Dutch Accreditation Council (RvA)

Explanatory notes on EN-ISO/IEC 17025

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RvA explanatory notes describe the policy and/or the procedures of the RvA concerning a specific field of accreditation. Where the policy and/or procedures for a specific field of accreditation as described in an RvA explanatory note are documented in an EA, ILAC or IAF document, the RvA will bring its policy and procedures into line with this EA, ILAC or IAF document.

A current version of the explanatory notes is available through the RvA website (http://www.rva.nl/

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1 Introduction

This explanatory document sets out details of how the RvA deals with a number of criteria in EN ISO/IEC 17025:2005 and EN ISO/IEC 17025:2017. This standard has been made for all testing and calibration laboratories and not exclusively for accreditation purposes. A number of criteria is explained to harmonise the application thereof. In a number of cases this is done by referring to existing guidance documents of EA and ILAC, that can be downloaded from www.european-accreditation.org (EA) or www.ilac.org (ILAC).

2 Explanatory notes on specific criteria of EN ISO/IEC 17025:2005

4.5.1 Outsourcing

Internationally, within ILAC and EA, it has been agreed that structural outsourcing under accreditation is not possible if the laboratory does not itself perform the activity concerned in its entirety. Accreditation is only possible for an activity for which a laboratory itself is competent to perform and that it does indeed perform itself.
It is also the case that:

- Temporary outsourcing (due to unforeseen circumstances) is possible under accreditation, provided that the requirements set out in 4.5 are met.
- Contractual outsourcing is permitted in the context of governmental designation, for example AP04 and AS3000, where package formats are used. In that case, the activity concerned is not part of the scope of accredited activities (for example see SAP L002).
- If there is a collaboration of various accredited laboratories on a contractual basis, the totality of the analyses can be offered on the market as being accredited. The client must be in agreement with the contractual collaboration and with the relevant agreements concerning, for example, the supply of samples, approval and reporting. Each laboratory can only be accredited for the activities for which the laboratory itself is competent and that it does indeed perform itself.
- Sampling, where the samples are always analysed by another laboratory (see RvA-T021), is not regarded as 'outsourcing', because analysing the samples is not part of the scope of the sampling body. See also RvA-T025, with regard to descriptions of scope on this point.

Also see the position taken with regard to 5.2 (Personnel).

4.14.1 Frequency of internal audits

At the end of 4.14.1 it is noted that the internal audit cycle should normally be completed in a year. The RvA policy is that each individual element of EN ISO/IEC 17025 and each individually accredited activity must normally be audited at least annually. If historical data (for example, few to no non-conformities found) can be used to demonstrate that it is a realistic option to depart from this frequency, a lower frequency can be accepted with good underpinning. In the case of larger scopes with many similar tests it can be accepted, also on

the basis of historical data, that each individual test is not audited annually, if provisions are made for each technique to be audited annually (and provisions are made for each individual test to be explicitly audited once every four years). Needless to say, that in the latter case, corrective action will have to be taken for all the other, similar tests, where relevant, if any non-conformities are found.

5.2 Personnel

Some laboratories incidentally or structurally involve external samplers. 5.2.3 states: “The laboratory shall use personnel who are employed by, or under contract to, the laboratory”. Therefore there must be some sort of formal employment relationship or contract.

Further 5.2.3 states that the laboratory shall ensure that temporary or additional personnel are supervised and competent et cetera. Therefore during RvA assessments specific attention will be paid to:

- the supervision and technical management regarding the (temporary/hired) employees;
- contracts/agreements with these employees;
- how it is ensured that these employees work according to the management system of the laboratory;
- determination of skills and the periodic review thereof;
- the way in which supervision is organized for example by means of internal audits, monitoring, peer evaluation, et cetera;
- recording of the qualifications (including substantiation).

The body from which the persons concerned are hired in or borrowed may not in any way refer to the accreditation of the body to which is hired or lent out.

