Raad voor Accreditatie
Dutch Accreditation Council - RvA)

Implementation of EN ISO/IEC 17025:2017

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An RvA Explanatory note describes the policy and/or the procedures of the RvA concerning a specific field of accreditation. In case the policy and/or procedures for a specific field of accreditation as described in an RvA Explanatory note, is documented by EA, ILAC or IAF, the RvA will bring its policy and procedures in line with the EA, ILAC or IAF document.
A current version of the Explanatory note is available from the website of the RvA. (www.rva.nl).

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1. Introduction

The standard EN ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories" has been published on 30 November 2017.
This standard replaces the standard EN ISO/IEC 17025:2005 with the same name.

The International Laboratory Accreditation Co-operation (ILAC) has decided there will be a transition period of 3 years for the transition from the 2005 version to the 2017 version, in other words until 30 November 2020.
The changes concern new texts that add new requirements, text changes that re-formulate requirements as well as the non-adoption of requirements from the 2005 version.
This explanatory note describes the RvA policy and the RvA procedure relating to assessments against EN ISO/IEC 17025:2017, the taking of decisions for accreditation against this new standard and the replacement of the accreditation declarations and scopes of accreditations.
This explanatory note is applicable to all accreditations for all activities that were formerly covered under accreditation against EN ISO/IEC 17025:2005.
This document also describes the consequences for schemes for which accreditation was granted under EN ISO/IEC 17025:2005.

2. Transition arrangement

2.1 General

The RvA uses the basic principle that the RvA assessments against the new or amended requirements in the new standard shall be undertaken as far as possible during the regular assessments. The RvA specified the transition provisions for the implementation of EN ISO/IEC 17025:2017 in more detail in the text below.

<u>New accreditation applications:</u>

- For assessments within the framework of new accreditation applications, EN ISO/IEC 17025:2017 will be used from 1 January 2019, unless the applicant explicitly requests assessment against EN ISO/IEC 17025:2005, whereby – in the latter case:
  1. the applicant explicitly accepts the risk in advance that the assessment can not result in accreditation for EN ISO/IEC 17025:2005 in the event that the accreditation decision cannot be taken before 30 November 2019, and,
  2. the applicant accepts that after obtaining accreditation against EN ISO/IEC 17025:2005 additional assessments are required for accreditation against EN ISO/IEC 17025:2017;
- Accreditation applications against EN ISO/IEC 17025:2005will not be accepted from 30 November 2019 onwards.
- At the request of the organisation, assessments can be undertaken against EN ISO/IEC 17025:2017 for new applications from 1 April 2018.

Existing accreditations:

- Annex A contains a comparison between EN ISO/IEC 17025:2005 and EN ISO/IEC 17025:2017. The new or changed requirements in the 2017 version are explicitly stated in the Annex. Organisations with an accreditation for the 2005 version shall provide the RvA with an Implementation Plan no later than 6 weeks prior to the first assessment that takes place after 1 January 2019. This Implementation Plan must mention when and which new or changed requirements as specified in Annex A will be implemented.
- From 1 January 2019 the RvA will undertake the normal assessments against the requirements contained in EN ISO/IEC 17025:2017, taking the organisation's Implementation Plan into account. Section 2.2 contains details of the assessment procedure.
- At the request of the organisation, an assessment against the 2017 version can take place from 1 April 2018, provided the Implementation Plan is provided to the RvA 6 weeks prior to the assessment date.
- At the request of the organisation, a full assessment against the 2017 version can be performed by means of an extra assessment in addition to the normal assessments. The organisation must submit a request for this to the RvA. The costs of such extra assessments will be charged to the organisation.
- There are special provisions for corrective measures for non-conformities established until 1 April 2020 against the new or changed requirements during assessments against the 2017 version where these non-conformities would not have been reported as a non-conformities against the requirements of the 2005 version. These special provisions are described in Section 2.3 of this explanatory note.
- The RvA will issue an amended accreditation declaration and scope of accreditation after compliance with the 2017 version has been established and after a positive decision has been taken in that respect (also see section 2.4 of this explanatory note).
- If this decision cannot be taken before 30 November 2020 then the existing accreditation against EN ISO/IEC 17025:2005 will be withdrawn.
- The Board of the RvA will determine the procedure for situations that deviate from the situations referred to above.

