DUTCH ACCREDITATION COUNCIL

Information document RvA

Explanation of EN ISO/IEC 17025

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Chapter 1. Scope of application

This information document explains how the Dutch Accreditation Council RvA interprets and applies criteria of EN ISO/IEC 17025 (General requirements for the competence of testing and calibration laboratories). RvA uses this document in its assessments of testing and calibration laboratories that are accredited, or wish to become accredited, against the requirements of EN ISO/IEC 17025.

It indicates how the RvA has interpreted the criterion in question and applies it in practice, but it is possible that other points of view can also be applied with adequate justification.

In drawing up this document, the starting point is that there are no additional requirements added by RvA itself with regard to EN ISO/IEC 17025 and that no requirements of EN ISO/IEC 17025 are watered down.

This document provides an explanation per sub-criterion. The information often stems from outcomes of disputes and from outcomes of discussions on cases by RvA Lead Assessors. Where there is more than one explanation per sub-criterion, a suffix is given to the sub-criterion (e.g. 4.1.4n1; this is the first explanation for criterion 4.1.4).

Individual schemes and protocols, etc. may impose additional requirements on accreditation. This is not discussed in more detail in this information document.

Chapter 2. Terms, definitions and abbreviations

Abbreviations

ILC	Interlaboratory comparison
PT	Proficiency Testing
ASR	Accreditation Specification RvA

Terms and definitions

The terms and definitions in EN ISO/IEC 17000:2020 and EN ISO/IEC 17025:2017 apply.

Chapter 3. Explanation and interpretation of criteria of EN ISO/IEC 17025

4.1 General requirements – Impartiality

4.1.4n1 "On going" / "Continuous" means that only in case of relevant changes of activities, relationships, or relationships of the staff, the relevant risks regarding impartiality must be reassessed; This does not automatically mean that all risks relating to impartiality must be taken into account in every assignment.

4.1.4n2 At least annually, the subjects mentioned in 4.1.4 (activities, relations and relations of staff) must be reassessed. This can be done, for example, in the context of the management review (following 8.9.2m).

4.1.4n3 With regard to staff relations: The RvA also accepts the opposite approach by having the staff declare whether they have relationships in which impartiality may be at stake; This statement must then be periodically verified.

4.1.4n4 A possible format for identifying risks to impartiality is given in Annex 1 of this information document (often referred to as 'risk analysis to impartiality').

4.1.4n5 EN ISO/IEC 17025 does not exclude the possibility to work with hired samplers. If a hired sampler takes samples from his own employer (or, for example, from customers of his own employer), this must be explicitly addressed in the impartiality risk analysis. Appropriate measures must also be taken to eliminate or minimize such risks (according to criterion 4.1.5). The body must ensure that there is no undue pressure (see criterion 4.1.3).

4.1.4n6 If employees receive financial bonuses (or otherwise) as a result of, for example, fewer complaints, fewer internal or external deviations, acquisition, etc., then this activity will have to be explicitly addressed in the risk analysis regarding impartiality (including associated measures to eliminate or minimize, etc.).

4.2 General requirements – Confidentiality

4.2.1 Even when the laboratory uses a cloud service to store information, the laboratory is responsible for managing this information.

5. Structural requirements

5.1 In addition to common legal forms such as Limited Company and a Foundation, other legal forms can also be accredited. Bodies that want accreditation to be notified/ /recognized and for whom the legal requirements prescribe that there must be legal personality can therefore (for example) not be a sole trader or a limited partnership.

6.2 Resource requirements – Staff

6.2 For the requirements related to hired personnel: see also 6.6.

6.2.5d Depending on the complexity of the test or calibration, it might be possible to supervise personnel remotely from another location. The laboratory must adequately explain why this may be justified (based on criterion 8.5).

6.4 Resource requirements – Equipment

6.4n1 A distinction is made between the verification of equipment for first use (6.4.4), the (possibly external) calibration of equipment (6.4.6 to 6.4.8.) and the (internal) intermediate check of equipment (6.4.10). For calibration and internal intermediate checks, laboratory requirements for frequency of calibration or intermediate checks will be required, where relevant; there should also be requirements for the related test criteria.

6.4n2 If volume glassware is used in an analysis and the volume is critical, then that glassware will have to be calibrated (6.4.6) or, depending on the risk, a verification before placing or returning to service (6.4.4) can be sufficient. Periodically it will have to be checked whether the volume glassware still meets the requirements (6.4.10).

