Raad voor Accreditatie (RvA) (Dutch Accreditation Council RvA)

Reference to reference-methods on scopes of test laboratories

Document code:	**RvA-T001-UK**
	Version 5, 23-6-2020

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

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1 Introduction

The RvA aims to create unambiguous descriptions of the scopes of accreditation for test laboratories. This explanatory document RvA-T001 sets out under which conditions the RvA refers to a reference method in the scopes or states that it relates to an in-house method. With the introduction of this version of RvA-T001, the RvA ceases to use the terms 'in accordance with' and 'equivalent to' in the scope of accreditation and only the reference method is still referred to. The use of the terms 'in accordance with' and 'equivalent to' remain applicable to the laboratories however, in particular in the manner in which the laboratories inform clients about the methods to be applied (e.g. in offers) and applied methods (e.g. in reports).

This document applies to the accreditation of test laboratories under EN ISO/IEC 17025[1] in the following sectors/areas of work:

- agricultural products, food stuffs, raw materials for the food industry and animal feed;
- environmental compartments water, soil and air;
- forensics;
- human health, animals and animal health, pharmacy;
- fuels, ores, minerals, chemicals, waste products, residues, metals and precious metals;
- textile, leather and leather products, paper.

In the event of doubt, the board of the RvA will make a decision on the applicability.

In section 2 of this document, the terms 'reference method', 'in-house method', 'in accordance with' and 'equivalent to' are further explained and it describes the conditions for the use of these terms in the scope. Section 3 explains the relationship of the terms 'in accordance with', 'equal to' and 'in-house method' with the specific requirements of EN ISO/IEC 17025. Finally, section 4 sets out the transitional arrangement for the introduction of the new RvA-policy.

2 Term description and conditions

2.1 Reference method

A reference method is a method published by an international, regional or national standardisation institute or by reputable technical organisations or in relevant scientific texts or journals or are specified by the manufacturer of the equipment (see also EN ISO/IEC 17025 criterion 7.2.1.4). A method that is generally accepted in the sector can also be used as a reference method.

A reference method must be publicly available. However, in some situations this is not possible, because a cancelled or withdrawn reference method must be used for example. For current reference methods, generally no year or other version-indication is placed after the reference method; however this does occur for cancelled or withdrawn reference methods (see the policy in RvA-BR003; Policy rule Scope of Accreditation).

[1] Where in this document a reference is made to EN ISO/IEC 17025, this means the standard EN ISO/IEC 17025:2017, including the Dutch translation (NEN-EN-ISO/IEC 17025:2018). The document can also be read with the 2005-version of EN ISO/IEC 17025, although the criteria numbers will then be different (see RvA-T049 for a cross-reference).

A reference method may be a draft method (draft standard (F)DIS, prEN, etc.), provided it meets the conditions set out above and below. A draft version of a reference method that is not yet publicly available will therefore not be named in the scopes.

It is essential that the reference method contains minimum information relating to:

- area of application in terms of matrices and measuring quantities (parameters or components);
- the method, including a description of measuring principles and techniques;
- the method of performance, possibly with various degrees of freedom or room for interpretation of which it is established that these do not significantly influence the result.

Specific protocols of manufacturers of equipment or test methods are not considered to be reference methods and are not mentioned in a scope; it can happen generically however (see 2.5 Producer protocols).

2.2 In-house method

EN ISO/IEC 17025 recommends making use of reference methods. Where the laboratory is unable to use a reference method, the method will be stated on the scope of the accreditation as ‘in-house method’. If the laboratory has adjusted a reference method in such a way that it can no longer claim that performance is ‘in accordance with’ this reference method and it is also unable to demonstrate it to be ‘equal to’, the method will be stated on the scope as ‘in-house method’.

Within an ‘in-house method’, the laboratory can have sub-processes where a reference method is applied. Examples of sub-processes include (sample) pre-treatment, access, destruction, extraction, clean-up, analysis, measurement, etc. The sub-processes specified by the laboratory that are subject to a reference method can be set out in the scope of accreditation. Examples of this include the performance of the sample pre-treatment in accordance with reference method X, a performance of the analysis in accordance with reference method Y, or a combination of both. This will then be included in the scope as follows:

> in-house method
>
> (performance of sample pre-treatment: reference method X; performance of analysis or measurement: reference method Y)

or, for example:

> in-house method
>
> (extraction/destruction: in-house method; performance of analysis: reference method Y)

On the basis of EN ISO/IEC 17025 criterion 7.2.2, the laboratory must demonstrate that a method is suitable for the intended goal. The laboratory is therefore obliged to validate an 'in-house method'. The degree of validation depends on the method being applied and what adjustments/changes have been implemented compared to any reference method. If it relates to a method developed by the laboratory itself, then a full validation must always be carried out. See also comments in 2.3.4.

