



Accreditation specification RvA

Accreditation of medical laboratories (EN-ISO 15189)

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Introduction

This is the accreditation specification RvA (ASR) that addresses the accreditation of medical laboratories according to the standard EN-ISO 15189. Annex D explains the framework that RvA uses for granting accreditation for EN-ISO 15189 next to regular medical diagnostics. In addition to this ASR, there may be an ASR for a particular field of activity – as mentioned in Annex B, which details aspects relevant to that field of activity.

1 Relevant documents

1.1 Standard used for accreditation

- EN-ISO 15189; Medical laboratories – Requirements for quality and competence

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 15189. The documents can be downloaded from the website of the organisation(s) concerned: ILAC (www.ilac.org), EA (www.european-accreditation.org), RvA (www.rva.nl).

2 Scope of accreditation

For accreditation of medical laboratories the scope is formulated as follows.

2.1 Flexible scope

For accreditation based on EN-ISO 15189, a flexible scope applies if the medical laboratory meets the conditions set out in RvA-T054 / ASR004.

2.1.1 Source scope

For each medical field of work, a source scope has been drawn up by the RvA in collaboration with the scientific associations, see also RvA-F004-3 'Bronscopes medische laboratoria' (Dutch).

A source scope is available from the following scientific/professional associations:

- FNT Federation of Dutch Thrombosis Services;
- KLEM Association for Clinical Embryology;
- NVKC Dutch Association for Clinical Chemistry and Laboratory Medicine;
- NVMM Dutch Association for Medical Microbiology;
- NVVI Dutch Association for Immunology;
- NVVP Dutch Association for Pathology;
- NVZA Dutch Association for Hospital Pharmacists;
- SAN Professional Association for Diagnostic Centres (Biometric testing);
- VKGL Association for Clinical Genetic Laboratory Diagnostics.

When drawing up the source scope, the question is based on the field of work and the technique used, the scope element is placed on the source scope of the field of work to which the diagnosis falls.

2.1.2 Borrowed scope elements from another medical field

It is possible to carry out a flexible scope element of another medical field on the own scope, this is called a borrowed scope element. The activities under this scope element shall meet the same conditions as a flexible scope element from the 'own' medical field, and specifically meet the requirements for the competence present at the laboratory.

In case of carrying out borrowed scope elements, it is important that the presence of competence in the laboratory is ensured by a documented agreement. It shall at least describe:

- the professional involvement of a specialist or laboratory with expertise for the borrowed scope, including validation/verification, IQC/EQA, and where relevant KPIs and the management review.
- sufficient participation in (re)training of relevant staff in the relevant borrowed medical field,
- proven competence in the relevant borrowed medical field.

This aspect is assessed at least once in the accreditation cycle by a TA from the borrowed medical field.

2.1.3 Technical execution by a laboratory from another medical field

When the technical execution of an activity takes place in another laboratory (from another medical field), but this is carried out under the full responsibility of the own laboratory, this activity may fall within the scope of accreditation of the own laboratory for both the technical execution and the interpretation. An example is the implementation of microbiological infection serology or molecular rapid diagnostics in a central 24-hour clinical chemistry laboratory. The own laboratory must be demonstrably responsible for all aspects of the activity. This includes validation/verification, IQC/EQA, handling of non-conformities, declaration of competency, competency assessment, and demonstrably conducting internal audits on the technical implementation by the executing laboratory. In addition, agreements and responsibilities must be demonstrably documented according to the documented agreement mentioned in § 2.1.2. In this case, the technical execution is not mentioned on the scope of the executing laboratory, but the accreditation falls entirely within the scope of the own laboratory.

If the own laboratory does not have full responsibility for this activity, [interpretation] will be added to the scope of the own laboratory, and to the scope of the executive laboratory [technical execution]. This can be done for a flexible or fixed scope.

2.1.4 Shared scope elements

When the scope of accreditation of a laboratory includes several medical fields in which activities can be performed under both fields, the laboratory links the activity to the scope element of one of the medical fields. This field of work should preferably be the field of work of the professional responsible for this activity. Examples include clinical chemistry and immunology, or medical microbiology and immunology.

2.1.5 Lay-out of flexible scope elements and POCT

Specifically for the 15189 accreditation, the scope is formulated as shown below, see figure 1.

