Dutch Accreditation Council (RvA)

Scopes of Testing Laboratories

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A current version of the explanatory document is available through the RvA website (www.rva.nl).

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1. Introduction

The publication ILAC G18, Guideline for the Formulation of Scopes of Accreditation for Laboratories (www.ilac.org), sets out the way in which tests, and any associated sampling, can be stated on the scopes of testing laboratories with an accreditation under EN ISO/IEC 17025. This explanatory document RvA-T025 is based on ILAC G18:04/2010.

Document EA-2/15 M: 2008, EA Requirements for the accreditation of flexible scopes, contains additional requirements with regard to the manner in which the activities in flexible scopes must be stated. Additional requirements have been laid down with regard to the information that must be made available to accreditation bodies and/or other interested parties in order to provide insight into the reach of the flexible scope.
This document describes the way in which accredited tests, and any associated sampling, can be stated on the scopes of RvA-accredited testing laboratories. It is currently limited to testing laboratories in the fields of chemistry, microbiology, hydrobiology, road construction, asbestos, air, et cetera. Laboratories in other fields are expected to follow a system that is identical to that described in this explanatory document. Agreements on this will, where possible, be made with the market players concerned.

A test, as defined in ISO/IEC 17000, is the determination of the properties of a product or process. The scope will have to set out clearly which properties of the product or process are determined by the laboratory.

Where 'testing' appears below in this document, it means 'testing and any associated sampling'.

2. Scope of accreditation

The scope contains the most precise possible description of the accredited tests. The definition of 'testing' must always be taken into consideration in this regard: 'the determination of the properties of a product or process'. Reference may be made here to standard/reference methods and to methods developed by the laboratory itself (see RvA-T001).

Accredited tests may be included in the scope in two ways: the RvA distinguishes between a **'fixed scope'** (specific) and a **'flexible scope'** (general). Neither the measuring range nor performance characteristics are included in either the 'fixed scope' or the 'flexible scope'. The laboratory must provide this data on request or, if applicable, include it in the reporting.

2.1 Fixed scope

The RvA uses the term 'fixed scope' to describe the scope of accreditation that sets out the method and scope of application. In this way the laboratory's client is informed about the methods. Any change of method or scope of application results (following an assessment) in a modification of the scope.

ILAC G18 states that the following items may be listed in the fixed scope: testing field, type of test, test object or product, test parameter, reference to standardised method and internal method reference. The RvA has interpreted this as follows:
The tests are preferably grouped in the scope according to specialism, for example, field measurements, inorganic analyses (wet chemistry), inorganic analyses (metal analyses), organic analyses, microbiological analyses, virological analyses, geotechnics, asbestos analyses and sampling. The specialism is shown in the scope in a table subheading. Normally there are no reference standards in the table subheadings, nor is there any reference to legislation and regulations. Possible exceptions are references to AS1000, AS2000, AS3000, AP04 and AP05, as shown in the SAP concerned, and reference to CEN/TS 15675 and "quality assurance in accordance with EN 14181" in the case of air emissions analysis.

Within the specialism the tests are as far as possible grouped by analysis technique.
Four things must be included for each individual test:

- The first column contains the serial number of the test. This number is allocated by the RvA to assist in tracing for each RvA assessment.
- The second column indicates the object or product (the matrix) on which the test is applied (for example, water, waste water, soil, coal, air, asphalt, grain). The matrix concerned must be unambiguous and clear. The term 'swimming water' for example not only means swimming pool water, but also surface water.
- The third column contains the title of the test, as far as possible, according to one of the following formats (the title of the reference document is used as far as possible here): 'Determination of the xxx content', 'Determination of the xxx' or 'Demonstration of xxx', followed by the technique or method used. In the case of multi-component analyses the individual components are also specified. The same applies for example to individual sieve fractions in sieve analysis. The technique referred to must also be unambiguous and clear. In some situations, to create clarity, any dissolution, or something similar, must be included in the description. For example: 'determination of the content of metals dissolved with aqua regia' or 'determination of the dissolved metal content'.
  NB 1 Some tests cannot be described using the above formats. In these situations the definition of 'testing': 'the determination of the properties of a product or process' must always be taken into consideration in the description of the test.
  NB 2 Separate calculations, such as 'the calculation of the total nitrogen content' are not given in the scope. What could for example be given is: 'the determination of the nitrate, nitrite and ammonium content and the sum of nitrate, nitrite and ammonium'. In such situations it must be clear how the determination of the sum is effected.
- The fourth column contains the internal reference number of the test and any information about the reference method used; see RvA-T001.