6.4.6 Equipment only needs to be calibrated if it has a significant influence/effect on the reported result and/or associated measurement uncertainty and/or if there must be acceptable traceability (see ASR009). This must be done by a calibration laboratory that is appropriately accredited or the laboratory may carry it out itself. In the latter situation, the internal (own) calibration must meet the requirements of a calibration laboratory (adequate procedure, competent personnel, adequate calculation of the measurement uncertainty of each step using Table 4.1 of EA 4/02, uninterrupted traceability chain, adequate records and adequate reporting, etc.). If an internal calibration is chosen, a separate calibration Technical Assessor will periodically be added to the RvA assessment team.

6.4.8n1 When labelling, coding or similar of calibrated equipment, there is no need to explicitly indicate the range on the relevant equipment. That range must be stated in the calibration certificate. The label, coding, etc., is only intended to indicate the calibration status.

6.4.8n2 Labelling, coding, or similar of equipment may also be done by means of, for example, coloured labels. It shall be unambiguously clear to the user what the calibration status of the equipment in question is.

6.4.8n3 The labelling, coding, or similar of equipment may also be done through a system that ensures that test or calibration results cannot be reported if equipment is not calibrated.

6.5 Resource requirements – Metrological traceability

6.5 See ASR009, Acceptable traceability. ASR009 indicates when acceptable traceability is necessary and when critical equipment is involved. The RvA-policy is based on ILAC P10.

6.6 Resource requirements – Externally supplied products and services

6.6n1 When hiring staff (the hiring of services), the laboratory must have a procedure that regulates, among other things:

- The hiring must be arranged by means of a legally enforceable agreement, so that the requirements of criterion 6.2 are also met for external personnel.
- The organisation from which the persons concerned are hired or borrowed may not in any way refer to the accreditation of the body to which the person is hired or borrowed.

6.6n2 If parts of a test or calibration are carried out (purchased) by another part of the own organization or by another legal entity, then all risks must be checked in this respect, clear contractual agreements must be made, adequate process controls must be in place, clear agreements must be made regarding confidentiality, etc.

6.6n3 If ICT services, HR services, facility services, etc. are used by another department of the own organisation, one must either periodically assess this supplier of the laboratory (based on predetermined assessment criteria) or ensure that the services provided comply with relevant requirements of EN ISO/IEC 17025.

6.6n4 If the laboratory is certified for the ISO 27001 with regard to ICT matters, the laboratory will still have to assess those ICT matters (criterion 6.6) and/or audit them (criterion 8.8), because the ISO 27001 does not cover all relevant aspects of ISO/IEC 17025.

7.1 Requirements of the process – Assessment of applications, tenders and contracts

7.7.1a For a body that is only accredited for sampling as a stand-alone activity and has the associated laboratory analyses carried out by another (accredited) laboratory: the customer's order or order confirmation to the customer (or otherwise) must clearly show how and by whom it is reported.

7.1.1c Internationally, within ILAC and EA, it has been agreed with regard to outsourcing that outsourcing on a structural basis under accreditation according to EN ISO/IEC 17025 is not possible. Accreditation can only take place for an operation for which a laboratory itself is competent and which it also carries out itself. In addition:

- Temporary subcontracting (due to unforeseen circumstances) under accreditation is possible, provided that the requirements as described in criterion 7.1.1c and 6.6. are met.
- If there is a contractual cooperation between several accredited laboratories, the total number of analyses can be offered to the market as being accredited. The client must agree to the contractual cooperation and agree to the agreements laid down in this regard with regard to, for example, sample delivery, approval and reporting. Each laboratory is only accredited for the operations for which the laboratory itself is competent and which it also carries out itself.
- In the case of sampling where the samples are always analysed by another laboratory (see ASR010), this is not seen as 'outsourcing' but as 'purchasing', because the analysis of the samples does not belong to the scope of the sampling body; It is a service that is purchased. See the ASRs with regard to scope definitions on this point.

7.1.3 If explicitly agreed and clearly stated in the analysis report, measurement uncertainty may be added to and/or deducted from the specification limits when testing against specification limits. (See also the same explanatory note under 7.8.6n3.)

7.2 Process requirements – Method selection, verification and validation

7.2 7.2.1.5 and 7.2.2 distinguish between verification and validation. For test laboratories, the application of this criterion is elaborated in ASR011.