Flexible scope¹

Code	Diagnostic question	Method/Technique	Material or product	Location
Medical field: Clinical Chemistry and Hematology In compliance with the standards in force (NVKC)				
CH.PRE.01	Pre analysis	Blood collection (extra-mural)	Blood	D1
CH.PRE.02		Blood collection (intra-mural)	Blood	D1
CH.PRE.03		Sample processing, sample reception, registration, processing, preprocessing for analysis (among other things centrifugation), post-analytic result processing, and progress check/turnaround time	All body fluids, blood cells, other body cells, punctures, bone marrow	D1
CH.KCA.01	Clinical Chemistry general	Routine analysis of electrolytes, enzymes, proteins, metabolites, blood gases and their derivatives using standard chemical techniques including all spectrophotometry, colorimetry, binding analysis, nephelometry, turbidimetry, electrophoresis, ion-selective electrodes {+POCT}	All body fluids	D1, G2, Z3, B6

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

Figure 1: Example of scope of accreditation

Flexibility

A flexible scope can be determined on the basis of a combination of the following elements that are shown on the scope:

- flexibility in terms of diagnostic question;
- flexibility with regard to method/technique;
- flexibility with regard to the material or product.

Code

The first column shows the code of the flexible scope element according to the source scope.

Diagnostic question

In the second column, the diagnostic question is listed.

Method/technique

The third column indicates the method/technique used, with the addition {+POCT}, [technical execution] or [interpretation] if applicable.

Material or product

The fourth column indicates the material or product (the matrix) on which the tests are carried out.

Location

The fifth column shows the locations. This column uses a letter-digit combination to show the location at which the scope element in question is executed. The number 1 always refers to the main location of the organization.

If examinations are (also) carried out in the field (*in situ*), that is outside the mentioned head office and locations mentioned in the scope, this is stated as such in the scope. This includes examinations that are carried out in mobile laboratories or in semi-permanent facilities, and point of care testing (POCT).

Blood collection sites

For blood collection sites where blood collection, preanalysis, POCT or biometrics are carried out, the following scope display has been agreed upon. This applies to the source scope elements listed below.

- CH.PRE.01: extra-mural blood collection. Only the main location is mentioned, the other hospital locations are not. There shall be an up-to-date list of blood collection sites in Part A.
- CH.PRE.02: intra-mural blood collection. Of all hospitals, the locations with a laboratory are listed on the scope.
- CH.PRE.03: pre analysis/sample processing. Of all hospitals, the locations with a laboratory are listed on the scope. Idem for MM, PA and other disciplines.
- CH.POC.01 and CH.BMT.0x: only the main location is indicated, the other hospital locations are not. There shall be an up-to-date overview in Part A.

The locations that are not shown on the scope are listed in § 1.4.2 of report part A or as an annex of part A (a list of blood collection sites and a list of biometric locations). The scope contains the main location for the relevant scope elements. See figure 2 for an example.

Medical field: Clinical Chemistry and Hematology In compliance with the standards in force (NVKC)				
CH.PRE.01	Pre analysis	Blood collection (extra-mural)	Blood	A1
CH.PRE.02		Blood collection (intra-mural)	Blood	A1, H2, H3, H4, A9
CH.PRE.03		Sample processing, sample reception, registration, processing, preprocessing for analysis (among other things centrifugation), post-analytic result processing, and progress check/turnaround time	All body fluids, blood cells, other body cells, punctures, bone marrow	A1, H2, H3, H4, A9

Figure 2: example locations on the scope per source scope element.

Location scope elements outside own laboratory

Of scope elements whose technical implementation takes place under the full responsibility of the own laboratory in another laboratory (from another medical field, see § 2.1.2), the locations of the other laboratory are also mentioned in § 1.4.1 of report part A. This is also the case when the address of both laboratories is the same, in that case this is not recognizable on the scope of accreditation stated.

Footnote flexible scope

The following sentence is included below the flexible scope: *'The laboratory is obliged to maintain an up-to-date list of activities performed under this flexible scope. This list can be requested from the laboratory.'*

Display field standards on the scope

A table header indicates the medical field and whether the laboratory complies with the field standards applicable to the professional field (published on the website of the professional association). See figure 3:

Flexible scope ¹				
Code	Diagnostic question	Method/Technique	Material or product	Location
Medical field: Clinical Chemistry and Hematology In compliance with the standards in force (NVKC)				
CH.PRE.01	Pre analysis	Blood collection (extra-mural)	Blood	D1

Figure 3: example of a field standard on the scope

Display of POCT on the scope

Additional requirements for Point of Care Testing (POCT) are incorporated in EN-ISO 15189:2022. The display in the scope is shown in figure 4.