The following options are available for mentioning the sampling on the scope:

1. Determination of the *xxx* content; <*technique*> (including associated sampling); for example:

Determination of the copper content; ICP-AES (including associated sampling).

2. Sampling for the *xxx testing* with internal reference numbers *zzz*. In this case sampling for more testing is stated separately without stating an activity number, but as a, b, c, etc. The sampling activities have a table subheading of their own.

If the body only take samples and the associated test is carried out by another body, the requirements laid down in RvA-T021 must be met. In the scope the sampling will then be stated as follows:

3. Sampling for the determination of the *xxx* content; <*technique*> (the associated test is carried out structurally by another accredited body).

If a laboratory also wishes to enter the pre-treatment method used as a separate activity in the scope of the laboratory, because for example it is applicable to several tests, an identical system to that for the sampling activities may be used; see also RvA-T001.

See Appendix 1 of this explanatory document for examples of fixed scopes.

2.2 Flexible scope

ILAC G18 states that in the case of flexible scopes there are different degrees of freedom in scope descriptions, such as: flexibility concerning object/matrix/sample, flexibility concerning parameters/components/analytes, flexibility concerning the performance of the method and flexibility concerning the method. The RvA has interpreted this as follows:

As part of the description of the tests in a flexible scope, the laboratory may, following validation, amend testing methods previously accredited, either to improve them or at the request of the client.

In such situations the description of the accredited tests can be set out in broader terms at the request of the body. This can be both with regard to the claimed matrix and the description of the test or a combination of the two. This under the condition that the body has a demonstrated expertise in the area of tests to be accredited and/or during previous assessments has demonstrated that it has implemented new and/or revised tests correctly.

Tests with a broader scope description are shown on the scope under the table subheading 'Flexible scope'.

For each test four things must again be included:

- The first column contains the index number of the test. This number is allocated by the RvA for traceability reasons for each RvA assessment.
- The second column indicates the matrix on which the test is applied. This can be similar to a fixed scope, but also by means of a more general description, such as: 'pharmaceutical products' or 'environmental matrices'.

- The third column contains the title of the test according to the following format (the title of any reference document is used as far as possible here): 'Determination of the *xxx* content' or 'Demonstration of *xxx*', followed by the unambiguous and clear description of the technique, measuring principle or method used.
- The fourth column contains the internal reference number of the applied test procedure and, where possible or relevant, information concerning the reference documents used (subject to RvA-T001).

See Appendix 2 of this explanatory document for examples of flexible scopes.

The body must keep an up-to-date list of activities carried out under accreditation relating to the 'flexible scope' (including the date of the internal release). What has to be laid down in this overview as a minimum is set out in Appendix 3 of this document. This up-to-date summary must be available to the RvA, or other interested parties, at any time; the body must send the summary to the RvA during the planning of the RvA assessment and again four weeks before the RvA assessment. The laboratory must include in this summary the terms 'in conformity with' 'equivalent to' or 'laboratory-developed method' as defined in RvA-T001. The RvA shall use the summary to determine, for example, the size of the assessment team. Any assessment already planned may, on the basis of this summary, be altered with regard to team composition and/or assessment duration.

The scope of accreditation will contain the following sentence:
"Under this flexible scope, a laboratory is obliged to maintain an up-to-date list of the methods that are carried out under this flexible scope.

New tests can only be added to the flexible scope , just as in the case of new tests within a 'fixed scope', following assessment by and with the consent of the RvA. This also applies to changes.

N.B. For specific specialisms not referred to in this document, further consultation may be held, at the suggestion of the relevant sector, to draw up a flexible scope description.