The NEN 777n series deals extensively with validation, performance characteristics, measurement uncertainty, etc. The use of these standards is not mandatory for testing laboratories according to EN ISO/IEC 17025, but often gives a good interpretation to the standard elements with regard to validation, performance characteristics, measurement uncertainty, and the like.

For calibration laboratories, validation is generally supported by an appropriate uncertainty calculation (see further under 7.6).

7.2.1.3 In the event of a revision of a technical standard, the laboratory will have to carry out a gap and impact analysis without undue delay, on the basis of a risk analysis, and will have to switch to the new version of that standard within a reasonable period of time. In the meantime, the laboratory will have to communicate clearly with the client which version of the technical standard is used (see criterion 7.1.2 of EN ISO/IEC 17025). If the expired version is used, the laboratory must clearly indicate in the test report or calibration certificate that it has applied the expired version.

7.3 Process requirements – Sampling

7.3.1n1 7.3.1 states that there must be a sampling plan. That plan should, where possible, be based on appropriate statistical methods. The body's report must show whether a representative sample has been taken, whether the sampling has been carried out on the basis of a (sampling) schedule agreed with the customer (in accordance with the order specification), or whether it has been carried out in accordance with a normative document. Only when reporting on the basis of a representative sample taken can a ruling be made on the sampled lot (see also 7.8.2.1k and ASR010).

7.3.1n2 If a sampling is carried out at / at a place / object explicitly indicated by the client (for example, a faucet), then it is not necessary to draw up a sampling plan for this.

7.4 Process requirements – Treatment of objects to be tested or calibrated

7.4 See the explanation under 7.8.2.1h n2.

7.5 Process requirements – Technical records

7.5.1 Records must show which specifically mentioned (critical) equipment has all been used for the execution of a test, calibration, etc. If the laboratory has access to several of the same equipment, it must be clear which of these equipment has been used for each individual test, calibration, etc.

7.6 Process requirements – Determination of measurement uncertainty

7.6 Test laboratories that self-calibrate critical equipment (see ASR009) to (inter)national standards shall perform the measurement uncertainty determination as described in EA-4/02. See 7.2 regarding the use of NEN 777n series standards by testing laboratories for the determination of measurement uncertainty for testing.

For calibration laboratories the measurement uncertainty shall be determined and expressed as described in EA-4/02 and ILAC P14.

7.7 Process requirements – Ensuring quality of results

7.7 Criterion 7.7.1 and 7.7.2 list different types of quality controls. In the Netherlands it is common practice for testing laboratories to use so-called first-, second- and third-line checks for quality control, but these are terms that are not used in EN ISO/IEC 17025. The laboratory itself will have to demonstrate that it fulfils the subjects mentioned in criteria 7.7.1 and 7.7.2.

7.7.1n1 Where certain subjects of criterion 7.7.1 do not apply to the laboratory, the laboratory will have to indicate this in a substantiated manner. When assessing this, the RvA assessment team will explicitly check whether the extent to which analytical methods are sensitive to matrix influences, whether critical points in the analysis process have been adequately safeguarded and whether the frequency of implementation of the relevant quality control is adequately substantiated.

7.7.1n2 For internal quality control, it is mandatory to use reference materials or quality control materials; however, it is not mandatory that these are certified materials (with metrological traceability).

7.7.2n1 This criterion is explicit: the laboratory is required to participate in a PT (proficiency test) or an ILC (interlaboratory comparison) for each operation/activity/calibration. See also ASR008 in this regard. When applying for accreditation and when applying for an extension, participants must have participated in a PT or an ILC and their results must have been evaluated and meet relevant requirements.

7.7.2n2 If an organisation has several laboratories within the same entity, and those individual laboratories carry out the same tests/calibrations, each individual laboratory should periodically participate in a PT (proficiency test) or an ILC (interlaboratory comparison).

Assurance between these laboratories can be done, for example, through intra-laboratory comparisons (criterion 7.7.1j).

7.7.2n3 If the laboratory also carries out tests or calibrations at customer sites, or if one also works with a mobile laboratory, PTs (proficiency test) or ILCs (interlaboratory comparisons) should also be periodically taken part at those sites. For example, assurance between the fixed laboratory and the laboratory activities at the customer sites can be done through intra-laboratory comparisons (criterion 7.7.1j).

7.7.3n1 For a calibration laboratory that has participated in a PT or ILC, the evaluation of the results should also take into account the measurement uncertainty of the individual laboratories.

7.7.3n2 Where possible and relevant, the evaluation of PT and ILC results should also consider possible trends over time.