CH.HCO.01	Clinical chemistry, hematology, hemocytometry incl haemato-oncology	Hematology and microscopy {+POCT}	Blood, other body fluids	U1
CH.HCO.02		Erythrocyte sedimentation rate	Blood	U1

Figure 4: representation of a POCT activity.

2.2 Fixed scope

A fixed scope is used if the medical laboratory does not meet the conditions of a flexible scope (RvA-T054 / ASR004) or if there is no existing flexible source scope element for an activity.

2.2.1 Borrowed scope elements

When borrowing a flexible scope element from another medical field, this can be displayed as a fixed scope element. The borrowed element is specified according to the activity actually performed. In this way, the available expertise is clearly indicated. For example, if amphetamine is determined in a clinical chemistry laboratory, and the consultation function is with the pharmacist, this is shown according to figure 5:

Code	Diagnostic question	Method/Technique	Material or product	Location
KF.TOX Fixed element 01	Toxicology (incl. drugs of abuse)	Determination by immunoassays: - Amphetamine [technical execution]	Urine	A1

Figure 5: fixed element Amphetamine on scope of a **clinical chemistry** laboratory, with 01 as the follow-up number for the fixed scope element, with the addition [technical execution].

The above example in figure 5 is based on the flexible Pharmacy source scope element as shown in figure 6:

Code	Diagnostic question	Method/Technique	Material or product	Location
KF.TOX.03	Toxicology (incl. drugs of abuse)	Immunoassays	Blood, urine or other body materials	A1

Figure 6: flexible source scope element, where 03 is a unique number in the source scope.

If the Pharmacy laboratory itself does not perform immunoassays but interprets the results, on the scope of the Pharmacy laboratory the mention [interpretation] is added to the flexible scope element (see Figure 7). This is subject to the condition that the technical implementation (and thus the chain) is carried out under accreditation.

Medical Field: Clinical Pharmacy				
Code	Diagnostic question	Method/Technique	Material or product	Location
KF.TDM.03	Therapeutic Drug Monitoring	Immunoassays [interpretation]	Blood, urine or other body materials	A1

Figure 7: a flexible source scope element with the addition [interpretation].

When carrying out fixed borrowed scope elements, it is important that the presence of expertise in the laboratory is ensured by means of a documented agreement, which meets the same requirements as stated in § 2.1.2 for flexible borrowed scope elements.

2.2.2 Activities that do not fit under an existing source scope element

If a laboratory cannot accommodate performed activities in the source scope, it first contacts the contact person of the scientific or professional association, as mentioned in the source scope (F004-3, Dutch). If this contact person confirms that the activity in question does not fall under one of the source scope elements, the laboratory may, in consultation with the RvA, have the activity included as a 'fixed element' on its own scope. The laboratory sends the confirmation from the scientific or professional association. This ensures that laboratory-specific matters do not lead to an adjustment of the RvA source scope. As long as the source scope has not been modified, the requested activity remains on the scope as a fixed element.

Matters that are identified by (the contact person of) a scientific or professional association as a gap in the source scope are submitted to the RvA. In consultation, further action will be taken in the process towards an adjustment in the source scope.

These fixed elements are preferably shown below the flexible elements of the medical field and the corresponding diagnostic question (Figure 8):

Code	Diagnostic question	Method/Technique	Material or product	Location
KF.TOX.03	Toxicology (incl. drugs of abuse)	Immunoassays	Blood, urine or other body materials	A1

Code	Diagnostic question	Method/Technique	Material or product	Location
KF.TOX Fixed element 01		Determination by immunoassays: - (name specifically)	<i>name specifically</i>	A1
KF.TOX.04		Atomic absorption and emission spectrometry	Blood, urine or other body materials	A1

Figure 8: fixed elements are displayed below the flexible elements.

2.2.3. Analysis of Clinical Trials

If a laboratory performs analyses in the context of clinical trials, this will be included in the scope of accreditation. This scope-element is included in the source scope for clinical chemistry.

2.3 Referring laboratory and referral laboratory

The following explanation applies to both fixed and flexible scope elements.