5.4.3 Methods developed in the laboratory

Accreditation can only take place for tests and calibrations that have been fully validated. In this regard a testing laboratory may apply a worst-case approach. It may suffice with a full validation with the most difficult matrix. The NEN 777n series considers validation, performance characteristics, measurement uncertainty, et cetera, in depth. The use of these standards usually is not mandatory for testing laboratories, but does often give a good interpretation of the requirements with regard to validation, performance characteristics, measurement uncertainty, et cetera. The way in which the RvA describes the scope of laboratories is set out in RvA-T025. This applies to both fixed and a flexible scopes.

5.4.6 Determining the measurement uncertainty

The EA in EA-4/16 has drawn up guidelines for testing laboratories to determine and express the measurement uncertainty. Chapter 3 of that document also sets out the policy on measurement uncertainty.
The Appendix to EA-4/16 includes a large number of references to standards and other documents setting out the calculation of the measurement uncertainty. This Appendix does not claim to be complete. It is a summary of the documents known to the writers at the time that EA-4/16 was drafted.

For calibration laboratories the calculation and expression of the measurement uncertainty must be in accordance with the procedure in EA-4/02 and ILAC-P14.
Testing laboratories that carry out calibrations for critical apparatus according to national or international standards themselves must carry out the calculation of the measurement uncertainty in accordance with the procedure in EA-4/02.
Also see the comment on 5.4.3 regarding the use of the NEN 777n series of standards by testing laboratories.

5.7 Sampling

In EN ISO/IEC 17025:2005 sampling (also see EN ISO/IEC 17025:2005, 1.2) is regarded as an activity in relation to the test to be performed.
If a body is not a laboratory or has no laboratory and only carries out sampling activities, or does not test samples taken in its own laboratory, then RvA-T021 ‘Accreditation of sampling’ applies.

The standard also contains a note (not a requirement) relating to the representativeness of the sample ‘for the whole’ (see 5.7, note 1).
It is a requirement that a sampling scheme and procedure shall be in place. Sampling schemes must be based, ‘whenever reasonable’, on suitable statistical methods.
The reports from the body must show whether a representative sample has been taken or whether the sampling was carried out on the basis of a sampling scheme agreed with the client (in accordance with order specification) or in accordance with a normative document.
The consequence of this is that only in the report based on a representative sample any judgment can be made about the batch having been sampled (also see 5.10.5 and RvA-T021).

The above means that the sampling can be stated in the scope (the list of accredited activities) in different ways. The way in which this can be done is set out in detail in RvA-T025, Scope of testing laboratories.

5.9 Guaranteeing the quality of the testing and calibration results

So-called 'first-line controls' must be set up in such a way that, with regard to the validity of the tests carried out, they are effective. Detailed considerations of dealing with first-line controls can be found in document RvA-T022, but T022 will be revoked with the publication of this SAP. For a replacement text see the explanation at 7.7 on page 15 and 16.

Participation in proficiency comparisons, and in particular the laboratory-evaluating proficiency comparisons, is becoming an increasingly important part of the assessment and accreditation of laboratories. The EA and ILAC have developed policies covering the minimum participation in the laboratory-evaluating proficiency comparisons (Proficiency Tests). This policy has been published in ILAC P9. The RvA has adopted this policy and published it in RvA-T030.

5.10 Reporting the results

5.10.1, among other things, states that the reporting must be unambiguous and clear. If the laboratory, for whatever reason, adds disclaimers or comments to results (for example, where shelf lives are exceeded), the disclaimer or comment must always be accompanied by a conclusion regarding that disclaimer or comment. In the event, for example, of the shelf life being exceeded, the disclaimer or comment must be accompanied by a statement about the (possibly reduced) reliability of the analysis result.

5.10.2.e) contains the requirement that a report must include a clear statement of the method used. This can be done in one of the following ways:

1. a brief description of the method used, including, among others, the technique used. In this regard the laboratory may also refer in the report to a directly retrievable and public document of the body, such as an information guide on its website;
2. identification of the work instruction used. This is only allowed when the client is aware of the content of the work instruction;
3. referring to the standard or other standard method if conformance or equivalence is stated in the scope. If the scope states equivalence, than equivalence shall also be reflected in the report.