2.3 Testing criteria

Assessment of the fixed scope and the flexible scope involves assessing against criteria from EN ISO/IEC 17025. In assessing the flexible scope attention is also explicitly focused on:

- the agreements with the client and any adjustment of the original agreements with the client;
- independence and freedom from undue influence/pressure;
- the competence and the responsibilities of the personnel (including the supervisory personnel), including an adequate deputising arrangement. It must be clear that the personnel involved are able to assess the suitability and the results of the methods used. There is explicit attention for training, experience, any participation in standards committees, research groups, etc.;
- the content of the validation procedure, the content of any research specification and/or the research plan and the approval by the client;

- the selection, validation, measurement uncertainty and release of the method applied or developed. Where relevant, legislation, sectoral agreements and equivalence with similar tests, among other things, must also be involved;
- the (metrological) conditions;
- the release and reporting of analysis results including, where relevant, specific information about the measurement uncertainty;
- dealing with the RvA accreditation mark;
- the archiving of all the project data involved;
- the performance of internal audits.

The degree to which the above are assessed depends in part on the relationship that the laboratory has with the client concerned. This will, among other things, involve any financing and control of the methods to be used.

For the analyses from the flexible scope the testing laboratory must have organised specific procedures for the matters referred to in this explanatory document and for the method of implementation.

If during an RvA assessment discrepancies are found with regard to a validation within the (flexible) scope that may have influenced the analysis result, then the clients involved in the analyses concerned must always be notified. The corrective action by the body may not be limited to the non-conformity, but must be applied to all areas where the non-conformity could have an impact. For example, if a non-conformity is found in the case of one change/addition, the corrective action must be taken as a minimum for all the analyses carried out for that purpose and related analyses. If a non-conformity is found for example regarding the validation and/or the measurement uncertainty, and this therefore leads to the report of an analysis result to which little or no value can be attached, then a category 'A' non-conformity will be granted.

3. Changes compared to the previous version

The following significant changes have been made compared to version 4 of February 2017:

- reference to EA-2/15 M: 2008 has been included;
- added in 2.2: reference on the scope to the list of methods carried out under a flexible scope;
- added in Appendix 3: aspects that need to be included in the list of activities carried out under a flexible scope;
- Appendix I: example of scope description of air measurement has been removed. Reason: scope description is included in SAP L001
- Appendix II: footnote at the bottom of the scope has been changed;
- Appendix 1 and 2 have been aligned with the changes in policy regarding the terms 'in accordance with' and 'equivalent to' on the scope (see RvA-T001)

Appendix 1 Scope examples for a fixed scope

No.	Material or product	Type of activity	Internal reference number
		Sampling	
a	Surface water	Taking samples for inorganic and organic tests with internal reference numbers AAx and OAy; random sampling	SPV1 NEN 6600-2
b	Air and (process) gases	Taking samples to determine the ammonia content; absorption method (the associated determination of content is carried out structurally by another accredited laboratory)	MDW-20 NEN 2826 and NEN-EN 15259
		Field measurements	
1	Swimming pool water	Determination of freely available and total available chlorine content; titrimetry	CL01 NEN 7399-1
2	Drinking water, groundwater, surface water and swimming pool water	Determination of the temperature; thermometer	WVS4 NEN 6414
		Inorganic analyses (wet chemical)	
3	Waste water	Determination of the chemical oxygen consumption (COC); titrimetry	CZV1 NEN 6633
4	Soil	Determination of the sieve fractions; wet sieve analysis fractions < 0.125 mm, < 0.400 mm, < 1.00 mm and < 1.25 mm	ZEEF04 laboratory-developed method
		Inorganic analyses (metal analyses)	
5	Soil	Determination of the copper content following dissolution with nitric acid and hydrochloric acid; AAS flame (including associated sampling)	IW098 NEN 5758
6	Groundwater	Determination of the metal content; ICP-AES chromium, copper, lead, nickel and zinc	AAMET-02 NEN 6426
7	Compost	Determination of the chromium and copper content; ICP-AES	WVS-07 and WVS-006 laboratory-developed method (dissolution NEN 6961 and dissolved material NEN-EN-ISO 17294-2)
8	Coal ash	Determination of the element content; XRF aluminium, calcium, iron, potassium, magnesium, sodium and phosphorus	KOLEN-02 ASTM D 4326