2.3 Reference to a reference method

In the scope of the accreditation, the RvA will only refer to a reference method if the test:

- is carried out in in accordance with the reference method, or
- can be viewed as equal to the reference method.

On condition, a reference method can also be specified for a test whereby the reference method is applied outside the area of application of the reference method.

2.3.1 In accordance with the reference method

'In accordance with' applies if the method is used for the area of application as described in the reference method and during execution there is no deviation from the reference method on critical elements. A deviation on non-critical elements is only acceptable if the RvA-technical experts in the field agree in advance that the deviation does not influence the result (in respect of which it is pointed out that the RvA takes the ultimate decision on this). A formal ruling by the relevant standards committee can of course also be accepted for this. For a number of examples, see annex 1 and annex 2 of this explanatory document.

On the basis of EN ISO/IEC 17025 criterion 7.2.1.5, the laboratory must verify and demonstrate that it is able to perform the method in accordance with the specifications in the reference method. This means that the laboratory must minimally be able to establish the demonstrability threshold, the measuring range, the linearity, correctness, retrieval, repeatability and reproducibility. These performance parameters must demonstrably permanently be controlled. The RvA-technical expert will assess this on the basis of the submitted work instruction, (validation) reports, quality controls, and by witnessing the performance of the test.

If the characteristics are specified in the reference method, then the performances achieved by the laboratory may not be significantly worse. With regard to trueness, this performance may not significantly depart from that specified.
If no performance characteristics are mentioned in the reference method, these will have to meet the performance characteristics from comparable reference methods.

The RvA expert assesses the claim of conformity on the basis of the submitted work instructions, (validation) reports, quality controls and a review of the execution of the test.

For umbrella standards, there is a modular approach whereby an umbrella standard refers to a number of (optional) sub-processes, such as sample pre-treatment, access and analysis. There are separate reference methods for these sub-processes, which can be carried out by the laboratory 'in accordance with'. If, for example, work is carried out in accordance with umbrella standard A, then the scope would appear as follows:

> umbrella standard A
>
> (sample pre-treatment: standard X; access: standard Y, measuring: standard Z)

As regard the umbrella standards it applies that the use of umbrella standards may result in methods where the results can be significantly influenced. However, this is in conflict with the third fundamental stated in 2.1 Reference method: '*The method of performance, possibly with various degrees of freedom or room for interpretation in respect of which it is established that these do not significantly influence the result*'. When using umbrella standards it therefore is always necessary to state the individual standards for access, destruction, clean-up, analysis, etc., explicitly and both the sub-processes and the entire process have to be fully validated or verified. When several options are offered in the relevant standard for the sub-process, the selected option must be stated unambiguously in the scope. The same of course also applies for reporting to the client.

In some situations the reference method refers to different reference methods for the pre-treatment. In those situations the method applicable for umbrella standards shall be used. If the reference method makes mandatory reference to just one other reference method which prescribes the sample pre-treatment, the pre-treatment method does not have to be stated explicitly in the scope (but it may be stated on the request of the organisation).

2.3.2 Equivalent to a reference method

'Equivalent to' is reserved for methods where the methods for carrying out the assessment and/or measuring principle depart from the reference method, but where the laboratory has demonstrated that equivalent results will be obtained. 'Equivalent to' applies to the same area of application as the reference method meaning: the same parameters in the same matrix.

On the basis of EN ISO/IEC 17025 criterion 7.2.2, the laboratory must validate the relevant changes. See as a reference source in this context NEN 7778, Equivalence may be claimed if the performance characteristics are not significantly worse than those stated in the reference method. Furthermore, the results in relevant matrices compared to those of the reference method should not produce any greater differences than can be explained on the basis of the reproducibility within the laboratory.

The laboratory must demonstrate the above by (see also the comments in 2.3.4):

- determining the performance characteristics for the equivalent method and to test these against those of the reference method. If the reference method does not refer to the characteristics then the laboratory should determine these for the reference method itself.
- analysing samples with relevant matrices in relevant concentration areas with both methods and by testing the correctness of the results.

The provisions in respect of the umbrella standards in the previous paragraph apply also to claiming 'equivalent to...'.