7.8 Requirements of the process – Reporting of results

7.8 If the accredited laboratory reports to another department within the same organisation and that department produces its own ‘test report’ (with any title) on the basis of the laboratory results, then that ‘test report’ (and that department) formally falls outside the scope of accreditation. However, if, directly or indirectly, the impression is created that results on that ‘test report’ (with any title whatsoever) fall within the scope of accreditation, then the requirements set out in EN ISO/IEC 17025 and ASR005 must be met. The core of this is the condition set out in the RvA decision letter, which states that the integrity of the system of accredited conformity assessments is not impaired.

7.8.1.1 n1

It is preferable that evaluation and approval of results be done by someone other than the performing laboratory worker. However, criterion 7.8.1.1 does not prohibit assessment and approval by the same laboratory operator.

7.8.1.1 n2

The release and approval of results may be an automated process, provided that it is adequate and risk-based (e.g. with regard to (‘logical’) results, correlated results, quality controls, etc.).

7.8.1.2 Results should be reported accurately, clearly, unambiguously and objectively. If an analytical result is rejected because it does not meet the expected result, it must first be examined what has gone wrong (according to 7.10 and/or 8.7); it is not entirely acceptable for a re-analysis to be carried out and for the first result to be rejected. However, it is possible that both individual results are reported (such a method must then be described procedurally and be attuned to the customer).

7.8.2.1f The method may be indicated in one of the following ways:

a) A brief description of the method carried out with, among other things, the technique used.

b) Identification of the working rule used. This is only allowed if the customer has access to the content of the working instructions.

c) Refer to a reference standard, if this reference standard is mentioned in the scope of accreditation. If there can be confusion about the version applied without indicating the year, the version of that reference standard used must be explicitly stated. ASR011 describes the conditions under which reference may be made to a reference standard.

7.8.2.1h n1

If the laboratory has not carried out the sampling itself, but the shelf life of the sample is critical, the laboratory must find out the sampling date (and, if relevant, also the time) to ensure that the sample can be tested/calibrated within the shelf life.
Information provided shall be identified as such on the report (see 7.8.2.2).
If the time of sampling is not known, or if the analysis (or assurance of the content) cannot be carried out within the required time interval, a disclaimer must be included on the report that the result may be less reliable.

7.8.2.1h n2

If an in-house courier service or a courier service hired by the laboratory (or otherwise) collects the sample from the customer, the date of collection of the sample is the ‘date of receipt of the sample to be tested’ (regardless of the date on which the laboratory worker continues to process the sample). If the customer places the sample in the laboratory’s storage site, the date of placing it in the laboratory’s storage site is the ‘date of receipt of the sample to be tested’ (irrespective of the date on which the laboratory staff member handles the sample further).

7.8.2.1i In situations where multiple dates have to be mentioned (and it may become unclear to the client), it is accepted that the dates are not mentioned, provided that

a) It is demonstrably regulated that in the event of a shelf life being exceeded, an unambiguous, clear comment (or disclaimer) is mentioned in the report. The comment in question must be accompanied by a conclusion on that comment; e.g. on the (possibly reduced) reliability of the analytical result; and
b) this, as stated in criterion 7.8.1.3, has been agreed with the customer.

7.8.2.1l n1

If samples are taken under accreditation, it should be clear from the report that the laboratory result relates to the sampled object (and not only to the sample taken).

7.8.2.1l n2

For calibration laboratories as well, the (calibration) certificate must contain a clear statement that the results only relate to the calibrated object. This statement can be omitted if it is clear

from the (calibration) certificate that the results only relate to the object uniquely described in the certificate. The calibration laboratory then has valid reasons, as indicated in the first line of criterion 7.8.2.1, not to mention the explanation of criterion 7.8.2.1l. NB This does not apply to test laboratory reports; A statement has been made by the EA Laboratory Committee that this statement is mandatory for all test laboratory reports (FAQ42.1).

7.8.3.1c n1

A test laboratory that does not include the measurement uncertainty in the report shall include in the report that the measurement uncertainty is retrievable.

Please note: A statement on measurement uncertainty must be explicitly included in the report in cases where the measurement uncertainty affects compliance with a specification limit. Exceptions to this may include: if there are demonstrable agreements in the industry not to mention the measurement uncertainty, if the measurement uncertainty is already included in the limit value, if the measurement uncertainty is not part of the test, or if the measurement value is far from the limit value.

