DUTCH ACCREDITATION COUNCIL

Accreditation specification RvA

Accreditation of reference material producers (EN-ISO 17034)

Document code: ASR108-UK

Version 1.0, effective date: 15-09-2025

Contents

Introduction

This is the accreditation specification RvA (ASR) that addresses the accreditation of Reference Material Producers (RMPs) according to the standard EN-ISO 17034.

1 Relevant documents

1.1 Standard used for accreditation

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

1.2 Additional documents (mandatory)

- ASR001 Overview of RvA, EA, ILAC & IAF documents

The current version of this document provides the overview of the relevant RvA, EA, ILAC and IAF documents, both mandatory and informative, applicable to accreditation for EN-ISO 17034. The documents can be downloaded from the website of the organisation(s) concerned: IAF (www.iaf.nu), ILAC (www.ilac.org), EA (www.european-accreditation.org), RvA (www.rva.nl).

1.3 Other additional documents (informative)

- ISO Guide 30, Reference materials — Selected terms and definitions
- ISO 33401, Reference materials — Contents of certificates, labels and accompanying documentation (former ISO Guide 31)
- ISO 33405, Reference materials — Approaches for characterization and assessment of homogeneity and stability (former ISO Guide 35)
- EN-ISO 10012, Measurement management systems - Requirements for measurement processes and measuring equipment
- ISO/IEC Guide 98-3; Uncertainty of measurement – Guide to the expression of uncertainty in measurement (GUM, JCGM 100)
- ISO/IEC Guide 99; International vocabulary of metrology – Basic and general concepts and associated terms (VIM, JCGM 200)

The current version of the documents above can be obtained from the website of the relevant organization: ISO (www.iso.org).

2 Scope of accreditation

For accreditation of RMPs the scope is formulated as follows.
Activities can be accredited in accordance with a fixed scope of accreditation or a flexible scope of accreditation. Document RvA-T054 / ASR008 describes the RvA-policy on flexible scopes and the requirements applicable to the RMP accordingly.

2.1 Fixed scope

For fixed scopes, the following format will be applied:

No./HCS code[1]	Matrix/Artefact	Property Value / Identity / Characterisation Range	Expanded measurement uncertainty [1,2]	Characterisation Procedure/ Technique	Location
HCS-code	**HCS-quantity**				
Number	Matrix or artefact	Property Value / Identity / Characterisation Range	Expanded measurement uncertainty	Reference to characterisation Procedure/ Technique	Where activities are executed

(1) HCS codes and expanded measurement uncertainties shall be applied for RMPs that are closely related to calibration laboratories. If this is not the case, the header on the scope is not used.
(2) In case the expanded measurement uncertainty is specified in the scope, the following footer will be added below the scope:
Calibration and Measurement Capability (CMC): demonstrated lowest possible expanded measurement uncertainty available to customers under normal conditions, 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".

An example for fixed scope activities is shown in the sample scope below:

No./HCS code	Matrix/Artefact	Property Value / Identity / Characterisation Range	Expanded measurement uncertainty [1]	Characterisation Procedure/Technique	Location
RM.02	**Gas mixtures**				
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	ABC
DV.02.00	**Viscosity**				
2	Organic solutions and oils	Kinematic viscosity (1 to 10^5 mm^2/s levels at 15 to 90 °C)	0.25 %	Measurement by a single primary reference measurement procedure: Measurement by Ostwald-type viscometers	XYZ

(1) Calibration and Measurement Capability (CMC): demonstrated lowest possible expanded measurement uncertainty available to customers under normal conditions, 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".

2.2 Flexible scope

For flexible scopes, the following format will be applied:

No.	Matrix/ Artefact	Property Value / Identity / Characterisation Range	Characterisation Procedure/Technique	Location
		Flexible scope[1]		
Number	Matrix or artefact	Property Value / Identity / Characterisation Range	Reference to characterisation Procedure/Technique	Where activities are executed

(1) Mandatory footnote for flexible scopes: The Reference Material Producer is obliged to maintain an up-to-date list of activities performed under this flexible scope. This list can be requested from the Reference Material Producer.

An example for flexible scope activities is shown in the sample scope below:

No.	Matrix/ Artefact	Property Value / Identity / Characterisation Range	Characterisation Procedure/Technique	Location
		Flexible scope[1]		
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	ABC

(1) The Reference Material Producer is obliged to maintain an up-to-date list of activities performed under this flexible scope. This list can be requested from the Reference Material Producer.

3 Accreditation assessments

3.1 Documents to be provided

For the purpose of RvA assessments, assessors shall be provided with relevant documents as specified in Annex A

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-BR001, the rules from the table below apply for this specific accreditation.

The nature and content of the assessment depend on the requested scope of accreditation, any pre-existing accreditation, the past performance of the RMP (if applicable) and risks.

Method of assessment	Initial assessment	Regular assessments in the cycle[1]	Scope extension[2]
Pre-assessment	√		If applicable for new cluster of activities.
Document assessment	√		If applicable
Office assessment including observation of execution of activities in the laboratory, fixed scope	All clusters of activities will be assessed / witnessed.	Annual assessment of a sample of the clusters of activities on the scope. During the accreditation cycle all clusters of activities will be assessed / witnessed	√
Office assessment including observation of execution of activities in the laboratory, flexible scope	All clusters will be assessed / witnessed. Assessment of management of the flexible scope.	Annual assessment of a sample of the clusters of activities on the scope. During the accreditation cycle all clusters of activities will be assessed / witnessed	Not yet accredited for flexible scope: assessment of the applied activities and management of the flexible scope. Already accredited for flexible scope: pre-assessment applicable in case of a new cluster of activities.