2.3.3 Application of the reference method outside the area of application

Where a reference method is used outside the area of application of this reference method (a different matrix or unspecified components for example), but where at least one of the following conditions is met, the laboratory can also refer to the reference method:

- The reference method is applied to a different matrix than the matrix specified in the area of application of the reference method but an official body has determined (by law), or the sector and the RvA have agreed, that the reference method may also be applied to this matrix.
- The reference method is applied to components not specified in the area of application of the reference method but an official body has determined (by law), or the sector and the RvA have agreed, that the reference standard can also be applied to these components.

The following also applies:

- On particular elements it is permitted, just as with the 'equivalent to', to deviate from the reference method in the performance, but the measuring principle must remain the same in this situation.
- In all situations it applies that the performance characteristics must demonstrably meet the comparable performance characteristics specified in the reference method (example: with different matrices, the performance characteristics must comply with the comparable specified matrix of the reference method, or, with different components, the performance characteristics must comply with the most comparable component specified in the reference method). See also 2.3.2 for the relevant performance characteristics, the testing and the determination of the equivalence of performance characteristics.

Note 1 The guideline is that the different matrix may not be a 'heavier' matrix than specified in the reference method and the components must fall in the same group of components as specified in the reference method. In respect of the matrix, it is permitted to first carry out an extra pre-treatment step resulting in a matrix to which the reference method can be applied.

Note 2 The laboratory must have notified the use of different components and/or a different matrix to the relevant document owner/manager (often the standards committee or shadow committee) except when there is a (statutory) obligation by an official body. During checks and reassessments by the RvA, this notification or (statutory) demand and, preferably, also the response of the document owner/manager, must be shown. Further to the response of the document owner/manager it may be decided that reference to the reference method is not possible.

Note 3 For accreditation schemes and accreditation programmes such as AS1000, AS2000, AS3000, AP04 and AP05 it is self-evidently not possible to apply those outside the area of application (it is possible for the underlying technical standards but not for the scheme or programme itself).

For a few examples, see annex 2.

The reference to an umbrella standard can take place in a comparable manner as stated under 2.3.1 (without the term 'in accordance with'), when the area of application of the umbrella standard deviates, under the same conditions as stated above.

2.3.4 Additional comments

Note 1:

Regarding the interpretation and use of the terms: trueness, repeatability, reproducibility, etc., the

NEN 7777-series can be used. For microbiology, it is also possible to use EN-ISO 16140 to this end.

Note 2:
Some reference methods specify performance characteristics which should not be interpreted as such (for example: results of proficiency tests used for method evaluation sometimes do not need to be regarded as a performance characteristic; these may be used as indicative performance characteristics).

Note 3:
See annex 1 for examples of critical and non-critical subjects of a reference method.
If the laboratory is of the opinion that a particular element of a standard should not be regarded as critical, it must discuss this with the relevant standardisation committee itself.

Note 4:
In case of statistical calculations, a confidence interval of 95% is assumed. Where the word 'significant' is used, this means 'statistically significant'.

Note 5:
For a scope description falling under a ‘flexible scope’, often no reference method is specified but this may be possible in some situations. The reference is then included in documentation that third parties can request from the laboratory itself (see RvA-T025).

2.4 Method-determined parameters

Tests in respect of which it is determined in the reference method that the test, or a specific part thereof, is considered to be *method-determined*, may not depart from the prescribed procedure for the method-determined part. If there is a departure from the method-determined part, then the laboratory is permitted to include such activities in the scope as an in-house method. In this situation, laboratories must point out to clients the lack of comparability of results.

2.5 Producer protocols

‘Reference methods' also includes protocols and testing methods of manufacturers of equipment. The laboratory must verify and demonstrate that the performance of the laboratory, excluding trueness, is not significantly worse than the performance characteristics specified in the protocol. With regard to trueness, this performance may not significantly depart from that specified.

If such a method meets the requirements of a reference method and the method is carried out in accordance with the, specified, producer’s protocol, then these methods can be included in the scope of accreditation as ‘producer’s protocol'*.

The laboratory must keep an up-to-date list of manufacturers’ details and methods used and this list must be available for everyone.
To indicate this, a footnote in the scope will state the following reference:

* Producer’s protocol: a current list of producers’ protocol details is available on request from the institution.

A reference to, for example, the manufacturer and any kit number is not included in the scope.