Organic analyses			
9	Lettuce and grain	Determination of the organo-chloro pesticide content; GC-ECD aldrin, ppDDD, opDDE, ppDDE, opDDT, α-HCH, β-HCH, γ-HCH, δ-HCH, hexachlorobenzene, telodrin, dichloran, quitozene, perthane, chlordane, chlorfenson, procymidone, bromopropylate, endrin, heptachlor, tetradifon, heptachlor-β and pentachlorobenzene and the sum of these 23 organo-chloro pesticides	CHE409W laboratory-developed method
10	Soil	Determination of the mineral oil content; GC-FID	AH1103W NEN 6970 (extraction NEN 6972, clean-up NEN 6975, measurement NEN 6978)
Microbiological analyses			
11	Poultry manure	Demonstration of *Salmonella*; MRSV	MICR01 PVE sector method
12	Surface water	Determination of the number of *Escherichia coli*; MPN (microtitre)	MICR02 NEN-EN-ISO 9308-3
13	Salmonella isolates from poultry	Confirmation and identification of Salmonella; agglutination reaction according to Kauffman-White classification S. Enteritidis, S. Typhimurium S. Infantis, S. Hadar, S. Virchow, S. Java.	MICR03 CEN-ISO/TR 6579-3
Hydro-biological analyses			
14	Sediment (soft) and surface water (fresh)	Determination of the abundance and coverage of water and riparian flora; vegetation survey according to Tansley	HYD-A1 Handboek Hydrobiologie – Bijkerk R. (chapter 11)
15	Surface water (fresh)	Determination of the species composition, density, organic volume and phytoplankton; cuvette method (microscopy and image analysis)	HYD-A2 EN 15204
Road construction			
16	Granular material (embankment or foundation material)	Determination of the rate of compaction; Proctor compaction test	WVS145 RAW2005 test 3.0
17	Element paving and surfacing (concrete paving stones)	Determination of the properties; dimensions, force measurement form and appearance, length, width and height, thickness and adhesion of the surface layer, and splitting tensile strength	WVS146 NEN-EN 1338
18	Aggregates	Determination of the Los Angeles coefficient; gravimetry	WVS147 EN 1097-2
19	Asphalt cores	Demonstration of PAH; PAH detector	WVS148 laboratory-developed method
20	Asphalt	Demonstration of PAH; thin-layer chromatography	WVS149 laboratory-developed method

21	Asphalt cores	Determination of the layer thickness and structure; straightedge	WVS 150 RAW 205 test 152
22	Paving material	Determination of the bending strength (bending tensile strength); strength test	WVS 152 NEN-EN 1344 Annex D
Tests for means of animal identification			
23	Low-frequency transponders (transponders for the identification of animals)	Determination of the resonance frequency; two-channel oscilloscope in combination with spectrum analyser	MET01 ISO 24631 part 1 ch. 7.2, 7.3 and 7.4

NB1 For special groups of activities additional scope description requirements can be set out in specific RvA documents. This is the case for example for AP04 and AS3000 (see SAP-L002), AP05 (see SAP-L004) and the hydro-biological activities (see RvA-T039).

NB2 For some activities, for example in different EMC tests, devices are exposed to specific conditions, the accredited laboratory only offering the conditions. Consultation about dealing with such scope descriptions is, where necessary, still to take place with the sectors concerned.

Appendix 2 Scope examples for a flexible scope

No.	Material or product	Type of activity	Internal reference number
Flexible scope*			
1	Environmental matrices	Determination of the copper content; AAS flame	IW100
2	Water	Determination of the metal content; ICP-AES	AAMET-12
3	Lettuce and grain	Determination of the organo-chloro pesticide content; GC-ECD	CHE410W
4	Vegetables and fruit	Demonstration of halogenated hydrocarbons; GC-ECD/FID/MS and/or HPLC	CHE411W
5	Pharmaceutical products	Determination of the composition and/or impurities; gravimetry, spectrophotometry, titrimetry, ICP-AES, GC-ECD/FID/MS and HPLC	FARM302 in accordance with pharmacopoeia

* Under this flexible scope, a laboratory is obliged to maintain an up-to-date list of the methods that are carried out under this flexible scope.

Appendix 3 Aspects to be mentioned in the list of activities carried out under a flexscope

This list must be kept up-to-date by the CAB and must always be available to the accreditation body RvA or other interested parties.

Aspect:
- Serial number
- Date of validation/addition on the list
- Reference to Flex scope ID (if more than one)
- Material or product/matrix
- Method
- Activity type / Parameter
- Reference to validation file(s)
- Period of validity (in case of interrupted quality control)
- Last date of re-validation (in case of interrupted quality control)
- Date of termination of the validated test