



# **Accreditation specification RvA**

## **Accreditation of biobanks (EN-ISO 20387)**

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## Introduction

This is the accreditation specification RvA (ASR) that addresses the accreditation of biobanks according to the standard EN-ISO 20387. In addition to this ASR, there may be an ASR for a particular field of activity, which details aspects relevant to that field of activity. Currently, accreditation is only granted for the specific field of biobanks containing human material, to which this ASR applies.

## 1 Relevant documents

### 1.1 Standard used for accreditation

- EN-ISO 20387; Biotechnology - Biobanking - General requirements for biobanking

### 1.2 Additional documents

- ASR001 Overview 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 20387. The documents can be downloaded from the website of the organisation(s) concerned: IAF ([www.iaf.nu](http://www.iaf.nu)), ILAC ([www.ilac.org](http://www.ilac.org)), EA ([www.european-accreditation.org](http://www.european-accreditation.org)), RvA ([www.rva.nl](http://www.rva.nl)).

### 1.3 Specific legislation and regulations

Specific legislation and regulations that make the relevant conformity assessment and/or accreditation mandatory for the subject of a specific SAP are mentioned here.

## 2 Scope of accreditation

For accreditation of biobanks the scope is formulated as follows.

### 2.1 Fixed scope

No.	Received material / matrix (incl. associated data)	Stored material	Storage conditions	Activities	Location
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[Source] Material

1.					
2.					

The scope of accreditation is limited to biobanks containing human material for scientific research. Biobanks for the purpose of diagnosis or treatment of patients are outside the scope of EN-ISO 20387. A source scope managed by the RvA has been established for biobanks containing human material, RvA-F043-2. This document can be downloaded from the RvA website. A guide to using the source scopes can be found on the second worksheet of this file. The methods used can be found in this file, these are not listed on the scope of accreditation for reasons of scope clarity.

## 2.2 Flexible scope

Currently, a flexible scope is not applied for Biobanking and only a fixed scope is possible.

## 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 the RvA assessments as laid down in RvA-BR001, the rules from the table below apply to this specific accreditation.

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

Method of assessment	Initial assessment	Regular assessment in the cycle <sup>(1)</sup>	Scope extension <sup>(2)</sup>
Pre-assessment	√		√
Document assessment			If applicable
Office assessment including witnessing of activities (on site assessment)	√	√	√
	All activities are assessed.	All activities are assessed at least once in the cycle.	If applicable all activities of the requested extension are assessed.

<sup>(1)</sup> 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.

<sup>(2)</sup> Based on the application, the RvA will determine how the assessments of the extension will be carried out.

## 4 Specific assessment issues

### 4.1 Assessment of data management

If necessary, an additional Technical Assessor assesses data management.

### 4.2 External services

If biobanks use services provided by third parties, the biobank must demonstrate that the service provided complies with EN-ISO 20387. Merely referring to, for example, accreditation by ISO 15189 is not sufficient.

### 4.3 Non-accredited in-house activities

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

- In-house calibrations;
- In-house testing.

## **5 Changes compared to the previous version of this document**

Not applicable, this is the first version of ASR112.

## Annex A: Documents to be provided

Documents to be provided EN-ISO 20387	Initial assessment	Extension	Surveillance	Reassessment	Witnessing
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 biobanks (F043-1)	√	√			
4. Completed RvA source scopes biobanks (F043-2)	√	√			
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. The work instructions for all methods/activities (if applicable: newly applied for)	√	√	√	√	√
9. Verification/validation reports for all tests applied for, for example preparation, analysis, storage, thawing etc. (article 7.9)	√	√			
10. The modified verification/validation reports, for example preparation, analysis, storage, thawing etc. (article 7.9)			√	√	√
11. Overview of participation in interlaboratory comparisons (EQA, proficiency testing, etc.) and the PT-plan (see <a href="#">RvA-T030</a> / ASR008) (article 7.8)	√	√	√	√	√
12. A cross-reference between the requirements of EN-ISO 20387 and your quality system	√	√	√	√	√
13. Amended chapter 1 and relevant Annexes of the Part A report for this accreditation		√	√	√	√
14. Example of an anonymised report	√	√			
15. Report(s) of recent internal audit(s) (not older than 6 months) including action plans	√	√	√	√	√
16. Planning of internal audits (year overview)	√	√	√	√	√
17. Report of the most recent management review (not older than 6 months)	√	√	√	√	√

Documents to be provided EN-ISO 20387	Initial assessment	Extension	Surveillance	Reassessment	Witnessing
18. List of all equipment related to the scope applied for	√	√	√	√	√
19. Catalogue of available collections (article 7.10.5)	√	√	√	√	√

## Annex B: Fields of activity RvA

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

Activities marked with <sup>(NL)</sup> 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.

### ***Performance of biobanking activities as referred to in EN-ISO 20387***

#### FIELDS OF ACTIVITY

Human material for the purpose of Research and Development (R&D)

## **Annex C: Examples of category A non-conformities for biobanks**

- a. The issued samples and associated data are not demonstrably suitable for the intended purpose.
- b. The continuity of storage of samples and associated data is not guaranteed.
- c. Due to the lack of adequate quality controls, it cannot be demonstrated that the results are correct.
- d. The biobank cannot demonstrate that the application of the method used produces correct results.
- e. The accreditation mark (or other expression) is used in a way that suggests that the institution is accredited for an activity when this is not the case.
- f. In one or more files, so many of the required registrations are missing that it is no longer possible to verify that activities have been carried out correctly.