Laboratory activities may not be provided by an external service provider on a structural basis (outsourcing) under the accreditation. Accreditation can only be granted for an activity for which a laboratory itself is competent and for which the laboratory carries out at least part of the activity by itself. If the laboratory does not carry out the entire activity itself, the accredited laboratory may use a referral laboratory, see figure 9.

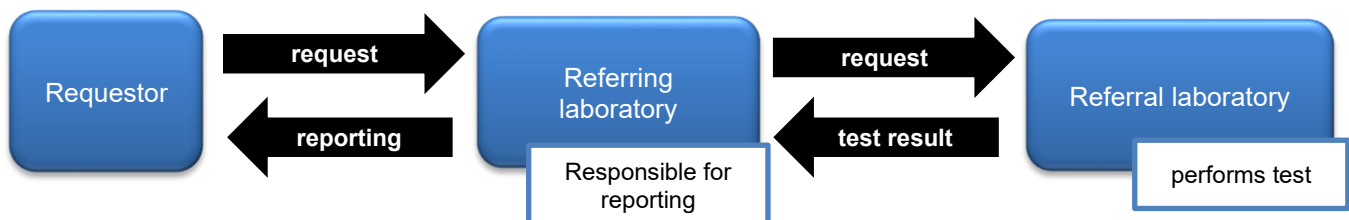


Figure 9: Clarification of referring and referral laboratory.

2.3.1 Display on the scope

If the laboratory has the competence to interpret the results, an activity is placed on the scope without addition. The interpretation can also come from a referral laboratory, in which case the RvA can accredit the referring laboratory for the activity. Reporting is done according to the requirements of ASR005. It is not desirable that parts of the testing and interpretation process are excluded from accreditation.

The different possible situations are described in the following sections:

1. The **referring** laboratory has the activities carried out (in whole or in part) by a referral laboratory, and interprets the results itself. This can happen occasionally (due to unforeseen circumstances) or this can take place structurally.
2. The **referring** laboratory has the activities and interpretation carried out by the referral laboratory, and reports these results with or without the results of other self-performed determinations.
3. The **referral** laboratory performs the activities itself, but does not interpret the results of that test, also not for its own laboratory.
4. The **referral** laboratory carries out the test itself and also interprets and reports for its own samples.

1. Referring laboratory only performs interpretation and reporting

If the laboratory normally carries out this test itself under accreditation, but has a referral laboratory temporarily carrying out this test due to circumstances, the test remains on the scope of the referring laboratory without any additions. The RvA assesses the temporary nature of this during the regular assessments.

If the laboratory has the tests structurally carried out by a referral laboratory and only performs the interpretation of the tests, the tests shall be listed on the scope indicating [interpretation] (see figure 10).

Medical Field: Clinical Pharmacy				
KF.TDM.03	Therapeutic Drug Monitoring	Immunoassays [interpretation]	Blood, urine or other body materials	A1

Figure 10: display on the scope if only the interpretation of tests is carried out.

2. Referring laboratory outsources the entire test and interpretation and only performs reporting

If the referring laboratory does not perform both the technical execution and the interpretation, the test is not listed on the scope of the referring laboratory.

3. Referral laboratory performs the test without interpretation

If the laboratory acts as a referral laboratory without interpreting the results, the test can be placed on the scope of the referral laboratory with the addition [technical execution] (see figure 11).

Medical Field: Biometric testing In compliance with the standards in force (SAN)				
BM.ECG.02	Exercise ECG	Electrocardiogram [technical execution]	Human body	A1

Figure 11: display on the scope if only the technical implementation takes place.

4. Referral laboratory also performs the test and interpretation for own requestors

A laboratory can act as a referral laboratory and also perform the same test for its own customers, including interpretation and reporting. In this case, the test can be placed on the scope of the referral laboratory without any additions.

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.

3.1.1 List of activities

The laboratory must keep an up-to-date overview of the tests/activities reported under accreditation in relation to the flexible scope: the list of activities (preferably Excel).

Together with the Dutch Health and Youth Care Inspectorate (IGJ), the RvA has designed a format that laboratories can use to avoid double administration. This format also takes into account the requirements

of IGJ with regard to the IVDR. The template can be found on the RvA website [via this link](#) (Sjabloon016-NL, in Dutch).