5.10.3.1.c contains requirements for the indication of the measurement uncertainty. A test body that does not include the uncertainty in the report should include in the report that the uncertainty is retrievable.

A statement on the estimated uncertainty of measurement shall be reported in cases where the uncertainty affects compliance to a specification limit. Exceptions may be: demonstrable sector agreements about (not) stating the uncertainty, or if the measurement uncertainty is already included in the limit, or if the measurement uncertainty is not part of the test, or if the measured value lies far from the limit.

Further explanation is available in ILAC G8, Guidelines on the Reporting of Compliance with Specification and NEN White Paper 'Meetonzekerheid' (Dutch only).

5.10.5 considers opinions and interpretations. Further explanation can be found in chapter 3 below.

3 Opinions and interpretations (EN ISO/IEC 17025:2005)

3.1 Policy

Testing laboratories may, under accreditation, include opinions and interpretations in their reports, provided that the requirements of this chapter are met. The RvA considers those bodies who are exclusively or partly concerned with sampling activities to be testing laboratories also.

The RvA considers opinions and interpretations as a professional judgment regarding the tests carried out, whether or not in combination with sampling, and regarding sampling as an independent activity.

It is the responsibility of an individual testing laboratory to decide whether it will include statements regarding opinions and interpretations in test reports and/or sampling reports and whether it will apply for accreditation for them.
This decision shall be clearly included in the laboratory's quality system documentation.

The accreditation for opinions and interpretations will be stated explicitly in the scope of accreditation once an assessment of the laboratory on this subject has been successfully completed. The laboratory seeking to include opinions and interpretations in the scope of accreditation must submit an application for scope extension (RvA-F105). The assessment by the RvA will in particular concern the subjects referred to in these explanatory notes.

The RvA will not accredit laboratories for opinions and interpretations only. Accrediting opinions and interpretations relates to the results within the accredited scope of the accreditation, as well as any outsourced work, provided that the requirements set out in chapter 2 are met.

If opinions and interpretations are not covered by the RvA accreditation, this must be clearly indicated in the test report if it contains opinions and/or interpretations.

3.2 Assessment of competence

The RvA will assess a laboratory's competence to make statements about opinions and interpretations by:

1. assessing the documented methods and assessing the application in practice;
2. assessing the suitability of the competence criteria;
3. verifying the qualifications, experience, training and knowledge of staff members;

4. assessing the suitability of mechanisms in place to monitor the competence of staff members;
5. assessing reports containing opinions and interpretations;
6. assessing the data on which the opinions and interpretations are based;
7. using other appropriate assessment techniques.

3.3 Explanatory notes on EN ISO/IEC 17025:2005 concerning opinions and interpretations

4.1.1 to 4.1.5

The emphasis in these criteria is very much on the laboratory being able to demonstrate that it maintains integrity and avoids conflicts of interest. The links with other parts of an organisation must be clearly defined when, for example, the laboratory draws on professional input from other parts of the organisation in giving opinions and interpretations.

These criteria, in particular 4.1.5 b), c) and d), also highlight the need for professional integrity and due diligence in giving opinions and interpretations.

4.2.1 and 4.2.2

The laboratory's policies and procedures for opinions and interpretations must be documented within the quality system, including any limitations. For example, that opinions and interpretations are limited to a certain part of the scope.

4.4.1 to 4.4.5

These criteria refer to the contract review. A robust contract review process is an essential part of a laboratory's demonstration of its competence to express opinions and interpretations.

The contract review process must include confirmation that:

1. the client's needs and wishes with regard to any statements of opinions and interpretations have been understood;
2. such statements are appropriate within the laboratory's accredited scope;
3. the client has understood and accepted the implications of such statements;
4. the laboratory has the necessary competence to make such statements;
5. any legal requirements are understood and can be met.

The laboratory must keep records of contract reviews.

