Dutch Accreditation Council (RvA)

Implementation of EN ISO 17034:2016

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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 a 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 is available through the website of the RvA. (www.rva.nl).

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1 Introduction

The standard EN ISO 17034:2016 “General requirements for the competence of reference material producers” was published on 1 November 2016.

According to the resolution of the International Laboratory Accreditation Cooperation (ILAC), EN ISO 17034:2016 replaces the similarly named standard ISO Guide 34:2009. ILAC Resolution GA 20.14 stipulates an implementation period of three years.

This explanatory note describes the RvA policy and procedure for the implementation of EN ISO 17034:2016.

This explanatory note is applicable to all accreditations for producers of reference materials for ISO Guide 34:2009.

2 Transition to EN ISO 17034:2016

2.1 General

The changes mainly concern the inclusion of requirements from the Common Elements for ISO CASCO standards. In addition, the structure (grouping into sections) has changed with regard to the 2009 version of ISO Guide 34; this is in line with the structure of other standards used for accreditation (ISO/IEC 170xx series).

The RvA has decided to arrange for the conversion of the accreditations to EN ISO 17034:2016 to coincide as much a possible with the normal accreditations.
The RvA has therefore specified the transition provisions for the implementation of EN ISO 17034:2016 in more detail as set out below.

For organisations already accredited on the basis of ISO Guide 34:2009:
Between 1 November 2017 and 1 November 2018, on the request of the organisation it will still be possible to be assessed against ISO Guide 34:2009 in accordance with the prevailing assessment regime.
Between 1 November 2017 and 1 November 2018, on request of the organisation it will already be possible to be assessed against the new EN ISO 17034:2016 in accordance with the transition regime.

- After 1 November 2018 all normal accreditation assessments will be undertaken against EN ISO 17034:2016.
- There are special provisions for corrective measures in the event of non-conformities established under the new standard during the transition period, which would not have been a non-conformity under the old standard (see Annex A). Those special provisions are described in paragraph 2.3 of this explanatory note.

- The RvA will issue a new accreditation declaration, but only after it has established compliance with the requirements of EN ISO 17034:2016, and after a positive decision has been made with regard to that (also see paragraph 2.5 of this explanatory note).

If this decision cannot be taken before 1 November 2019 then the existing accreditation for ISO Guide 34: 2009 will be withdrawn.

For new organisations seeking accreditation there is the possibility of being assessed against EN ISO 17034:2016 from 1 November 2017. After 1 November 2018 it will become mandatory for all accreditation assessments to be undertaken against EN ISO 17034:2016.

2.2 RvA assessment of the transition to EN ISO 17034:2016

During the first normal assessment after 1 January 2018 the RvA can assess the documented management system and the dossiers with regard to the implementation of the new standard (see the points in Annex A).

Topics of this assessment are:

- a cross-reference list between the requirements under EN ISO 17034:2016 and the organisation's documented management system as drawn up by the organisation;
- the documented management system;
- the conducting and reporting of an internal audit by the organisation with regard to the implementation of the changes;
- if the organisation has multiple locations: the implementation at all locations;
- dossiers that demonstrate the implementation of changes.

The assessment of these points shall be undertaken without spending extra time. However, the assessment of the corrective measures for any "(B) non-conformities" (see 2.3) shall be undertaken as an extra, charged assessment and will in principle not be undertaken during the next normal assessment unless the time required is insignificant.

The organisation can opt to start later than the first normal assessment after 1 January 2018 with its assessment of the new and changed requirements. The assessment of these points shall be undertaken without spending extra time. However, the assessment of the corrective measures for any "(B) non-conformities" (see 2.3) shall be undertaken as an extra, charged assessment and will in principle not be undertaken during the next normal assessment unless the time required is insignificant.

2.3 Non-conformities under the new requirements

Non-conformities against paragraphs from EN ISO 17034:2016 that would not have been non-conformities under the previous standard shall be classed during the transition period as "(B)".The RvA has prepared a list of the new requirements, which is included as Annex A in this explanatory note.

The organisation must submit the corrective measures with regard to the (B) non-conformities to the RvA (in accordance with RvA-BR004) before 1 July 2019. The RvA will assess these measures before 1 September 2019 and take accreditation decisions before 1 November 2019.

If the RvA is unable to make a positive decision before 1 November 2019 with regard to the granting of accreditation for EN ISO 17034:2016, for example as a result of being unable to close off non-conformities, then the accreditation will be withdrawn.

2.4 Applicable guidelines and explanations

In the coming period the RvA will amend the current RvA explanatory notes and RvA documents that are applicable for accrediting producers of reference materials. These documents will remain in force until the changes have been implemented.
References in them to ISO Guide 34:2009 must be read as references to EN ISO 17034. Where reference is made to the new standard, this can also be read as a reference to ISO Guide 34:2009 up to the end of the transition period.

2.5 Accreditation declaration

The accreditation declaration will be amended to show the accreditation for EN ISO 17034:2016 after an assessment against the new standard has been successfully completed and a decision about the continuation, the maintenance or the renewal of the accreditation has been taken. The accreditation number will remain the same.

The date of the accreditation declaration will be the date of the accreditation decision under the new standard. The date of the first accreditation for the previously granted accreditation(s) for ISO Guide 34:2009 will also be stated on the new accreditation declaration. The expiry date for the new accreditation will be adopted from the previous accreditation.

3 Changes with regard to the previous version

None, this is the first version of this document.

Annex A: Summary of changes

The following (parts of the) requirements from the EN ISO 17034:2016 standard contain changes with regard to the ISO Guide 34:2009 standard. Only the most significant changes to the text of the standard are stated. The most prominent changes within these textual parts are shown in italics. There are also many smaller changes in part because the structure of the standard has changed considerably and not all of these are listed below.

GAP ANALYSIS

EN ISO 17034:2016		ISO Guide 34:2009		Change	Consequence for the Conformity Assessment Body
Criterion		Corresponding criterion			
4	**General requirements**				
4.2	Impartiality	4.2.3	Organisation and Management	Change	Risk-based analysis. Frequent re-assessment and taking appropriate control measures
4.3	Confidentiality	4.2.3 c		Change	Expanded criteria and more inclusive.
5	**Structural Requirements**	4.2	Organisation and Management		
5.3 g				New	Covering liability risk
6	**Resource Requirements**				
7	**Technical and Production Requirements**				
7.10	Assessment of homogeneity	5.13	Assessment of homogeneity	Editorial	7.10.5 is new
7.11	Assessment and Monitoring of Stability	5.14	Assessment of Stability	Change	Different phrasing for various existing criteria. New aspects: - 'in use' stability checks when material is intended for reuse or sub-division. - Stability of batches (7.11.3). - Inclusion of instability in uncertainty (7.11.1^{e})
7.12	Characterisation	5.15	Characterisation	Change	Different approach. Use of dedicated strategy now required.

EN ISO 17034:2016		ISO Guide 34:2009		Change	Consequence for the Conformity Assessment Body
Criterion		Corresponding criterion			
7.13	Assignment of property values and their uncertainties	5.16	Assignment of property values and their uncertainties	Editorial	Partly withdrawn text. Basically the same. Uncertainty contribution (7.13.6) now defined more explicitly.
7.18	Complaints	4.8	Complaints	Change	An explicit procedure is now required.
8	**Management System Requirements**				
8.6	Management Review	4.15	Management reviews	Editorial / New	New: e) Evaluate risk assessment (see 8.8) and k)
8.8	Action to address risks and opportunities			New	New approach. Partly in place of G34 - 4.11