Dutch Accreditation Council (RvA)

Accreditation of sampling

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

Contents

1 Introduction

The RvA has accredited a number of organisations for sampling. This can be organisations with an accreditation based on EN ISO/IEC 17020 as well as test laboratories with an accreditation based on EN ISO/IEC 17025.

The RvA acknowledges that in many cases, sampling cannot be regarded as an inspection or test activity and that it can therefore be argued that these should not be included as a separate activity on the scope of accreditation. However, the importance of sampling within inspection and test activities is such that the RvA wishes to meet the need in the market for having these activities accredited as a separate activity. In so doing, the RvA is also following the procedure that has been agreed internationally.

In this explanatory document the RvA has recorded the conditions under which sampling can be accredited as a separate activity.

Where criteria of the EN ISO/IEC 17025 are listed, the criteria of the 2005 version are between ( ) and those of the 2017 version are displayed between [ ].

2 The inspection and test activities

The schedule below shows that sampling has an important position in both inspection and testing. However, sampling is not covered by the accredited activities in all cases or is undertaken by third parties. A schematic representation of a number of possibilities is given below.

Potential situations	Activities in the inspection and test process			
	1. Establishing inspection/measuring strategy	2. Sampling	3. Measurements, assessments	4. Interpretation and conclusions
1	Inspection EN ISO/IEC 17020			
2		Inspection EN ISO/IEC 17020		
3			Inspection EN ISO/IEC 17020	
4	Test EN ISO/IEC 17025			
5		Test EN ISO/IEC 17025		
6			Test EN ISO/IEC 17025	

Situation 1: The inspection body (IB) is responsible for the entire process. The report of inspection results must contain a justification for the selected inspection strategy.

Situation 2: The IB does not establish the sampling strategy directly but works on the basis of the strategy pre-defined by the client, or in accordance with a prescriptive document. The report of inspection results must make reference to the inspection strategy prescribed by the client, or to the prescriptive document.

Situation 3: The IB inspects the objects supplied and is not responsible for the sampling. The report clearly states that an opinion is only provided in respect of the objects provided and, for example, not about a batch of objects.

Situation 4: The laboratory is responsible for the entire process. The report of test results must contain a justification for the measuring strategy selected however the opinion of the laboratory must not extend beyond whether the object/batch does or does not meet the pre-defined specifications.

Situation 5: On the basis of a specified strategy or prescriptive document, the client arranges for the laboratory to take samples and to measure. In the report of test results reference is made to the measuring strategy prescribed by the client or to the prescriptive document.
Situation 6: The laboratory conducts tests on a sample that has been supplied. The report clearly states that the results only concern the sample that has been provided.

Also see RvA-T015 concerning how to deal with 'opinions and interpretations'.

In addition to the fact that the organisation can be exclusively responsible for part of the process, elements can also be subcontracted or a client can arrange for different elements to be undertaken by separate organisations. In the latter case, ambiguity can arise about the responsibility for the test and inspection results and the interfaces must be considered more critically. However, provided the report clearly states which activities have been undertaken under the responsibility and accreditation of the laboratory or the inspection body then accreditation contributes towards clarity for the client or the subsequent user of a report.

3 Scope

For reporting sampling on the scope by organisations that perform this activity in the framework of their accredited tests, see RvA-T025.

For sampling for tests carried out by another organisation the sampling will be reported on the scope as follows:

EN ISO/IEC 17025:

No.	Material or product	Type of activity	External/Internal reference number	Location
Sampling				
a	<……>	Sampling for the determination of the content of*; < technique>*[*1]	*ZZZ*	Location from which the sampling is coordinated

[*1] the corresponding test is structurally carried out by another accredited laboratory.

EN ISO/IEC 17020:

No.	Field of inspection	Type and range of inspection	Methods & procedures
Sampling			
a	<……>	Sampling for the purpose of determining the content of *xxx;*	*ZZZ*
b	<……>	Sampling for the purpose of < *inspection activities to be specified* >	*ZZZ*

[*1] the corresponding test is structurally carried out by an accredited laboratory.