2.2 RvA assessment of the transition to EN ISO/IEC 17025:2017

The RvA will assess the implementation of the new and changed requirements in accordance with the following procedure:

- When assessing documents during and in preparation for the transition assessment, the assessment team will verify whether the new and changed requirements have been adequately incorporated into the documented management system. For this purpose, the organisation shall make available to the assessment team a cross-reference list between the requirements from EN ISO/IEC 17025:2017 and the organisation's documented management system.

- On the basis of the organisation's internal audits and management reviews the assessment team will verify whether the organisation itself has established the implementation of these requirements.
- The team will verify the implementation on the basis of file reviews, interviews and observations of activities.

2.3 Non-conformities against the new requirements

Non-conformities against the requirements of EN ISO/IEC 17025:2017 that would not have been non-conformities against EN ISO/IEC 17025:2005 will be categorised "(B)" non-conformities during assessments undertaken against the 2017 version.
Annex A of this explanatory note specifies the requirements against which a (B) non-conformity can be formulated.

If it is established during a regular assessment that the organisation does not yet have an implementation plan or cross-reference table to the 2017 version, or the organisation has not yet taken steps to implement all new or changed requirements, a general deviation (B) may be issued against criterion 8.1.1. This implies that the assessment against the new and changed requirements must be carried out during the next assessment. If the next regular assessment takes place before 30 April 2020, this can be done during this assessment. If this will take place after this date, it is advisable for the organisation to request an additional assessment for this. This is because there is a chance that a positive decision cannot be made before 30 November 2020 and the accreditation will be withdrawn.

For the other (B) deviations also applies that until April 30, 2020 it is possible to have the corrective measures based on (B) deviations assessed during the regular assessment. If this will take place after this date, it is advisable for the organisation to request an additional assessment. In these cases too, there is a chance that a positive decision cannot be made before 30 November 2020 and that the accreditation will be withdrawn.

The organisation has the possibility until 1 September 2020 to implement corrective actions and submit its report on these to the RvA (see RvA-BR004). The RvA will assess these actions and the assessment team will issue its recommendation regarding these to the Board of the RvA no later than 1 November 2020. The Board of the RvA will take its accreditation decisions before 30 November 2020.
If the RvA is unable to make a positive decision before 30 November 2020 with regard to the granting of accreditation for the 2017 version, for example as a result of being unable to close non-conformities, then the accreditation based on EN ISO/IEC 17025:2005 will be withdrawn with effect from 30 November 2020.

2.4 Accreditation declaration

The accreditation declaration (including the scope annex) will be amended to show the accreditation for EN ISO/IEC 17025:2017 after an assessment against the new standard has been concluded

successfully, and a decision about the accreditation, its continuation or its renewal has been taken. The accreditation number for existing accreditations will remain the same.
The date of the first accreditation against an earlier version of EN ISO/IEC 17025:2017 will also be stated on the new accreditation declaration. The expiry date for the new accreditation will be taken from the existing accreditation cycle.
In the event an existing declaration or scope has to be replaced during the transition period, but no positive decision has been taken regarding accreditation against EN ISO/IEC 17025:2017, then the new declaration or scope will have an expiry date which does not extend beyond the end date of the transition period.

2.5 Schemes under accreditation

It is the responsibility of the scheme (sometimes also referred to as accreditation programme) administrators to amend this scheme where necessary to the requirements contained in EN ISO/IEC 17025:2017. However, it is the responsibility of the accredited bodies to ensure compliance with these requirements in a timely manner. If a scheme has not (yet) been amended by the time the organisation wishes to complete the transition then the organisation shall - on the basis of an analysis of the potential conflicts of requirements under the scheme with the requirements from EN ISO/IEC 17025:2017 – demonstrate how these conflict have been resolved. If these conflicts are not resolved in the scheme or by the organisation itself within the periods described above for the category (B) non-conformities, then the accreditation for the scheme will end with effect from 30 November 2020.