The contract review must establish the extent to which the statement of opinions and interpretations will be based on test results, compared to information drawn from other sources, such as documentary research or experience previously acquired. Care must be exercised in this regard. It is possible that opinions and interpretations based on such sources, although being within the professional competence of the laboratory, may fall outside the accredited scope of the laboratory.

The contract review must also establish the extent to which such statements may incorporate information from tests outside the laboratory's scope of accreditation or externally supplied data. The laboratory must determine the validity of the data for the purposes of forming opinions and interpretations.

If the laboratory reports results of statistical calculations (for example, modelling) which have been based on an assumption, the contract review must ensure that the client is aware of this and accepts the basis for the calculations.

4.9.1 and 4.9.2

These criteria also apply if there is any doubt about the validity of statements with regard to opinions and interpretations or of any source of information on which these statements are based.

5.2.1 to 5.2.5

Laboratory management must be able to demonstrate that the staff members it has authorised to express opinions and interpretations are competent to do so within the accredited scope. Competence criteria must specify the qualifications, experience and knowledge required, in line with notes 1 and 2 in 5.2.1. Competence criteria established by professional groups, business organisations, et cetera, may be used for this purpose.

Laboratories must have procedures for ensuring that personnel authorised to make statements of opinions and interpretations keep their knowledge and understanding of the relevant technical issue up to date.

5.10.2 and 5.10.3

Test reports will normally contain the actual results of the tests performed (and if applicable the sampling), unless the laboratory has a valid reason for omitting them. An example of this is where the client has specifically requested the laboratory only to make a statement on whether or not the item tested is in compliance with a specification containing measurable criteria, without giving details. As such, and if based solely on objective evidence, these statements would not normally not be regarded as opinions and interpretations. However, the laboratory must record the test results for possible future reference for a period of time consistent with its record retention policy. The laboratory must also take the requirements described in ILAC G8 into account when including statements on compliance with requirements.

Normally a test report only contains results relating to the item examined. Where opinions and interpretations are given that extrapolate those results beyond the item tested, for example where the item is a sample from a wider set, the laboratory must verify that the opinions and interpretations are consistent with that established in the contract review before issuing the report. This implies that a laboratory can only give opinions and interpretations concerning a batch if the sampling is performed under accreditation and the sampling is representative for the batch.

5.10.5

If opinions and interpretations are given on an item that has not been tested to its complete specifications, the report must contain a statement such as: “these opinions and interpretations are based on results from a limited set of tests” or words to similar effect. The report must state which tests have been performed as the basis for such opinions and interpretations.

If in the context of opinions and interpretations a laboratory states that an item may meet a specification despite having failed one or more tests, it must give a clearly reasoned explanation as to how and why it has arrived at this conclusion. The laboratory must present the detailed test results to enable the client to assess the validity of the opinions and interpretations given itself.

5.10.6

Special attention is required where reports contain opinions and interpretations which rely on results obtained from tests performed by subcontractors and/or data provided by the supplier of the test item. The records of such reports must clearly identify the source of the data used in forming opinions and interpretations and the steps taken by the laboratory to establish their validity. This is only allowed if the criteria set out above in chapter 3 are met.

4 Explanatory notes for specific criteria of EN ISO/IEC 17025:2017

4.1.4 Risks concerning impartiality

In 4.1.4 it states that identifying potential risks concerning impartiality must be undertaken on an "on-going basis". This means that in the event of relevant changes of activities, relationships or relationships of its personnel, the laboratories must reassess the relevant risks with regard to impartiality; however, it does not mean that all risks concerning impartiality have to be reassessed during every order.
The topics referred to in 4.1.4 (activities, relationship and relationships of personnel) have to be reassessed at least annually. For example, this can be undertaken within the framework of the management review (as a result of 8.9.2 m)).

5.6 Quality Manager

The majority of activities referred to in 5.6 a) up to and including e) were assigned to the Quality Manager (or similar job title) in the 2005 version. It is now also permitted to have these activities undertaken by one (or more) other official(s), however the tasks may of course also be assigned to a Quality Manager (or similar job title).