4 Standards for accreditation in relation to sampling

Standards EN ISO/IEC 17020 and EN ISO/IEC 17025 can be used for accreditation of sampling however EN ISO/IEC 17025 contains the most specific criteria for sampling.

EN ISO/IEC 17025 states that the scope of the standard is 'tests and/or calibrations, including sampling'. Paragraph (5.7) [7.3] stipulates more detailed requirements for sampling, and (5.10.3.2) [7.8.2.2., 7.8.5] gives the requirements for the reporting of sampling results.

The RvA shall therefore use EN ISO/IEC 17025 for the accreditation of sampling as a separate activity. An organisation that wishes to have sampling as a separate activity on the list of activities (scope of accreditation) will therefore be accredited on the basis of EN ISO/IEC 17025.

There are two possible exceptions to this rule:

1. If the organisation is also accredited or becomes accredited for inspection activities (other than taking samples) in accordance with EN ISO/IEC 17020, then a separate sampling activity is possible within the 17020 scope however in that case the requirements contained in EN ISO/IEC 17025 will be applied in addition to those in EN ISO/IEC 17020, as described in Section 5 of this explanatory note.
2. If independence requirements are stipulated for the sampling organisations at the level of a Type-A inspection body then the RvA will base the accreditation on EN ISO/IEC 17020 but in that case the requirements in EN ISO/IEC 17025 will also be used, as described in Section 5 of this explanatory note.

Sampling activities can only be accredited as a separate activity if these activities are undertaken within the framework of accredited tests or inspections. In many cases there will be a 1 to 1 relationship between the accredited sampling and the accredited testing (for example in the case of Legionella). An accredited analysis can be a multi-component analysis (for example PCBs with GC-MS), whereby not all components of the analysis are necessarily covered by the accreditation. In this situation it remains clear for the (end) user that the sampling was undertaken under accreditation and what components were determined under accreditation.

The schematic overview given in Section 2 is therefore, for sampling only, expanded with the following options:

<table>
<tr><td rowspan="2">Possible situations</td><td colspan="4">Steps in the inspections and test process</td></tr>
<tr><td>1.
Establishing inspection/measuring strategy</td><td>2.
Sampling</td><td>3.
Measurements, assessments</td><td>4.
Interpretation and conclusions</td></tr>
<tr><td>7</td><td colspan="2">Test EN ISO/IEC 17025</td><td colspan="2" rowspan="4">(Other) accredited organisation</td></tr>
<tr><td>8</td><td></td><td>Test EN ISO/IEC 17025</td></tr>
<tr><td>9</td><td colspan="2">Inspection EN ISO/IEC 17020</td></tr>
<tr><td>10</td><td></td><td>Inspection EN ISO/IEC 17020</td></tr>
</table>

Situation 7: The organisation is responsible for determining the sampling strategy and for undertaking the sampling. The report about the sampling must contain a justification for the chosen strategy.

Situation 8: The organisation does not determine the strategy directly but works on the basis of the strategy prescribed by the client, or in accordance with a prescriptive document. In the report about sampling reference must be made to the strategy prescribed by the client or to the relevant prescriptive document.
The accredited sampling organisation can report the sampling and the subcontracted accredited analyses. For the method of reporting the results of the subcontracted activities please refer to RvA-VR003.

Situation 9: Same as situation 7, but only used under the aforementioned conditions.

Situation10: Same as situation 8, but only used under the aforementioned conditions.

5 Requirements to be specified for sampling

The RvA has formulated specific explanatory notes for the accreditation requirements relating to the following topics:
- personnel competence;
- technical resources;
- methods to be used;
- acceptance of assignment;
- guaranteeing the quality of the sampling.

A further explanatory note is not considered appropriate for the other requirements from the standards.

5.1 Personnel

The requirements set out in EN ISO/IEC 17025, paragraph (5.2) [6.2], relating to the availability and competence of personnel are applicable in full to organisations taking samples.

When determining the required qualifications it is necessary to take into account the question about whether the sampling strategy is prescribed in standardised methods, or whether this strategy has to be determined directly by the organisation. In the latter case, the organisations must possess knowledge relating to the statistical validations of sampling.