3. Changes with regard to the previous version

Compared to version 2 of December 2018, the following changes have been made:

- in paragraph 3.2 an additional explanation has been added regarding the risk for a body if there still are (B) non-conformities unsolved and the next regular assessment takes place after 30 April 2020.

Annex A: Summary of changes

This Annex provides a schematic overview of the changes in the accreditation standard. The requirements against which a category (B) non-conformity can be reported are marked as such.
Note: this Annex is not a complete cross reference list and will, if necessary, be changed due to gained experiences.

17025:2017	Subject	17025:2005	Nature of the change	
1.	Scope	1.	Substantially shortened, Sampling is part of the standard (7.3), but is not specifically mentioned here.	
2.	Normative references	2.		
3.	Terms and definitions	3.	Next to general referrals, various definitions are now included explicitly	
4.	General requirements	4.	New: text based on ISO QS=CAS-PROC33 (common elements)	
4.1	Impartiality	4.1.4	Conflict of Interest is deemed to be eliminated (see 3.1)	(B)
4.1	Impartiality	4.1.5.d	Expanded. Verify regularly (on an on-going basis) Risk analysis	(B)
4.2	Confidentiality	4.1.5.c	New/more extensive	
5.	Structural requirements	5.	Title	
5.1	Legal entity	4.1.1		
5.2	Lab management	4.1.5.h	General responsibility instead of technical responsibility	
5.3	Scope of activities under 17025	4.1.3	Also responsible for on-site activities. Structurally-subcontracted work is explicitly excluded.	
5.4	Lab responsibility	4.1.2	Added: "Customer's facility"	
5.5.a	Organisational structure	4.1.5.e		
5.5.b	Staff responsibilities	4.1.5.f		
5.5.c	Documented system	4.2.1	Must be sufficiently expanded to guarantee a consistent procedure and valid results.	

17025:2017	Subject	17025:2005	Nature of the change	
5.6	QA staff responsibilities	4.1.5.a	Different wording, no fundamental changes	
5.6	Quality manager	4.1.5.i	Word 'quality manager' is replaced by 'personal', the QA tasks are described in more detail	
5.7.a	Management of change	4.1.6		
5.7.b	Communication about QMS effectiveness	4.2.7		
6.	Resource requirements	new	See 6.1 to 6.6 below	
6.2	Personnel	4.1.5.j	"Deputies" no longer described explicitly	
6.2	Personnel	5.2	Title	
6.2.1	Competent and impartial staff	5.2.1	New: emphasis on impartiality	(B)
6.2.2	Training requirements	5.2.2	Described differently	
6.2.2	Competence requirements	5.2.5	Different, now separate clause	
6.2.3	Competent staff for given responsibilities	5.2.1	Relationship between competency and responsibilities now more explicit	
6.2.4	Duties and responsibilities	4.1.5.f		
6.2.5	Personnel records	5.2.5	Described differently	
6.2.6	Authorisation of staff	5.2.5	Various aspects stated more explicitly	
6.3	Facilities and environmental conditions	5.3	Title	
6.3.1	Suitable not to invalidate results	5.3.1		
6.3.2	Environmental requirements documented	new	Explicit recording requirement	(B)
6.3.3	Monitored and controlled environment	5.3.2	More abridged	

17025:2017	Subject	17025:2005	Nature of the change	
6.3.4.a	Access	5.3.4	New: periodic review Risk analysis	(B)
6.3.4.b	Contamination	5.3.3	New: periodic review Risk analysis	(B)
6.3.4.c	Separation	5.3.3	New: periodic review Risk analysis	(B)
6.4	Equipment	5.5	Title	
6.4.1	Available suitable equipment	5.5.1	Phrased differently	
6.4.2	Equipment outside control of lab	5.5.1	Ditto as 5.5.1 2nd sentence	
6.4.3	Handling and transport of equipment	5.5.6	Ditto	
6.4.4	Verify equipment prior to use	5.5.2	Ditto as 5.5.2 2nd part	
6.4.5	Equipment having appropriate accuracy	5.5.2	Ditto as 5.5.2 1st part	
6.4.6	Necessity for calibration	5.6.1	More abridged description in 6.4.6, but now incl. in Annex A	
6.4.7	Calibration program	5.6.2.1.1	Much more abridged description. Rest to Annex A. Now general obligation. Periodic review of recalibration periods. Also see ILAC-G24/OIML-D10 Technical Risk analysis	
6.4.8	Identification of equipment	5.5.8	Continued reporting of validity and calibration status. Now "readily identify status" instead of Explicit last calibration date and due date. Requirement for stickers is not explicit.	
6.4.9	Overloaded equipment	5.5.07	Extra: reference to use of procedure non-conforming work 7.10	
6.4.10	Intermediate checks	5.5.10	Identical	
6.4.11	Apply correction factors	5.5.11	Extra: reference material data	