6.2 Personnel

The 2005 version of EN ISO/IEC 17025 required that personnel had to be employed or contracted by the laboratory. This explicit requirement is no longer included in the 2017 version. Indirectly, it can be derived from 6.2.1 that there has to be a contract (of employment), agreement or something similar in order to organise matters such as the impartiality, competencies, working in accordance with the management system and suchlike.
6.2 addresses, amongst other things, the impartiality and competent execution of tasks. If the laboratory uses external personnel (temporary personnel, hired personnel and suchlike, for example external samplers or other external personnel) then during its assessment the RvA will pay specific attention to, amongst other things:

- supervision and management relating to the (temporary, hired in/external) personnel;
- contracts/agreements with these personnel;
- the way in which is assured that these personnel work in accordance with the laboratory's management system;
- the recording of competencies and their periodic validation;
- implementation of supervisions by internal audits, monitoring, peer review, for example;
- recording qualifications (including documentary evidence).

The organisation from which the relevant personnel are hired in or seconded from may not in any way make reference to the accreditation of the organisation to which the personnel are hired or seconded.

6.4 Equipment

A distinction is made between the verification of equipment for initial use (6.4.4), the (potentially external) calibration of equipment (6.4.6 up to and including 6.4.8.) and the

(internal) interim check of equipment (6.4.10). For the calibration and internal interim checks the laboratory must, where relevant, impose requirements for the frequency of calibration or interim checks; requirements also have to be set for the associated review criteria.

6.5 Acceptable traceability

See RvA-T018, Acceptable traceability. That explanatory document explains how the requirements for traceability of measurements applicable for laboratories and inspection bodies can be met. RvA-T018 also explains when acceptable traceability is necessary and when there is a case of critical equipment. The RvA policy regarding this is based on ILAC P10, ILAC Policy on Traceability of Measurement Results.

6.6.2 c) Provided products and services

6.6.2 c) states that relevant requirements of EN ISO/IEC 17025 have to be complied with. This concerns requirements that have a direct and technical relationship with the test results and/or calibration results.

7.1.1 c) Subcontracting

Internationally, within ILAC and EA, it has been agreed with regard to subcontracting that subcontracting on a structural basis is not possible under accreditation. Accreditation can only be undertaken for an activity for which a laboratory is itself competent and which also undertakes that activity.

The following also applies:

- Temporary subcontracting (due to unforeseen circumstances) is possible under accreditation, provided that the requirements described in 7.1.1 c) and 6 are met.
- Within the framework of a governmental appointment, for example AP04 and AS3000, which uses the division of services into packets, contractual subcontracting is permitted. The relevant activity does not then belong to the scope of the accredited activities (see SAP L002 for an example).
- If there is collaboration between various accredited laboratories on a contract basis then the total of analyses can be offered to the market as being accredited. The client must accept the contractual collaboration and approve the agreements recorded in this context relating to, for example, supply of samples, approval and reporting. Each laboratory is only accredited for the activities for which the laboratory is itself competent and which it also undertakes itself.
- For sampling whereby the samples are always analysed by another laboratory (see RvA-T021), this is not regarded as 'subcontracting' because the analysing of samples is not part of the scope of the sampling organisation; it is a service that is procured. Also see RvA-T025 and the RvA SAPs concerning scope descriptions on this point.

7.2 Verification and validation

In 7.2.1.5 and 7.2.2 a distinction is made between verification and validation.

The following applies for test laboratories:

- If an activity is undertaken 'in conformity with' a reference method (see RvA-T001) then verification of the method will suffice. On the basis of its own assessment, the laboratory must at least investigate the demonstrability threshold, the measuring range, the linearity, correctness, retrieval, repeatability and reproducibility. The results must meet the performance characteristics specified in the reference method. If the reference method contains no performance characteristics then the performance characteristics must comply with the performance characteristic from comparable reference methods.
- If the test laboratory uses its 'own method', or for one or more aspects deviates from the reference method then a validation of the method must be undertaken. For this, the laboratory may use a worst-case approach (test laboratories may, for example, suffice with a full validation of the most difficult matrix).