3 Reference to reference method by the laboratory

EN ISO/IEC 17025 states that the laboratory must notify the client about the method applied (including criterion 7.2.1, 7.8.1 and 7.8.2). See also the explanation on this in RvA-T015. If in this notification, the laboratory claims to use a reference method specified in the scope of accreditation, the reference shall be in accordance with the conditions set out in section 2. It must make clear whether i) the method is performed in accordance with the reference method, ii) the method is equal to the reference method, or iii) it is an application of the reference method outside the area of application specified in the method. It must be clear on which elements there is (any) departure from the reference method and it must be clear as to why it is justified to refer to the relevant reference method. If the laboratory does not claim a reference method in one of the ways listed above, the method will be designated as an 'in-house method'.

The laboratory is free in the manner it communicates this to its client: via an offer, contract, Service Level Agreement (SLA), reference to an information guide (or suchlike) on the website, etc. If the offer, contract, analysis report, etc. only specifies the reference method (without the prefix 'in accordance with' or 'equivalent to'), then an unambiguous, clear reference to an information guide (or suchlike) must be included with information on conformity, equivalence or use outside the area of application). If the laboratory chooses to use an information guide (or such like), this document must be up-to-date and directly available and must fall under the document control of the institution (previous revisions must also be available to the RvA assessment team or other stakeholders on request).

4 Transitional period

The application of the new policy, as set out in this T001, will start at the first regular assessment of the accredited laboratory after 1 April 2019. All scopes will have been adjusted at the latest by March 2021. Prior to the first assessment after 1 April 2019, the office of the RvA will ask the laboratory Whether it is ready to implement these changes in the scope and wishes this to be assessed. For laboratories stating they are not yet ready or do not wish to implement the changes yet, the scope will automatically have to be changed during the next regular assessment and this will be assessed.
The office of the RvA shall, prior to the assessment during which the changes will be implemented, together with the laboratory, prepare a proposal for adjustment of the scope. The starting point will be that the terms 'equivalent to' and 'in accordance with', which precede the specified reference methods, are removed from the scope.
The next regular assesment will assess whether the laboratory procedures provide that the customer is correctly informed about the methods used.

5 Changes compared to the previous version

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

- Section 2.3.1 has been brought into line with what has been laid down in this regard RvA-T015
- Chapter 4: the condition that the scope can only be converted after it has been assessed, has been omitted.

Annex 1 Examples of critical and non-critical elements of a reference method

Examples of **critical** elements of a reference method are:

- Storage life is per definition critical. If storage life (also referred to as 'conservation period') deviates from the reference method and the laboratory can demonstrate equivalence of the analysis results on this point, then it applies, contrary to previous RvA policy, that the method is at most 'equivalent to'. If the longer storage life does satisfy the requirements from other leading reference documents such as (NEN EN-)ISO 5667-3, there is conformity though. The relevant (technical) reference method will then be followed, in brackets, by 'conservation standard xxx'.
- Measurement technology. In the analysis of organic components with the aid of LC-MS no reference can be made to a reference method for the GC-MS technology.
- Method-determined procedure in the reference method. For example:
  - When accessing soil samples with the aid of nitric acid to analyse the elements content, there may not be a reference to the reference method prescribing aqua regia access.
  - In a leach method with a L-S ratio of L:S=10 with an agitation time of two hours, there may not be a reference to a reference method with a deviating L-S-method and/or deviating agitation time.
- All critical elements specified in the reference method. For example:
  - a normative reference in the reference method to a specified reference method for sample pre-treatment; this must then be carried out in accordance with the relevant reference method.
  - the application of prescribed sieving for sorting or grinding;
  - a start of a microbiological analysis within the retention period stated in the reference method;
  - the application of the specified incineration period and temperature;
  - the drying to a consistent mass;
  - the reference method describes a minimum number of points for calibration of which the calibration function must exist; this is then a compulsory element. (Note: please also see non-critical elements relating to the calibration function below);
  - specific requirements for mineral oil determination relating to the separation of aliphatic compounds, to the relative sensitivity of C_{10} t/m C_{40} and to the yield of a number of specific components in the clean-up with florisil;
  - frequency of the quality controls to be carried out;
  - number of internal and/or injection standards to be added;
  - number of times the test must be performed (some reference methods prescribe duplicate or triplicate determination);
  - accreditation schemes and programmes, AS1000, AS2000, AS3000, AP04 and AP05 for example, where all requirements specified in the document must be complied with;
  - the fat content determination with reference method ISO 1211 / IDF1, where the entire procedure is deemed critical. The definition of the fat content in milk is method-determined (Codex Type I method) ISO 1211 / IDF1 and serves as an 'anchor method' for the calibration of alternative methods, infrared spectrometry in accordance with ISO 9622 / DF141 for example.

