment method

For reference material producers already holding an accreditation for testing and/ or calibration activities (ISO 17025, ISO15189), combined assessments will be considered by RvA

### 4. Miscellaneous

#### 4.1 Relevant regulations

Depending on National regulations connected to hazardous materials (e.g. labelling and transportation)

#### 4.2 Internal RvA expertise holder

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#### 4.3 Specific assessment subjects

Refer to RvA-T034.

#### 4.4 Organisations which will be informed by RvA

Not applicable

#### 4.5 Remaining information

Not applicable

#### 4.6 Changes from previous version

Accreditation conducted in accordance with ISO Guide 34: 2009 alone