The NEN 777n series covers validation, performance characteristics, measurement uncertainty, et cetera, in detail. The use of these standards is often not specified as mandatory for test laboratories however it often does provide a good implementation of the standard elements relating to validation, performance characteristics, measurement uncertainty and suchlike.
The way in which the RvA deals with describing the scopes for test laboratories is specified in RvA-T001 and RvA-T025. This applies for a fixed scope and for a flexible scope.

For calibration laboratories the validation is generally substantiated using an appropriate uncertainty calculation (also see 7.6).

7.3 Sampling

Sampling is regarded as an activity in relation to the test or calibration to be undertaken.
If an organisation is not a laboratory / does not have a laboratory and only undertakes sampling activities, or does not test samples taken in its own laboratory, then RvA-T021, Accreditation of sampling, is applicable.
It can be derived from 7.3.1 that a representative sample has to be taken ("…to ensure the validity of subsequent testing or calibration results.")
It also states in 7.3.1 that there has to be a sampling plan. Where possible, that plan must be based on suitable statistical methods. The organisation's report must show whether a representative sample has been taken, or that the sampling has been undertaken on the basis of a (random sample) schedule agreed with the customer (in accordance with the order specification), or in accordance with a normative document. During reporting, a judgement can only be made about the sampled batch on the basis of a representative sample (also see 7.8.2.1 k) and RvA-T021).
The aforementioned means that sampling can be included in the scope (the list of accredited activities) in various ways. The way in which this can be done is further described in RvA-T025, Scope of test laboratories.

7.6 Measurement uncertainty

In EA-4/16 the EA has prepared quantitative test guidelines for test laboratories for determining and expressing measurement uncertainty. Section 3 of that document also contains the policy with regard to measurement uncertainty.
The annex to EA-4/16 contains a large number of references to standards and other documents on how to determine measurement uncertainty. This annex does not pretend to be complete. It is a representation of the documents known at the time when the authors drafted EA-4/16.
Test laboratories that undertake calibrations themselves against (inter)national standards for critical equipment (see RvA-T018) must undertake the determination of measurement uncertainty in the manner described in EA-4/02. Also see the comment at 7.2 with regard to test laboratories using the standards from the NEN 777n series.

For calibration laboratories the determination and expression of the measurement uncertainty must be undertaken in the manner described in EA-4/02 and ILAC P14.

7.7 Quality controls

A summary of the various types of quality controls is included in 7.7.1. In the Netherlands it is common practice for test laboratories to use so-called first, second and third line controls for the quality controls. In its assessments the RvA assumes the following definitions:

- First line control: quality control by the actual laboratory technician undertaking the work; often on the basis of a blank and an adequately selected control sample (see below).
- Second line control: quality control by the laboratory, independently of the laboratory technician undertaking the work; often on the basis of control samples or certified reference material in respect of which the laboratory technician does not know it is a control sample.
- Third line control: an independent quality control on the basis of proficiency testing or comparable testing with other laboratories.

The controls stated in 7.7.1 are options for implementing the first, second and/or third line controls.

Test laboratories must undertake a first line control and a third line control. If no third line control is available then the laboratory may resort to a second line control (whereby the laboratory must then ensure that the component 'correctness' is covered by that second line control).

In the past there has been discussion between the RvA and a number of test laboratories about the choice of the first line control. Agreements were made at that time about the choice and implementation of the first line control, which were at that time recorded in RvA-T022. The essence of the text from RvA-T022 is included below and RvA-T022 has thus been withdrawn.

The laboratory must configure the first line controls in such a way that they are effective. This means that errors that can potentially occur in the process and which have an effect on the

result of the test are actually revealed during the first line controls. The errors that can occur during a test (from start to end) and which cannot manifest in a way other than via the use of the first line controls must be identified by the laboratory. In practice this means that the work has to be undertaken using a 'negative control sample' (often called a 'blank') and a 'positive control sample'.