The current list of activities must be made available to the RvA at any time and must be publicly available. As soon as the RvA indicates that it starts planning the next assessment, the laboratory will make this overview available to the RvA. In the list of activities the laboratory clearly indicates by a different colour (and / or with track changes), which tests are changed, new or deleted compared to the previous RvA assessment, using the following colour coding: 'Activities: **changed/added/deleted**'. If there are interim changes, the RvA receives the updated overview from the laboratory no later than four weeks before carrying out the assessment.

The list of activities shall include at least the following aspects:

- Source scope code.
- Component(s), test, parameter(s) or characteristic(s) to be determined.
- Material or product/matrix.
- Method/technique/device (POCT).
- Technical implementation and/or interpretation.
- All sites where the test/activity is performed, including the site where POCT/Biometric testing is performed.
- Date of addition to the list (for version control).

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 ⁽¹⁾	Scope extension ⁽²⁾
Pre-assessment	√		√
Document assessment			If applicable
Office assessment including witnessing of activities in the laboratory (On-site assessment)	Extensive sample of the entire scope, in such a way that all techniques and matrices will be assessed.	During a cycle, at least one activity of each scope element is assessed	√
Borrowed scope elements	All requested scope elements will be assessed	Assessed at least once in the accreditation cycle	All requested borrowed scope elements will be assessed
Assessment of blood collection sites/POCT/biometric testing	A sample of the locations is assessed	A sample of the locations is assessed	A sample of the requested locations is assessed
Witnessing of blood cultures (MM.BAC.03)	All requested activities are assessed	Assessed at least once in the accreditation cycle	All requested activities are assessed

Method of assessment	Initial assessment	Regular assessment in the cycle ⁽¹⁾	Scope extension ⁽²⁾
Witnessing of POCT Medical Microbiology (MM.POC.01)	All requested POCT activities (MM) are assessed	At least once in the cycle the execution of the POCT on location. If no POCT takes place in the season of the regular assessments, an attendance of the POCT is preferably planned as part of the reassessment	All requested POCT activities (MM) are assessed
Assessment of bioinformatics	All activities applied for using bioinformatics are assessed	A sample of activities using bioinformatics are assessed at least once in the cycle, preferably during the reassessment	All activities applied for using bioinformatics are assessed
Assessment semen banks and IUI as part of a clinical chemistry laboratory	All requested activities are assessed	During each assessment. When performing well for two consecutive years, assessment twice in the cycle	All requested activities are assessed
Witnessing of Mohs (PA.HIS.08, micrographic surgery)	All requested activities are assessed	Witnessing at least once in the cycle	All requested activities are assessed

⁽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 will determine how the assessments of the extension will be carried out.

3.2.1 Blood sampling / Biometric testing

Blood sampling activities and testing/activities carried out under biometric scope elements (BM.xxx.00) are carried out in blood collection sites. These locations are not mentioned on the scope, unless there is a laboratory at the same location. The RvA assesses the locations where these activities are carried out by taking a sample of the locations. The blood collection sites are included as an annex in the RvA report Part A of the laboratory.

Technical Assessors of the Pre-analysis (TA-PRE) usually start at 7.30 a.m. with the assessment of blood collection sites because of the opening hours. Therefore, for these TAs not 8 hours but 9 hours are noted in the assessment specification and charged. Where appropriate, this also applies to TAs-FNT (thrombosis).

3.2.2 Intra-mural and extra-mural blood collection

Clinical Chemistry – source scope element CH.PRE.01 - Blood collection (extra-mural):

If there are blood collection sites outside the hospital (extra-mural), a TA-PRE is called in. This scope element applies if there are multiple collection points (outpatient clinic of a hospital (address x), hospital annex (address y)) within one city.

Clinical Chemistry – source scope element CH.PRE.02 - Blood collection (intra-mural):

The RvA has the policy to not call in a separate TA-PRE if a hospital has one intra-mural blood collection point, the outpatient clinic. The blood collection and pre-analysis is then assessed by a Clinical Chemist.

3.2.3 Bioinformatics

For laboratories that use data analysis (pipelines), a bioinformatician will be part of the assessment team. In addition to the standard preparation and reporting time, 2 hours of additional preparation and reporting time will be added to this.