The personnel coordinating and undertaking the sampling must in all cases have adequate, demonstrable knowledge about the objects to be sampled and the processes or systems. This is required in order to determine the suitability of the place and time of sampling, and in order to be able to determine the effects of the circumstances under which the sample is to be taken on the suitability of the sample.

5.2 Technical resources

The requirements set out in EN ISO/IEC 17025, paragraphs (5.3) [6.3] and (5.5) [6.4], relating to the availability and suitability of resources are applicable in full to organisations taking samples.

The organisation must implement specific measures, where relevant, to guarantee the sterility and inertness of materials used for undertaking the tests or inspections. As with other potential forms of influencing the properties of the sampling object, contamination by and absorption of materials must be prevented.

5.3 Methods

The requirements set out in EN ISO/IEC 17025, paragraph (5.4) [7.2], relating to the methods used are applicable in full to organisations taking samples. The requirements contained in EN ISO/IEC 17025, paragraph (5.7) [7.3], are particularly applicable.

Sampling requires clearly recorded methods that are matched to the purpose of the tests or inspections. In practice, sampling is often undertaken in accordance with methods set out in prescriptive documents that have been agreed in and for a specific sector.
The laboratory or the inspection body determines the strategy for sampling. If, on request of the client, the strategy determined by the laboratory or inspection body is to be deviated from, then the laboratory or inspection body must record this in the report, together with a statement about whether – in the opinion of the laboratory or the inspection body – the sampling is still representative.
If the sampling is not undertaken in accordance with standardised methods then the organisations must itself demonstrate the validation of the method used. As a minimum, this means it is to be demonstrated that the method:
- guarantees the representativeness of the samples taken;
- does not change the properties of the test or inspection object in such a way that the results of the test or inspection are influenced.

5.4 Acceptance of assignments

The requirements set out in EN ISO/IEC 17025, paragraph (4.4) [7.1}, relating to assessing requests and assignments are applicable in full to organisations taking samples.

The instruction for sampling must clearly record whether the sampling has to be undertaken in accordance with a prescribed standard or whether the sampling plan has to be drawn up directly by the organisation that will be undertaking it.

Every sampling must be undertaken in accordance with a pre-defined sampling plan which clearly records the conditions under which and the degree to which deviations from the plan are permitted during the sampling.

The assignment must state unambiguously that the sampling is being undertaken within the framework of accredited inspection or testing.

5.5 Guaranteeing the quality of sampling

The requirements set out in EN ISO/IEC 17025, paragraph (5.9) [7.7], relating to quality control are also applicable to organisations taking samples. The organisation must have demonstrably implemented procedures which, as a minimum, provide:

- clear verification points for the execution of the activities by the person taking the sample. These verification points must be determined on the basis of the critical steps in the sampling process. The execution of the prescribed verifications by the person undertaking the work must, where possible, be recorded;
- supervision of the execution of the sampling by persons who are competent in the relevant sampling methods and who are aware of the aims of the sampling. This supervision must be undertaken in a systematic and planned manner. Amongst other things, the supervision must focus on correct observance of the instructions, working in accordance with the sampling plan and the recording and reporting of any deviations;
- assessment of the result of every sampling activity by an authorised member of staff designated for that purpose, during which this member of staff must establish whether, on the basis of – amongst other things – the requirements have been complied with;
- periodic mutual agreement of the procedures between the various samplers of the organisation.

6 Using the accreditation mark

Organisations that are accredited for sampling must use the accreditation mark in accordance with the conditions contained in RvA-VR003, Regulation for the Use of Accreditation marks and Logos. Because such an organisation does not issue any test reports, inspection reports and/or inspection certificates then where such reports or certificates are referred to in RvA-VR003, these should read as reporting on the sampling.

7 Changes

The following changes have been made compared to version 4 of August 2016:

- Following the publication of the 2017 version of the EN ISO/IEC 17025, the references to the 2017 version are included in this document in addition to the references to the criteria of the 2005 version.
- A new chapter 3 “Scope” has been added.