Raad voor Accreditatie (Dutch Accreditation Council, RvA)

Specific Accreditation-Protocol (SAP) for Accreditation of Reference Material Produces (general)

Document code:	**RvA-SAP-P000-UK**
	Version 4, 18-9-2018

A Specific Accreditation Protocol (SAP) describes the assessment service for a specific accreditation. It should be read in conjunction with the generic RvA regulations and policy documents.
A current version of the SAP is available from the website of the RvA. (www.rva.nl).

Contents

0 Introduction

- The previous versions of this document have been published with document code SAP-P00**1**-UK. Starting with this version (version 4) the document code has been changed to SAP-P00**0**-UK, to bring the numbering in line with other general SAPs.
- The key elements of explanatory document RvA-T034 have been included in this SAP. RvA-T034 therefore has been withdrawn at the publication date of this SAP.

1 Relevant documents

1.1 Accreditation standard

- EN ISO 17034; General requirements for the competence of reference material producers

1.2 Additional documents

- EN ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories
- ISO Guide 30, Terms and definitions used in connection with reference materials
- ISO Guide 31, Reference materials-Contents of certificate and labels
- ISO Guide 35, Reference materials- General and statistical principles for certification
- EA-4/02, Expression of the Uncertainty of Measurement in Calibration
- RvA-T001, Application of the terms 'Own method', 'Conforming to' and 'Equivalent to'
- RvA-T002, Explanatory document on microbiology
- RvA-T018, Acceptable traceability
- RvA-T025, Scope of testing laboratories
- RvA-T030, Interlaboratory comparisons
- ILAC P9; ILAC Policy for Participation in Proficiency Testing Activities
- ILAC P10; ILAC Policy on Traceability of Measurement Results
- ILAC P14; ILAC Policy for Uncertainty in Calibration

1.3 Additional documents (indirect)

- EN ISO/IEC 17000, Conformity assessment - Vocabulary and general principles
- EN ISO 10012, Measurement management systems - Requirements for measurement processes and measuring equipment
- International vocabulary of metrology – Basic and general concepts and associated terms (VIM):2012, also issued as ISOIEC Guide 99: 2008.
- Evaluation of measurement data — Guide to the expression of uncertainty in measurement (GUM): 2008
- EA 2/18; Guidelines for accreditation bodies on the content of scopes of accreditation for proficiency testing providers

The current version of the documents above can be obtained from the website of the relevant organization: ILAC (www.ilac.org), EA (www.european-accreditation.org), ISO (www.iso.org), RvA (www.rva.nl).

1.4 Documents related to the conformity assessments to be carried out

The Reference Material Producer (RMP) shall uniquely identify and document the methods and related activities applied for the production and characterisation of RM materials.

1.5 Specific requirements from legislation and regulations

Depending on the type of activity; the producer is expected to identify any related legal requirement and have it implemented where relevant.

2 Scope of accreditation

The general rules for defining scopes have been defined by the RvA in RvA Policy rule RvA-BR003. More specific rules are provided in RvA-T025.

For fixed scopes, the following format will be applied (including samples of activities):

Nr./HCS code[1]	Matrix/Artefact	Property Value / Identity / Characterisation Range	CMC[1]	Characterisation Procedure/Technique
1	**Coke oven gas** Hydrogen Methane	0.2 % – 70 % 4 % – 35 %	0.5 % 0.5 %	Preparation by a single primary reference procedure (gravimetry). Verification method selected from: GC-TCD and/or GC-FID
DV 12	**Viscosity**	**CRM's** CGM's are produced by industry and certified by the CAB		
19	Organic solutions and oils	Kinematic viscosity (1 to 10^5 mm^2/s levels at 15 to 90 ^oC)	xx %	Measurement by a single primary reference measurement procedure: Measurement by Ostwald-type viscometers

[1] HCS codes and application of CMC's may be applied for RMPs that are closely related to calibration laboratories.