Examples of **non-critical** elements:

- Fewer water samples are treated than described in the reference method. Explanation: after the issue of analysis standards, technological developments may result in the sensitivity specified in the reference method being realised, even if fewer samples are treated.
- Note: for samples consisting of fixed matrices, the situation is different; through the use of modern equipment it may be possible to satisfy the sensitivity requirements if fewer samples are treated but the representativeness of the partial sample could be an issue. Guidelines for the minimum quantity of (partial) samples to be treated in relation to particle size must be strictly adhered to.
- In many cases, the extraction solvent described in the reference method will be method-determined (see also under 'critical elements' to this end) but exceptions are possible. An example of an exception is the extraction of organic components with petroleum ether. The use of the strongly comparable solvents hexane, cyclohexane, pentane and heptane may be considered to be 'in accordance with' the reference method.
- The creation of 'standard solutions' can often be labelled as 'non-critical': The laboratory itself may make a choice for the most suitable calibration range and use commercially available standards solutions.
- The type of calibration curve is at the discretion of the laboratory if it has demonstrated that a nonlinear calibration function has a better fit than a linear function as described in the reference method for example.
- The frequency of the calibrations to be carried out, as described in the reference method, can be viewed as a guideline if the laboratory has demonstrated that the used detector is stable over a longer period than described in the reference method. The laboratory may then apply a lower frequency. (Note: please see also the comment above under 'critical elements' relating to the number of calibration points).
- Through the use of modern equipment it may not be necessary to concentrate an extract for the benefit of low detection limits.
- Use of modern equipment may result in a clean-up method described in the reference method no longer being necessary as the relevant equipment is better able than before to handle the relevant disrupting influence on the measurement. Comment: this does not apply for method-specific clean-up-steps (for example: the application of immuno-affinity columns in the determination of mycotoxins).
- If a manual method described in the reference method is carried out in an automated manner, it is permitted to refer to the reference method. For example:
  - automated splitting of aliphatic and aromatic fractions with the aid of silica gel instead of manual execution;
  - the automated analysis with an auto-analyser of ammonium with the aid of a colour reaction with a manual execution in the reference method;
  - the extraction of water samples with the aid of a robotic system, but follows the manual procedure of the reference method;
  - performance of an automated potentiometric chloride titration in cheese instead of a manual

titration in accordance with ISO 5943 | IDF88;
- use of an online method linked to LC-MS SPE (solid phase extraction), described in the reference method as manual.

- The reference method is applied at lower limits than referred to in the reference method. Example: if a reference method indicates that the method is applicable from 0.01 mg/l, but the validation shows that 1 µg/l is also feasible, by further concentrating the extract, by treating more samples and/or by using more sensitive equipment, for example.
- If the laboratory has a limit of detection for a test which is higher than the reference method and the laboratory can demonstrate that it only analyses samples with values (significantly) above its own limit of detection, then this is not viewed as critical.
- Note: the NEN has formally stated that the NEN standards committee on Environmental Quality is of the opinion that, provided it is validated by the user, a reference method can also be used under (or above) the measuring range given in the standard (reference method) and that these measuring results can be reported in the analysis report in accordance with the standard method. The RvA applies this ruling not only to the environmental laboratories but also to the other laboratories referred to in the introduction to this explanatory document RvA-T001.

Annex 2 Examples of permitted expansion of the area of application

Expansion relating to components

The principle is that the relevant component or parameter belongs to the group of components or parameters described in the reference method. For example:

- mercury (Hg) is analysed with ICP-MS but is not specified in the relevant reference method for element analysis with ICP-MS;
- component 1-methylnaphthalene is analysed together with other PAH but is not specified in the relevant reference method for the PAH-analysis;
- the oil fraction C_{10}-C_{12} is analysed in accordance with the reference method for C_{10}-C_{12} but as sub-fraction is not specified in the relevant reference method;
- the sum of two components is not specified in the reference method and the analysis of these two components is carried out in accordance with the relevant reference method; the sum of cis and trans 1,2-dichloroethylene for example.

Expansion relating to the matrix

The principle is that the relevant matrix may not be ‘heavier’ than the matrix set out in the reference method. For example:

- the area of application of the reference method is boiler water and is applied to groundwater and surface water;
- the area of application of the reference method is milk and cheese and is applied to curd;
- the area of application of the reference method is grains but is also applied to animal feed.