7.8.3.1c n2

Usually, the measurement uncertainty, in the case of results close to the specification limits, will have to be reported. However, if the laboratory can adequately argue that failure to report measurement uncertainty cannot lead to misunderstandings (criterion 7.8.2.1 and 7.8.1.2), this can be accepted.

7.8.6n1 If a conclusion or statement of conformity is included in the report or certificate, it must always comply with the requirements set out in criterion 7.8.6.

7.8.6n2 If the measurement uncertainties are reported and the specification limits are also stated, it is not an explicit obligation to also state a statement of conformity if this has not been agreed with the customer. But if results, for example, are in italics, printed in bold, or with a color, or something similar, and this gives the impression that specifications have or have not been met, then there is indeed a statement of conformity and must be tested for this.

7.8.6n3 If explicitly agreed and clearly stated in the analysis report, measurement uncertainty may be added to and/or deducted from the specification limits when testing against specification limits. (See also the same explanatory note under 7.1.3.)

7.8.7n1 By opinions and interpretations the RvA means a professional judgement with regard to the tests and/or calibrations carried out, whether or not in combination with sampling. An opinion and interpretation goes beyond the statement of conformity mentioned in 7.8.6.2. See also the related explanatory note in EA-4/23.

The accreditation for opinions and interpretations will be explicitly mentioned in the scope of accreditation, after an assessment of the laboratory on this subject has been successfully completed.

Accreditation of opinions and interpretations relates to the results within the accredited scope of accreditation. If opinions and interpretations are included in the report that are not covered by the RvA accreditation, this must be clear from the report.

7.8.7n2 Opinions & interpretations may also be based on results from another accredited laboratory. However, it is not possible to be accredited as a stand-alone activity for opinions & interpretations. See also EA 4/23.

7.8.8 The change must always be clearly stated. However, not every request for modification must be automatically accepted by the laboratory. If this would damage the integrity of the laboratory (e.g. cooperation in fraud or deception), the laboratory should not accept the request for modification (see criterion 7.1.4.: "Deviations requested by the customer shall not affect the integrity of the laboratory or the quality of the results.").

7.8.8.1 The change must always be mentioned in the report or certificate itself. It is not permitted to mention them only in a separate cover letter (see also 7.8.2.1d).

7.11 Requirements of the process – Management of data and information management

7.11.2n1 Even if internal ICT services are used, the activities of that service should be validated with regard to the laboratory activities, etc. See also criterion 6.6.

7.11.2n2 When a laboratory uses standard commercial software, the versions used must be managed and, in the event of changes, the software must be appropriately validated.

7.11.6 ‘Systematic’ control does not mean ‘periodic’ control. This can be applied risk-based, taking into account the entire software and hardware environment in which these calculations and transfers take place.

8.1 Requirements for the management system – Options

8.1 If the laboratory chooses Option A, the RvA assessment team will refer to the relevant (sub-) criterion for any findings and deviations with regard to criterion 8.2 to 8.9.

If the laboratory chooses Option B, the RvA assessment team will not assess compliance with ISO 9001 requirements, but will check whether the requirements from (sub-)criterion 8.2 to 8.9 are met. For findings and possible deviations with regard to (sub-)criterion 8.2 to 8.9 reference will be made to criterion 8.1.3 (including naming the relevant requirements from (sub-)criterion 8.2 to 8.9).

8.4 Requirements for the management system – Management of registrations

8.4.2 The laboratory must periodically check the operation of the backup application, including the (full) recovery of digital data; even if you are using an external ICT-supplier.

8.5 Requirements for the management system – Actions to address risks and opportunities

8.5n1 Laboratories are expected to appoint work processes to main and sub-process steps. Risks of errors (in terms of test and/or calibration results) must be identified, but the opportunities and possibilities for improvement are also deemed to be identified. Management and improvement measures must be documented and tested for effectiveness.

It is obvious to deal with these processes during specific consultations and in the context of the management review (criterion 8.9.2 m).

There are several models for risk analysis and the laboratory is free in its choice. The attention is drawn to relevant standards in this area, including ISO 31000 and CEN ISO/TS 22367.

8.5n2 When identifying risks, ICT issues should also be taken into account. For example, when using the internet and e-mail, using internal ICT services, using external ICT services, critical applications, possible vulnerabilities, etc.

8.5n3 Although practical, there is no obligation to have a comprehensive overview of identified risks and opportunities; the list of identified risks and opportunities may also consist of several separate registrations.