- If it becomes clear from the validation assessment, or if explicitly specified in the standardised method or generally-accepted literature that the analysis method is not sensitive for matrix influences then it is sufficient to use a control sample that is prepared in a ‘simple matrix’ (for analyses in different types of water this includes, for example tap water, demineralised water, ‘milli-Q-water’, buffers, other matrix).
- If it becomes clear from the validation assessment, or if explicitly specified in the standardised method or generally-accepted literature, that the analysis method is sensitive for matrix influences then the first line control must be configured in such a way that sufficient control steps are incorporated for the critical points. This can mean that work is undertaken using a well-selected control sample (a sample with ‘relevant components’, a ‘relevant matrix’, etcetera) but it can also mean that work is undertaken using other well-selected assurance steps (such as control on destruction, distillation and/or extraction yield, (labelled) internal standards, inter-element corrections).
- If it becomes clear from the validation test, or if explicitly specified in the standardised method or generally-accepted literature, that the analysis method is sensitive for matrix influences and it is not possible to select a control sample or otherwise configure the first line control in such a way that sufficient control steps are incorporated for the critical points and it is also not possible to assure the matrix influences using an internal standard (added to each sample), then ‘standard addition’ must be applied to each sample.
- For tests such as BOD, pH measurement and EC measurement the influence (almost always present) of the matrix on the analysis result is not important, and it is suffice to use a control sample that is prepared in a ‘simple matrix’.

When choosing the frequency of the controls, the laboratory must take the following into consideration:

1. The extent to which there are variables that can result in uncontrolled quality during the execution of a series or several series of tests.
2. Whether a control sample is ‘covering’ for all samples that preceded it or follow it.

Participation in proficiency comparisons, in particular the laboratory-evaluating proficiency tests, is becoming increasingly important when assessing and accrediting laboratories.
EA and ILAC have developed a policy with regard to the minimum participation of laboratories in the laboratory-evaluating proficiency tests. This policy is published in ILAC P9. The RvA has adopted this policy and published it in RvA-T030.

7.8 Reporting of results

- It states in 7.8.2.1 f) that the report must state the method used. This can be done in one of the following ways:

a) a brief description of the method used stating, amongst other things, the technique used. In the report the laboratory may also potentially refer to the organisation's directly retrievable and public document, for example an information guide on its website;
b) identification of the work instruction used. This is only possible if the customer is aware of the content of this work instruction;
c) reference to a reference standard, if this reference standard is stated in the scope of the accreditation. RvA-T001 describes the conditions under which reference may be made to a reference standard.

- In 7.8.2.1 h) it states, amongst other things that – when relevant – the date of sampling has to be reported. If the laboratory did not undertake the sampling itself and the use-by date of the sample is critical, then the laboratory must find out the sampling date in order to be certain that the sample can be tested/calibrated within the use-by date.
- In 7.8.2.1 i) it states that the date must be reported on which the laboratory activity was undertaken. In situations whereby several dates have to be reported (and whereby it may potentially be unclear for the client) then it is accepted that the dates are not reported, on condition that:
  a) it is demonstrably organised that in the event that any use-by date is exceeded then an unambiguous, clear comment (or disclaimer) will be included in the report. The relevant comment must accompanied by a conclusion relating to that comment; for example about the (potentially reduced) reliability of the analysis result.
  b) the report includes an explanation about why the analysis date is not reported.
- Requirements regarding the reporting of the measurement uncertainty are included in 7.8.3.1 c).
  A test laboratory that fails to include the measurement uncertainty in the report must state that the measurement uncertainty is available on request.
  Attention: A statement about the measurement uncertainty must be explicitly included in the report in cases where the measurement uncertainty has an influence on compliance with a specification limit. Exception to this can be: if demonstrable arrangements exist in the sector about the (non-) reporting of the measurement uncertainty, if the measurement uncertainty is already incorporated in the limit value, if the measurement uncertainty is not part of the testing or if the measured value is far from the limit value.
  A further explanation is available in ILAC G8, Guidelines on the Reporting of Compliance with Specification and in the NEN 'Whitepaper Measurement Uncertainty' (Dutch only).