4 Specific assessment issues

4.1 Donor testing laboratories

A laboratory needs a Farmatec permit to act as a donor testing laboratory. At the request of the Dutch Health and Youth Care Inspectorate (IGJ), the RvA team explicitly assesses the activities for which the permit has been granted. This explicit assessment will be included in the report. Examples of activities mentioned in the permit are Chlamydia, CMV, EBV, Hepatitis B, Hepatitis C, HIV 1 and 2, Syphilis, Toxoplasmosis, blood type, etc. These tests are explicitly mentioned in the assessment report in the context of the donor test lab permit. The laboratory has the explicit mention of 'Donor testing laboratory' on the scope.

4.2 Converting fixed scope element(s) to flexible scope element(s)

As indicated in § 2.2, a laboratory can display borrowed scope elements on its own scope as a fixed scope element. Upon request, this can be converted into a flexible scope element during an assessment. In addition to the assessment of the requirements of EN-ISO 15189 and RvA-T054 / ASR004 for flexible scopes, the RvA pays special attention to:

- service agreement in which the responsibilities regarding the scope element are laid down and guaranteed (amongst others consulting)
- involvement in the release/reporting of results of the scope element
- the scope element in question is a part of the management review
- the scope element in question is part of the internal audits
- the scope element in question is a part of the complaint registration
- IQC and EQC of the scope element and their follow-up
- Involvement in validations of the scope element
- surveillance and reassessment of competences of all persons involved regarding the scope element
- accessibility (in case of calamities concerning the scope element)

4.3 Non-accredited in-house activities

When an accredited laboratory 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 the laboratory can demonstrate that it assesses these activities itself against the relevant criteria. The activities referred to here are:

- calibrations of pipettes and equipment where the laboratory determines metrological traceability according to RvA-T018/ASR009;
- management of the LIMS system.

5 Organisations to be informed

- FNT Federation of Dutch Thrombosis Services;
- KLEM Association for Clinical Embryology;
- NVKC Dutch Association for Clinical Chemistry and Laboratory Medicine;
- NVMM Dutch Association for Medical Microbiology;

- NVVI Dutch Association for Immunology;
- NVVP Dutch Association for Pathology;
- NVZA Dutch Association for Hospital Pharmacists;
- SAN Professional Association for Diagnostic Centres (Biometric testing);
- VKGL Association for Clinical Genetic Laboratory Diagnostics.
- Advisory Committee 15189

6 Changes compared to the previous version of this document

This is the first English version of ASR101 (former SAP-M000) Compared to the Dutch SAP-M000 version 5.0 of 22 November 2023, the following changes have been made:

- Application new SAP/ASR template. Changes include:
 - Chapter 1.2: Updated references to other documents by referring to ASR001
 - Chapter 4.3 added: assessment framework for non-accredited in-house activities (such as calibrations and LIMS management), including the degree of assessment.
 - Annexes A, B and C added as a result of the publication of the new policy rule RvA-BR001. In the Annexes parts of the previous policy rules are incorporated in this ASR document.
- Restructuration of the document.
- Removal of overlapping information already described elsewhere in other policy documents or regulations.
- Explanation on assessment of POCT removed, after inclusion ISO 22870 in ISO 15189:2022.
- The 2Hregime for biennial reassessments is no longer applicable.
- Chapter 2.1.2: Extension of the description of borrowed scope elements.
- Chapter 2.1.3: Addition of the description of execution of activities from another medical field
- Chapter 2.1.4: Addition of the description of shared scope elements.
- Chapter 2.1.5: additions in the display of flexible scope elements:
 - Explanation *in situ* investigations, taken from BR003 Article 29.
 - Explanation of blood collection sites and display on the scope.
 - In Part A report, specify the location of shared scope elements.
- Chapter 2.2.3: Addition of specification on the scope for analyses for Clinical Trials
- Chapter 3.2: Table of assessments inserted in accordance with the ASR-template and supplemented with the list previously mentioned in the text. Addition: Assessment of Mohs.
- Annex A: Change in requested documents compared to the previous list in BR005.
 - Addition of the Farmatec permit.
 - Management review *not older than 6 months*
 - Additional documentation for thrombosis services removed.
 - Additional documents for Legionella have been removed because this is no longer accredited under ISO 15189.
- Annex D: Addition of annex on the frameworks of accreditation under ISO 15189.