8.7 Requirements for the management system – Corrective measures

8.7.1 Any corrective action should be evaluated by the laboratory for effectiveness. However, it is possible that, depending on the nature of the deviation and corrective measure, this sometimes needs to be checked with less depth (this may be approached in a risk-oriented manner).

8.8 Management system requirements – Internal audits

8.8n1 Topics to be considered for the preparation of the audit plan will include: the core activities of the laboratory, coverage of the EN ISO/IEC 17025 criteria, findings from previous internal audits, effectiveness of measures taken, the ability to perform an adequate management review and covering the scope and management system within the accreditation cycle.

8.8n2 For an initial accreditation, the RvA requires that the laboratory itself has confirmed by means of internal audits, prior to the RvA assessment, that all requirements are met for the entire scope requested.

In the case of extension of the accreditation, the requested operations must also be assessed by means of an internal audit and the laboratory itself must confirm that the extension meets the relevant requirements.

8.8n3 Part of the internal audit process is also the qualification of internal auditors. For this purpose, reference is made to criterion 6.2.5 and 6.2.6. Internal auditors may be expected to include

knowledge of the content of EN ISO/IEC 17025, knowledge of the subject/field to be audited, knowledge of auditing and the independent position in relation to the audit subject in their training and qualification.

8.8n4 See the explanatory note under 6.6n4.

8.9 Management system requirements – Management review

8.9.2 When reviewing the input to the management review, it should be clear what the opinion/conclusion on each component is. In the case of no particular remarks, this opinion / conclusion can be summarized very briefly per subject; more detail will have to be given on the subject. This is risk-based and partly depends on the size and complexity of the organization.

Chapter 4. References

EN-ISO/IEC 17025	General requirements for the competence of testing and calibration laboratories
EN-ISO/IEC 17020	Conformity assessment — Requirements for the operation of various types of bodies performing inspection
EA-4/02 M: 2022	Evaluation of the Uncertainty of Measurement in Calibration
ILAC P10:07/2020	ILAC Policy on Metrological Traceability of Measurement Results
ILAC P14:09/2020	ILAC Policy for Measurement Uncertainty in Calibration

Chapter 5. Changes compared to the previous version

This is the first version of this information document INF002. INF002 replaces RvA-T015, which was not published in English. Compared to the T015 version 8.0 (in Dutch) dated 17 October 2024, the following significant changes have been made:

- Some non-content editorial adjustments / fix some typos.
- The explanatory notes to 6.6n3, 7.8.2.1i and 7.8.6n2 have been supplemented/adjusted.
- Some new explanatory notes have been included; i.e.: 6.4n2, 6.6n4, 7.7.1a., 7.1.3, 7.2.1.3, 7.4, 7.7.3n1, 7.7.3n2, 7.8, 7.8.1.1 n2, 7.8.2.1h n2, 7.8.3.1c n2, 7.8.6n3, 7.8.7n2, 8.5n3, 8.8n4 and 8.9.2.
- Where reference is made to another RvA document, the new coding has been used (see ASR001).
- A chapter 4 with references to external documents is added.

Annex 1 Possible format for the impartiality risk analysis

Criterion 4.1.4 calls for risks of impartiality to be identified and Criterion 4.1.5 calls for any risks to be eliminated or minimised. In practice, the combination of these criteria is often referred to as the 'risk analysis on impartiality'. A possible format for this risk analysis is given below:

Situation	**Impartiality risk**	**Management measure**	**Embedding the measure in the management system (quality manual, procedure, instruction, statement, etc.)**
1. Laboratory activities			
.....	Risk / No risk, because		
.....	Risk / No risk, because		
.....	Risk / No risk, because		
2. Relationships of the laboratory			
.....	Risk / No risk, because		
.....	Risk / No risk, because		
.....	Risk / No risk, because		
3. Relationships of laboratory staff			
.....	Risk / No risk, because		
.....	Risk / No risk, because		
.....	Risk / No risk, because		

With regard to '1. Laboratory activities': Despite the fact that criterion 4.1.4 asks about the activities of the laboratory, if one is part of a larger organization, one should actually also name the activities of the entire organization (on the main line).
At '2. 'Relationships of the laboratory' explicitly refers to the relationships of the laboratory; Not the staff's. One can think of customers, suppliers, external service providers, other departments within the same organization, parent and sister organizations, shareholders, hired advisors, supervisors, etc.
Concerning '3 Staff Relations': see also the explanatory note in Chapter 3 of this explanatory document under point 4.1.4n3.