In case CMC is specified in the scope, the following foot note will be added below the scope table:
Calibration and Measurement Capability (CMC): Demonstrated measurement uncertainty, with coverage probability of 95%, in a given measurement point or measurement range. Measurement uncertainty, U, is calculated according to EA-4/02 "Expression of the Uncertainty of Measurement in Calibration" and/or GUM "Evaluation of measurement data - Guide to the Expression of Uncertainty in Measurement".

A column referring to the location might be added to the table in case there are locations of the accredited organization with key activities (see RvA-BR003).

The scope of producing RM's can also be defined in a flexible way. This approach shall follow the requirements of ISO/IEC17011 clause 3.7, 7.8.4 and RvA-T25 clause 2.2.

Nr./HCS code[1]	Matrix/Artefact	Property Value / Identity / Characterisation Range	CMC[1]	Characterisation Procedure/Technique
		Flexibele scope		
1	Frozen liquid milk or broth	Micro-organism in a low concentration for detection Micro-organism in a high concentration for enumeration		SOPxx Flexscope SOPyy Preparation and validation of microbiological reference materials

The laboratory maintains an up to date list, specifying the tests that have been conducted under the flexible scope. This list is available to interested parties on request

3 Accreditation assessments

3.1 Documents to be submitted

For the RvA assessments, the assessors have to be provided with relevant documents as stated in the relevant application form (RvA-F001a; -F042, -F105) and/or in the annex to RvA-BR005.
A SAP can require additional documents/registrations from the RMP.

3.2 The nature and content of the assessments

In addition to the general rules for the nature and content of RvA assessments as defined in RvA-BR002 and RvA-BR005, for this accreditation the requirements from the following table apply. The type and size of the assessment depend on the requested scope of accreditation, other accreditations possibly existing and the functioning of the RMP in the past (where relevant).

Method of assessment	Initial assessment	Assessments during the accreditation cycle	Scope extension[1)]
Document assessment	√		√
Office assessment	√	Annually	√
Witnessing of the critical technical process activities: (see 4)	All activities will be assessed/ witnessed.	Annual assessment of main activities of the scope[2)] During the accreditation cycle all activities will be assessed/ witnessed	√

[1)] Based on the application(form RvA-F105 and -F042) RvA determines how the assessment of the extension will be performed.
[2)] In RvA report part A, a four-years assessment planning is documented.

4 Specific points of attention for RvA assessments

According to ISO 17034 clause 6.2.3, a number of key processes in producing a reference material, shall not be subcontracted. These processes are given in italics:

- *production planning;*
- *selection of subcontractors*;
- material preparation;
- homogeneity/stability testing;
- characterization of property values;
- *assignment of property values and their uncertainties*;
- *authorization of property values and their uncertainties;*
- *authorization of RM documents;*
- handling and storage (including monitoring integrity of reference material);
- distribution and post distribution services.

The assessment team shall, when applicable, pay special attention to any subcontracted work and/or supplied materials.

- If within the conditions of the accreditation standard, part of the work is subcontracted, the assessment team shall pay explicit attention to the subcontractor audits performed by the RMP. In case the assessment team is not convinced that key activities performed by and competence of the subcontractor are adequately audited by the RMP or that traceability is not proven, the RvA team will require the activity be witnessed by the RvA team.
- Similar conditions apply for verification of suitability of supplied materials or substances.

The applied statistics for the RM production are part of the assessment and will be scheduled depending on initial applications, extension of scope and when changes in statistics are foreseen.

5 Other information

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6 Changes with regard to the previous version

Compared to version 3 of May 2013, the following significant changes have been made:
- The lay-out of the SAP has been changed to the latest version of the lay-out.
- This general SAP has been renumbered from SAP-P001 to SAP-P000.
- The SAP now refers to EN ISO 17034, instead of ISO Guide 34.
- Specific points of attention for the RvA assessments have been included in chapter 4.
- Document RvA-T034 has been incorporated in this SAP and has been revoked.