7.8.7 is about opinions and interpretations.
Under opinions and interpretations the RvA means a professional judgement relating to the tests and/or calibrations undertaken, whether or not combined with sampling, and with regard to sampling as an independent activity. An opinion and interpretation goes beyond the 'statement of conformity' referred to in 7.8.6.2. Also see the explanation regarding this in EA-INF/13.
The accreditation for opinions and interpretations will be stated explicitly in the scope of accreditation, after the assessment of the laboratory on this aspect has been completed

successfully. The accreditation of opinions and interpretations relates to the results within the accredited scope of the accreditation, as well as any procured work. If opinions and interpretations not covered by the RvA accreditations are included in the report then this must be stated clearly in the report.

7.9 Complaints

It states in 7.9.2 that a description of complaint handling must be available on request. This may be a written procedure but it may also be a general description.

8.1 Option A and Option B

If the laboratory chooses Option A, the RvA assessment team will refer to the relevant (sub-) paragraph in the event of any findings and non-conformities with regard to 8.2 up to and including 8.9.

If the laboratory chooses Option B, the RvA assessment team will not asses compliance with the ISO 9001 requirements but will investigate whether there is compliance with the requirements contained in 8.2 up to and including 8.9. In the event of any findings and non-conformities with regard to 8.2 up to and including 8.9 then reference will be made to 8.1.3 (which will include naming the relevant requirements from 8.2 up to and including 8.9).

8.3 Document control

The 2005 version required that each document had to be uniquely identified using issue and/or version information, page numbering, the total number of pages (or mark to indicate the end of the document) and the name of the issuing organisation. These explicit requirements are no longer included in the 2017 version. However, it can be indirectly derived from 8.3.1 and 8.3.2 e) that such aspects are important within the framework of adequate document control.

8.5 Actions to address risks and opportunities

The laboratories are expected to report work processes on primary and sub-process steps. Risks of errors (with regard to test ad/or calibration results) also have to be identified however opportunities and possibilities for improvement also have to be reported. Management and improvement measures have to be documented and they have to be tested effectively.

The clear choice is for these processes to be handled during specific discussions and within the framework of the management review (8.9.2 m)).

There are various models for risk analyses and the laboratory is free to make its own choice. Attention is drawn to relevant standards in this area, including ISO 31000 and CEN ISO/TS 22367 (also see ISO 9001:2015; 6.1 and ISO 15189:2012; 4.14.6).

8.8 Internal audits

For this aspect, the 2005 version included a comment that the cycle for internal audits should normally be completed within a year. The RvA policy is that generally each individual element of the EN ISO/IEC 17025 and each individual accredited activity have to be audited at least annually. If it can be demonstrated using historic data (for example few to no non-conformities

found) that it was justified to deviate from this frequency, then provided it is substantiated properly a lower frequency can be accepted. For larger scopes with many comparable tests it can also be accepted on the basis of historic data that not every individual test has to be audited annually, provided it was ensured that each technique was audited annually (and it was ensured that each individual test was explicitly audited at least once every four years). It goes without saying that in this latter situation, if non-conformities were found then, where relevant, corrective measures were taken for all other comparable tests.

The RvA policy remains unchanged. However, laboratories are explicitly challenged, on the basis of a risk analysis, to formulate their own adequate and substantiated policy concerning the frequency of performing internal audits (also see 8.5).

Part of the procedure for internal audits also includes qualifying internal auditors. In that context, reference is made to 6.2.6. It is expected of internal auditors that during their training and qualifications they are tested, amongst other things, on their knowledge of the content of EN ISO/IEC 17025, knowledge of the object/subject area to be audited, knowledge of auditing and the independent position with regard to the audit object.

5 Changes compared to the previous version

The following significant changes have been made compared to version 5 of March 2017:

- An explanation of various criteria of the 2017 version of EN ISO/IEC 17025 has been added.