17025:2017	Subject	17025:2005	Nature of the change	
6.4.12	Prevent unintended adjustments	5.5.12	"Unintended adjustments" instead of "safeguard from…"	
6.4.13	Equipment records	5.5.5	Formulated slightly differently. New: f) ref. Materials	
6.5	Metrological traceability	5.6	Changed substantially. Condensed in the text of the standard, but much is included in the informative Annex A. 2005: par. 5.6.3.3 and 5.6.3.4 are now placed under 6.4.10 and 6.4.3 respectively	
6.6	Externally provided products and services	4.5	Was separate purchasing and subcontracting. Now also hiring in services in 6.6.3.c	(B)
6.6	Externally provided products and services	4.6	Was separate purchasing and subcontracting. Now also hiring in services in 6.6.3.c	(B)
6.6	Results obtained from subcontractors	5.10.6	Different descriptions	
7.	Process requirements	new	New classification = primary process tasks	
7.1	Review of requests, tenders and contracts	4.4	Phrased differently	
7.1.1.c	Contract review of subcontracted work	4.5.2	Client permission required	
7.1.2	Inform customer about inappropriate methods	4.4	New aspect regarding contract review, but is stated below 2005: 5.4.2	
7.1.3	Statement of conformity	4.4	New: agree decision rule	(B)
7.1.4	Differences between tender and contract	4.4.1	Addition: client request may not affect integrity of test.	(B)
7.1.5	Deviation from contract	4.4.4	Idem	
7.1.5	Deviating from contract	5.7.2	2005 text "deviating from sampling procedure" is cancelled but is covered via contract review	
7.1.6	Amended contract	4.4.5	Idem	

17025:2017	Subject	17025:2005	Nature of the change	
7.1.7	Cooperation with customer	4.7.1	Comparable	
7.1.8	Record of reviews	4.4.2	Comparable	
7.2	Selection, verification and validation of methods	5.4	Title	
7.2.1.1	Appropriate methods	5.4.1	Subdivided	
7.2.1.2	Documented methods and availability	5.4.1	"Methods" now documented explicitly, up-to-date and readily available.	
7.2.1.4	Lab selected method	5.4.2	Subdivided	
7.2.1.5	Method verification before use	5.4	New, verification if formal validation not necessary	
7.2.1.6	Planned method development	5.4.3	Same	
7.2.1.7	Deviation of method	5.4.1	5.4.1 last sentence	
7.2.2	Validation	5.4.5	Title	
7.2.2.1	Non-standard methods	5.4.4	Validation excludes normative methods. Verifications should be used here.	
7.2.2.2	Changes --> revalidation	5.4.5.2.note3		
7.2.2.3	Validation relevant to customers' need	5.4.5.3	More abridged	
7.2.2.4	Recording validation evidence	5.4.5	New criteria	(B)
7.3	Sampling	5.7	Title	
7.3.1	Sampling plan & procedures	5.7.1	New: sampling under 17025 only if the intention is subsequent analysis. The sampling procedure should be such that it allows a valid analysis.	
7.3.2	Sampling procedure elements	5.7.1 note 2	Now normative	(B)
7.3.3	Recording sampling data	5.7.3	Data elements divided into sub-clauses	
7.4	Handling of test or calibration	5.8	Title	