Annex A: Documents to be provided

Documents to be provided for EN-ISO 15189	Initial assessment	Extension	Surveillance	Reassessment	Separate witnessing ⁽¹⁾
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 medical laboratories (F004-2)	√	√			
4. Completed RvA source scopes medical laboratories (F004-3)	√	√			
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 ISO 15189 and your quality system	√	√	√	√	√
9. Report(s) of recent internal audit(s) (not older than 6 months) including action plans	√	√			
10. Two internal audit reports including action plans of the previous year, and the audit program	√	√	√	√	√
11. Report of the most recent management review (not older than 6 months)	√	√	√	√	√
12. The work instructions for all activities applied for, where applicable including POCT and R&D	√	√	√	√	√
13. Amendments for chapter 1 of the Part A and relevant Annexes report for this accreditation, if not previously communicated			√	√	√
14. Verification/Validation reports for all tests applied for	√	√			
15. The modified verification/validation reports			√	√	√
16. Overview of participation in inter-laboratory comparisons (EQA, proficiency testing, etc.) (see RvA-T030 / ASR008)	√	√	√	√	√

Documents to be provided for EN-ISO 15189	Initial assessment	Extension	Surveillance	Reassessment	Separate witnessing ⁽¹⁾
17. Example of an anonymised report for a requesting doctor	√	√			
18. A list of all current and concluded research (only applicable in the case of an R&D scope)	√	√	√	√	√
19. Farmatec authorisation/recognition (If applicable)	√	√	√	√	√
20. A list of activities traceable to the flexible scope elements under accreditation	√	√	√	√	√

⁽¹⁾ This concerns witnessing of activities which cannot be assessed during the initial assessment, surveillance or reassessment.

Annex B: Areas of work RvA

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.

Performance of (medical) tests as referred to in EN-ISO 15189

SPECIALITIES

Clinical Chemistry and haematology;
 Clinical Embryology;
 Thrombo-embolic disease;
 Medical Immunology;
 Medical Microbiology;
 Clinical Pharmacy;
 Clinical Genetics;
 Clinical Pathology;
 Biometric testing.

In these specialities the Dutch Accreditation Council accredits, where relevant, also for:

- Point of Care Testing;
- Sampling;
- Research.

Annex C: Examples of category A non-conformities

- The laboratory has reported erroneous results.
- In the absence of adequate quality controls it is not demonstrable that results are correct.
- The laboratory cannot demonstrate that the application of the method used gives correct results.
- 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.
- 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.

Annex D: EN-ISO 15189 framework

EN-ISO 15189:2022 is intended for use in currently recognised medical laboratory disciplines. In addition, it is also applicable to other healthcare services such as diagnostic imaging, respiratory therapy, physiological sciences, blood banks and transfusion services.

In order to set out clear frameworks for which activities the RvA can currently accredit for ISO 15189, a number of specific activities are set out in this Annex. If a different view is published at EA level, the RvA will follow this view.

Human materials versus non-human materials

An EN-ISO 15189 accreditation is only applicable for the examination of materials derived from the human body (see definition 3.20 EN-ISO 15189:2022). Where animal material is used, EN-ISO/IEC 17025 applies.

Scientific research

Scientific research on human material must fully comply with EN-ISO 15189. If there is no direct link with the patient and the laboratory does not advise patients, the mention [technical execution] will be added to the scope element.

Clinical trials

Laboratories that process samples with human material within clinical trials must fully comply with EN-ISO 15189. If there is no direct link with the patient and the laboratory does not interpret/advise, the mention [technical execution] will be added to the scope element.

In the event that, in addition to routine diagnostics, the laboratory also conducts clinical trials on already accredited activities, the mention 'clinical trials' is added to the scope to make clear that a sample should be taken during assessment to assess the pre-analysis and post-analysis of this sample flow.

Biobanks

Materials stored in biobanks for scientific research are not covered by an EN-ISO 15189 or EN-ISO/IEC 17025 accreditation. For this purpose, EN-ISO 20387 applies.

Population screening and screening laboratories

The EN-ISO 15189 is suitable for population screening and screening laboratories (on human materials). To the scope the mention [technical execution] is added if the laboratory does not interpret/advise.

Forensic obduction pathology

The RvA preferably accredits forensic obduction pathology with EN-ISO/IEC 17025. Reasons for this are the absence of a (living) patient, absence of diagnostics and absence of a connection with healthcare and medical laboratories.