(1) A(n) (accreditation) cycle covers a period of four years, starting after a decision on an initial assessment or reassessment has been taken; the cycle therefore includes surveillance assessments and reassessments during this period.
(2) Based on the application, the RvA determines how the assessment of the extension will be carried out.

4 Specific assessment issues

4.1 Subcontracting

According to EN-ISO 17034 clause 6.2.3 a number of key processes in producing a reference material shall not be subcontracted. 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 RvA assessment team identifies a nonconformity on the topic of insufficient auditing of the subcontractor or when traceability is not proven, the team will witness the activity.
- The same policy as the first bullet applies for the verification of the suitability of materials or substances supplied by a subcontractor.
- The subcontracted activities are defined and described in table 1.6 of the RvA report Part A.

4.2 Statistics

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.

4.3 PT/ILC results

For testing activities performed as RMP the applicable requirements from ISO/IEC 17025 should be taken into account. Within this context, special attention will be for participation and results of PT/ILC. Please refer to document RvA-T030 / ASR008 for further information.

4.4 Non-accredited in-house activities

When a RMP carries out in-house activities as a part of accredited activities for which it is not separately accredited, the RvA will explicitly assess this. The nature and content of the accreditation assessment of these activities will depend among other things on the extent to which a RMP can demonstrate that it assesses these activities itself against the relevant criteria. The activities referred to here are:

- In-house calibration;
- In-house testing.

5 Changes compared to the previous version of this document

Compared to version 4 of September 2018, the following significant changes have been made:

- Obsolete references have been removed.
- In chapter 2 a policy for Flexible scopes is added (RvA-T054 / ASR004).
- In chapter 2 a column for Location has been added to the scope examples.
- In chapter 3.2 addition of pre-assessment and flexible scope to the assessment table.
- In chapter 4 headers have been added, and PT/ILC for testing activities as assessment issue.
- Chapter 5 from the previous version “Other information” has been removed.
- New ASR-template has been applied, which changes the structure and headers of certain chapters. Chapter 4.4 is part of the updated ASR-template.
- Annex A, B and C are added because of the publication of the updated policy rule BR001. Information from the previous policy rules has been included in the ASR documents per accreditation standard.

Annex A: Documents to be provided

Documents to be provided EN-ISO 17034	Initial assessment	Extension	Surveillance	Reassessment
1. Completed RvA application form for accreditation (F001a)	√			
2. Completed RvA application form for scope extensions and/or scope adjustments (F105)		√		
3. Completed RvA supplementary application form Reference Material Producers (F042)	√	√		
4. Amended chapter 1 and relevant Annexes of the Part A report for this accreditation			√	√
5. Proof of Chamber of Commerce registration (not more than six months old)	√	√		√
6. An organisational chart and description of your organisational structure	√	√		
7. Documentation (e.g. quality manual or similar documentation) and general management system procedures	√	√	√	√
8. A cross-reference between the requirements of EN-ISO 17034 and your documented management system	√	√	√	√
9. Overview of participation in inter-laboratory comparisons (ILC, proficiency testing, etc.) (see RvA-T030 / ASR008)			√	√
10. Report(s) of recent internal audit(s) (not older than 6 months)	√	√		
11. Report of the most recent management review (not older than 6 months)	√	√		
12. The technical procedures and work instructions for all reference materials applied for	√	√	√	√
13. General procedures developed or adapted and not included in the quality manual	√	√		
14. Requirements of competency and qualification procedure	√	√		
15. Example of a certificate	√	√		
16. Certification scheme (normative document)	√	√		
17. A list of activities traceable to the flexible scope elements under accreditation (if applicable)			√	√
18. Own assessment of the certification scheme, as explained in ASR007, if applicable to the new activity or activities. If you consider this not to be applicable, you shall mention this.	√	√		
19. In the case of an external scheme owner: Own assessment of the scheme, as explained in ASR007, in combination with a request for scheme evaluation (F207) If the specific version of the scheme for which accreditation is being requested is included in the list of schemes for which the RvA can grant accreditation (see RvA-BR010 list), a new application for scheme evaluation is not necessary.	√	√		

Annex B: Field of activities

Conformity assessment activities for which accreditation can be requested from the RvA.

Activities marked with (NL) are only accredited by bodies established in the Netherlands.

If the RvA no longer has active accreditations in a field of activity, the field of activity is considered inactive.

The production of reference materials as referred to in EN-ISO 17034 **(NL)**
AREAS
Reference materials with microbiological properties; Gas mixtures; Liquids.

Annex C: Examples of category A non-conformities

a. The RMP has reported erroneous results.
b. In the absence of adequate quality controls it is not demonstrable that results are correct.
c. The RMP cannot demonstrate that the application of the method used gives correct results.
d. The accreditation mark (or other communication) is used in a way that suggests that the body is accredited for an activity where this is not the case.
e. In one or more files so many of the records required are lacking that it is no longer possible to see that tests have been carried out correctly.