17025:2017	Subject	17025:2005	Nature of the change	
	items			
7.4.1	Handling procedure	5.8.1	Merged with 5.8.4	
7.4.1	Handling procedure	5.8.4.dl1	5.8.4 1st part merged with 7.04.1	
7.4.2	Item identification	5.8.2		
7.4.3	Abnormalities or deviations upon receipt of item	5.8.3		
7.4.4	Maintaining and monitoring storage	5.8.4.dl2	5.8.4 2nd part separate as 7.04.4	
7.5	Technical records	4.13.2	Partial different description, can also be used for electronic records	
7.6	Evaluation of measurement uncertainty	5.4.6	New: in 7.6.1 uncertainty in testing, is now also a requirement for sampling	(B)
7.7	Ensuring the quality of results	5.9	Title	
7.7.1	Quality control monitoring	5.9.1	New: more elements stated	(B)
7.7.2	Participation in PT	5.9.1.b	Separated and with slightly more detailed description	
7.7.3	Quality monitoring data	5.9.2	New added: also aimed at lab performance improvement	
7.8	Reporting of results	5.10	Title	
7.8.1	General	5.10.1		
7.8.2	Reports: common elements	5.10.2	New elements added. New par. 7.8.2.2 explicit requirements for Reporting supplied samples/data	(B)
7.8.2.2	Responsible for subcontracted work	4.5.3	Only if data is included in own report	
7.8.3	Reports: testing	5.10.3	7.8.3.2 gives extra requirements if sampling is an element	
7.8.4	Reports: calibration	5.10.4	New: a) measurement value with uncertainty in same unit or relative	
7.8.5	Reports: sampling	5.10.3.2	F) is described differently	

17025:2017	Subject	17025:2005	Nature of the change	
7.8.6	Statement of conformity	5.10.4.2	New: separated and now also applicable to testing New: specify Decision rule and associated risk. Technical risk evaluation	(B)
7.8.7	Opinions and Interpretations	5.10.5	New: slightly expanded and extra requirement for separate qualification of personnel undertaking the interpretation. Dialogue recording.	(B)
7.8.8	Report amendments	5.10.9	New 7.8.8.1: clearly identify changes	(B)
7.9	Complaints	4.8	New: described in much more detail and more explicit requirements 7.9.6 to be detailed further with regard to Small organisations	(B)
7.10	Management of nonconforming work	4.9	Expanded description New: requirement for impact analysis Risk analysis	(B)
7.11	Control of data – Information management	4.13.1	New: expanded requirements for data and information. More emphasis on ICT and special requirements for LIMS Risk analysis	(B)
8.	Management system requirements	4	Different section layout and composition	
8.1	Options	new	New: option A via 17025, Option B via 9001: consequence for RvA audits: for option B the elements of option A have to be demonstrated for the lab activities. NCs against 8.1.3	
8.1.1	General	4.2.1	The management system must comply with 4 - 7	
8.1.2	Option A	new	The management system must comply with 8.2 - 8.9	
8.1.3	Option B	new	Option B: management system detailed according to 9001: consequence for RvA audits: for option B the elements of option A have to be demonstrated for the lab activities. For any Non-conformities a deficiency is to be recorded against 8.1.3	

17025:2017	Subject	17025:2005	Nature of the change	
8.2	Management system documentation (Option A)	4.2	Some sub-paras. moved from 4.2. Top management replaced by lab management.	
8.3	Control of management system documents (Option A)	4.03	Same principles, described differently	
8.4	Control of records (Option A)	4.13.1	Same principles, described differently	
8.5	Actions to address risks and opportunities (Option A)	4.12	Same principles, described differently, now focussed on risk based approach Risk analysis	(B)
8.6	Improvement (option a)	4.10	2005-4.7.2 changed to 2017-8.6.2 Risk analysis	
8.7	Corrective action (Option A)	4.11	Same principles, described differently (cause analysis no longer stated explicitly)	
8.8	Internal audits (Option A)	4.14	B) and c) are new, "quality manager responsibility" not longer stated. Reference to ISO 19011. Risk analysis	(B)
8.9	Management reviews (Option A)	4.15	Expanded number of items to be covered, incl. Results of risk analyses.	(B)